THE DEVELOPMENT AND VALIDATION OF A COMPUTERISED EXPERT SYSTEM FOR IMPORT RISK ANALYSIS

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Abstract

Since the establishment of the World Trade Organization, and the need to base trade restrictions that exceed those recommended by the relevant international organisations on a scientific assessment of the risks to human, animal or plant health, import risk analysis has been recognised as a discrete scientific discipline. As such, import risk analysis has seen the trends in methodologies typical of an emerging scientific discipline. The OIE International Animal Health Code chapter on import risk analysis has recently been revised, and the changes made reflect an international move toward a closer adherence to the requirements of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the so-called SPS Agreement.

This thesis examines the SPS Agreement and other pertinent components of the current regulatory environment for trade in animal products. The thesis also examines risk analysis methodologies. Fifty-five sample qualitative and quantitative import risk analyses were obtained for review. Methodologies reported in these analyses were evaluated in conjunction with those advocated in the current and previous OIE Code chapters on import risk analysis. The OIE International Aquatic Animal Health Code was also included in the review, since many of the sample analyses were carried out for aquatic animals or products. These evaluations led to a synthesis of existing methodologies for import risk analysis, and the identification of key areas for continued research and development.

An expert system was designed and implemented to enable the results of the evaluations to be conveyed to risk analysts. It was envisaged that delivering these results by way of an expert system would enable analysts to carry out risk analyses efficiently and in a structured manner. The expert system was designed in a modular format and by using the object-orientated paradigm. This approach enabled expert knowledge to be stored efficiently, and meant that the system could be easily updated as research in the specified areas continued. The design also meant that the system could be extended to pest risk analysis, or to non-biological disciplines such as actuarial and project risk analysis.

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PREFACE

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1 Background

Throughout the 20th Century, international trade in animals and products of animal origin has burgeoned. This period has been characterised by the developing autonomy of former European colonies, two major world wars, dramatic and universal advancements in technology and communication and a progressive decline in the degree of isolation arising from geographical or political boundaries. Underlying these developments and unifying a myriad of global socioeconomic trends, has been the ubiquitous requirement for greater efficiency in the production and marketing of tradeable commodities (Blancou, 1993). The need for greater efficiency in the production and marketing of animals and animal products, led by developed nations with strong agricultural industries, has been met by:

- Larger and more efficient animal production operations
- Technological advances in animal production and the processing of products of animal origin
- Advances in the transport and shipment of animals and products of animal origin
- Advances in marketing and marketing efficiency
- The formation of international trade blocs with reduced internal boundaries
- The signing of free trade agreements among many of the major agricultural nations (Blancou, 1993)

Increased efficiency in the production and marketing of animals and animal-derived products has resulted in lower cost and higher demand for these commodities, both within individual countries and on the global market. This general trend, while fragmented by international conflicts and fluctuations in the development or fortunes of individual trading nations, has in turn led to the following significant changes in the characteristics of the global market for animal-related commodities:

- An increase in the volume and diversity of trade,
- An increase in the diversity of end-users,
- A reduction in the time taken to select, market and transport animals and a consequent decrease in the level of stress imposed, and,
- A shift from the tendency for the risk of animal or zoonotic diseases to be used as disguised non-tariff trade barriers, toward a freer international trade environment (Kellar, 1993; Wilson and Banks, 1993)

Each of these changes has enhanced the potential for movement of animal and zoonotic diseases between trading countries and has led to global recognition of the constant need to re-assess national measures for biosecurity (Kellar, 1993). Of particular note, however, is the effect of increased efficiency in the production, marketing and transport of animals, and the shift toward a freer international market for animals and animal-derived products.

1.1 Increased marketing and transport efficiency

Historically, the time taken to transport animals played a major role in agricultural security, particularly for countries such as Australia and New Zealand which are isolated by large bodies of water (Kellar, 1993; Wilson and Banks, 1993). Long and arduous sea journeys provided an effective period of quarantine during which incubating animals died, recovered or were identified. In numerous cases, serious diseases such as rinderpest were detected during the sea voyage, or upon inspection of transported animals, and entry of the disease prevented (Kellar, 1993; Nairn et al, 1996). In addition, the cost and inefficiency of transport meant that animals to be exported were generally sourced from a particular region in the exporting country (Kellar, 1993), and usually one that represented a relatively low risk of occurrence of the more serious production-limiting or zoonotic diseases (Kellar, 1993; Nairn et al, 1996).

Modern methods for transporting animals now mean that the period in transit is often measured in

hours rather than days or weeks (Kellar, 1993). In addition, recognition of the role that stress plays in the health and productivity of animals (and a global move toward the consideration of animal welfare) have led to dramatic improvements in the treatment and housing of exported animals and a resultant decreased risk of clinical disease being induced during the period of transportation (Kellar, 1993; Nairn et al, 1996). The combination of these factors means that transportation and marketing no longer provide a passive means of guarding against the movement of animal diseases. It follows that formal importation protocols demanding, for example, periods of quarantine and/or the use of various diagnostic procedures are required if the agricultural security of importing countries is to be protected.

1.2 The shift toward a freer international trade environment

A favourable national or regional animal disease status is important both for internal disease control (Kellar, 1993), and because freedom from specific pathogenic organisms is a powerful means of securing and maintaining valuable export markets (Doyle, 1980; Kellar, 1993; Nairn et al, 1996). Consequently, it is in the interests of countries trading in animals and animal-derived products to take any reasonable steps toward protecting their boundaries from disease incursions (Nairn et al, 1996). Historically, many countries have applied, or have been perceived to apply, a 'zero risk' policy when trading in animals or animal-derived products (Blancou, 1993; Kellar, 1993; Nairn et al, 1996). This stance implies that importations considered to present any measure of risk to human health, or to animal populations in the importing country, are refused or restricted to such a degree that regulatory authorities consider the threat to have been nullified. It is now generally recognised however that this approach restricts international trade unnecessarily since it eliminates only efficiently monitored movements while doing little to hinder illegal or uncontrolled movements (eg bird migration). Zero risk, as applied to a disease agent, thus can never be attained (Kellar, 1993; Acree, 1993; Wilson and Banks, 1993; Nairn et al, 1996).

The rational alternative to a zero risk policy is to assess objectively the probability that susceptible humans or animals will be exposed to the agent of concern, to determine the severity of this outcome should it occur, and to propose risk-mitigating conditions where the risk is considered to be unacceptable. This process has been successfully practised for many years by the major agricultural nations and, since the establishment of the World Trade Organisation (WTO), has become a vital component of the movement toward freer international trade in animals and animal-derived products (Nairn et al, 1996; WTO, 1997b; WTO, 1997c). Specifically, the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, the so-called "SPS

Agreement", states that import refusals or restrictions for animal-derived commodities beyond those recommended in the Office International des Epizooties' (OIE) International Animal Health Code (OIE Code) must be based on a "*scientific assessment of the risks to human or animal health*". The SPS Agreement also states that "*such assessments should take into account risk assessment techniques developed and endorsed by the relevant international organisations (OIE or IPPC)*" (WTO, 1997a).

The outcome of changes to international trading policy has been the diversification of markets for animals and animal products and an increase in the complexity of the movements of these commodities (Nairn et al, 1996). This represents a freer and fairer trade environment, although significant resources must now be allocated to individual investigations of the hazards that may be associated with each proposed importation. In addition, existing import protocols must be kept under constant review and adjusted to take account of changes in the status or epidemiology of diseases in the exporting country or region, and of technical advances in diagnostic procedures or knowledge of the disease agent. Finally, any investigations must be carried out and documented at a level of technical proficiency sufficient to satisfy the WTO arbitrators in the event of an international trade dispute. While this is within the capabilities and resources of developed and economically stable nations, many smaller and less developed countries with substantial importations of animals and animal products face serious difficulties in adequately assessing the hazards associated with individual import requests. Yet they cannot, under the terms of the new trade agreements, refuse or impose restrictions on any other basis (Kellar, 1993; Nairn et al, 1996).

2 Import risk analysis

Import risk analyses have traditionally consisted of informal and loosely structured qualitative or semi-quantitative assessments of the hazards posed to animal health by proposed importations, and the expected magnitude of adverse consequences. While such analyses have helped to protect many trading countries from disease incursions (Nairn et al, 1996), the WTO requirements for 'transparency', 'equivalence', 'harmonization' and scientific rigour have led to a global re-evaluation of approaches and methodologies for risk analysis and, particularly, to experimentation with quantitative techniques (Kellar, 1993; Nairn et al, 1996). Following early enthusiasm for quantitative analysis there has since been a shift toward the pragmatic view that such analyses are in many cases limited in precision by a paucity of adequate data. In addition, quantitative analyses are by nature extremely time-consuming and resource-intensive and are generally too expensive

for all but a relatively small number of commercially significant or politically important import decisions.

Various solutions to these difficulties have been proposed by key figures within the international community of import risk analysts. Vose (pers comm 1997)[1] maintained that the OIE's continued commitment to improving the standard of international animal health information and reporting will inevitably lead to an increased willingness to carry out assessments based on these data. This risk analyst also welcomed the OIE's formal agreement with the WTO to act as an international reference for guidelines for import risk analysis, and suggested that the evolution of such guidelines would help countries to evaluate the strengths and weaknesses of various quantitative methodologies and approaches. MacDiarmid (pers comm, 1999)[2] suggested that, while purely quantitative assessments may not always be achievable, potential may exist for analyses based on a mixture of qualitative and quantitative methods, provided that such an approach could be carried out in a structured, transparent manner and within a generic framework. Finally, Acree (1993) suggested that potential may exist for the automation of (quantitative) methods, such that complex assessments might be conducted rapidly and efficiently, whilst retaining the credibility of an internationally recognised methodology. This author also stressed the need to constantly revise and review methodologies, and to improve data collection, if analysts are to keep pace with the requirements of trade and agriculture (Acree, 1993).

From these comments, and an accumulation of the personal sentiments of risk analysts worldwide, it was postulated that a computerised system for import risk analysis based on an assessment of current trade requirements and an evaluation of existing guidelines and methodologies would be of considerable interest to the international community of import risk analysts. Such a system might, if widely adopted, encourage a structured approach to individual analyses and allow quantitative techniques to be implemented practically and efficiently.

3 Project objectives

The principal objectives of this doctoral project were:

1. To review and summarise pertinent aspects of the regulation of international trade in animals and animal products

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[1] Vose, D: Vose Risk Analysis Services, La Cahue, Dordogne, France
[2] MacDiarmid, SC: Regulatory Authority, Ministry of Agriculture and Fisheries, Wellington. New Zealand

2. To evaluate alternative approaches to, and methodologies for, import risk analysis

3. To implement the results of the evaluations in a computerised expert system for import risk analysis

These objectives are discussed in Chapters 1-3, respectively.

1.1 Review of the regulation of international trade in animals and animal products

The emphasis on import risk analysis resulting from the establishment of the WTO has led to the need to harmonise approaches, and to ensure that methodologies are transparent and scientifically sound. These requirements have been implemented through the SPS Agreement, and through arrangements between the WTO and both the OIE and the International Plant Protection Convention (IPPC) which ensure that guidelines for animal and plant risk analysis are available to all WTO Member Countries.

The objective of this review is to explore and document these issues, and to identify the relevant standards or guidelines for the importation of animals and animal products.

3.1 Evaluation of import risk analysis approaches and methodologies

Approaches to import risk analysis, and the specific methodologies developed by individual analysts, have been determined to some extent by international guidelines available at the time of writing. Import risk analysis is a relatively new and emerging discipline and its conceptual and technical underpinnings have evolved through marked phases as analysts explored the benefits and limitations of prescribed approaches and techniques. In order to facilitate the evolutionary process, the international organisations responsible for the development and maintenance of guidelines have encouraged contributions and suggestions from individual analysts, and have circulated draft revisions to the international community of regulatory veterinarians for comment. This process has meant that sequential editions of guidelines reflect, to a large extent, the trends in focus and methodology that characterise the evolution of import risk analysis. The iterative nature of the process has also meant that approaches and methodologies represented in the guidelines have lagged to some extent behind those utilised and advocated by leading analysts.

The objective of Chapter 2 was to evaluate methodologies offered by international organisations (notably the OIE) and by individual analysts or regulatory bodies. While it was necessary to examine analyses in the context of the prevailing 'international standards' or guidelines, it was also important to bear in mind the process of multilateral review, critique and compromise through which the latter were derived. Finally, the evaluations were intended to highlight advantages of particular approaches as much as to investigate possible limitations and, as the conclusions testify, the 'optimal' approach was often chosen because of its applicability in a wide range of scenarios.

3.2 Design and implementation of an expert system for import risk analysis

The final objective was to design and implement an expert system for import risk analysis. It was envisaged that such a system might enable analysts to carry out analyses efficiently and in a structured and methodologically sound manner, and that the system's output would help to facilitate the WTO requirement for transparency.

In meeting this objective, the principal challenge was that the expert system be applicable to the importation of a wide range of animals and animal products. This requirement implied that the system should be based upon a flexible generic structure. The structure should in turn be sufficiently intelligent as to enable import risk analyses to be constructed without the operator's personal interpretation of technical issues pertaining to import risk analysis.

CHAPTER 1

A Review of the Regulation of International Trade in Animals and Animal Products

Contents

1 Introduction

This review was based on two primary objectives:

1. To identify and briefly describe the international organisations and agreements relevant to trade in animals and animal products

2. To outline the role that these organisations play in determining approaches to, and methodologies for, import risk analysis.

A subsidiary objective was to identify and describe those components of the current regulatory environment which may determine the relevance and acceptability of an expert system for import risk analysis, and thus influence its adoption by regulatory agencies.

2 International regulatory organisations and trade agreements

In the context of trade in animals or animal products, the two most significant international organisations are the WTO and the OIE. Other important bodies or conventions include:

- The World Health Organisation (WHO) of the United Nations
- The Food and Agriculture Organization (FAO) of the United Nations
- The Codex Alimentarius Commission (Codex)
- The International Plant Protection Convention (IPPC)

The role each of these plays in determining policies for trade in animals and animal commodities is described below. Finally, there exist a number of marginally relevant conventions, including:

- The Convention on Biological Diversity (CBD)
- The Convention on International Trade in Endangered Species of Wild Fauna and Flora
- The International Convention for the Prevention of Pollution from Ships
- The United Nations Convention on the Law of the Sea

These conventions may influence a country's approach to the regulation of trade in animals and animal products and, as such, are briefly outlined and described.

2.1 The World Trade Organization

The WTO is the legal and institutional foundation of the global multilateral trading system. Established in 1995, the WTO provides the principal contractual obligations determining the manner in which countries frame and implement trade legislation and regulations, and is the platform on which international trade relations evolve through collective debate, negotiation and adjudication (WTO, 1995; WTO, 1997b).

2.1.1 Foundation

The WTO is the successor to the General Agreement on Tariffs and Trade (GATT), a set of *multilateral* (all Member Countries) and *plurilateral* (selected Member Countries) trade agreements established following the Second World War. Seeds for the revision of GATT articles and the formation of the new WTO were sown as early as 1982 at a ministerial meeting in Geneva. Early efforts to clarify the issues and principles on which a revised multilateral agreement should be based seemed doomed to fail but, after 4 years of clarification, a new round of talks was launched in Punta del Este, Uruguay.

Further discussions were held in 1988 (Montreal), 1989 (Geneva), 1990 (Brussels), and in 1991 (Geneva) a draft of the Final Act was submitted. In 1993 negotiations were formally completed, and in 1994 a final agreement was signed by participating countries in Marrakesh, Morocco. The WTO was itself officially launched as the successor to the GATT in Geneva on January 1, 1995 (WTO, 1995; WTO, 1997b).

2.1.2 Functions and principles of the WTO

The constitution and 29 legal texts or agreements that form the basis of operation of the WTO cover issues relating to trade in goods, services and intellectual property. Together, the functions of this conglomerate of international agreements include the following:

- To administer and implement the multilateral and plurilateral trade agreements
- To act as a forum for trade negotiations
- To seek to resolve trade disputes
- To oversee national trade policies
- To cooperate with international institutions involved in global economic policy-making (WTO, 1995)

Underlying the functions of the WTO are four key principles on which Member Countries have agreed that trade should be based:

- Trade without discrimination
- Predictable and growing access to markets
- Promotion of fair competition
- Encouragement of development and economic reform (WTO, 1995)

Trade without discrimination

For almost 50 years, key provisions of the GATT outlawed discrimination between Member Countries and between imported and domestically produced merchandise. These sentiments have been carried over into the charter of the WTO. Of particular significance to this review is the SPS Agreement (WTO, 1997a), which contains several articles that outline provisions to ensure that Members do not, for example,

"*... arbitrarily or unjustifiably discriminate between other members where identical or similar conditions prevail, including between their own territory and that of other members.*"

Similar articles outlining requirements for 'harmonisation' and 'transparency' in trade negotiations between countries are promulgated in the SPS Agreement, and in many respects govern the non-discriminatory approach that Member Countries must take when assessing the hazards associated with importing animals or products of animal origin (Nairn et al, 1996; WTO, 1997c). The SPS Agreement is described in further detail in Section 2.1.5.

Predictable and growing access to markets

The multilateral trading system is an attempt by governments worldwide to provide investors, employers, employees and consumers with a business environment that encourages trade, investment and job creation, as well as choice and low prices in the market place (WTO, 1995). The existence of secure and predictable market access is largely determined by regulating the use of tariffs and customs duties. While tariffs are permitted by the WTO, they are subject to disciplines and are largely 'bound' (that is, the tariff level for a particular commodity becomes a commitment by the Member Country and cannot be raised without compensation negotiations with trading partners).

One of the implications of the abolition of quotas and other import restrictions is the need to consider the potential for SPS measures to be applied as disguised non-tariff trade barriers. Although this will be discussed in more detail elsewhere (Section 2.1.5), the legal texts of the WTO contain articles specifically dedicated to the correct application of SPS measures. Paradoxically, the degree of scientific justification required in order to disallow or restrict the entry of goods may, in some situations, be sufficiently severe as to threaten a country's ability to take reasonable measures to protect against hazards of genuine animal or public health concern. This issue directly supports the proposal to review and summarise developments in import risk analysis methodologies, and to explore the feasibility of an expert system that may allow robust analyses to be carried out more efficiently.

Promoting fair competition

While it is inaccurate to describe the WTO as a 'free trade' institution, given that tariffs are permitted in some circumstances, it is appropriate to say that the trading rules and agreements it provides comprise a system dedicated to open, fair and undistorted competition. For example, the requirement for non-discrimination when trading in animals or animal products is designed to secure fair conditions of trade (WTO, 1995; WTO, 1997c).

Encouragement of development and economic reform

More than two thirds of the WTO Member Countries are developing countries, or countries in the process of economic reform from non-market systems (WTO, 1995). Measures in favour of least-developed countries give flexibility in implementing WTO agreements, call for an acceleration in the implementation of market access concessions affecting goods of export interest to those countries and seek to provide technical assistance where this is required.

Import risk analysis is one area in which technical assistance may benefit developing nations. This might involve the development of programs to aid in the training of regulatory personnel. Alternatively, assistance might be offered by making available an expert system for import risk analysis. An expert system, if based on internationally accepted methodologies, could guide analysts through the process of carrying out technical import risk analyses, and could provide outputs that ensured transparency and effective risk communication.

2.1.3 Differences between the WTO and the GATT

Although the constitution of the WTO contains the many articles and agreements described in the 'Revised GATT' or 'GATT 1994', the WTO differs fundamentally from the GATT in several important respects (WTO, 1995):

- The WTO is a permanent institution with its own secretariat whereas the GATT was simply a set of rules, a multilateral agreement, with no institutional foundation
- The GATT was applied on a 'provisional basis' although after 40 years many governments chose to treat it as a permanent commitment
- The GATT rules applied to trade in merchandise goods whereas the WTO covers trade in goods, services and in intellectual property
- The agreements that constitute the WTO are almost all multilateral - that is they apply to all Member Countries, the exception being the group of by-rules affording developing countries special concessions in trade negotiations. In contrast, many agreements within the GATT were of a plurilateral and therefore selective nature
- The WTO dispute settlement system is significantly faster, more automatic and therefore less prone to blockages than the system in place under the GATT

2.1.4 The Agreement on Agriculture

Although the original GATT applied to trade in animals and animal products, various exceptions to the disciplines regarding the use of non-tariff measures and subsidies meant that it did so ineffectively, particularly with regard to export subsidies. One objective of the Uruguay Round was to bring order and fair competition to this highly distorted sector of world trade, and this was achieved through the formation of a revised Agreement on Agriculture. Specifically, the Agreement on Agriculture provides for commitments in the areas of:

- Market access
- Domestic support
- Export competition (WTO, 1995; WTO, 1997b)

Market access

For agricultural products, market access is now governed by a 'tariffs only' regimen. Under the Agreement on Agriculture, developed countries are to reduce tariffs over 6 years, while developing countries may extend this to 10 years. It is expected that the net effect of the tariffication of agricultural products will be to open many national markets to international competition by removing advantages previously afforded to domestic suppliers, and by promoting the stability and predictability of prices (WTO, 1995; WTO, 1997b).

Domestic support

Under the new Agreement on Agriculture, Member Countries have undertaken to decrease the level of support given to each category of agricultural product. Domestic support is quantified using a metric known as the Total Aggregate Measure of Support (Total AMS). The Total AMS is to be systematically reduced by 20 percent over 6 years (developed countries) or 13 percent over 10 years (developing countries), each period commencing on January 1, 1995, with the formal initiation of the WTO. Some special cases of domestic support, such as government funded research activities or disease-control programs, will be exempt from these conditions (WTO, 1995; WTO, 1997b).

Export competition

Developed Member Countries are required to reduce the value of direct export subsidies 36 percent below the 1986-1990 base period level over a 6 year implementation period, and to reduce the quantity of subsidised exports by 21 percent over the same period. The requirement for developing countries is that reductions must equal two thirds those given above, and that they must be achieved within a 10-year period (WTO, 1995; WTO, 1997b). It is envisaged that the combination of tariffication, reduced export subsidies and the commitment by Member Countries to decrease the Total AMS will help to encourage international trade in agricultural products and thus promote the global free-trade principle that underpins the new WTO (WTO, 1995; WTO, 1997b).

2.1.5 The Agreement on Sanitary and Phytosanitary Measures

The SPS Agreement defines the basic rights and obligations of WTO Member Countries with regard to imposing 'sanitary' and 'phytosanitary' measures to protect the life and health of their human, animal and plant populations (WTO, 1995; WTO, 1997a).

In the context of animal health, the objectives of the SPS Agreement are twofold. Firstly, by rigorously defining SPS measures, the WTO is able to put a legal structure in place that will help to prevent Member Countries from using animal or zoonotic diseases as non-tariff trade barriers. Secondly, by restricting the application of SPS measures to the situation in which hazards have been scientifically assessed according to international standards and techniques, the WTO minimises the potential for trade disputes based on unsubstantiated claims (WTO, 1995; WTO, 1997b).

The SPS Agreement defines nine principles relating to the application of SPS measures. Each of these has a direct impact on international trade in animals and animal products:

- Basic rights and obligations
- Harmonisation
- Equivalence
- Risk assessment
- Regionalisation

- Transparency
- Control, inspection and approval procedures
- Technical assistance
- Special and differential treatment

The following text, cited from Articles 2-10 of the SPS Agreement, describes the WTO's commitment to each of these principles.

Basic rights and obligations (Article 2)

"Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the agreement.

Members shall ensure that any measure is applied only to the extent necessary to protect human, plant or animal health or life, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided in paragraph 7 of Article 5 (Risk Assessment).

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

Harmonisation (Article 3)

"To harmonise sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations.

Sanitary or phytosanitary measures which conform to international standards shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and with GATT.

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher

level of protection than those based on international standards, guidelines or recommendations if there is scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of Article 5 (Risk Assessment).

Members shall play a full part, within the limits of their resources, in the relevant international organisations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics and the international and regional organisations operating within the framework of the International Plant Protection Commission, to promote the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures."

Article 3 introduces the role of international 'standards', 'guidelines' and 'recommendations' as benchmarks by which WTO Member Countries should base or gauge their SPS measures. International standards are central to the continuing development of the free trade environment as they provide both a credible point of departure for individual disease-minimisation protocols and the context within which disputes may be arbitrated (Thiermann, 1997).

Equivalence (Article 4)

"Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given to the importing Member for inspection, testing and other relevant procedures.

Members shall, on request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures."

While the sentiments of objectivity and scientific justification that underlie Article 4 are echoed elsewhere in the SPS Agreement, these paragraphs specifically establish the WTO's cardinal requirement for 'equivalence' - that is, for Member Countries to recognise alternative methodologies or protocols if their equal efficacy can be demonstrated. The importance of this

principle is that it reduces the restrictiveness that might otherwise result from the SPS Agreement and, to this end, Article 4 stresses the need for exporting countries to accommodate investigations of SPS measures deemed to be equivalent to those required by an importing Member Country.

Risk assessment (Article 5)

"Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations.

In the assessment of risks Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological or environmental conditions; and quarantine or other treatment.

In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the cost of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimising negative trade effects.

With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the level it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate with the Committee, in accordance with Article 12, to develop guidelines to further the practical implementation of this provision.

Without prejudice to Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall

ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of the risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measures may be requested and shall be provided by the Member maintaining the measure."

In the context of this project, Article 5 is possibly the single most important article in the SPS Agreement and, as such, has been examined in greater detail.

In the opening paragraph, the need to base evaluations of risk on guidelines developed by the 'relevant scientific organisations' is reiterated. In the context of animal health, the OIE has been given the responsibility of providing guidelines both for risk assessment methodology, and for appropriate SPS measures alluded to elsewhere in this document.

The second paragraph outlines a series of factors that should be considered when assessing the risks associated with a proposed importation. Despite the use of the term 'shall', these factors appear to be suggestions rather than an inflexible set of criteria and appear to relate to stages in importation rather than exposure pathways. Importation and exposure pathways are discussed in greater detail in Chapter 2.

The third paragraph stresses a need to include a consequence assessment in the risk assessment process, and describes some of the dimensions that should be considered. The requirement for

consequence assessment appears logical, since a 'risk' *per se* is not meaningful from a trading perspective without some measure of the seriousness of the outcome. It will be shown in Chapter 2, however, that although these criteria provide a sensible approach to consequence assessment, it is seldom that they have been estimated with any degree of accuracy.

The fourth paragraph describes the need to determine the 'appropriate level of SPS protection' and, specifically, to consider the effects of this decision on trade. Although not described as such, these words introduce the contentious issue of 'acceptable risk'. This issue is contentious since it involves combining the likelihood of disease entry and exposure with an estimate of the consequences, and interpreting the result in the light of trade and the level of restriction placed on other commodities. Regardless of the rigour or accuracy with which either component of 'risk' is estimated, methods by which they are jointly assessed, and the interpretation subsequently placed on the result, will always be to some extent subjective. This issue has been the subject of debate amongst regulatory analysts and will be examined in greater detail in Chapter 2.

The fifth paragraph continues the discussion of guidelines for determining an appropriate level of SPS protection. In particular, paragraph 5 describes the need to avoid 'arbitrary or unjustifiable distinctions' between individual importation scenarios. That is, that Member Countries should not impose a greater degree of protection on one or other imported commodity or for different countries of similar health status.

The sixth paragraph of Article 5 requires Member Countries to consider both the degree of risk-mitigation that importation procedures or protocols may provide, and the degree of trade restriction that may result. In some respects this may be seen as an extension of the principle of 'equivalence' (Article 4) since in designating risk-mitigation procedures, Member Countries should also consider any alternative strategies that may that may be less trade-restrictive and yet provide an equivalent degree of SPS protection.

Paragraph seven extends the guidelines for implementing SPS measures - as distinct from those concerned with either the derivation of risk estimates, or the determination of an appropriate level of SPS protection - and provides countries with the flexible option of adopting SPS measures on the basis of 'available pertinent information'. Pertinent information may be obtained from 'the relevant international organisations' or from other Member Countries. In the latter case, countries are encouraged to carry out an objective assessment of risk and to review the adopted measures as

soon as the required data is available.

Finally, paragraph eight states that countries whose SPS measures are considered constraining to trade, and are not based on any relevant international standards, must be prepared to justify such measures scientifically. This clause makes the implicit requirement that import risk analyses be transparent. That is, that a country basing SPS measures on procedures other than those identified in the relevant guidelines should be able to clearly illustrate the underlying scientific principles. This requirement implies that risk analysis methodologies utilised by individual countries should, in turn, be based either on recognised guidelines or on methodologies that can be adequately defended.

In summary, Article 5 is a key component of the SPS Agreement, both from the perspective of the trade policies of WTO Member Countries and with regard to the objectives of this review. That is, Article 5 both outlines the requirements with which Member Countries must comply with regard to their approach to import risk analysis, and describes the orientation of this discipline in the context of the WTO mission for a freer trade environment. Given this, Article 5 can be seen to provide a 'requirements analysis' for the flexible generic approach to import risk analysis upon which the proposed expert system will be based.

Regionalisation (Article 6)

"Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organisations.

Members shall, in particular, recognise the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

Exporting Members claiming that areas within their territories are pest- or disease-free areas or

areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures."

Article 6 protects the genuine sanitary or phytosanitary concerns of importing countries by requiring that claims of zonal freedom or low prevalence be substantiated with objective evidence and by allowing importing countries to investigate or evaluate the situation for themselves.

Transparency (Article 7)

"Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with Annex B, Transparency of Sanitary and Phytosanitary Regulations."

The objective of Article 7 and Annex B is to ensure that WTO Member Countries adequately describe the derivation of their SPS measures to trading partners and, by doing so, allow the latter to determine whether such measures are appropriate given the requirements of this agreement.

From the perspective of this project, Article 7 is extremely important since it formalises the WTO's requirements for clearly structured and reported import risk analyses. That is, the generic framework and methodologies upon which the proposed expert system will be based must have a clear structure and generate outcomes that are easily interpreted, if the system is to be considered acceptable by the WTO and its Member Countries.

Control, inspection and approval procedures (Article 8)

"Members shall observe the provisions of Annex C, Control, Inspection and Approval procedures, in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

Article 8 and Annex C (not cited) allow Member Countries to maintain commercial confidentiality,

while ensuring that all stages in the production and inspection of a product are clearly identified and consistently upheld. This provision enables importing countries to make judgements regarding their SPS measures on secure grounds, and with complete knowledge of the stages or processes involved in the production, certification and export of any given commodity.

Technical assistance (Article 9)

"Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through appropriate international organisations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection.

Where substantial investments are required in order for an exporting developing Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product concerned."

Article 9 has been included in the SPS Agreement to ensure that Member Countries enjoy a similar standard of technical expertise in relation to the establishment and maintenance of SPS measures. This promotes the successful operation of trade rules as applied to SPS measures and helps to maintain and expand the market access of countries with less ability to achieve high technical standards.

Special and differential treatment (Article 10)

"In the preparation and application of sanitary or phytosanitary measures, Members shall take into account the special needs of developing country Members, and in particular of the least-developed country Members.

Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary, measures, longer time frames for compliance

should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified time-limited exceptions in whole or part from obligations under this Agreement, taking into account their financial trade and development needs.

Members should encourage and facilitate the active participation of developing country Members in the relevant international organisations."

Article 10 provides developing countries, and particularly the 'least developed' countries, with the ability to participate in trade without being penalised for an inability to immediately comply with each of the clauses described above. This does not mean that such countries are exempt from the requirements of the SPS Agreement, but that other Member Countries and the WTO Committee should grant time-limited exemptions or allow for the phased introduction of SPS measures. This implies that developing or least-developed countries will not be disadvantaged in the move toward a freer trade environment.

Conclusions

The SPS Agreement represents both the legal framework and free trade philosophy of the current environment for international trade in animals and animal products. Given this, the articles and annexes of the SPS Agreement provide an outline of the essential criteria that the proposed expert system must fulfil if it is to be acceptable to regulatory analysts. Simply stated, such a system should be based on existing guidelines for import risk analysis, or on transparent and scientifically sound methodologies, and should produce outputs that enable analysts to effectively communicate methods and results.

2.1.6 The Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT Agreement) covers food standards that are not related to the protection of human health, including threats arising from additives, contaminants, toxins, disease-causing organisms or diseases carried by animals (WTO, 1997b). The TBT Agreement thus encompasses rules intended to provide relevant information and to protect consumers against deception and fraud. Labelling and nutritional requirements also fall within the scope of the TBT Agreement (Nairn et al, 1996; WTO, 1997b).

Under the TBT Agreement, Member Countries shall ensure that products imported from one country are afforded treatment no less favourable than that accorded to like products from other countries or to products of national origin. Members shall also ensure that technical regulations are "*... not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.*" (WTO, 1997b). Technical regulations shall be no more trade-restrictive than necessary to fulfil a legitimate objective, taking into account any risks that non-fulfilment would create. Legitimate objectives specifically include:

- National security requirements
- The prevention of deceptive practices
- The protection of human, animal, plant or environmental health or safety (Nairn et al, 1996; WTO, 1997b)

The global objective of the TBT Agreement thus parallels that of the SPS Agreement - that is, to ensure that Member Countries of the WTO do not hinder the development of a freer international trade environment by adopting disguised restrictive measures (WTO, 1997b). As was the case for the SPS Agreement, the TBT Agreement also contains clauses to protect importing countries from legitimate cases of fraud or deception (WTO, 1997b).

Interestingly, the TBT Agreement does not appear to make reference to an international standard for either risk analysis purposes or for designating specific TBT measures. Given this, it is unlikely that techniques or methodologies adopted to satisfy TBT requirements would substantially increase the value or applicability of a generic format for animal disease orientated import risk analysis.

2.2 Office International des Epizooties

The OIE was established in 1924 by international treaty. In establishing the OIE, the principal objective was to promote and coordinate the surveillance and control of animal diseases, thus improving animal production and human health and safety, and facilitating freer trade in animals and products of animal origin (Nairn et al, 1996; OIE, 1997c; OIE, 1997d). The OIE operates under the authority and control of an International Committee formed by 'permanent delegates' appointed by the governments of the 150 Member Countries. The International Committee coordinates the activities of the OIE and is responsible for electing the Commissions that carry out specific tasks. These include the Administrative Commission, Regional Commissions and Specialist Commissions (OIE, 1999a).

The tasks undertaken by the commissions and subsidiary bodies of the OIE reflect its global mission and fall into three broad categories:

- The collection and publication of international animal health information and statistics
- The derivation and publication of international standards
- Research and expertise on animal diseases (OIE, 1999a)

2.2.1 Collection and publication of animal health information and statistics

The principal function of the OIE is to inform national veterinary services of the occurrence and course of epizootics that could endanger the life or health of animals or humans (OIE, 1999a). To facilitate this service, the OIE has categorised epizootics considered to be important to human or terrestrial animal life or health into two formal lists (OIE, 1997a).

The first, termed *List A*, contains " ... *the list of transmissible diseases which have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or public health consequence and which are of major importance in the international trade of animals and animal products*.". Veterinary administrations within importing countries are encouraged to take measures to ensure that exotic List A diseases are not imported as a result of trade, and to do so by using the provisions set out in import health standards. It is the requirement of the WTO (WTO, 1997c) that when formulating import health standards, or SPS measures, Member Countries should observe the recommendations within the OIE International Animal

Health Code (OIE Code). If additional safeguards are stipulated, they should be justified by way of a scientific risk assessment (WTO, 1997c)(Nairn et al, 1996).

The second list, termed *List B*, contains those " ... *transmissible diseases which are considered to be of socio-economic and/or public health importance within countries and which are significant in the international trade of animals and animal products.*". The OIE Code states that "... *wherever a List B disease is under consideration, bilateral discussion between veterinary Administrations seems essential. This should be done in the context of the recommendations of the Code* ...". The OIE Code goes on to suggest that "... *if world trade in livestock and animal products is to be facilitated, the unnecessary inclusion of List B diseases in health certificates should be avoided* ...".

Information regarding the occurrence of List A and B diseases is collected by the Central Bureau of the OIE and stored in a central database. In the event of an outbreak of a List A disease or any other disease that may have serious repercussions on public health or on the economy of animal production, Member Countries directly at risk are notified within 24 hours. In addition to this form of emergency reporting, the OIE disseminates statistics relating to the international distribution and prevalence of List A and B diseases through the following channels:

- The weekly publication, Disease Information, available through the Internet or by post
- The two monthly OIE Bulletin, which emphasises List A diseases but also contains information regarding the epidemiology of other major contagious diseases and a summary of current OIE activities
- The annual World Animal Health, which provides a wide variety of information on animal health status and control methods (OIE, 1999a)

To support the integrity and accuracy of this service, Member Countries are required to notify the OIE within 24 hours of the following events:

- The first occurrence or re-occurrence of a List A disease
- Important new findings regarding a List A disease, where such information is of epidemiological significance to other countries
- A provisional diagnosis of a List A disease, if this represents important new information of epidemiological significance to other countries (OIE, 1997a)

Reports regarding the occurrence of List B diseases are submitted annually to the OIE Central Bureau. Notification within 24 hours is required, however, in the situation of an outbreak that represents the new entry of a disease to a country or zone previously free of that disease, or if information of epidemiological significance to other countries comes to light (OIE, 1997a; OIE, 1999a).

The OIE Aquatic Animal Health Code (OIE Aquatic Code) lists notifiable diseases of fish, molluscs and crustaceans. These are diseases regarded as having the potential for serious damage to national aquaculture industries or wild populations of fish. Introduction of these diseases could cause serious economic loss. When a new outbreak of a notifiable aquatic disease occurs in a previously free country or region, the Central Bureau should be informed within 24 hours.

In addition to the collection and dissemination of information relating to animal diseases, the OIE has instigated a program aimed at classifying the veterinary services of Member Countries (OIE, 1999a). The principal function of this program is to enable countries to base their SPS measures on an objective and accurate assessment of the hazards relating to the introduction of List A or B diseases. The program thus seeks to minimise the potential for disputes relating to the ability of an exporting country to detect or monitor disease incidence within its boundaries, or to enforce effectively and reliably any specified import regulations.

2.2.2 Development and publication of standards

While the OIE was established specifically to aid in the control of animal and zoonotic diseases, it was always intended for this to be achieved without disruption to trade in animals or animal products. To ensure that this occurred, the International Committee established the Standards Commission to compile the Manual of Standards for Diagnostic Tests and Vaccines (OIE Manual) and the International Animal Health Code Commission to compile and maintain the OIE Code, as mentioned above. In addition to these, the Fish Diseases Commission has compiled the Diagnostic Manual for Aquatic Animal Diseases (OIE Aquatic Manual) and the OIE Aquatic Code, also mentioned above.

With the establishment of the WTO, these standards and codes for terrestrial and aquatic animals were endorsed as the benchmarks by which a country's sanitary measures should be evaluated (WTO, 1995; Thiermann, 1997; WTO, 1997c). Given this, WTO Member Countries are required both to adhere to the principles and recommendations stated in each, and to make a commitment to support their ongoing development (Thiermann, 1997). In order to maximise the scientific contribution of each Member Country, and to allow each Member Country to comment on the applicability of any recommendations, the OIE Code and OIE Aquatic Code are developed and periodically revised through an iterative process of consultation. This process entails the following steps:

- A Working Group of international specialists compiles an outline of the text
- The Code Commission (OIE Code) or Fish Diseases Commission (OIE Aquatic Code) reviews and discusses the text and prepares a draft for circulation
- The draft is distributed to all Member Countries for comment
- The Working Group and Code Commission/Fish Diseases Commission review the comments and revise the text
- The cycle is repeated if the process of revision leads to a fundamentally different text, or to further questions
- The Working Group and Code Commission/Fish Diseases Commission finalise the text
- The International Committee debates and votes on the text at the General Session

Individual chapters of either code are usually revised in isolation of the main text. The OIE Code chapter on Import Risk Analysis was in fact reviewed and adopted by the International Committee in May 1999. It follows that a majority of the sample import risk analyses obtained for evaluation was written under older versions of the OIE Code. The OIE Aquatic Code was last revised in 1997 (second edition).

2.2.3 Research and expertise on animal diseases

The first objective assigned to the OIE following its formation in 1924 was to promote and coordinate research into the surveillance and control of animal diseases worldwide (OIE, 1999a). This task is undertaken by Specialist Commissions, Working Groups, the Reference Laboratories and Collaborating Centres, each of which operate under the control of the International Committee.

The role of *Specialist Commissions* is to study problems related to the epidemiology and control of specific animal diseases, and to consider issues related to the harmonisation of international regulations. Specialist Commissions are formed at the discretion of the International Committee and assigned a period of operation considered appropriate for the problem at hand.

OIE Working Groups are similar to the Specialist Commissions, although orientated toward collecting and summarising research and development in specific areas of animal health and taking steps toward ensuring that Member Countries are able to benefit from this information. OIE Working Groups also conduct national, regional or worldwide surveys, and organise training workshops, scientific seminars and international exchange of information. The four Working Groups currently operating are:

- Biotechnology
- Informatics and Epidemiology
- Veterinary Drug Registration
- Wildlife Diseases (OIE, 1999a)

The third group of scientific bodies coordinated by the OIE incorporates the *Reference Laboratories and Collaborating Centres.* The role of these is to provide Member Countries of the OIE with scientific and technical assistance and expert advice on topics linked to disease surveillance and control. Support may take various forms, including:

- The provision of experts in times of crisis or difficulty
- The preparation and supply of diagnostic kits or reference reagents
- The organisation of practical workshops and training courses in diagnostic techniques
- The organisation of scientific meetings or seminars for the discussion of issues relating to animal disease diagnosis and control

2.3 World Health Organisation

The World Health Organization (WHO) was established in 1946 as part of the United Nations with the principal objective of " *... attaining the highest possible level of health for the world's population.*" (Nairn et al, 1996; WHO, 1998). The WHO, with a membership in 1997 of 190 countries, is responsible for directing and coordinating issues pertaining to international health, and for providing both aid and technical assistance. The WHO also proposes conventions,

agreements and regulations and makes recommendations with respect to international health matters (Nairn et al, 1996).

With a direct responsibility for human health, it can be seen that the WHO is actively involved in the management of zoonotic diseases and, by extension, in many aspects of the production, marketing and trade in animals and animal products (WHO, 1998). This is notably the case for developing countries or countries requiring technical or financial assistance for the effective control of human or zoonotic diseases. Of greater significance to the context of this review however, is the joint role the WHO has played with the United Nations Food and Agriculture Organization (FAO) in the formation and management of the *Codex Alimentarius Commission* (Codex), as discussed below.

2.4 Food and Agriculture Organization

The Food and Agriculture Organisation (FAO) of the United Nations was founded in 1945 with the following objectives:

- To raise the levels of nutrition and standard of living in developing countries
- To improve agricultural productivity
- To better the conditions of rural populations (FAO, 1998b)

The FAO is presently the largest autonomous agency within the United Nations system, with 174 Member Countries plus the European Union (EU). The organisation offers direct development assistance, collects, analyses and disseminates information, provides policy planning advice to governments and acts as an international forum for debate on food and agriculture issues. A specific priority is encouraging sustainable agriculture and rural development, a long-term strategy for the conservation and management of natural resources (FAO, 1998b).

The FAO has also established a focus on helping Member Countries to respond to the changes in the international trade environment that have resulted from the Uruguay Round of GATT and the establishment of the new WTO (FAO, 1998a). In particular, the FAO maintains that less developed nations may face difficulties while adjusting to loss of markets and capturing new trade, particularly with regard to agricultural products (FAO, 1998a). In this context, the FAO has undertaken to provide specific marketing advice and consultancy and to provide intermediaries or

advisers for trade negotiations based on the provisions of the revised SPS Agreements, the Agreement on Agriculture, the Agreement on Technical Barriers to Trade, and other WTO agreements (FAO, 1998a).

While the FAO provides technical assistance in the context of the freer agricultural trade environment, it does not contribute directly to the designation of standards or technical guidelines, nor evaluate or revise import assessment methodologies. As such, neither the organisation's charter nor its numerous publications were considered to be particularly relevant to the development and assessment of a generic format for animal health import risk analysis and were not pursued further.

2.5 Codex Alimentarius Commission

The Codex was established in 1962 with the following objectives:

- To guide and promote the elaboration and establishment of definitions and requirements for foods
- To assist in the harmonisation of the above
- To facilitate international trade in foods and foodstuffs (Nairn et al, 1996; Codex, 1998a; Codex, 1998b)

The Codex, with a membership in 1997 of 147 countries, has produced 250 commodity standards and more than 40 hygiene and technology codes of practice, has evaluated more than 700 food additives and contaminants, and developed more than 3200 maximum residue limits for pesticide-commodity combinations (Nairn et al, 1996; Codex, 1998a).

The importance of the Codex to international trade lies in the fact that both the SPS and TBT Agreements of the WTO have accorded special status to its standards, guidelines and recommendations (WTO, 1995; WTO, 1997b). Importing countries demanding that their exporting counterparts meet or impose standards over and above those recommended by the Codex must justify their position scientifically or face penalisation for breaching the relevant sections of the SPS or TBT Agreements.

In reference to this project, the importance of the Codex lies principally in its recognition as one of the three 'relevant scientific organisations' for SPS/TBT standards. That is, while standards and

recommendations developed by the Codex relate specifically to human food safety issues, the methodologies and SPS/TBT principles on which they are based are essentially equivalent to those developed by the OIE for animal health.

2.6 International Plant Protection Convention

The IPPC was adopted by the FAO Conference in 1951 and came into force the following year (Nairn et al, 1996; IPPC, 1998). The IPPC, with a membership in 1997 of 103 countries, was formed with the objective of " ... *securing common and effective action to prevent the spread and introduction of pests and diseases of plants and plant products and to promote measures for their control* ..." (FAO, 1995; Nairn et al, 1996; IPPC, 1998). It can be seen that while the focus of the IPPC is on plant health, it has a very similar mission statement to that of the OIE.

The IPPC describes the principles of plant quarantine and the appropriate actions to be taken by Member Countries when undertaking quarantine for specific plant diseases. From this position, the IPPC was adopted by the WTO as the 'relevant international organisation' responsible for determining and maintaining standards for plant quarantine and other principles applicable to trade in plants or plant products. For this reason, the IPPC is viewed by the WTO as the plant-orientated equivalent of the OIE (Kellar, 1993) and, in keeping with the principles underlying all WTO Agreements, WTO Member Countries that choose to apply measures other than those recommended by the IPPC must justify their position scientifically (Kellar, 1993; Nairn et al, 1996; IPPC, 1998). Typically this will involve the conduct of a scientific risk assessment. The IPPC thus helps to ensure harmonisation in the trade in plants and plant-derived products and to promote the development of a freer international market for these commodities.

2.7 Convention on Biological Diversity

The Convention on Biological Diversity (CBD) was negotiated in June, 1992, in the lead-up to the United Nations Conference on Environment and Development. The CBD, which has currently been ratified by more than 130 countries, has the following objectives:

- The conservation of biological diversity
- The sustainable use of biological commodities
- The fair and equitable sharing of benefits arising from the use of genetic resources (Nairn et al, 1996; UN, 1999)

The provisions cited below are taken from Article 8 of the CBD and are particularly pertinent to the issue of trade in animals and animal-derived products;

" ... to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity."

" ... to prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats and species."

These provisions indicate international recognition of the environmental hazards associated with the movement of or trade in biologically modified organisms, particularly those organisms that pose a potential threat to individual species or biological systems. Indeed, one significant outcome of the first Conference of the Parties to the Convention on Biological Diversity was the decision to initiate a process to " ... *consider the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms resulting from biotechnology that may have adverse effects on biodiversity* ..." (Nairn et al, 1996; UN, 1999). The process agreed upon was the formation of a negotiating group with the purpose of deriving an appropriate protocol - it was envisaged that an agreement between countries regarding the movement of biologically modified organisms could be reached by 1998 (Nairn et al, 1996)

When interpreted in the context of the WTO, the articles of the CBD and, in the near future, the international protocol for the movement of biologically modified organisms, allow countries to modify their SPS measures in-line with recommendations regarding the potential environmental threat posed by trade in these commodities. In keeping with the rules governing trade in other products, countries choosing to enforce restrictions over and above those recommended by the CBD must justify their position scientifically - that is, by conducting a thorough risk assessment. This requirement has lead to the development of risk analysis methodologies for biologicals as a distinct sub-field of the more general discipline of import risk analysis, and the OIE's decision to publish an issue of the journal of the Scientific and Technical Review specifically dedicated to this subject (OIE, 1995b).

2.8 The Convention on International Trade in Endangered Species of Wild Fauna and Flora

International trade in wildlife has contributed to the decline in the numbers of many species of animals and plants (Nairn et al, 1996). The scale of over-exploitation for trade has led to the formation of an international treaty to protect wildlife and to prevent international trade from threatening many species with extinction. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) came into force in 1975 and now has more than 130 Member Countries. Member countries participate in meeting the requirements of CITES by placing controls on trade in an agreed list of endangered species and by regulating and monitoring trade in others that might become endangered (Nairn et al, 1996).

2.9 International Convention for the Prevention of Pollution from Ships

The International Convention for the Prevention of Pollution from Ships (ICPPS) is the most comprehensive international initiative to regulate and minimise pollution from ocean-going vessels (Nairn et al, 1996; UN, 1999). The 'Convention deals with all forms of ship-generated waste marine pollutants and regulates more than ninety percent of the world's shipping tonnage. In particular, the transfer of ballast water and the resulting potential for introductions of organisms could impact adversely on local and regional economies, human health and marine biodiversity (UN, 1999).

From the perspective of this project, the ICPPS is important since it employs risk assessment methodology to determine the extent and consequence of hazards associated with transportation by sea. These assessments are not 'import risk assessments' but nevertheless examine the risks to animal health and life and carry weight with regard to the determination of shipping regulations. Given this, approaches and techniques employed by the ICPPS should be examined as a component of the derivation of a generic format for import risk assessment.

2.10 The United Nations Convention on the Law of the Sea

Member Countries of the United Nations Convention on the Law of the Sea have the general obligation to protect and preserve the marine environment. Under the articles of this convention, Member Countries must observe the specified measures to " ... *protect and preserve rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life*." (Nairn et al, 1996; UN, 1999). While the regulations within this convention may be based on informal risk assessments, the latter were not considered to be of particular relevance to the project objectives and were not evaluated during the derivation of a generic standard.

3 Conclusions

This review was undertaken with two important objectives:

1. The identification of international organisations and agreements relevant to trade in animals and animal products

2. The description of the role that each play in determining approaches or methodologies used to assess animal health risks associated with the movement of these commodities

Arising as a secondary objective was the need to identify and describe those components of the current regulatory environment which may determine the relevance and acceptability of an expert system for import risk analysis, and thus influence its adoption by regulatory agencies.

One of the key conclusions drawn from this review was the central role that the establishment of the WTO and the SPS Agreement have played in shaping the current trade environment. The WTO regulates trading practices in line with its mission to encourage a freer international market place. With regard to trade in animals and animal products, it bases its agreements on the principle that protocols for disease-minimisation should adhere to recommended standards unless there is a scientifically-justified reason to do otherwise.

It is this philosophy of fair trade, and the removal of disguised non-tariff trade barriers, that has prompted the recent development and application of risk assessment methodologies. By extension, the specific requirements of the WTO for structure, transparency and harmonisation have lead to a

need to clarify international guidelines for this discipline. Each of these requirements is outlined in the articles of the SPS Agreement and should be adhered to in the design and implementation of an expert system for import risk analysis.

Of additional importance is the role undertaken by the OIE as the official source of standards and guidelines for animal disease risk assessment, and the reciprocal commitment by WTO Member Countries to support the development and review of such standards. This cooperative strategy ensures that standards are based on worldwide research and expertise, and that they are not designed to favour particular countries or groups of countries.

Finally, a number of less significant agreements and conventions were explored in the course of this review. Of these, the Agreement on Agriculture and the Agreement on Technical Barriers to Trade provided further insight into the regulatory environment for agricultural products, although it is unlikely that specific methodologies developed to satisfy these agreements will be relevant to the proposed expert system. Conversely, brief assessments of the Convention on Biological Diversity and the International Convention for the Prevention of Pollution from Ships revealed that these bodies utilised disease-based risk analysis methodologies, had a similar need for recognised international standards, and that a further evaluation of techniques and approaches may be beneficial.

CHAPTER 2

An Evaluation of Approaches and Methodologies for Import Risk Analysis

Reference base for Chapter 2

Contents

1 Introduction

In order to carry out the evaluations in Chapter 2, a reference base of largely unpublished information was accumulated from a wide range of sources, and categorised as shown below:

- Sample import risk analyses
- Sample allied disease risk analyses
- Sample consequence assessments

2 Sample import risk analyses

Veterinary regulatory authorities within the so-called 'Quadrilateral Group' of countries (New Zealand, Australia, Canada and the United States), and various other countries or trading blocks thought to have contributed to the field of import risk analysis, were identified. Regulatory authorities were contacted by the New Zealand Chief Veterinary Officer and asked to provide examples of quantitative and qualitative import risk analyses for review.

In addition to this targeted search, a number of sample analyses were obtained from conference seminar or workshop proceedings, and from various issues of the OIE Scientific and Technical Review. These documents encompassed a broad range of techniques and approaches, and provided an interesting panorama of the trends that have occurred in this rapidly evolving discipline during the last 10 to 15 years.

A list of the analyses obtained for examination is given below. This list has been divided into qualitative and quantitative analyses, and subsequently categorised by country. It should be noted, however, that while analyses may have been produced by or for each named country, they were carried out by a range of authors whose approaches reflect personal preferences and the existing trends in risk analysis methodology. Thus the analyses display a spectrum of approaches both within and between countries, and do not at all times represent any given country's official policy concerning risk analysis methodology.

Finally, each of the sample import risk analyses has been assigned an abbreviated name (as shown in parentheses) that conveys information regarding either the commodity or a specific disease, and the country that carried out the analysis. These names will be cited throughout Chapter 2.

2.1 Qualitative import risk analyses (n=34)

New Zealand qualitative import risk analyses

1. Diseases of anseriforms and the importation of their eggs from Denmark: a discussion paper (Anseriforms NZ, 1988)
2. The importation into New Zealand of meat and meat products: a review of the risks to animal health (Meats NZ, 1991)
3. Review of conditions applied to the import of hides and skins into New Zealand (Hides NZ, 1991)
4. The risk of introducing exotic diseases of fish into New Zealand through the importation of ocean-caught Pacific salmon from Canada (Salmon1 NZ, 1994)
5. Disease risk assessment for the importation of porcine semen into New Zealand from European Union member countries (PRRS1 NZ, 1995)
6. Importation into New Zealand of aquatic animal products for use as fish bait (Baitfish

NZ, 1996)

7. Contamination of fish products: risks and prevention (Fish products NZ, 1997)
8. The potential risks to animal health from imported sheep and goat meat (Sheep and goat meat NZ, 1997)
9. Import health risk analysis: salmonids for human consumption (Salmon2 NZ, 1997)
10. Risk Analysis for the Importation of passerine birds to New Zealand from Australia and the United Kingdom (Passerines NZ, 1997)
11. Risk analysis for the importation of live ratites (ostriches, emus and rheas) and their products (hatching eggs, uncooked meat) into New Zealand (Ratites NZ, 1997)
12. An assessment of the risks to New Zealand's native psittacine species associated with international trade in avians and avian products, natural avian migration and the legal or illegal importation of avian species (Psittacines NZ, 1998)
13. Import health risk analysis: Live equines and equine semen (Equines/semen NZ, 1998)
14. Import risk analysis: Unprocessed fibre of sheep and goats (Fibre NZ, 1998)
15. Import risk analysis: Chicken meat and chicken meat products (Chicken NZ, 1999)

Australian qualitative import risk analyses

1. A qualitative assessment of current exotic disease risks for Australia (Exotic AUS, 1990)
2. Import risk assessment for salmon meat (Salmon1 AUS, 1993)
3. Risk assessment on the importation of milk and milk products (excluding cheese) from countries not free from foot and mouth disease (Mlk AUS, 1993)
4. Australian quarantine policies and practices for aquatic animals and their products: A review for the Scientific Working Party on Aquatic Animal Quarantine (Aquatic1 AUS, 1995)
5. Aquatic animal quarantine in Australia: report of the Scientific Working Party on Aquatic Animal Quarantine (Aquatic2 AUS, 1995)
6. Salmon import risk assessment (final report): An assessment by the Australian Government of quarantine controls on uncooked, wild, adult, ocean-caught Pacific salmonid product sourced from the United States of America and Canada (Salmon2 AUS, 1999)
7. Risk Analysis for the Practice of Importing Frozen Fish As Bait by the Rock Lobster Industry of Australia (Lobster AUS, 1997)
8. Draft import risk analysis report on the revision of import policy related to scrapie

(Scrapie AUS, 1999)

9. Draft import risk analysis paper for live crocodilians (Crocodiles AUS, 1999)
10. Draft porcine semen import risk analysis (Porcine semen AUS, 1999)

Canadian qualitative import risk analyses

1. Risk analysis and international trade principles applied to the importation into Canada of caprine embryos from South Africa (Goat embryos CAN, 1997)
2. Potential animal health hazards of pork and pork products (Pork CAN, 1997)

USA qualitative import risk analyses

1. Risk of spread of paenaeid shrimp viruses in the Americas by the international movement of live and frozen shrimp (Shrimp USA, 1997)
2. Bee health and international trade (Bees USA, 1997)

Other qualitative import risk analyses

1. Risks related to the introduction of exotic disease: a European perspective (Exotic EU, 1995)
2. The risk of exotic virus disease to Ireland (Exotic IRE, 1995)
3. Animal health risks associated with the transportation and utilisation of wildlife products (Wildlife SA, 1997)
4. Health hazards to the small ruminant population of the Middle East posed by the trade of sheep and goat meat (Sheep/goats ME, 1997)
5. Animal health risks associated with ostrich products (Ostrich SA, 1997)

2.2 Quantitative import risk analyses (n=21)

New Zealand quantitative import risk analyses

1. The risk of introducing exotic diseases of fish into New Zealand through the importation of ocean-caught Pacific salmon from Canada (Salmon1 NZ, 1994)

2. The risk of introducing bovine spongiform encephalopathy (BSE) through the importation of bovine semen (BSE NZ, 1996)
3. Scrapie: the risk of its introduction and effects on trade (Scrapie NZ, 1996)
4. The risks of introducing rabies through the importation of dogs (Rabies NZ, 1997)
5. Importation of poultry meat: assessing the risk of IBD introduction (IBD NZ, 1997)
6. Import health risk analysis: salmonids for human consumption (Salmon2 NZ, 1997)
7. Introduction of anthrax via the importation of green hides: a risk analysis revisited (Anthrax NZ, 1998)[1]
8. Quantitative risk analysis: a model for the risk of introducing PRRS into New Zealand with the importation of porcine semen from the United States (PRRS2 NZ, 1998)

Australian quantitative import risk analyses

1. An Assessment of the Risks of Introducing Foot and Mouth Disease Through the Importation of Cassava Pellets From Thailand (Cassava AUS, 1992)
2. A report for the Australian Quarantine and Inspection Service on the development of a quantitative model for import risk assessments, using the importation of uncooked chicken meat from Denmark, Thailand and the USA as examples (Chicken AUS, 1996)

Canadian quantitative import risk analyses

1. Quantitative risk assessment of the risks associated with the importation of pigs to abattoirs (Pigs CAN, 1993)
2. Assessment of the probability of introduction of bluetongue with the importation of USA cattle (Bluetongue CAN, 1994)
3. Risk assessment for the introduction of camelids from the USA (Camelids CAN, 1996)

USA quantitative import risk analyses

1. An assessment of the risk of foreign disease introduction into the United States of

[1] This document reviews quantitative aspects of an earlier New Zealand import risk analysis - Harkness, J (1991). *Review of conditions applied to the import of hides and skins into New Zealand.* National Agricultural Security Service Publication 91-3, Ministry of Agriculture and Fisheries, Wellington, New Zealand

America through garbage from Alaskan cruise ships (Garbage USA, 1993)

2. Equine piroplasmosis and the 1996 Olympic Games at Atlanta, Georgia: a risk assessment (Piroplasm USA, 1994)
3. Risk assessment study on a proposed change to the Hawaii rabies quarantine policy (Rabies USA, 1996)
4. Likelihood of introducing selected exotic diseases to domestic swine in the continental United States through uncooked swill (Swill USA, 1997)

Other quantitative import risk analyses

1. Quantitative assessment of the risk of disease transmission by bovine embryo transfer (Bov Embryos BR, 1995)
2. Assessment of the risk of foot and mouth disease introduction into the CARICOM countries through the importation of meat from Uruguay (Meat BR, 1995)
3. Risk assessment for the importation of raw hides from Brazil (Hides BR, 1996)
4. Risks and economic consequences of introducing classical swine fever into The Netherlands by feeding swill to swine (CSF NL, 1997)

3 Sample allied disease risk analyses

One of the ancillary benefits to arise from the international search for import risk analyses was the identification of numerous risk analyses that were not based on on animal importation scenarios. Some of these, such as the analyses of the risks related to the introduction of insect pests with imported fruit, provide interesting comparisons between the analytical approach recommended by, in this case, the IPPC, and the more familiar OIE Code. Others were simply assessments of the risk of a disease-related event within a given country and thus were unrelated to trade. Regardless of their focus, each of these analyses contributed to an understanding of the range of techniques available.

Allied risk analyses were named according to the convention adopted for the larger group of import risk analyses. The allied risk analyses identified for review are listed in chronological order below:

1. Our immigrant insect fauna (Fauna USA, 1978)
2. Importation of avocado fruit (*Persea americana*) from Mexico (Avocado MEX, 1995)

3. Risk assessment of the practice of feeding recycled commodities to domesticated swine in the US (Recycled USA, 1995)
4. Addendum 1: Estimates for the likelihood of pest outbreaks based on the final draft (Pest outbreaks USA, 1996)
5. Risk of hydatids (*Echinococcus granulosus*) infection in farm dogs from feeding untreated sheepmeat (Hydatids NZ, 1996)
6. Risks of spreading foot and mouth disease through milk and dairy products (Milk UK, 1997)
7. Report from the Scientific Committee on the risk analysis for the transmission of BSE in colostrum, milk and milk products (BSE Milk, 1997)
8. Assessment of the risk of bovine spongiform encephalopathy (BSE) in pharmaceutical products (BSE Drugs EU, 1998)

4 Sample consequence assessments

Some of the sample risk analyses contained assessments of the consequences of each identified hazard. Aside from these, a group of consequence assessments carried out in isolation of risk assessment were identified. These were named according to the convention adopted for the sample import risk analyses, and are listed below:

1. A cost-benefit analysis of quarantine (Quarantine AUS, 1991)
2. Potential economic impacts of an avocado weevil infestation in California (Avocado USA, 1993)
3. Cost-benefit aspects of food irradiation processing (Irradiation USA, 1993)
4. Final economic analysis of revisions to 7 CFR Part 319, quarantine 37 regulations: importations of nursery stock, plants, roots, bulbs, seeds and other plant products (Nursery plants USA, 1994)
5. Economic impact of salmonid diseases (furunculosis and infectious hematopoietic necrosis) (Salmon econ AUS, 1994)
6. Welfare effects of the national pseudorabies eradication program (Pseudorabies USA, 1994)
7. An economic assessment of the costs and benefits of African swine fever prevention (ASF USA, 1994)
8. Modelling the potential impact of exotic disease on regional Australia (Exotic2 AUS, 1995)

9. Economic basis and disastrous risk basis for brucellosis eradication (Brucellosis USA, 1997)

EVALUATION I

Frameworks for Import Risk Analysis

Contents

1 Introduction

The first stage in evaluating approaches and methodologies was to identify a generic framework for import risk analysis. This framework will represent the ordered series of steps typically undertaken in carrying out an import risk analysis. Frameworks for import risk analysis have been recommended in the OIE guidelines (past and present). These will be described and evaluated. Individual authors have also adopted frameworks for analyses and these will be examined in the light of the purported advantages and/or constraints of the official OIE guidelines.

2 Frameworks for import risk analysis

2.1 The framework recommended in the OIE Code

According to the current OIE Code, the principal aim of risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals[1], animal products, animal genetic material, feedstuffs, biological

[1] A mammal (with the exception of marine mammals) or bird (domestic and wild species)

products[2] and pathological material[3]. Objective and defensible risk assessment is necessary if a country is to justify scientifically trade restrictions and/or import refusals in accordance with the SPS Agreement.

The OIE Code also stresses the need for transparency, maintaining that without a clear description of uncertainties and incompleteness in available data, the distinction between facts and the analyst's value judgements will be blurred.

In order to carry out risk analyses that will meet these objectives, the OIE Code suggests the following framework:

- Hazard identification
- Risk assessment, consisting of
    - Release assessment
    - Exposure assessment
    - Consequence assessment
    - Risk estimation, taking account of
        - Veterinary services
        - Zoning and regionalisation
        - Surveillance and monitoring of animal health
- Risk management, consisting of
    - Risk evaluation
    - Option evaluation
    - Implementation
    - Monitoring and review
- Risk communication

This framework is illustrated schematically in Figure 1.

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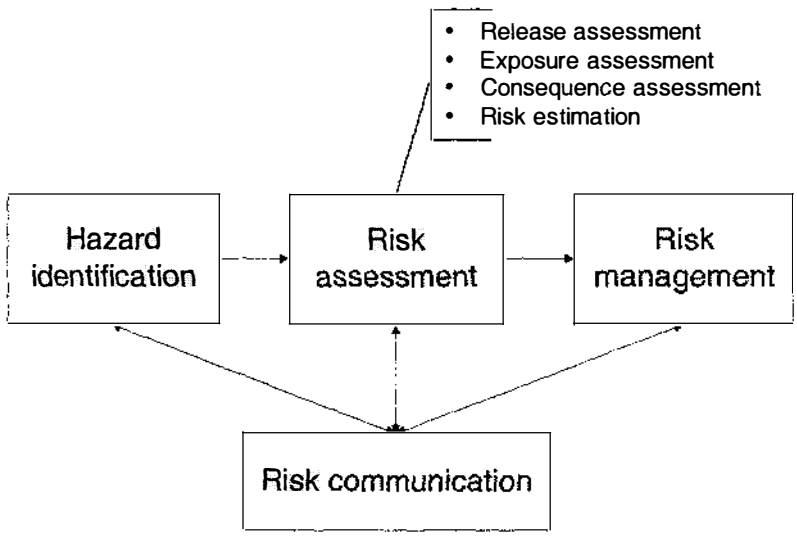
[2] Either:

- Biological agents for use in the diagnosis of certain diseases
- Sera for use in prevention or treatment of certain diseases
- Inactivated or modified vaccines for use in the preventive vaccination against certain diseases
- Microbial genetic material

[3] Strains of infectious agents, specimens of infectious or parasitic material obtained from live animals, excreta and tissues and organs obtained from carcasses, to be sent to a specialised laboratory or to a reference laboratory recognised by the OIE, WTO, FAO, etc

Figure 1: The OIE framework for import risk analysis



Definitions for each of these component processes are cited below:

Hazard identification: The process of identifying the pathogenic agents that could potentially be introduced in the commodity considered for importation.

Risk assessment: The evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country.

Release assessment: A description of the biological pathways necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and an estimation of the probability (qualitative or quantitative) of the complete process occurring.

Exposure assessment: A description of the biological pathways necessary for the exposure of animals and humans in the importing country to the hazards 'released' from a given risk source, and an estimation of the probability of this occurring.

Consequence assessment: A description of the potential consequences of a given exposure and an estimate of the likelihood that each will occur. The consequence assessment may be qualitative or quantitative.

Risk estimation: An integration of the results of the release assessment, exposure assessment and consequence assessment to produce an overall measure of the risks associated with each identified hazard.

Risk management: The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

Risk communication: The process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision makers and interested parties.

This framework is similar to that which appeared in the previous OIE Code, the most significant modification being the explicit description of risk estimation as an integration of likelihood and consequence evaluation. This is a critical requisite, although it will be shown in the discussion of sample analyses (see below) that not only have consequence assessments frequently been excluded from published risk analyses, but that the number of identified analyses that actually formulate an integrated 'risk estimate' is quite small.

The importance of consequence assessment is exemplified in the excerpt from the Article 5 of the SPS Agreement:

" ... In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the cost of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks."

Here it can be seen that the WTO explicitly describes the need to consider the outcomes of a hazard when assessing risk. It can also be seen that while this consequence assessment may become a complex or controversial process, it is important that the principle of an integrated risk estimate is described in the international guidelines. Integrated likelihood and consequence assessment was in fact alluded to in the earlier edition of the OIE Code, where 'risk' was defined as:

"*The probability of an adverse event of animal health, public health or economic importance, such as a disease outbreak, and the magnitude of that event*".

Given this, a 'risk estimate' was simplistically described later in this document as the product of the likelihoods of disease entry and exposure. Consequence assessment did not appear in this later description and, indeed, was not discussed any further in the document.

The second important difference between current and former versions of the OIE Code chapter concerns the delineation of hazard identification as a discrete step in the import risk analysis process. According to the earlier version, hazard identification was considered an element of risk assessment. That is, risk assessment was previously considered to represent "*the processes of identifying and estimating the risks associated with the importation of a commodity, and evaluating the consequences of taking those risks*". This definition was in fact quite unintuitive, since hazard identification will be based on the characteristics of the proposed importation (the commodity, the species from which it will be derived, the exporting and importing countries, etc), while the remaining elements of risk assessment will be carried out iteratively for each identified disease agent.

By the same logic, it could be argued that the current designation of risk management as a discrete phase of risk analysis is unintuitive. That is, risk management will be instituted on a disease-by-disease basis following an estimation of the likelihood and consequences of each, and may thus be viewed by some analysts as a continuum of this process rather than a discrete *post hoc* procedure. Alternatively, it could be maintained that by separating risk management from risk assessment *per se*, the OIE Code reiterates the need to first evaluate the unrestricted risk, and subsequently apply risk management only if the latter is shown to be unacceptable. By outlining a framework for import risk analysis that describes risk management as a separate procedure, the OIE Code is able to formalise this two-stage process. Thus while risk management options may well be considered within the assessment of each identified disease agent, the approach outlined in the current OIE Code is preferable.

In summary, the framework for import risk analysis described in the current OIE Code appears to provide a template that will enable analysts to carry out analyses that are clearly-structured and transparent, and that will address the WTO's mission to minimise unnecessary trade restrictions.

2.2 The framework recommended in the OIE Aquatic Code

The framework for import risk analysis provided in the OIE Aquatic Code (1997) is in fact quite similar to that which upon which guidelines in the current version of the OIE Code are based. That is, hazard identification, risk assessment, risk management and risk communication are presented as discrete processes, and are complemented by an evaluation of 'Competent Authorities' and of zoning. Moreover, both the framework for import risk analysis and definitions provided in the previous (1995) edition of the OIE Aquatic Code appear to be identical to those in the later version.

Even so, the OIE Aquatic Code is not entirely consistent. That is, risk assessment is defined in a list of terms at the start of the publication as:

"*... the process of identifying and estimating the risks associated with the importation of a commodity and evaluating the consequences of taking those risks*"

This definition includes hazard identification, and yet the bullet-point outline of risk assessment in Article 1.4.1.2 describes hazard identification as a separate procedure. The definition above is in fact identical to that which appeared in the earlier OIE Code and it would seem that in compiling the Aquatic Code, the Fish Diseases Commission of the OIE have simply copied terminology without comparing it to the modified text in the document itself. As stated above, hazard identification should probably be described as a separate preliminary phase of the risk analysis process and, from this perspective, the outline in the document text is the preferred alternative.

The OIE Aquatic Code appears to consider the evaluation of likelihood of disease entry and exposure, and the consequences of a disease, to be components of an integrated risk estimate. A flow chart within Article 1.4.1.2 describes 'probability' and 'consequences' as the two fundamental components of the 'risk assessment report'. Likewise, it can be seen from the definition of 'risk' cited above that this metric includes an evaluation of the both the likelihood and the consequence of an adverse event. Whether this was explicitly intended, or simply an artefact of the adaptation of the OIE Aquatic Code from the existing OIE Code chapter, is not clear.

Aside from the need to be consistent with terminology, there are no other significant advantages or constraints with the framework for import risk analysis offered in the OIE Aquatic Code.

Indeed, Section 1.4 is reasonably brief and superficial, a surprising observation given the relatively large number of import risk analyses that have been carried out for aquatic animals and their products.

2.3 Frameworks adopted in the sample import risk analyses

Table 1 lists and summarises the frameworks for import risk analysis adopted in individual analyses. These analyses were published between 1988 and 1999, and therefore represent both developing trends in the discipline and changes to the prevailing international guidelines. The analyses also encompass both aquatic and terrestrial animals and should thus be evaluated against either the OIE Code or Aquatic Code in place at the time of publication.

Table 1: A summary of frameworks for import risk analysis

Analysis	*Hazard ID*[1]	*Consequence assessment*[2]	*Integrated risk estimate*[3]	*Risk management*[4]
Qualitative analyses				
1988 Anseriforms NZ	0	0	0	1
1990 Exotic AUS	0	1	0	1
1991 Meats NZ	0	0	0	1
1991 Hides NZ	0	0	0	0
1993 Milk AUS	0	0	0	1
1993 Salmon1 AUS¥	0	0	0	1
1994 Salmon1 NZ¥	0	1	0	1
1995 Aquatic1 AUS¥	0	1	0	1
1995 Aquatic2 AUS¥	0	0	0	1
1995 Exotic EU	0	0	0	1
1995 Exotic IRE	0	1	0	1
1995 PRRS1 NZ	0	0	0	1
1996 Baitfish NZ¥	0	0	0	1
1996 Salmon2 AUS¥	0	0	0	1
1997 Bees USA	0	0	0	1
1997 Fish products NZ¥	0	0	0	1
1997 Goat embryos CAN	0	0	0	1
1997 Lobster AUS¥	1	1	0	0

Analysis	*Hazard ID*[1]	*Consequence assessment*[2]	*Integrated risk estimate*[3]	*Risk management*[4]
1997 Ostrich SA	0	0	0	1
1997 Passerines NZ	0	0	0	0
1997 Pork CAN	0	0	0	1
1997 Ratites NZ	0	1	0	0
1997 Salmon2 NZ¥	0	1	0	1
1997 Sheep and goat meat NZ	0	0	0	1
1997 Sheep/goats ME	0	0	0	1
1997 Shrimp USA¥	0	0	0	1
1997 Wildlife SA	0	0	0	1
1998 Equines/semen NZ	0	0	0	0
1998 Fibre NZ	0	1	1	0
1998 Psittacines NZ	0	1	0	0
1999 Chicken NZ	0	1	0	0
1999 Crocodiles AUS	0	1	1	0
1999 Porcine semen AUS	0	1	1	0
1999 Scrapie AUS	0	0	0	0
Totals (n=34)	**n=1**	**n=12**	**n=3**	**n=23**
Quantitative analyses				
1992 Cassava AUS	0	0	0	0
1993 Garbage USA	0	0	0	0
1993 Pigs CAN	0	0	0	1
1994 Bluetongue CAN	0	0	0	1
1994 Piroplasm USA	0	0	0	1
1994 Salmon1 NZ¥	0	0	0	1
1995 Bov Embryos BR	0	0	0	1
1995 Meat BR	0	0	0	1
1996 BSE NZ	0	0	0	1
1996 Camelids CAN	0	1	0	1
1996 Chicken AUS	0	0	0	1
1996 Hides BR	0	0	0	1
1996 Rabies USA	0	0	0	0
1996 Scrapie NZ	0	1	0	1
1997 CSF NL	0	1	0	1
1997 IBD NZ	0	1	0	1

Analysis	*Hazard ID*[1]	*Consequence assessment*[2]	*Integrated risk estimate*[3]	*Risk management*[4]
1997 Rabies NZ	0	0	0	1
1997 Salmon2 NZ[¥]	0	0	0	1
1997 Swill USA	0	0	0	1
1998 Anthrax NZ	0	0	0	1
1998 PRRS2 NZ	0	0	0	1
Totals (n=21)	**n=0**	**n=4**	**n=0**	**n=18**
Overall totals (n=55)	**n=1**	**n=16**	**n=3**	**n=41**

Legend

[¥] Import risk analyses for aquatic animals or animal products (13 of 55 sample analyses)

[1] Hazard ID
1 = Carried out as a component of risk assessment
0 = Carried out as a separate procedure

[2] Consequence assessment
1 = Undertaken
0 = Not undertaken

[3] Integrated risk assessment
1 = Likelihood and consequence assessments combined
0 = Likelihood and consequence assessments not combined

[4] Risk management
1 = Undertaken as a component of risk assessment
0 = Undertaken as a separate procedure

It can be seen from Table 1, that only one of the 55 sample analyses included hazard identification as a component of risk assessment. This analysis was carried out for an aquatic animal product. It was, admittedly, difficult in many cases to extrapolate from the text of a report to either the author's precise perception of hazard identification or the precise sequence of steps undertaken in carrying out a particular risk analysis. In addition, 21 of the analyses were carried out for diseases that had been identified *a priori* as the subject of the analysis. In this situation, hazard identification was obviously an external procedure. Overall, the result would appear to support the supposition made in Sections 2.1 and 2.2 above. That is, that the delineation of hazard identification as a discrete preliminary step in the risk analysis process is likely to be viewed by analysts as a practicable component of any framework for import risk analysis.

The second and third columns of Table 1 describe aspects of consequence assessment. Here it can be seen that despite the WTO's clear requirement for consequence assessment, only 16 were documented. Of these, just three integrated the likelihood of an adverse event and its consequences to form an overall estimate of 'risk'. Two of the three were recently conducted

Australian analyses, obtained from an authority that has clearly stated in its internal guidelines for risk analysis (AQIS, 1998a) that integrated risk estimates are a necessity. The third analysis was a New Zealand report obtained after the distribution of similar internal guidelines (Murray, 1998). These guidelines, based on the framework for import risk analysis outlined in the current OIE Code and discussed in Section 2.1, clearly indicate that risk estimation should involve the integration of likelihood and consequence assessment. One other qualitative New Zealand analysis postdating the distribution of these internal guidelines was obtained for review. This analysis, however, was carried out externally by an academic institution and used a different methodology.

These results may illustrate the first stages of a developing trend in the emphasis given to consequence assessments. That is, that while the difficulty inherent in carrying out an accurate consequence assessment cannot be denied, the requirements of the WTO, as stated in the SPS Agreement, must also be upheld. Recent activity in the WTO dispute settlement system illustrates that countries failing to carry out analyses according to the principles of the SPS Agreement will be unlikely to attain a favourable result if their trade practices are called to question. An unfavourable result is likely to be expensive for the importing country, and may interfere with trade in other commodities. Given this, it is expected that WTO dispute settlement procedures currently in progress will encourage both regulatory authorities and individual analysts to include consequence assessments in import risk analyses. More specifically, regulatory authorities and analysts will be encouraged to integrate estimates of the likelihood and outcome of an adverse event in a single measure of risk.

The final issue examined in Table 1 was the manner in which analysts have incorporated a consideration of risk management. In the discussion of the current OIE Code it was noted that risk management is portrayed as a discrete process to be carried out after risk assessment *per se.* It was stated that this approach, while perhaps cumbersome to implement in some situations, stresses the need for analysts to consider the risks associated with the unrestricted importation of a commodity before instituting risk management.

It can be seen from Table 1 that only 14 of the 55 reports described risk management as a discrete procedure. Rather than detracting from the framework recommended by the OIE, this result is again likely to reflect the fact that recent activity in the WTO dispute settlement system has reiterated the need for a more strictly structured and transparent approach to risk analysis. Australian or New Zealand regulatory authorities compiled seven of the 14 analyses, after the

circulation of their respective internal guidelines for import risk analysis (AQIS, 1998a; Murray, 1998). These guidelines were based on the OIE framework for import risk analysis that, as described above, requires analysts to identify a risk as unacceptable before implementing risk management. The approach is designed to maximise transparency and to minimise unnecessary or unjustified trade restrictions, and is likely to become increasingly popular as the potential for trade disputes based on issues of risk analysis methodology become more evident.

3 Conclusions

From these discussions it was concluded that the framework outlined in the current edition of the OIE Code provided a transparent and clearly structured approach to import risk analysis. In particular, it was noted that, A) the separation of hazard identification as a discrete process, B) the integration of likelihood and consequence estimation as necessary components of risk assessment, and, C) the delineation of risk management as a separate procedure, each contributed to an approach that was closely linked to the WTO principles. Alternative approaches proposed in the earlier edition of the OIE Code, in the Aquatic Code, or in many of the identified import risk analyses, ignored at least some of these principles and may thus unnecessarily complicate trade negotiations or disputes.

EVALUATION II

Hazard Identification

Contents

1 Introduction

It was concluded from the discussions in Evaluation I that hazard identification should be recognised as a discrete preliminary process, distinct from risk assessment *per se*. In a practical context, hazard identification is carried out according to one of two approaches. In the first case, disease agent(s) or hazard(s) is/are known before the analysis is started - that is, the analysis is conducted to assess the risk attributed to a disease or diseases of particular concern. It will be shown below that this was the case for 22 of the 55 analyses obtained for review. In the second case, disease agents will be known but not specified *a priori* and the process of identifying them and classifying them as hazards forms an important component of the risk analysis. The remaining discussions focus on this second scenario.

2 Approaches to hazard identification

2.1 Hazard identification in the OIE Code and OIE Aquatic Code

Hazard identification is defined in the OIE Code as:

"The process of identifying the pathogenic agents which could potentially be introduced in the commodity considered for importation"

This process is further described as a categorisation step, whereby a preliminary list of disease agents "*appropriate to the species being imported, or from which the commodity is derived*" is refined or minimised by considering the following criteria:

- *Is the disease agent reported to be present in the exporting country?*
  If not, should veterinary services, surveillance and control programs, or zoning and regionalisation systems be considered further?

- *Is the disease agent present in the importing country?*
  If so, is it subject to a control or eradication program?
  If not, is it notifiable?

The OIE Code concludes that if no disease agents are identified as potential hazards, the risk analysis should be terminated. Alternatively, if the importing country is content to apply the OIE's recommended safeguards for any identified hazards, then a risk assessment is not required.

Aside from minimising the bulk of the ensuing risk assessment, the benefit of a categorical system for hazard refinement is that analysts are able to provide trading partners or stakeholders with a transparent summary of the reasons for the inclusion or otherwise of particular disease agents. If the system is rigorously upheld, then it also follows that the ensuing risk assessment may be more focussed and relevant. Given this, it is advantageous to limit hazard refinement to criteria that are clearly dichotomous, and for which responses can be justified without undue contention. That is, the hazard refinement procedure should not constitute a preliminary risk assessment, and should not require the support of an extensive scientific review.

The two criteria put forward by the OIE appear to be practicable, and will serve to limit risk assessments to those disease agents that are likely to constitute a measurable risk to the importing country. If the system were to be questioned, it would probably relate to the suggestion to interpret the exporting country's disease status in the light of its veterinary services and disease surveillance programs. The OIE continues, however, to develop a register in which veterinary services are assessed and graded. By utilising this system, countries may avoid contention but still incorporate an appropriate degree of confidence in a country's reported disease status.

Overall, the approach represents a significant improvement over either the OIE Aquatic Code or

the previous version of the OIE Code. In both of these publications, hazard identification was referred to in descriptions of the risk analysis framework but was not explicitly defined or discussed.

2.2 Hazard identification in the sample import risk analyses

As mentioned, 22 of the 55 sample import risk analyses were based on hazards identified *a priori.* The remaining 33 analyses are presented in chronological order in Table 2 below.

Table 2: Hazard identification in the sample import risk analyses

Analysis	Approach to hazard identification						
		Screening criteria					
	Prior list hazards refined[1]	OIE criteria		Other criteria			
		Importing country[2]	Exporting country[3]	Commodity[4]	Exposure potential[5]	Consequence assessment[6]	
Qualitative analyses							
1988 Anseriforms NZ	0	-	-	-	-	-	
1990 Exotic AUS	0	-	-	-	-	-	
1991 Meats NZ	1	1	0	1	1	0	
1993 Salmon1 AUS¥	0	-	-	-	-	-	
1994 Salmon1 NZ¥	0	-	-	-	-	-	
1995 Aquatic1 AUS¥	0	-	-	-	-	-	
1995 Aquatic2 AUS¥	0	-	-	-	-	-	
1995 Exotic EU	0	-	-	-	-	-	
1996 Baitfish NZ¥	0	-	-	-	-	-	
1996 Salmon2 AUS¥	0	-	-	-	-	-	
1997 Bees USA	0	-	-	-	-	-	
1997 Fish products NZ¥	0	-	-	-	-	-	

Analysis	Approach to hazard identification					
		Screening criteria				
	Prior list hazards refined[1]	OIE criteria		Other criteria		
		Importing country[2]	Exporting country[3]	Commodity[4]	Exposure potential[5]	Consequence assessment[6]
1997 Goat embryos CAN	1	1	1	1	0	0
1997 Lobster AUS¥	1	1	1	1	1	1
1997 Ostrich SA	0	-	-	-	-	-
1997 Passerines NZ	1	1	1	1	1	0
1997 Pork CAN	1	1	0	1	0	0
1997 Ratites NZ	1	1	0	0	1	1
1997 Salmon2 NZ¥	1	1	0	0	0	0
1997 Sheep and goat meat NZ	0	-	-	-	-	-
1997 Shrimp USA¥	0	-	-	-	-	-
1997 Wildlife SA	0	-	-	-	-	-
1998 Equines/semen NZ	0	-	-	-	-	-
1998 Fibre NZ	1	1	0	1	1	0
1998 Psittacines NZ	1	1	1	1	1	0
1999 Chicken NZ	0	-	-	-	-	-
1999 Crocodiles AUS	1	1	0	0	0	1
1999 Porcine semen AUS	1	1	0	0	0	1
Totals (n=29)	**n=11**	**n=11**	**n=4**	**n=7**	**n=6**	**n=4**
Quantitative analyses						
1993 Garbage USA	0	-	-	-	-	-
1993 Pigs CAN	0	-	-	-	-	-

Analysis	Approach to hazard identification						
		Screening criteria					
	Prior list hazards refined[1]	OIE criteria		Other criteria			
		Importing country[2]	Exporting country[3]	Commodity[4]	Exposure potential[5]	Consequence assessment[6]	
1996 Chicken AUS	0	-	-	-	-	-	
1997 Swill USA	0	-	-	-	-	-	
Totals (n=4)	**n=0**	**n=0**	**n=0**	**n=0**	**n=0**	**n=0**	
Overall totals (n=33)	**n=11**	**n=11**	**n=4**	**n=7**	**n=6**	**n=4**	

Legend

¥ Import risk analyses for aquatic animals or animal products (13 of 55 sample analyses)

[1] Prior list of hazards refined
0 = No screening of a preliminary species-specific list
1 = Preliminary species-specific list screened according to specified criterion

[2] Importing country
0 = Disease occurrence in the importing country not used as a screening criterion
1 = Disease occurrence in the importing country used as a screening criterion

[3] Exporting country
0 = Disease occurrence in the exporting country not used as a screening criterion
1 = Disease occurrence in the exporting country used as a screening criterion

[4] Commodity
0 = The role of the commodity as a vehicle for transmission of the disease not used as a screening criterion
1 = The role of the commodity as a vehicle for transmission of the disease u used as a screening criterion

[5] Exposure potential
0 = Potential for exposure in the importing country not used as a screening criterion
1 = Potential for exposure in the importing country used as a screening criterion

[6] Consequence assessment
0 = Consequence assessment not used as a screening criterion
1 = Consequence assessment not used as a screening criterion

It can be seen that 11 of the 33 analyses used screening criteria to refine a preliminary list of disease agents. All 11 of these analyses were qualitative. Of these analyses, only one was carried

out before 1997, an observation that suggested that the screening of a preliminary list of agents might represent another of the developing trends in import risk analysis.

All 11 analyses that reported screening used the two OIE criteria - that is the occurrence of each disease in the exporting and importing country. In addition to these, three other criteria were commonly used:

- The ability of the commodity to act as a vehicle for the transmission of each disease agent
- The ability of each disease agent to be transmitted within the importing country - that is the presence of necessary vectors, appropriate climatic conditions, etc
- The consequence of an incursion of each disease agent

The first two of these additional criteria may be problematic, since they will require a degree of justification and thus detract from the principal advantage of the classification-based approach - that is, to focus the risk assessment without detracting from its transparency. In contrast, the dichotomous classification of a disease outcome as 'significant' or otherwise may be practicable. This criterion was advocated in the internal guidelines for risk analysis produced by both Australian (AQIS, 1998a) and New Zealand (Murray, 1998) regulatory authorities. Specifically, the Australian guidelines require that a disease to be included in the risk assessment should either be listed by the OIE, or be exotic to Australia and have the potential to cause "... *a significant untoward effect on animal or human health or the environment ...*". Alternatively, the New Zealand guidelines state that a disease agent should be included if it is likely to result in one or more of the following:

- *Losses associated with trade, animal production or costs of control or eradication*
- *Adverse effects on animal welfare or wildlife populations*
- *Adverse effects on public health*

While it is unrealistic to 'critique' these guidelines too closely, it would appear that the more expanded New Zealand version covers the aspects of disease consequence outlined by the WTO, and thus could be considered a more satisfactory approach.

3 Conclusions

It was concluded that a screening or classification system, included as a component of hazard

identification, provided a transparent and efficient means by which analysts could justify the scope of the ensuing assessment. A blend of the criteria suggested in the OIE Code, and the preliminary consequence assessment outlined in the New Zealand internal guidelines for import risk analysis, would appear to be appropriate.

According to this system, a disease agent should be included in the risk assessment if it:

1. Is reported to be present in the exporting country

   (If the disease is not reported in the exporting country, veterinary services, surveillance and control programs, or zoning and regionalisation systems should be considered)

And

2. Is not reported to be present in the importing country

   (If the disease is reported in the importing country, the following should be considered:

   - Is it of a different strain or pathogenicity to that in the exporting country?
   - Is it subject to a control or eradication program?
   - Is it notifiable?)

And

3. Is likely to result in one or more of the following:

   Losses associated with trade, animal production or costs of control or eradication

   Adverse effects on animal welfare or wildlife populations

   Adverse effects on public health

Evaluation III

Part I: Qualitative Likelihood Evaluation

Contents

1 Introduction

Likelihood evaluation describes the process of determining the likelihood of an adverse event. In the domain of import risk analysis, an 'adverse event' is generally the entry of an unwanted disease agent or the exposure of susceptible animals to that agent. Qualitative likelihood evaluations are expressed in literal terms, such as 'extreme', 'high', 'moderate', 'low', 'minimal', 'negligible', etc and, as such, do not provide a measured or directly estimated outcome. Regardless, such terms are well understood and easily translated, and form useful categories by which to classify import proposals.

Qualitative estimates of the risks associated with the importation of animals and animal products have formed a central component of regulatory decision making throughout the history of trade in these commodities (Kellar, 1993; Nairn et al, 1996). Indeed, regulatory authorities within the developed trading nations continue to face an enormous number of new import requests each year, a vast majority of which are assessed qualitatively by considering existing protocols for similar commodities, or by conducting new qualitative analyses. For example, the USDA's

National Centre for Imports and Exports (NCIE) conducts more than 10,000 qualitative import risk assessments annually (APHIS, 1994b).

There are three distinct advantages to the qualitative approach:

- Evaluations may be carried out relatively quickly and, while a thorough examination of the literature is essential, technical input and expertise can be minimised
- The results of evaluations are relatively easy to interpret and communicate
- The amount of numerical data required is relatively minimal

Semi-quantitative likelihood evaluation refers to the adaptation of qualitative results, such that the component likelihoods, the final likelihood, or both are given categorised scores. The specific intention of semi-quantitative scores is to encourage the analyst to actively interpret each likelihood according to standard categories, thus promoting objectivity and repeatability, and creating an end result that is in some respects easier to use as the basis for policy decisions. Given this, the advantages of qualitative evaluations - that is, their clarity and simplicity, and speed, ease and efficiency of conduct - hold equally for the semi-quantitative approach.

The principal disadvantage to qualitative likelihood evaluation is that without a model based on importation and exposure pathways, and the use of clearly defined semi-quantitative scores, it will be virtually impossible for another analyst to repeat the procedure and arrive at precisely the same set of conclusions. Repeatability is viewed by some authors as synonymous (or at least similar to) to 'objectivity' or 'accuracy' and, indeed, Kellar (1993) concluded that neither can be achieved using a qualitative approach. This author stated that:

" ... risk managers may not proceed beyond paying lip service to uncertainty unless they can move beyond the current haphazard qualitative treatment of the subject.",

and that the qualitative approach provides,

" ... a piecemeal laundry list of uncertain assumptions with the results tending not to improve the decision-making process." (Kellar, 1993)

While it is doubtful that such an extreme position accurately reflects the merit of the traditional qualitative approach, there can be no mistaking the fact that this is essentially based on a

structured epidemiological review, and is aimed at illuminating the issues most pertinent to a particular importation scenario. As such, qualitative likelihoods are the unique synthesis of a given analyst and, by definition, must to some extent be based on a subjective interpretation of the relative importance of individual aspects of importation scenarios. Whether this impacts on their accuracy is entirely a function of the adequacy of the individual analyst.

The practical implication of the lack of repeatability is that the WTO places a high priority on the related issues of 'objectivity' and 'technical validity', and that it may be difficult to explain or rationalise a lack of repeatability without casting doubt in these directions. The extent to which this threatens the credibility of a qualitative evaluation will then be a function of its transparency and structure, and the ability of the analyst to decompose the 'model' systematically so as to explain its format and rationale.

A second, although equally fundamental, constraint is the quandary that arises when attempting to assign somewhat arbitrary descriptors to probabilistic events. That is, while qualitative estimates may be based on a structured evaluation of an importation scenario, and a similarly rigorous characterisation of the epidemiology of identified disease agents, they must then conclude with a purely descriptive summary statement, such as 'high', 'moderate', 'extreme', etc. Whether this is actually a 'constraint' as such remains contentious, since many analysts maintain that the information upon which import risk analyses are based is generally of insufficient quality for conclusions to be any more specific than 'high', 'moderate', 'extreme', etc. Regardless, the fact remains that these and other qualitative terms are simply adjectives with no formal interpretation. That is, superimposed on the low likelihood that a particular model or assessment can be reproduced by an independent analyst, is the additional consideration that an independent analyst may classify a conclusion using a different descriptor or, indeed, that two independent policy makers may interpret a given descriptor differently.

The final constraint to qualitative likelihood evaluation is the tendency for analysts to place less emphasis on the biological importation or exposure pathways, and relatively more emphasis on the ability of the given commodity to act as a vehicle for transmission of a given disease agent. When it is remembered that the overriding objective of likelihood evaluation is to determine the need for, and subsequently validate the application of risk management, it can be seen that it is essential to consider all steps in the importation and exposure pathways. Not only this, but it is equally important to consider the sequential order of steps, and to bear in mind the fact that each component likelihood will be conditional on the previous event occurring.

This quasi-mathematical approach will be examined in further detail in Section 2.4 but hinges on the need for likelihood evaluation (whether qualitative or quantitative) to be based on a structured 'model' that clearly represents the entry and exposure pathways, and the discrete steps within each. The single most challenging aspect of qualitative likelihood estimation is thus to maintain the analytic concept of a model, while carrying out a descriptive analysis of component likelihoods.

2 Approaches to qualitative likelihood evaluation

2.1 Qualitative likelihood evaluation in the OIE Code

The OIE Code does not define qualitative likelihood evaluation as such, but describes qualitative risk assessment as "... *an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms, such as high, medium, low or negligible* ...". In addition, the OIE Code does not favour either qualitative or quantitative approaches, but states that the "... *the risk assessment should be based on the best available information that is in accord with the current scientific thinking* ...". The OIE Code suggests an approach to likelihood evaluation that is based on the separate consideration of disease entry and exposure pathways, and stresses that this rationale can be applied equally to the qualitative or quantitative approach.

Specifically, the OIE Code defines the 'release assessment' and an 'exposure assessment' as follows:

Release assessment *consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring*

Exposure assessment *consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring*

It can be seen that the definitions stress the need to consider the biological pathways for disease entry and exposure, and to evaluate from these the likelihood that the 'complete process' will

occur. This is a critical issue for qualitative likelihood evaluation, and echoes the concluding sentiments in Section 1 above. The OIE Code describes both the release and exposure assessment in terms of biological, country and commodity factors. This is not in itself intended to provide a model for the entry or exposure pathways, but simply to outline the factors that may contribute to each of the overall likelihoods. That is, it is the responsibility of the analyst to consider these factors when determining entry and exposure pathways, and to formalise them as components or steps in each model. This process may be quite complex, and should involve the analyst acquiring an intimate knowledge of the relevant industries in both exporting and importing countries. The OIE Code does not give any guidelines for the description of biological pathways and, indeed, it would be impractical do so in a manner that would be applicable to a general range of commodities and countries.

While not explicitly discussed in the OIE Code, it can be seen that there are two approaches by which biological pathways could be used to derive a qualitative likelihood of disease entry or exposure. In the first instance, each pathway would be identified as a series of sequential steps, and these would be duly considered in the formation of a single overall descriptive likelihood of entry or exposure. Alternatively, qualitative likelihoods could be assigned to each of the component steps, and these subsequently combined to yield the overall likelihood of entry or exposure. The second approach has the significant advantage of requiring an analyst to explicitly consider the cumulative effect of each step on the resulting likelihood. The disadvantage of this approach is that methods for combining the qualitative component likelihoods would need to be established and formalised. If this approach were adopted, care should be taken to ensure that the process of combining likelihoods does not introduce additional subjectivity, or lead to the compression of information.

Another important issue to arise from the approach to likelihood evaluation outlined in the OIE Code is the clear delineation between release and exposure assessments, and the fact that no mention is made of the combination of the two prior to risk estimation *per se*. This is interesting since it differs markedly from the approach advocated in the previous edition of the OIE Code, in which likelihoods of entry and exposure were combined by a simplistic mathematical formula. The distinction is particularly important since it opens up the possibility for a quantitative release assessment and qualitative exposure assessment, or *vice versa*, and stresses the fact that the two likelihoods are essentially independent. Approaches to this aspect of risk assessment that have been adopted in individual analyses will be examined in the following section. Suffice it to say that while a combined estimate is not necessarily an advantage, it will be important to understand

the overall likelihood of an adverse event in order to weigh this against its consequence and derive an integrated measure of 'risk'. This issue is discussed further in Evaluation V.

2.2 Qualitative likelihood evaluation in the OIE Aquatic Code

According to the OIE Aquatic Code, likelihood evaluation should involve the elaboration of the scenarios by which a disease agent could be introduced into a country with the importation of aquatic animals of aquatic animal products. This requirement reiterates the need to document the component steps in biological pathways, as discussed above in reference to the OIE Code. The OIE Aquatic Code in fact presents a template for the disease entry and exposure, which, in contrast to the OIE Code, suggests that the entry and exposure pathways be combined. For the reasons stated above, this approach would not seem to be as flexible as one in which the two component likelihoods are independent. The OIE Aquatic Code also provides a summary of country, commodity and exposure factors that should be considered when formulating likelihoods for each step in the template. These descriptions appear to be very similar to those that appeared in the earlier edition of the OIE Code.

2.3 Qualitative likelihood evaluation in the sample import risk analyses

Three significant issues were drawn from the discussions above:

- That qualitative likelihood evaluation should be based on the consideration of biological pathways for disease entry and exposure, and that these should in turn be described by series of sequential steps
- That procedures for the combination of likelihoods attributed to the component steps of each biological pathway should be established
- That the likelihood of disease entry and that of exposure should be evaluated independently

In addition to the above, it was evident when reviewing the sample qualitative risk analyses that many were based on a 'generic' approach. That is, they were carried out as a means by which to evaluate the risk of introducing diseases from *any* exporting country. The principle behind this approach is evidently to provide a more efficient means of evaluating hazards, since the analysis would otherwise be repeated for each potential exporter. The obvious drawback is that an *unrestricted* estimate of the likelihood that trade from a given country will result in the entry of

disease, cannot be derived.

When it is considered that the WTO principles rest on the demonstration of unacceptable risk as the basis for risk management, it can be seen that generic likelihood evaluations may be criticised. The only exceptions to this rule would be the situations where, A) country-specific steps or factors were shown to be unimportant to the likelihood of entry, or, B) countries could be grouped with regard to country-factors, and separate risk assessments carried out for each group. An investigation of the role of country-specific factors can be carried out using sensitivity analysis, although this would obviously require a quantitative model. This facility of quantitative analysis will be discussed in Part II of Evaluation III.

It can be seen from Table 3 that 18 of the 34 qualitative analyses derived likelihoods of entry that were not country-specific. Thirteen of these were published in or after 1997, suggesting the development of a trend toward such 'generic' risk assessments. As discussed previously, the practice of carrying out generic analyses may be problematic if no attempt is made to consider country-specific factors, or country-specific steps in the importation pathway(s).

Of the 18 generic analyses identified in this review, four (Exotic IRE; Bees USA; Ostrich SA; Crocodiles AUS) categorised exporting countries and effectively carried out a discrete analysis for each category. The remaining 15 analyses simply evaluated the likelihood that the given commodity could act as a vehicle for the transmission of identified disease agents, and/or the likelihood that importation would result in exposure of susceptible animals. In some of these analyses, authors examined the risks associated with a particular import protocol or strategy. In others, however, the explicit reporting of the unrestricted likelihood of agent entry exacerbated the danger of this approach, since these authors subsequently used this likelihood as the justification for risk management.

Table 3: Approaches to qualitative likelihood evaluation

Analysis	*Biological pathway specified*[1]	*Steps in pathway considered*[2]	*Separate likelihood of entry and exposure*[3]	*Derivation of a generic likelihood of entry*[4]
1988 Anseriforms NZ	0	-	0	0
1990 Exotic AUS	0	0	0	1

Analysis	*Biological pathway specified*[1]	*Steps in pathway considered*[2]	*Separate likelihood of entry and exposure*[3]	*Derivation of a generic likelihood of entry*[4]
1991 Meats NZ	1	0	0	1
1991 Hides NZ	1	1	0	0
1993 Milk AUS]	0	-	0	1
1993 Salmon1 AUS¥	1	0	0	0
1994 Salmon1 NZ¥	1	1	0	0
1995 Aquatic1 AUS¥	0	-	0	0
1995 Aquatic2 AUS¥	0	-	0	0
1995 Exotic EU	0	-	0	1
1995 Exotic IRE	0	-	0	1
1995 PRRS1 NZ	0	-	0	0
1996 Baitfish NZ¥	0	-	0	0
1996 Salmon2 AUS¥	1	1	0	0
1997 Bees USA	0	-	0	1
1997 Fish products NZ¥	1	1	0	1
1997 Goat embryos CAN	0	-	0	0
1997 Lobster AUS¥	1	1	0	0
1997 Ostrich SA	0	-	0	1
1997 Passerines NZ	0	-	0	0
1997 Pork CAN	1	1	0	1
1997 Ratites NZ	0	-	0	1
1997 Salmon2 NZ¥	1	0	0	0
1997 Sheep and goat meat NZ	1	1	0	1
1997 Sheep/goats ME	0	-	0	1
1997 Shrimp USA¥	0	-	0	0
1997 Wildlife SA	0	-	0	0
1998 Equines/semen NZ	0	-	0	1
1998 Fibre NZ	0	-	0	1
1998 Psittacines NZ	1	0	0	1
1999 Chicken NZ	1	1	0	0
1999 Crocodiles AUS	1	1	1	1
1999 Porcine semen AUS	0	-	1	1
1999 Scrapie AUS	1	1	0	1
Totals (n=34)	**n=14**	**n=10**	**n=2**	**n=18**

Legend

¥ Import risk analyses for aquatic animals or animal products (10 of 34 qualitative sample analyses)

[1] Biological pathway specified	0 = report did not describe biological pathways 1 = report described biological pathways
[2] Steps in pathway considered	0 = Likelihood estimation was not based on a consideration of each step in the biological pathway 1 = Likelihood estimation based on the consideration of each step in the biological pathway
[3] Separate likelihoods of entry and exposure	0 = Separate likelihood of entry and exposure not provided 1 = Separate likelihood of entry and exposure provided
[4] Derivation of a generic likelihood of entry	0 = Likelihood estimate(s) derived for individual exporting countries 1 = Likelihood estimate(s) derived common to all exporting countries

From Table 3 it can also be seen that only 14 of the 34 qualitative analyses explicitly described the biological importation and/or exposure pathways. Of these, 10 considered the pathways in the evaluation of likelihoods. It was difficult to identify any patterns in the temporal distribution of these analyses, or their country of origin. Of these 10 analyses, only one (Crocodiles AUS) assigned likelihoods to the component steps of the pathways, and proposed a scheme whereby these could be combined to yield an overall likelihood of entry and exposure. In this report, component likelihoods were labelled as 'low', 'moderate' or 'high', and were combined according a series of complex rules. While the concept was appealing, it was difficult to follow the rationale for using different rules in different situations, and difficult to understand how a resultant likelihood could logically be higher (ie a larger probability) than at least one of its components. Unfortunately there were no other analyses that reported likelihoods for the component steps of entry or exposure pathways. Given this, it was necessary to derive alternative schemes for the combination of likelihoods, from first principles.

2.4 Alternative semi-quantitative approaches to likelihood evaluation

There are two broad means by which the semi-quantitative likelihoods assigned to steps in entry or exposure pathways can be represented:

- Semi-quantitative scores
- Probability ranges

The principle of semi-quantitative scores and probability ranges is illustrated in Table 4. It can be seen that while both representations describe the likelihood of an event, the probability ranges provide a more solid and transparent point of reference. This is likely to be viewed by regulatory analysts as an advantage, since transparency is a key factor in the WTO requirements for risk analysis.

Table 4: Semi-quantitative scores and probability ranges

Likelihood	Descriptive definition	Semi-quantitative score	Probability Range
Extreme	The event would be virtually certain to occur	6	$(0.99 \leq P < 1)$
High	The event would be likely to occur	5	$(0.7 \leq P < 0.99)$
Moderate	The event would occur with an even probability	4	$(0.3 \leq P < 0.7)$
Low	The event would be unlikely to occur	3	$(0.01 \leq P < 0.3)$
Very low	The event would be very unlikely to occur	2	$(10^{-6} \leq P < 0.01)$
Negligible	The event would almost certainly not occur	1	$(0 < P < 10^{-6})$

Underlying both the semi-quantitative scores and probability ranges is the need to provide a method that enables the 'ballpark' qualitative estimates attributed to the steps in entry or exposure scenarios to be combined in a structured, transparent and repeatable manner, and provides a technically sound estimate for the final likelihood. An additional requirement is that the method adopted for semi-quantitative likelihood evaluation enables the inclusion of multiple exposure pathways. It is commonly the case that susceptible animals in the importing country can be exposed to contaminated commodity by a number of routes, or that various discrete subgroups of susceptible animals have the potential to be exposed. In either case there will be more than a single exposure scenario, and any formal method for likelihood evaluation based on biological pathways will need to be sufficiently flexible as to allow each of these scenarios to be included in the assessment.

The fundamental principle governing the inclusion of multiple exposure pathways in a single risk assessment is that they must be 'weighted'. The weights assigned to scenarios are probabilities that reflect their relative 'importance', or the likelihood that each will be initiated. It follows that the sum of all weights must equal one. The product of the probability of exposure by a given

scenario and its relative weight will provide an estimate of the *partial probability of exposure* for that scenario. Finally, the sum of all partial probabilities of exposure will give an estimate of the overall probability that susceptible animals in the importing country will be exposed.

In the following discussions, the advantages and limitations of various approaches to semi-quantitative scores and probability ranges are presented. These discussions utilise hypothetical importation and exposure pathways to illustrate the relevant principles.

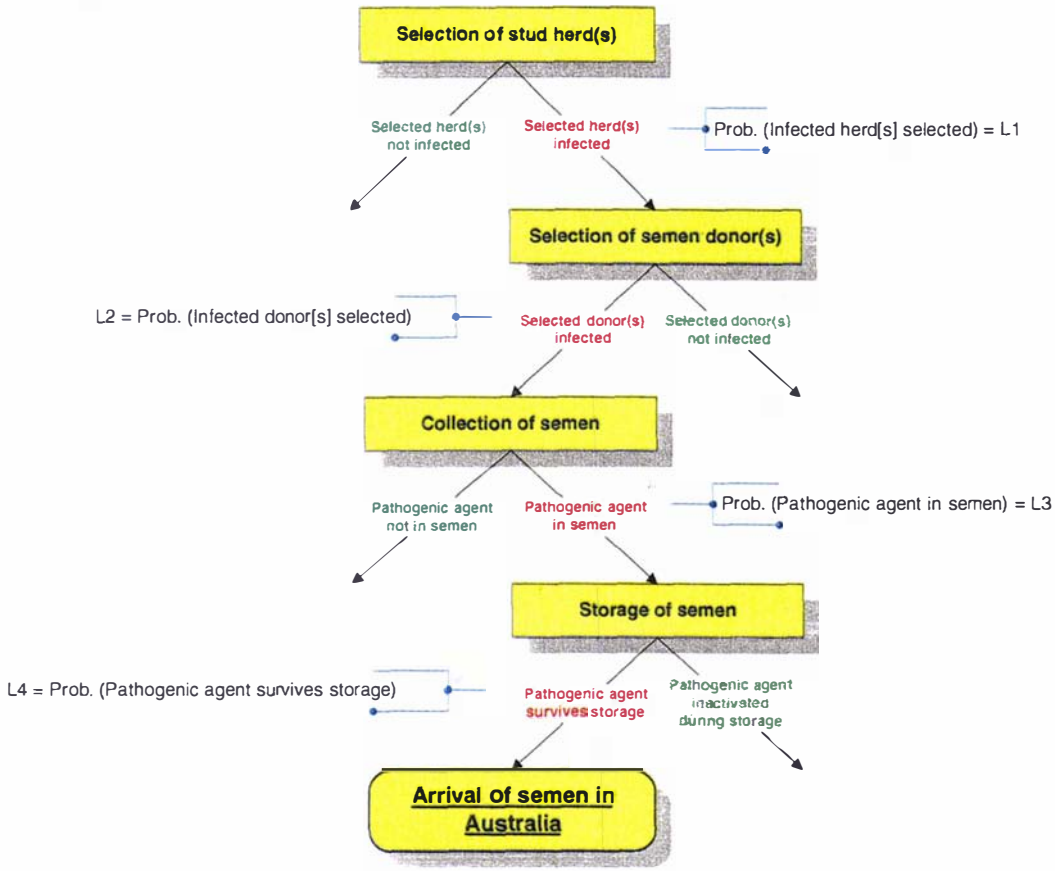
2.4.1 Evaluating likelihood using semi-quantitative scores

There are three uncomplicated methods by which scores could be combined:

- Summation
- Multiplication
- Picking the lowest score

A simplified hypothetical pathway describing four steps in the importation of pig semen was used to illustrate these methods (Figure 2). It can be seen that each step has a likelihood (L_1-L_4) to which will be assigned a semi-quantitative score (1-6), as illustrated in Table 4 above.

Figure 2: Hypothetical pathway for the importation of pig semen



Using this hypothetical pathway, three scenarios were created (Table 5). The first consisted of randomly assigned scores, the second of events which were mostly considered 'extremely unlikely', and the third of events which were 'extremely likely'. This range of extremes was chosen so as to maximise the ability to identify and illustrate the strengths and weaknesses of each protocol.

Table 5: Three protocols for combining semi-quantitative scores

Scenario		Step				Protocol[1]		
		1	2	3	4	A	B	C
I	Scores	2	4	1	5	**12**	**40**	**1**
II	Scores	1	1	1	1	**4**	**1**	**1**
III	Scores	6	6	6	6	**24**	**1296**	**6**

Legend

[1] Protocol A = Summation
B = Multiplication
C = Lowest score

Summation (A)

Scores assigned to each of the component likelihoods are summed. In the three example scenarios described above, this approach led to aggregate scores of 12, 4 and 24, out of a possible 24. The advantage of this system is that it is intuitive and extremely simple to administer. The difficulty however lies in interpretation. Since aggregate scores are unweighted summations, a score of, for example, 12 from a possible 24 (Scenario I) is equivalent to a step-level score of 3 from a possible 6, and may descriptively be termed 'unlikely' (Table 4). However, it can be seen that in Scenario I, the event occurring at the third step is considered to have a 'negligible' probability of occurring, and that if the pathway represents the flow of events required for a hazard to occur, it is difficult to imagine that the final probability could be 'higher' than this. For example, if the third step represented a diagnostic test and the probability that 'the test will fail to detect the disease', then with a step-level component estimate of 1, it is nonsensical for the aggregate score to be anything other than 'negligible'.

Similar results were obtained for the second and third scenarios and on this basis, the system based on simple summation was discarded.

Multiplication (B)

Another intuitive and easily administered protocol involved the multiplication of component likelihoods so as to gain a product score, which may subsequently be expressed as such or divided by the maximum product score to yield a proportion. Once again however, there were difficulties with regard to interpretation.

In the first of the scenarios shown above, the procedure yielded a total score of 40 out of a possible 1296, or approximately 0.03. What can be said about a score of 40 or, equivalently, about 0.03? If the product score is reported in its original non-fractional form (eg '40') then it is clear that factors which have been scored highly (eg '5') will contribute disproportionately more to the product score than those factors that receive low scores (eg '1'). That is, a single or few high scores may inflate the product estimate to a greater degree than a series of moderate scores, when the latter would constitute, in all likelihood, a lower risk scenario. While sample analyses other than Crocodiles AUS did not assign or interpret component likelihoods, it may be useful to note that a recent analysis, Psittacines NZ, did combine semi-quantitative scores for risk and consequence estimates using the multiplication algorithm. This scheme did, in my opinion, obtain spurious 'product rankings' for the identified disease agents - purely as a result of the principle discussed above.

Accepting then that fractions should be instituted if the product method is to be used, the remaining issue to be considered is the fact that, according to this system, a form of true quantitative analysis has been derived. That is, that in the hypothetical example above, each step has been assigned a likelihood ranging from approximately 0.17 (score 1) to 1.0 (score 6), and that these have been multiplied using the fundamental "multiplication rule" borrowed from standard probability theory (Smith, 1994). While there is no technical invalidity with the mathematics of this approach, the philosophical difficulty relates to the fact that semi-quantitative risk assessments are generally formalisations of the qualitative approach, and that the latter are usually adopted in the situation where an analyst has insufficient concrete or quantifiable evidence upon which to base a purely quantitative assessment. In this situation, it is obviously dangerous to surreptitiously create a quantitative system without a structured means of accounting for both uncertainty and the degree of natural variation that is likely to exist in these frequently superficial estimates. This issue is the subject of the following discussion (see Probability ranges).

Lowest score (C)

The third method, the least intuitive but easiest to administer, simply involves the analyst identifying the lowest recorded value and using this as an estimate for aggregate score. The principal advantage of this method over that described above is that it is conservative, such that if a particular step-level event is, for example, 'very unlikely', then given that the template represents a chain of sequential likelihoods, the final likelihoods will not be any higher than this. The method does not assume that step-level likelihoods are precise or overly accurate estimates and, as such, does not utilise subsequent probabilities to further minimise the final score.

While this approach may appear to be wasteful of information, it will be shown in Part II of this evaluation that where any given score in a model is substantially lower than others, then this score alone will tend to approximate the final likelihood. A very conservative estimate was obtained from the lowest score method when applied to the second scenario, in which the reverse is true - that is, where all estimates but one were equal to 1 and, thus, no single estimate could dominate the calculation. In this example, the lowest score method yielded a value of 1 from a possible 6 (0.17), while the multiplication method yielded 1 out of a possible 1296 (0.0008).

Summary: Protocols for combining qualitative likelihoods

From these trials and observations, it appeared that the more conservative method of adopting the lowest observed step-level score as an estimate for the likelihood of disease entry or exposure, was the most appropriate of the three examined. This choice was based both on the technical merits of each method and the philosophical need to keep essentially qualitative assessments as simple and free from mathematical interpolation as possible.

Theoretically, the lowest score method may be applied in the context of multiple exposure pathways, where the *partial probabilities of exposure* are simply the product of the lowest step-level score in each exposure pathway, and its weight (as described above). The difficulty that arises is that scores must first be converted to probabilities, and that if this approach is to be adopted then it would seem more sensible and transparent to utilise the method of probability ranges (see below) from the outset.

2.4.2 Evaluating likelihood using probability ranges

As shown in Table 4, this method hinges on the definition of step-level qualitative likelihoods

such as 'low', 'moderate', 'extreme', etc, in terms of clearly demarcated probability ranges. An overall estimate for an entry or exposure pathway can then be obtained by calculating the product of the mid-point of each step-level estimate. By comparing the result of this calculation with the table of probability ranges (Table 4), the overall probability may be converted back into a descriptive likelihood.

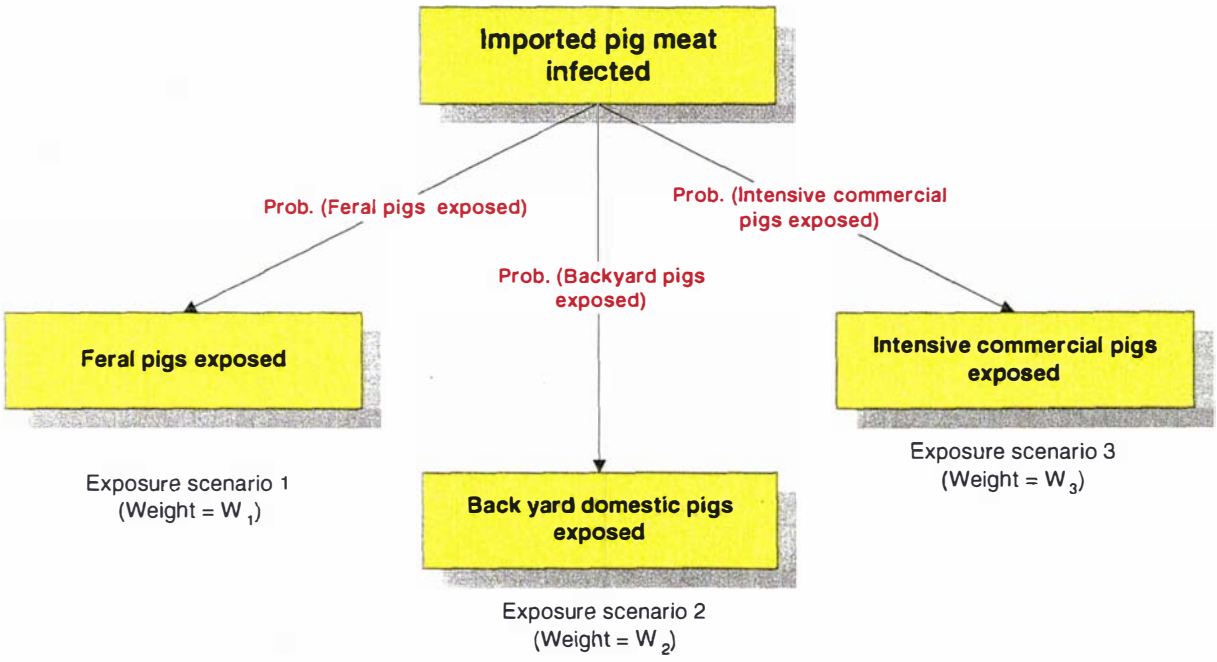
This method has the inherent advantage of providing for a greater degree of consistency and transparency, both within and between risk assessments. This will be particularly beneficial if the method was to be adopted by a national agency that regularly undertakes import risk analyses and seeks to demonstrate the WTO principle of consistency. The method also enables the consideration of multiple exposure pathways, since the probability derived for each pathway can simply be multiplied by the weight assigned to that pathway. The result of this calculation will then provide an estimate for the partial probability of exposure, as described previously.

Application of the semi-quantitative method is illustrated in the simplified and hypothetical example of an exposure assessment for imported pig meat. The exposure assessment is carried out in three phases:

- Identification of possible exposure scenarios
- Assignation of qualitative likelihoods
- Calculation of partial probabilities of exposure

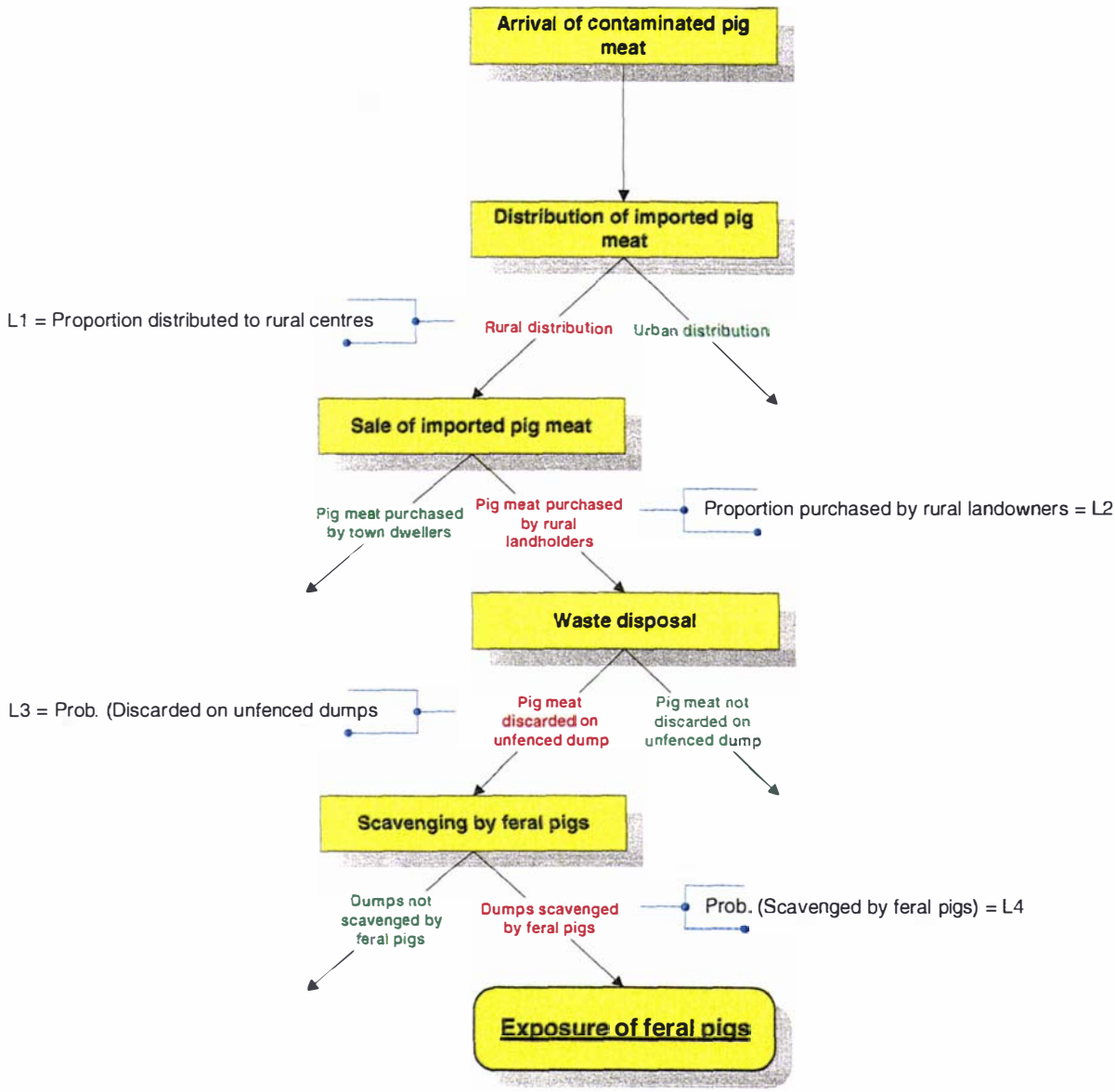
Exposure scenarios relevant to imported pig meat are shown in Figure 3. Here it can be seen that three groups of pigs may be exposed to a disease agent in contaminated pig meat - feral pigs, domestic pigs housed in 'backyard' facilities and domestic pigs housed in commercial piggeries. It can also be seen that each exposure scenario has a weight (W_1-W_3). For the purpose of illustration, these weights have been assigned values of 0.35, 0.60 and 0.05, respectively (Table 6).

Figure 3: Hypothetical exposure scenarios for imported pig meat



Having identified exposure pathways and assigned weights, the second step is to assign qualitative likelihoods to the component steps in each. The expansion of the first pathway (the exposure of feral pigs) is illustrated in Figure 4. Here it can be seen that there are four likelihoods (L_1-L_4) representing the four steps in the pathway. In the manner described at the start of this discussion, a qualitative estimate ('low', 'moderate', 'extreme', etc) should be assigned to each of these likelihoods, and the probability of exposure by this pathway determined by calculating the product of the mid-point of the corresponding probability ranges (Table 4).

Figure 4: Steps in the exposure of feral pigs to imported pig meat



The final step in an exposure assessment based on multiple exposure pathways will be the derivation of estimates for, A), the partial probabilities of exposure, and, B) the overall probability that susceptible animals will be exposed in the importing country. This procedure is illustrated in Table 6. Here it can be seen that if the weights described previously are combined with hypothetical estimates for each exposure pathway, then the three partial probabilities of exposure can easily be obtained. It can also be seen that the sum of these partial probabilities provides an estimate for the overall probability of exposure, and that this may be rephrased as a qualitative likelihood by referring to the original table of probability ranges (Table 4).

Table 6: Calculation of partial probabilities of exposure for hypothetical pig meat exposure pathways

Exposure pathway	Weight (W_i)	Probability of exposure	Partial probability of exposure
Feral pigs exposed	$W_1 = 0.35$	$PE_1 = 2.16 \times 10^{-5}$	$PPE_1 = 7.56 \times 10^{-6}$
Domestic backyard pigs exposed	$W_2 = 0.60$	$PE_2 = 4.15 \times 10^{-2}$	$PPE_2 = 2.49 \times 10^{-2}$
Intensive commercial pigs exposed	$W_3 = 0.05$	$PE_3 = 3.16 \times 10^{-5}$	$PPE_3 = 1.58 \times 10^{-6}$
Overall probability of exposure = $PPE_1 + PPE_2 + PPE_3$			$PE = 2.49 \times 10^{-2}$ = 'Low'

While entirely hypothetical, the semi-quantitative method of probability ranges is simple and transparent, and would enable risk analysts to carry out structured and repeatable qualitative risk assessments without the embarking on the complexities of a purely quantitative model. As will be shown in later evaluations, the method is also compatible with a similarly structured semi-quantitative approach to consequence assessment and risk estimation, and thus enables the entire risk assessment to be undertaken in a qualitative, and yet transparent and consistent manner. The method of probability ranges uses a mathematical approach and yet unlike the unfavoured mathematical manipulations of qualitative 'scores' (as discussed in the previous section), is based on a clearly stated numerical definition of each qualitative descriptor. Finally, it can be seen that the method rests entirely on the consideration of 'biological pathways', whether entry or exposure, a principle described in the OIE Code and thus endorsed by the WTO.

3 Conclusions

From these discussions the following conclusions were drawn:

- Qualitative likelihood evaluation should be based on the consideration of biological pathways for disease entry and exposure, and these should in turn be described by series of sequential steps
- The likelihood of disease entry and the likelihood of exposure should be evaluated independently
- The likelihood of disease entry and the likelihood of exposure may be qualitatively

assessed using a number of approaches, although the most structured and transparent is that which is based on weighted exposure scenarios and the use of step-level probability ranges

- Where likelihood evaluations are to be based on a more than one exporting country (so-called, 'generic' evaluations), analysts should either group these countries with respect to country factors and carry out assessments for each group, or demonstrate using sensitivity analysis that country factors do not significantly influence the likelihood of entry

Evaluation III

Part II: Quantitative Likelihood Evaluation

Contents

1 Introduction

The OIE Code does not describe separate methodologies for qualitative and quantitative likelihood estimation. Given this, many of the more general conclusions drawn in the previous evaluation can be extended to the quantitative context. In brief, these included the following:

- Likelihood evaluation should be based on the consideration of biological pathways for disease entry and exposure, and these should in turn be described by series of sequential steps, or stages
- The likelihood of disease entry and exposure, as defined in the OIE Code, should be evaluated independently
- Where quantitative likelihood evaluations are to be based on a more than one exporting country (so-called, 'generic' evaluations), analysts should derive strategies that enable exporting countries to be grouped with respect to particular factors, or that enable the relevance of exporting countries factors to be evaluated

Table 7 provides a summary of the manner in which these issues were dealt with in the sample quantitative risk assessments.

Table 7: Approaches to quantitative likelihood evaluation

Analysis	*Biological pathway specified*[1]	*Stages in pathway considered*[2]	*Separate likelihood of entry and exposure*[3]	*Derivation of a generic likelihood of entry*[4]
1992 Cassava AUS	1	1	1	0
1993 Garbage USA	1	1	0	0
1993 Pigs CAN	1	1	0	0
1994 Bluetongue CAN	1	1	1	0
1994 Piroplasm USA	1	1	1	1
1994 Salmon1 NZ[¥]	1	1	1	0
1995 Bov Embryos BR	1	1	1	0
1995 Meat BR	1	1	1	0
1996 BSE NZ	1	1	0	0
1996 Camelids CAN	1	1	1	0
1996 Chicken AUS	1	0	1	0
1996 Hides BR	1	1	1	0
1996 Rabies USA	1	0	0	1
1996 Scrapie NZ	1	1	1	1
1997 CSF NL	0	-	0	1
1997 IBD NZ	1	1	1	0
1997 Rabies NZ	1	1	1	1
1997 Salmon2 NZ[¥]	1	1	1	0
1997 Swill USA	1	1	1	1
1998 Anthrax NZ	1	1	0	0
1998 PRRS2 NZ	1	1	1	0
Totals (*n*=21)	**n=20**	**n=18**	**n=15**	**n=6**

Legend

[¥] Import risk analyses for aquatic animals or animal products

[1] Biological pathway specified
0 = Report did not describe biological pathways
1 = Report described biological pathways

[2] Stages in pathway considered
0 = Likelihood estimation was not based on a consideration of each stage in the biological pathway
1 = Likelihood estimation based on the consideration of each stage in the biological pathway

[3] Separate likelihoods of entry and exposure
0 = Separate likelihood of entry and exposure not provided
1 = Separate likelihood of entry and exposure provided

[4] Derivation of a generic likelihood of entry	0 = Likelihood estimate(s) derived for individual exporting countries 1 = Likelihood estimate(s) derived common to all exporting countries

From this table it can be seen that the requirement for biological pathways to be clearly specified, and for their component stages to be utilised in deriving likelihoods, was upheld in all but a small number of the sample analyses. Indeed, one of the strengths of the quantitative approach is the intuitive tendency to decompose importation and/or exposure pathways into a series of sequential steps, and to consider the role each of these plays in reducing the magnitude of the outcome likelihood. This issue will be expanded in the discussion of advantages and constraints of quantitative likelihood evaluation.

Table 7 also shows that 15 of the 21 analyses separated the likelihood of entry and exposure. The fact that entry and exposure pathways are essentially independent, and the potential to use both qualitative and quantitative approaches in a single risk assessment, indicate that it will generally be advantageous to consider these phases separately.

Finally, it can be seen that six of the 21 quantitative likelihood evaluations were 'generic' - that is, they were not specific to a single exporting country. When these were examined more closely it was found that one analysis (Piroplasm USA) was based purely on evaluating the likelihood of exposure in the importing country, and that two others (Rabies USA; Rabies NZ) simply assigned a single value to the country factor, prevalence. The remaining three analyses (Scrapie NZ; CSF NL; Swill USA) either listed the relevant countries and repeated the evaluation for each, or categorised them and assigned global values to the country factors to each category. All of these strategies are practicable, and all circumvent the danger of ignoring country factors in evaluating the likelihood of disease agent entry. It was noted in the discussion of *qualitative* assessments that a number of these did ignore country factors and did base risk management on the resultant partial estimates. The implications of this with regard to WTO principles need not be reiterated.

1.1 Advantages and limitations of quantitative likelihood evaluation

The quantitative approach to likelihood evaluation has two distinct strengths. Firstly, it provides an ostensibly 'concrete' assessment of the risks attributed to the importation of a given commodity and, regardless of the approximations or assumptions upon which this is based, yields

a finite and outcome (whether a single probability or a probability distribution) clearly expressed in numeric terms. Together these facilities lead to a perception of security, and a sense that the riskiness of a given import scenario has been comprehensively assessed. Whether this is the case or not will depend on a number of factors (see below). Regardless, a quantitative assessment conducted by or on the behalf of a reputable organisation will generally be a successful means of convincing stakeholders and trading partners that the relevant regulatory organisation has taken the import proposal seriously, and has estimated its riskiness with adequate precision and accuracy.

The second, and perhaps more 'real' advantage of a quantitative evaluations is that it allows the analyst to determine the specific phases in an importation that contribute most significantly to the final risk estimate. This process, termed *sensitivity analysis*, is discussed further in Section 4.4.5. Suffice it to say that identifying the influential stages in an importation pathway allows the analyst to create an import protocol that is maximally efficient, and to justify a requirement for particular risk-management strategies by demonstrating the specific effect that each will have on the riskiness of the import. Sensitivity analysis may also be used to identify those stages of importation and/or exposure pathway(s) for which good information is particularly important. This will help to justify targeted research efforts, or to explain why conservative or constrictive import measures should be taken. Finally, it may in some circumstances be feasible to use sensitivity analysis to demonstrate that country factors have little impact on the likelihood of disease entry. Where this is the case, it would be legitimate for an importing country to formulate 'generic' import conditions.

Quantitative modelling is the only approach with the facility to represent explicitly both natural variation and uncertainty as recognised characteristics of input variables. Natural variation and uncertainty are discussed further in Section 4.4.3. Suffice it to say that, regardless of the criticism that the various quantitative techniques may receive, the ability to utilise rather than simply acknowledge this information is considered by many risk analysts to be a major advantage of the quantitative approach.

While the advent of accessible methodology and software for quantitative likelihood evaluation was greeted with considerable enthusiasm in the early 1990s (Kellar, 1993; Morely, 1993; MacDiarmid, 1993; Wilson and Banks, 1993; Miller et al., 1993), it was noted that this approach is currently the least popular with import risk analysts worldwide. The reasons for this may include the following:

- The inability to *exactly* model any real life scenario
- A lack of adequate quantitative data
- The intensive demand on time and other resources
- The degree of technical difficulty inherent in constructing quantitative models
- The lack of adequate guidelines for quantitative techniques
- The lack of transparency in some complex quantitative models
- The difficulty in interpreting and basing policy decisions on quantitative outcomes

The most fundamental (although not necessarily the most constraining) feature of quantitative models is the fact that they explicitly attempt to replicate the behaviour of a biological system by summarising its components as discrete quantifiable events. While some biological models may indeed be reasonably successful in this endeavour, it will generally be difficult to critically assess those developed for quantitative import risk assessment since the events they consider, that is, disease incursions, are either infrequent or have never actually occurred.

In addition to this, the mathematical[1] structure of any model is also based on certain assumptions regarding the behaviour of a biological system. Typically these would include the independence or otherwise of components, or the probability distributions governing the occurrence of events in the model pathway. Given this, a quantitative model will always be constrained by the requirement that each component of the system behave in the manner predicted, regardless of correctness or validity. When the complexity of animal disease, and the dynamics of disease in animal populations, are considered, this may indeed prove to be a dubious or unreliable assumption. Finally, it should be noted that many importation and exposure pathways are extremely complex or poorly understood and, where either of these situations exist, quantitative modelling will be problematical.

An elementary constraint facing import risk analysts is the frequent lack of adequate data upon which to base assessments (Kellar, 1993). While the OIE is endeavouring to improve the quality and availability of information on the prevalence or occurrence of animal diseases (OIE, 1999a), there remain many other poorly defined components of import risk assessment scenarios. Some of these may impact seriously on the credibility or 'usefulness' of a purely quantitative model.

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[1] **Mathematical**: Of or pertaining to mathematics - that is, where quantities sought are deducible from other quantities known or supposed (Webster, 1999)

The problem may be remedied to a minor extent through the use of Monte Carlo simulation, whereby uncertainty is represented in the probability distribution assigned to each 'uncertain' input variable, although this simulation-based method is not without its own difficulties and constraints (Wilson and Banks, 1993; Vose, 1996b). Alternatively, sensitivity analyses may be used to determine the effect of deliberate variation in particular input variables on the output risk estimate and, thus, to determine the importance of imperfect knowledge of these variables (Roe, 1997). Regardless, the fact remains that while quantitative estimates are frequently viewed as 'concrete' indicators of the riskiness of an import proposal, they are actually derived from imperfect or inadequate information and are based on mathematical assumptions.

The third constraint of the quantitative approach is that such models are generally time-consuming, complex and expensive. Given this, it can be seen that quantitative assessments are simply impractical for many agencies and for the bulk of import decisions. Closely aligned to this constraint is another imposed by the lack of adequate guidelines for quantitative analysis, and the fact that this will not only impede the construction of individual models, but may create difficulties with regard to trade disputes based on the results of quantitative estimates (Thiermann, 1997). Similarly, with the lack of a standardised approach, the inherent complexity of quantitative models will impair their 'transparency', where the latter is one of the principal requirements of the WTO.

The final limitation of quantitative likelihood evaluation is the difficulty faced by analysts and policy makers when interpreting the output. Separate probabilities or probability distributions obtained for the likelihood of entry and exposure will have to be combined with an assessment (qualitative or quantitative) of the consequence of the disease, and the result interpreted on a scale of acceptability. In some respects, this inevitably arbitrary procedure is more easily facilitated using qualitative likelihoods, since quantitative estimates require a specific numeric cut-off point. Once stated, it may be difficult to justify this 'acceptable level of protection' to stakeholders or trading partners, or to ensure that it is based on a level of protection equivalent to that afforded to other commodities.

In conclusion, while the community of import risk analysis initially greeted quantitative methods with enthusiasm, these now appear to be viewed with some reserve. Extrapolating the advantages and constraints described above, however, it can be said that quantitative methods may be useful in the following situations:

- To enforce the concept of structured importation and exposure pathways
- Sensitivity analysis
  - to enable risk management to be targeted and efficient
  - to identify stages for which information should be most reliable
  - to determine whether country-specific stage in the importation pathway are significant determinants of the likelihood of disease entry
- In combination with qualitative methods
  - to create separate approaches for the release and exposure assessments
  - to create quantitative stages within a qualitative release or exposure assessment

Finally, if analysts or decision-makers feel uncomfortable interpreting quantitative results, there may be some benefit in converting these to qualitative or semi-quantitative likelihoods. This approach would ensure that the risk assessment was based on a structured series of identified stages in the importation and exposure pathways, and that quantitative considerations such as the predictive values of tests or the volume of imported commodity, were considered. This approach would also ensure that too much emphasis was not placed on specific probability statements, and that variance in the final likelihood, as evidenced in percentiles, was not interpreted too literally. This approach was not adopted in any of the identified analyses, nor described in any of the technical texts. In combination with the notion of quantifying individual stages in a largely qualitative assessment, however, it would seem to be one means by which some of the advantages of quantitative likelihood evaluation could be utilised, without incurring the constraints.

1.2 Approaches to quantitative likelihood evaluation

Quantitative likelihood evaluation may be divided into two broad groups of modelling approaches:

- Deterministic models
- Stochastic models

According to the On-Line Dictionary of Computing (Howe, 1999), deterministic modelling "... *describes a system whose evolution can be predicted exactly* ...". This contrasts with a probabilistic or 'stochastic' system. Deterministic models are therefore those traditional mathematical models in which quantifiable events are linked by a mathematical formula so as to produce a single quantitative output (Averill andKelton, 1992). Accepting this, deterministic

import risk analysis models generally comprise an algebraic mathematical structure in which may be inserted probabilities, whole numbers or other numerical[2] forms or values, and from which a single number[3] will be derived.

In contrast, stochastic quantitative models are those in which at least one random variable[4] has been specified, thus producing an output that is a distribution of results rather than a single value (Averill andKelton, 1992; Vose, 1996b). Given this, stochastic models are also 'probabilistic', since it is known that " ... *the behaviour of a probabilistic system cannot be predicted exactly but the probability of certain behaviours is known* ... " (Marriot, 1990). Finally, the underlying structure of stochastic and deterministic import risk analysis models is essentially identical, and any important technical and/or philosophical differences between the two approaches will arise principally as implications of the use of random variables in the place of fixed point estimates. This is a unique feature of quantitative import risk analysis, and has arisen principally as a result of the advent of spreadsheet-based Monte Carlo simulation packages, which allow deterministic models to be 'converted' into stochastic models by simply substituting probability distributions for single values. The same is not necessarily true for other fields or disciplines in which the two approaches to quantitative modelling are used.

2 General quantitative issues

2.1 Statistical processes in quantitative likelihood evaluation

The objective of this section is to investigate the use of standard statistical processes and their probability distributions in the field of quantitative risk analysis, and to determine their strengths, constraints and general applicability. The following statistical processes and probability distributions will be examined:

The binomial process

- the Bernoulli distribution
- the binomial distribution
- the geometric distribution

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[2] **Numerical**: Expressed by numbers and not letters (Webster, 1999)

[3] **Number**: That abstract species of quantity which is capable of being expressed by figures (Webster, 1999)

[4] **Random variable/variate**: A quantity which may take any of the values of a specified set with a specified relative frequency or probability (Marriot, 1990)

- the negative binomial distribution
- the beta distribution

The hypergeometric process and hypergeometric distribution

The Poisson process

- the Poisson distribution
- the exponential distribution
- the erlang distribution
- the gamma distribution

Table 8 documents the use of each of the statistical processes and their distributions. It can be seen that all of the identified quantitative analyses used the binomial process and, by definition, that all reported Bernoulli trials. In contrast, only one analysis (PRRS2 NZ, 1998) described the hypergeometric distribution or process, or discussed the possibility that the assumptions of the binomial distribution might be compromised by small samples. Finally, a single analysis (Anthrax NZ, 1998) reported the use of the Poisson process and, concurrently, the Poisson distribution, although the authors of this analysis opted to apply the simpler binomial distribution in the model itself.

Table 8: Statistical processes and probability distributions used to model systems or phenomena in quantitative risk analyses

Analyses	Binomial process					Hypergeometric process	Poisson process			
	Bernoulli	Binomial	Geometric	Negative binomial	Beta	Hyper-geometric	Poisson	Exponential	Erlang	Gamma
1992 Cassava AUS	1	1	0	0	0	0	0	0	0	0
1993 Garbage USA	1	0	0	0	0	0	0	0	0	0
1993 Pigs CAN	1	1	0	0	0	0	0	0	0	0
1994 Bluetongue CAN	1	0	0	0	0	0	0	0	0	0
1994 Piroplasm USA	1	1	0	0	0	0	0	0	0	0

Analyses	Binomial process					Hypergeometric process	Poisson process			
	Bernoulli	Binomial	Geometric	Negative binomial	Beta	Hyper-geometric	Poisson	Exponential	Erlang	Gamma
1994 Salmon1 NZ	1	1	0	0	0	0	0	0	0	0
1995 Bov Embryos BR	1	1	0	0	0	0	0	0	0	0
1995 Meat BR	1	1	0	0	0	0	0	0	0	0
1996 BSE NZ	1	0	0	0	0	0	0	0	0	0
1996 Camelids CAN	1	1	0	0	0	0	0	0	0	0
1996 Chicken AUS	1	1	0	0	0	0	0	0	0	0
1996 Hides BR	1	0	0	0	0	0	0	0	0	0
1996 Rabies USA	1	1	0	0	0	0	0	0	0	0
1996 Scrapie NZ	1	1	0	0	0	0	0	0	0	0
1997 CSF NL	1	1	0	0	0	0	0	0	0	0
1997 IBD NZ	1	0	0	0	1	0	0	0	0	0
1997 Rabies NZ	1	1	0	0	0	0	0	0	0	0
1997 Salmon2 NZ	1	1	0	0	0	0	0	0	0	0
1997 Swill USA	1	1	0	0	0	0	0	0	0	0
1998 Anthrax NZ	1	1	0	0	0	0	1	0	0	0
1998 PRRS2 NZ	1	1	0	0	0	1	0	0	0	0
Process totals (n=21)			**n=21**			**n=1**			**n=1**	
Distribution totals (n=21)	**21**	**16**	**0**	**0**	**1**	**1**	**1**	**0**	**0**	**0**

Legend

1 = analysis reported this distribution

0 = analysis did not report this distribution

2.1.1 The binomial process

The binomial process is a discrete exposure process[5] characterised by the observation of (n) independent (Bernoulli) trials in which the probability (p) of observing a particular event (x) is constant between trials (Vose, 1996b). The principal limitation of the binomial process is its governing assumption that the probability of observing the event in question remains constant between Bernoulli trials. This assumption may be upheld or approximated in practical situations, or may be threatened by various phenomena. Examples of situations in which the assumption may be threatened include without-replacement sampling from small populations, stratification of the population (where the probability of observing a diseased animal is not homogeneous between strata), or the removal of animals with a particular immune or infection status and the subsequent disruption of infection dynamics.

The following probability distributions are defined by the binomial process:

- Bernoulli distribution
- Binomial distribution
- Geometric and negative binomial distributions
- Beta distribution

Bernoulli distribution

A Bernoulli trial is a sampling experiment in which the probability of observing the event in question is designated p. A discrete random variable X is therefore said to have a Bernoulli distribution with parameter p, and is written X ~ Binomial (1,p), if X has a probability distribution given below (Larsen andMarx, 1986; Smith, 1994):

X	0	1
$P_X(x)$	(1 - p)	p

Some authors (Marriot, 1990; Vose, 1996b) consider the Bernoulli and binomial distributions to be synonymous. That is, that the Bernoulli distribution is simply a special case of the binomial in which the number of Bernoulli trials is one. While this perspective is acknowledged, the properties of the Bernoulli distribution in the context of quantitative risk analysis imply that

[5] **Discrete exposure process**: A process in which an event may occur only among a set of discrete

separate discussions of the two distributions are likely to be worthwhile.

Applications

Examples of the application of the Bernoulli distribution in the context of import risk analysis are almost inexhaustible, since they include each instance of simple statements such as:

" ... the probability that an event (x) will be observed is p ... "

Adopting the syntax for model structure described in the previous section of this evaluation, it can be seen that an 'event' may refer to a phenomenon *within* a stage of an importation scenario, such as the correct diagnosis of a single infected animal (PRRS2 NZ, 1998). In this case the parameter (p) of the Bernoulli distribution is provided by the sensitivity of the test used. Alternatively, the Bernoulli distribution may be used to model a *stage-level* phenomenon, such as the probability that infectious IBD virus will not be removed from an infected chicken carcass by processing (IBD NZ, 1997). Finally, and relatively unusual amongst the group of quantitative analyses identified for review, a Bernoulli distribution may be used to explicitly model the likelihood of either disease entry or the exposure of susceptible animals in the importing country. An example of this was provided in an analysis of the risks associated with the importation into Uruguay of cattle hides from Brazil (Hides BR, 1996), where exposure of susceptible animals in Uruguay to FMD virus was modelled using a Bernoulli distribution with a single specified parameter (p).

Constraints

The Bernoulli distribution is such a simple and fundamental distribution that its single constraint or limitation arises as a result of the application of its single assumption. That is, that *the probability of observing an event (x) is p.* The difficulty here is that in order to apply the Bernoulli distribution and make this statement, the probability of observing the event (x) must *always* be *p.* Unfortunately, many of the events modelled as a simple Bernoulli trial do not occur with a constant probability. For example, infected herds may tend to be clustered in a region (Thrushfield, 1986; Martin et al, 1987), or infected animals may tend to fall into particular age groups (Thrushfield, 1986). Where either of these apply, analysts must decide whether to follow the scenario to a deeper level and consider the likelihood of selecting from each stratum of the

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opportunities (Vose, 1996b)

population, or to acknowledge the approximation and accept the Bernoulli model on account of its simplicity.

An example of the above was provided in an assessment of risk of introducing porcine reproductive and respiratory syndrome (PRRS) into New Zealand with imported pig semen (PRRS2 NZ, 1998). In this analysis, the authors acknowledged the disparity between the reported national prevalence of infected herds, and that which was likely to be the case in the states in which pig production and semen exportation were concentrated. Given the need to consider all American states in this analysis, the authors took a pragmatic view and described a single input for the herd-prevalence of PRRS derived from the likelihood that pigs would be sourced from certain areas, and the herd-prevalence within each of these. It will be shown in Section 4.3 that a further simple and pragmatic means by which the assumption of the Bernoulli distribution may be upheld in a quantitative risk analysis model, is to incorporate its single parameter (p) as a random variable, and use Monte Carlo simulation to obtain a series of 'random' iterations of the model.

Conclusions

The Bernoulli distribution is the cornerstone of the binomial process. The Bernoulli distribution rests on the single assumption that the parameter p is constant (or approximately so) across all members of a specified population, an assumption which should be verified and documented within the analysis.

Binomial distribution

The binomial distribution is defined as the sum of a fixed number of (independent and identical) Bernoulli trials (Larsen andMarx, 1986; Smith, 1994). That is, for $0 < p < 1$, and a fixed positive integer n, the discrete random variable X has a binomial distribution with parameters n and p, and is written X ~ Binomial (n,p), if:

$$X = X_1 + X_3 + X_3 + X_4 + ... X_n$$

Where X_1, X_2, X_3, ..., is a sequence of n Bernoulli trials, each with probability of success, p (Smith, 1994). Given this, the probability that X=x is defined by:

$$P(X = x) = {}^{n}C_{x} p^{x} (1 - p)^{n-x}$$

Binomial probabilities tend to become normally distributed when the number of Bernoulli trials becomes large - that is, when both np and $n(1-p)$ are greater than or equal to 5 (Smith, 1994). This approximation enables the calculation of a standard normal pivot[6] in which the mean (μ) and variance (θ) are the corresponding mean and variance of the binomial distribution (np and $np(1-p)$, respectively), and thus enables normal probabilities to be used in statistical hypothesis testing. Given this, the normal approximation to the binomial is not generally considered useful in the context of import risk analysis, since it is the definition of the binomial distribution as a discrete set of Bernoulli trials, and the intuitive algebraic form of its probability mass function and cumulative density function that provide analysts with such a useful framework for quantitative modelling. In contrast, the normal distribution has a probability density function that is notoriously difficult to manipulate, and a cumulative density function that cannot be calculated in closed form (Snedecor, 1972; Larsen andMarx, 1986; Smith, 1994).

Applications

In the context of quantitative risk analysis, the binomial distribution provides analysts with the means to calculate the following probabilities:

- The probability of observing exactly x events in n trials
- The probability of observing less than or equal to x events in n trials
- The probability of observing at least x events in n trials

For the first case, the binomial probability mass function shown above provides the required probability. The most common direct application of the binomial probability mass function in import risk analysis involves the situation in which x is equal to zero and the algebraic form shown above thus simplified to:

$$P(X = 0) = (1 - p)^n$$

An example of this is given in the quantitative analysis PRR2 NZ (PRRS2 NZ, 1998), where the authors repeatedly model the probability that all infected animals in a group will test negative. In this case, the binomial parameter p was given by the test sensitivity, and the number of trials (n)

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[6] **Pivot**: Consider a random sample $X_1, X_2, X_3, \ldots X_n$ taken from a population with parameter θ. If q is a function of only the data and the parameter, then the quantity Q, defined by $Q = q(X_1, X_2, X_3, \ldots X_n, \theta)$, is called a pivot if the probability distribution for Q does not depend on θ (Smith, 1994)

calculated to be the product of the prevalence of infected animals and the number of animals in the group. Thus, while the total number of tested animals was in fact greater than *n*, this represented the subset of tests or trials in which there was a (presumed constant) probability (p) of correctly identifying an infected animal. Similar examples in which the probability that no events will be observed in *n* Bernoulli trials are provided in an analysis of the risk of introducing foot-and-mouth disease into Australia with the importation of cassava pellets from Thailand (Cassava AUS, 1992), and in two epidemiological papers (Marchevsky et al., 1989; Martin et al., 1992), both of which examine the herd-testing scenario discussed above.

The second question that may be answered using the binomial distribution is:

" ... what is the probability of observing less than or equal to x events in n trials? ... "

In this case, the binomial cumulative density function shown below is used to determine the required probability (Larsen andMarx, 1986; Marriot, 1990; Smith, 1994):

$$P(X \leq x) = \sum_{x_i=0}^{x_i=x} {}^{n}C_{x_i} P^{x_i} (1-p)^{n-x_i}$$

None of the authors of the group of sample analyses identified for review appeared to require this form of the binomial distribution. Given this, the situation in which it might be applied is that which arises when a particular number of events is considered to be an upper 'acceptable' limit, and the analyst is interested in the probability of exceeding this limit. This is frequently the scenario for countries such as Italy, which import large numbers of animals and for whom the probability of *at least one* disease incursion is less important than the probability of fewer than an acceptable number of incursions (Caporale et al, 1997).

The third, and perhaps the most common, question that may be answered using the binomial distribution is:

" ... what is the probability of observing at least x events in n trials? ... "

This is in fact a similar question to that posed above, since the probability of observing at least *x* events in *n* trials is evidently the complement of the probability of observing less than *x* events. However, in import risk analysis *x* is often considered to be '1' and thus the cumulative density

function is not generally used to solve this question. That is the probability of observing at least 1 event is equivalent to 1 minus the probability of observing *exactly* no events, where the probability of observing no events is calculated using the binomial probability density function with x equal to zero.

An example of this was provided in an analysis of the risk of introducing anthrax into New Zealand with the importation of green hides from Australia (Anthrax NZ, 1998). In this analysis, the authors calculate the probability that there will be at least 1 day per year on which there is both a flood and an infected hide processed in any given tannery. Here it can be seen that the required probability may be calculated using the binomial cumulative density function and summing the probability that there will be 1 day, 2 days, 3 days, etc, up until and including the total number of working days in a year. Alternatively, and more simply, the required probability may be calculated as one minus the probability that there will be exactly zero days on which this event occurs:

$$P(X \geq 1) = 1 - (1 - p)^n$$

This is in fact the approach that was adopted in the analysis (Anthrax NZ, 1998). Similar examples to that described above were identified amongst the quantitative analyses (Meat BR, 1995; Scrapie NZ, 1996; Chicken AUS, 1996; IBD NZ, 1997; PRRS2 NZ, 1998).

Constraints

Given the range of situations in which the binomial distribution may be applied it is important to reconsider the constraints or assumptions upon which it rests - that is, that each of the Bernoulli trials is indeed identical and independent.

The first of these constraints states simply that the parameter p does not change between trials, an assumption which, when applied in the context of animal disease, may be difficult to uphold. An example of this is given in the analysis of the risk of introducing anthrax into New Zealand, as discussed above (Anthrax NZ, 1998), in which a single estimate is given for the probability that a green hide imported from Australia will be contaminated with anthrax spores. If however, the distribution of anthrax in Australia is examined more closely, it will be noted that, A) this disease occurs only within a specific 'anthrax belt' in which soil and climatic conditions favour the longevity of the organism, and, B) that in certain years, the incidence of new cases and the prevalence of spores in green hides from this belt will be markedly increased (Blood

andRadostits, 1989). Given this, it is evident the assumption that the binomial parameter *p* will be constant between 'trials' may be inaccurate and, indeed, it would be reassuring to be given more information regarding the manner in which this estimate was calculated from "... *reports of the annual incidence of anthrax in Australia and of the number of cattle and sheep slaughtered each year* ..."

A similar situation was encountered in an Australian analysis of the risk of foot and mouth disease associated with the importation of cassava pellets from Thailand (Cassava AUS, 1992). Here however, the author explicitly acknowledged that the incidence of foot and mouth disease varied between species and district, and deliberately chose a conservative overall estimate. Alternatively, in an analysis of the risk of introducing bovine spongiform encephalopathy (BSE) into New Zealand (BSE NZ, 1996) with the importation of bovine semen, the author calculated the overall probability that a selected bull will be incubating the disease as a weighted-average of the stratum-specific probabilities for various age groups. Finally, and although stated in the discussion of the Bernoulli distribution, it should be reiterated that virtually all of these analyses are stochastic and, as such, variation in the binomial parameter *p* was modelled by randomly sampling at each iteration from a probability distribution.

The second assumption governing the binomial distribution was that each of the Bernoulli trials should be independent. The most common cause for a lack of independence will be the situation termed 'sampling without replacement' whereby each sampled unit reduces the population size by 1 and, regardless of its status with respect to the event in question (coded 1 or 0), alters the probability that the status of the following sampled unit will be either 1 or 0 (Smith, 1994). In the context of quantitative risk analysis, the importance of sampling without replacement will generally be seen when a group of animals or commodity units from a limited population are tested before removal from the population. Since a single positive animal will generally imply disqualification of the group and the cessation of the process, it stands to reason that the prevalence of diseased animals in an infected population of limited size will increase with each tested-negative animal removed. That is, that the parameter (p) of each 'Bernoulli trial' will be *dependent* on the result of the preceding trial.

The severity of this problem will be determined by the 'sampling fraction'. That is, the proportion of the population that will be sampled without replacement (Snedecor, 1972; Cannon andRoe, 1982; Smith, 1994; Vose, 1997b). Since the smallest number of animals that can be sampled is 1, it follows that the principal determinant of the sampling fraction and, in turn, the adequacy of the

binomial distribution, will be the size of the parent population (Cannon andRoe, 1982). Two authors (Smith, 1994; Vose, 1997b) state that an adequate approximation will be provided by the binomial distribution if the sampling fraction is less than 5 percent, which implies that a sample of 5 animals would require a population of at least 100 animals. Another author (Snedecor, 1972) recommends that a sampling fraction of less than 10 percent, or a population of 50 animals for a sample of 5, will enable the binomial distribution to provide an adequate approximation. This issue will be discussed in greater detail within the evaluation of the *hypergeometric distribution*, later in this section.

Conclusions

The binomial probability distribution provides import risk analysts with a simple and intuitive means by which to calculate many of the common probabilities encountered in quantitative risk analysis. Indeed, Table 8 shows that the binomial distribution was applied, in one or other of the forms described above, in 16 of the 21 identified quantitative analyses. Given this, it was also noted that the assumptions on which the binomial distribution rests will not always be upheld in import risk analysis scenarios. In particular, it was shown that where the probability of the event in question - generally infection or the persistence of infection - is unlikely to be consistent between the animals or commodity units to which the model will apply. Likewise, where this probability is specifically dependent on the status of the animal(s) or commodity units that have been sampled, tested or otherwise 'trialed', then the adequacy of the binomial model should be examined and verified in the analysis. The reader is directed to the evaluation of the hypergeometric distribution for a complete analysis of this issue.

Geometric and negative binomial distributions

The negative binomial distribution and its special case, the geometric distribution, are less commonly used or reported members of the binomial process. The negative binomial distribution models the number of Bernoulli trials (x) carried out before observing the s^{th} event - where the probability (p) of observing an event is constant between trials - while the geometric distribution models the number of Bernoulli trials carried out before observing the first event.

Thus, the probability mass function for the geometric distribution is give by:

$$P(X = x) = p(1-p)^x$$

while the more general probability mass function for the negative binomial is defined as (Larsen andMarx, 1986; Smith, 1994; Vose, 1996b):

$$P(X = x) = {}^{s+x-1}C_x p^s (1-p)^x$$

Applications

In the context of import risk analysis, the geometric or negative binomial distributions might be used to model, for example, the expected number of importations before a disease incursion or, alternatively, the expected number of importations before 's' incursions. It was mentioned in the discussion of the binomial distribution above that for some countries that import large numbers of live animals or animal-derived products, the probability that disease will 'eventually' be introduced as a result of trade in a given commodity is understood and accepted to be 1 (Caporale et al, 1997). Where this is the case, the probability that a single disease incursion or a given number of disease incursions will occur as a result of a specific volume of trade may be modelled using the geometric or negative binomial distributions, respectively. Alternatively, if it is estimated that a given number of infected commodity units is required to precipitate an event, then the negative binomial may be used to model the probability that at least this number of infected units will result from a given volume of trade in the commodity. Following this example, it can be seen that there is potential for the negative binomial to be adopted in the context of dose-response models, where the objective is to determine the likelihood that a susceptible animal(s) will be exposed to the threshold number of causal organisms.

None of the identified import risk analyses, or overviews of risk analysis methodology, reported or advocated the use of the negative binomial or geometric distribution, although a number of technical papers or texts (Larsen andMarx, 1986; Grimmett andStirzaker, 1991; Smith, 1994; Vose, 1996b; Vose, 1997a; Vose, 1997b) described their potential. It is difficult to understand the lack of practical examples of the application of these distributions. Indeed, when it is considered that the assumptions upon which they rest are identical to those which apply to the much used binomial distribution, the only plausible explanation is the fact that both the geometric and negative binomial distribution are less publicised and less familiar to most analysts, and that the questions they answer are less commonly encountered than those addressed by the binomial distribution.

Conclusions

Where the assumptions of the binomial process are upheld, the geometric and negative binomial distributions will provide import risk analysts with the ability to model responses to questions that cannot be answered using the more common binomial distribution. In particular, the geometric and negative binomial distributions have the potential to be applied in the context of dose-response models or those in which the probability of observing at least a threshold number of events is required.

Beta distribution

The beta distribution, the final member of the binomial process, is used to model the probability (p) of an event, given that it has been observed *r* times from *n* Bernoulli trials. Given this, the beta distribution has two parameters (α,β), and is governed by the probability density function shown below. It should be noted that the cumulative density function for the beta distribution does not have a closed form:

$$f_P(p) = \frac{p^{\alpha-1}(1-p)^{\beta-1}}{\int_0^1 t^{\alpha-1}(1-t)^{\beta-1}dt}$$

Where, $0 < p < 1$

$\alpha > 0$

$\beta > 0$

Given the above, α and β may be calculated from observed data according to the following algebraic relations:

$\alpha = r + 1$

$\beta = n - r + 1$

Where *n* is the number of Bernoulli trials and *r* denotes the number of 'successes' or times that the given event has been observed.

Application

The beta distribution has been applied extensively in stochastic import risk analyses as a

probability distribution to represent uncertainty in the parameter p. However, only one example of the use of the beta distribution as a means by which to explicitly calculate the probability that p was equal to, greater than or less than a certain value was identified amongst the group of sample quantitative risk analyses. In this analysis (IBD NZ, 1997), the authors took a novel approach to quantitative modelling by using a simulation experiment to estimate the *mean probability* that a chicken will be carrying IBD virus at the time of slaughter, and subsequently employed the beta distribution to calculate confidence limits for this value. The confusing aspect of this procedure was that, having determined confidence limits for the mean probability, the authors appeared to simply ignore these in the simulation model and insert the mean alone. This observation may in fact be incorrect as the description of the method was brief, and important details such as the specific percentage points for the confidence limits were not stated. Regardless, the example does illustrate the potential for the beta distribution to be used as a means by which to generate additional information about the parameter p, as used in a model based on the binomial process.

The limitations of the beta distribution are simply those that applied to the Bernoulli, binomial, geometric and negative binomial distributions - that is, that the system or process being modelled should conform to, or approximately conform to, the assumptions of the binomial process.

Conclusions

It can be seen that while the potential for the application of the beta distribution is perhaps less obvious than that of the other probability distributions arising from the binomial process, there is scope for its use as a means to provide further information regarding the probability distribution of the binomial parameter p. It is evident that this parameter commonly represents estimates for prevalence, proportions or the 'probability of an event', or test characteristics such as sensitivity and specificity. Alternatively, if the release or exposure assessment has been calculated from a deterministic model, then the beta distribution may be used to calculate confidence limits for this probability, or to calculate the probability of observing a result greater than (or less than) that observed.

2.1.2 The hypergeometric process

The 'hypergeometric process' arises when a finite population of size N, in which there are s individuals of a given type, is sampled *without replacement* to gain a sample of size n. The limiting form of the hypergeometric process, as N tends toward infinity and the ratio n/N tends toward zero, will be the binomial process discussed above.

The hypergeometric distribution

If X ~ Hypergeometric (N,s,n), then X has the probability mass function (Smith, 1994):

$$P(X = x) = \frac{{}^{s}C_{x}\,{}^{N-s}C_{n-x}}{{}^{N}C_{n}}$$

Where, min {n, s} ≥ x ≥ max {0, n - N + s}.

The hypergeometric probability mass function thus models the probability that $X=x$ events of a given type will be observed when a random sample of size n is drawn from a finite population (N) in which there are s events of that type.

One of the constraints faced in the application of this distribution is the situation that arises when finite populations are sampled (or tested) without replacement. Indeed, it was stated that unless the 'sampling fraction' ($f = n/N$) is less than 5 percent (Smith, 1994; Vose, 1997b) or 10 percent (Snedecor, 1972), then the binomial probability distribution may not provide an adequate model. The reason for the disparity between the probabilities produced by the binomial and hypergeometric distributions is that the former assumes that each sample or 'trial' is independent and identical, whereas the latter considers that the probability of observing the given event at each sampling will depend on the results obtained from the previous sample(s). In mathematical terms, this equates to a result that states that while the expected value of each distribution will be identical, the variance of the hypergeometric distribution will be *reduced* by a fraction termed the 'finite population correction factor' (F):

$$\begin{aligned} F &= \frac{N-n}{N-1} \\ &\gg 1-\frac{n}{N} \\ &= 1-f \end{aligned}$$

It can be seen from the algebra above that the finite population correction factor (F) may be approximated as the complement of the sampling fraction (f). Finally, given that the variance of the binomial parameter p is given by:

$$s^2 = p(1-p)$$

It follows that *difference* between the variance of two distributions will also be determined strongly by the size of the parameter *p*. Specifically, it can be seen that this quadratic expression for *p* will be *maximised* when *p* is equal to +/- 0.5, implying that as *p* increases or diminishes from 0.5, the absolute effect of the finite population correction factor, for a given sampling fraction, will decrease.

The degree of difference between binomial and hypergeometric probabilities when the sampling fraction is increased from 5 percent to 10 percent, and subsequently 25 percent, is illustrated in the probability mass functions in Figures 5-8. In each of these plots, the binomial parameter *p* and the hypergeometric ratio *s/N* were set at 0.5, the value for which the effect of the finite population correction factor will be most noticeable (see above). It can be seen (Figure 6) that while the less conservative estimate for a threshold sampling fraction (10 percent) provides a reasonable approximation of the binomial distribution, the variance of the hypergeometric distribution is noticeably smaller, suggesting that tail probabilities for this distribution are likely to be lower. In contrast the two distributions are virtually indistinguishable when the sampling fraction is set to 5 percent (Figure 5).

The effect of sampling fraction will persist with large populations. That is, Figure 8 shows that the variance of the hypergeometric distribution obtained when a population of size N=1000 is sampled 250 times (such that the sampling fraction is 25 percent) remains considerably less than that of the binomial equivalent, and that the probabilities obtained from the two distributions are markedly different. While this result may be predicted from the formula for the finite population correction factor, it may nevertheless be intuitive to suppose that the two distributions would merge as the population became 'less finite'. In practical terms, it can be seen that circumstances demanding a sampling fraction as large as 25 percent when the population is also large would be unusual. However, the result should be acknowledged and sampling fraction, rather than population size *per se*, used as the determinant of the adequacy of the binomial approximation to the hypergeometric distribution.

Finally, it is interesting to note that the normal distribution included in Figure 8 in which the mean (μ) and variance (θ^2) were approximated by the corresponding mean and variance of the binomial distribution provided, as expected, an excellent approximation for the binomial distribution.

Figure 5: Comparison of Binomial (5,0.50) and Hypergeometric (100,50,5) probability mass functions - sampling fraction equals 5 percent

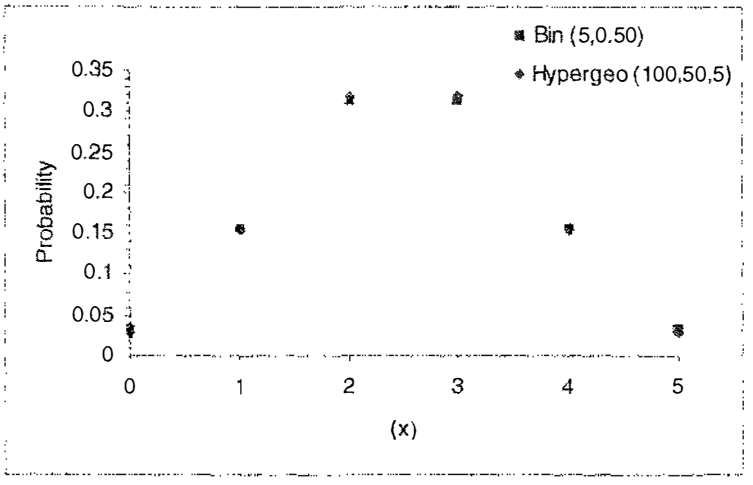


Figure 6: Comparison of Binomial (10,0.50) and Hypergeometric (100,50,10) probability mass functions - sampling fraction equals 10 percent

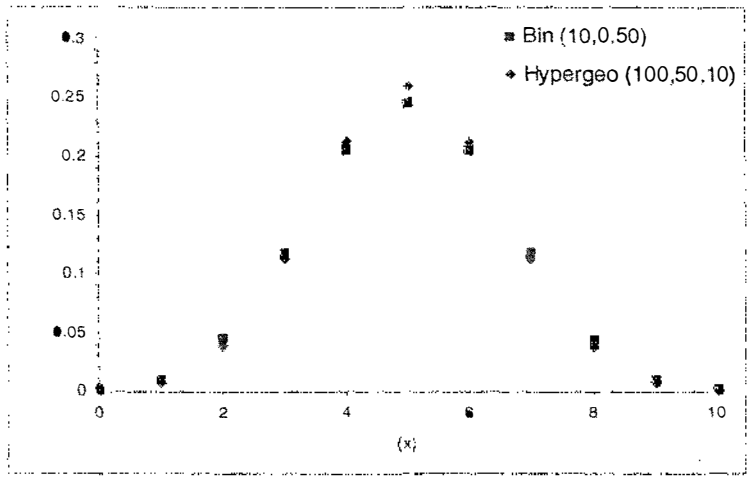


Figure 7: Comparison of Binomial (25,0.50) and Hypergeometric (100,50,25) probability mass functions - sampling fraction equals 25 percent

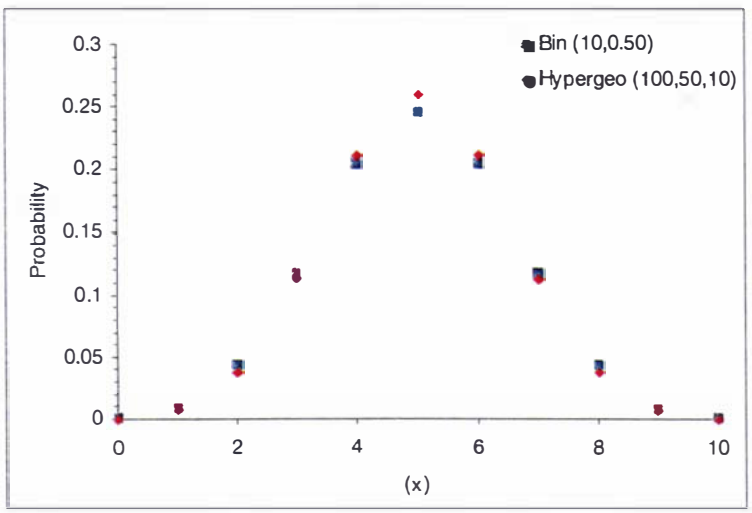
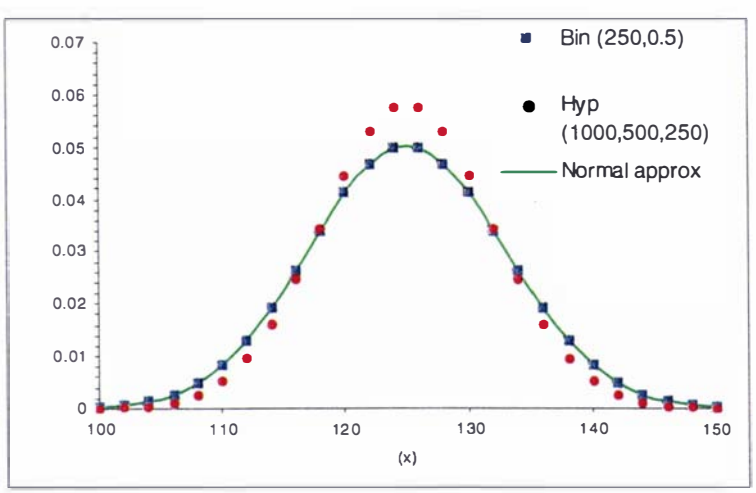


Figure 8: Comparison of Binomial (250,0.50) and Hypergeometric (1000,500,250) probability mass functions - sampling fraction equals 25 percent



Application

The hypergeometric distribution has not been commonly reported in import risk analyses and, indeed, only two direct references in the context of non-replacement random sampling of small groups were identified (PRRS2 NZ; Scrapie NZ). In the first of these (PRRS2 NZ), the authors

noted that the 'populations' from which they were sampling would frequently be quite small (N<20), and that the sampling fraction would frequently exceed the less conservative threshold of 10 percent. These authors were however also able to demonstrate that where this was the case, the standard summation result for the binomial series described in the model was also the result that would be obtained were the series manipulated and treated as a hypergeometric summation.

Aside from the sample risk analyses, the application of the hypergeometric distribution was discussed in various technical papers and texts (Larsen andMarx, 1986; Smith, 1994; Vose, 1996b; Vose, 1997b) and in the handbook of tables for livestock disease surveys (Cannon andRoe, 1982). In each of these publications, the role of the hypergeometric distribution in the situation where finite populations are sampled without replacement, and the conditions under which the binomial distribution may be used as approximation, were reiterated.

Conclusions

Given the above, it can be seen that the hypergeometric distribution provides a valuable alternative to the binomial distribution in the situation where the conditions of the 'hypergeometric process' apply. Given this, it was also recognised that the hypergeometric probability mass function has a more complex and less flexible algebraic form than the binomial alternative, and that the latter may be applied as approximation where the sampling fraction is less than 10 percent (Snedecor, 1972) or, more conservatively, 5 percent (Smith, 1994; Vose, 1997b).

2.1.3 The Poisson process

The random variable X_t denoting the number of occurrences of an event A in t units of a continuum is a Poisson process with rate $\omega > 0$ if:

- The probability of A occurring exactly once in a small interval of length ε, is $\omega\varepsilon + 0(\varepsilon)$, where $0(\varepsilon)$ is of small order relative to ε, so that $\lim_{\varepsilon \to 0} 0(\varepsilon)/\varepsilon = 0$
- The probability of A occurring more than once in a subinterval of length ε is $0(\varepsilon)$
- The occurrence of A in a subinterval of length ε, is independent of the occurrence of A in any other non-overlapping subinterval of length ε (Smith, 1994)

The Poisson process describes a continuous exposure process[7] in which the probability of an event occurring per unit interval is constant, and independent of however many events have occurred in the past or how recently the last event occurred (Vose, 1996b). Regardless of whether a mathematical or descriptive definition is adopted, the Poisson process enables the following three groups of statistical measures to be calculated:

- The number of events observed per unit time
- The time until the observation of the next event
- The time until n events have occurred

Calculation of these measures are provided by the Poisson, exponential and gamma/erlang distributions, respectively.

Poisson distribution

According to the definition above, if the conditions for X_t are satisfied, then $X_t \sim$ Poisson (λ), where $\lambda = \omega t$. Given this, the probability mass function for the Poisson distribution is:

$$P(X = x) = \frac{\lambda^x e^{-\lambda}}{x!}$$

Where $\lambda > 0$.

The Poisson probability density function models the first of the statistical measures identified above - that is, the probability that the number of events in an interval t is equal to x. Alternatively, the Poisson cumulative density function (as shown below) models the probability that less than or equal to x events will be observed during the interval t.

$$P(X \leq x) = e^{-\lambda} \sum_{i=0}^{x} \frac{\lambda^i}{i!}$$

Applications

The Poisson distribution has been traditionally considered the appropriate distribution with which

[7] **Continuous exposure process**: A continuous exposure process describes the situation in which the unit of interest is the mean interval between events (MIBE) (Vose, 1996b)

to model the probability of the occurrence of rare events. The Poisson distribution provides an approximation for the binomial distribution when the number of independent Bernoulli trials is large ($n > 100$), the probability of an event in any trial is small ($p < 0.01$) and the expected number of events (np) is less than 20 (Larsen andMarx, 1986; Smith, 1994). The original purpose of this substitution of the Poisson for the binomial was to avoid the calculation of the complex binomial combinatorial form, ${}^{n}C_{r}$, which can be arduous when performed by hand. In the current environment of statistical calculators, computer spreadsheets and statistical software this feature of the binomial distribution is no longer a hindrance and, indeed, it has been shown that the binomial is the most popular distribution amongst import risk analysts (Table 8). Given this, it unlikely that the 'Poisson approximation to the binomial' will be adopted by analysts and more probably the case that the Poisson distribution will be reserved to model events that truly occur according to the assumptions of the Poisson process. Finally, it is also well known that Poisson probabilities tend to become normally distributed as the conditions for the binomial approximation are met. While this result has been invaluable to traditional hypothesis testing it is not as useful in the context of quantitative import risk analysis since the normal distribution has a notoriously intractable probability density function and a cumulative density function that cannot be represented in closed form. This issue was discussed in the introduction to the binomial distribution and will not be further reiterated.

Accepting the above, it was perhaps not surprising to note that the Poisson process was only mentioned in one of the quantitative analyses identified for review (Anthrax NZ, 1998). Here the Poisson 'event' was the coincidence of a flood on the day that an anthrax-contaminated hide was processed, and the period of time was specified to be one year. The authors of this analysis appeared to reverse the 'Poisson approximation to the binomial' and having described the application of the Poisson probability distribution, elected to use a 'binomial approximation to the Poisson' to model the said probability. In this case, the mathematics for the model based on the Poisson process were little more complicated than those required for the binomial equivalent and it is perhaps likely that these authors elected to use the binomial approach on account of its intuitive form and general familiarity.

Aside from this example, there were no others amongst the group of quantitative risk analyses, although the Poisson distribution was advocated in various technical papers and texts (Grimmett andStirzaker, 1991; Winston, 1996; Vose, 1996a; Vose, 1996b; Vose, 1997b).

Conclusions

From this discussion it can be seen that while the Poisson has potential to be applied in quantitative risk analysis, it use is likely to be limited to scenarios in which the assumptions of the Poisson process are rigorously upheld. That is, this distribution has traditionally been applied as an approximation for the binomial distribution, current technology and the intuitiveness of the binomial distribution now mean that, in the field of quantitative risk analysis, the approximation is perhaps more likely to be reversed.

The exponential distribution

The exponential distribution, or negative exponential distribution, may be derived mathematically from the Poisson distribution the probability that a given time will elapse between the occurrence of events, when these events occur at a rate ω. The exponential probability density function is defined by:

$$f_X(x) = \frac{1}{\beta} e^{-\frac{x}{\beta}}$$

Where, $\beta = 1/\omega$ (Smith, 1994).

Finally, and while of less importance in the context of import risk analysis, it should be noted that the exponential distribution is a special case of the Weibull distribution such that Weibull $(1,\beta)$ = Exponential (β) (Larsen andMarx, 1986; Smith, 1994; Vose, 1996b).

Applications

Although the exponential distribution was not used in any of quantitative risk analyses reviewed, it was advocated in various technical papers and texts (Grimmett andStirzaker, 1991; Winston, 1996; Vose, 1996a; Vose, 1996b; Vose, 1997b). Indeed, it is likely that there is potential for models which seek to answer questions such as, *how many years are likely to elapse before an incursion of disease?* or, *how many years are likely to elapse before favourable climatic conditions coincide with the importation of an insect vector?*. It is perhaps the combination of a widespread lack of familiarity with this distribution, and a reluctance to pose questions or construct models that are unusual and, therefore, yet more difficult to communicate, that has limited the willingness of analysts to explore possibilities for its use.

Conclusions

There is certainly potential for the exponential distribution to be used in quantitative risk analysis, and I envisage that as the disciplines matures, the questions asked by analysts will broaden and distributions such the exponential will gradually become familiar and accepted.

The gamma and erlang distributions

A random variable X has a gamma distribution with parameters $\alpha > 0$ and $\beta > 0$, and is written X ~ Gamma (α,β), if X has the probability density function given by:

$$f_X(x) = \frac{1}{\beta^{\alpha}\Gamma(\alpha)} x^{\alpha-1} e^{-\frac{x}{\beta}}$$

if $x > 0$, otherwise, $f_X(x) = 0$ (Snedecor, 1972; Larsen andMarx, 1986; Smith, 1994)

Given the above, it should be noted that the following relationships apply (Smith, 1994):

- A Gamma (1,β) distribution is the same as an exponential (β) distribution
- A Gamma (n,β) distribution is the same as an erlang (n,β) distribution
- A Gamma (½ν,β) distribution is the same as a chi-squared (ν) distribution

From these relationships it follows that A) the erlang distribution is simply a special case of the gamma distribution in which α can only take discrete values, and, B) the erlang distribution is the sum of *n* independent and identically distributed exponential distributions (Snedecor, 1972).

Applications

The erlang or gamma distributions may be used to provide a probability distribution for the time until α continuous (gamma), or *n* discrete (erlang) events have occurred (Vose, 1996b). Examples of the application of this measure in the context of import risk analysis might include the following hypothetical questions:

- What is the probability that exactly n months will pass before a threshold number of disease incursions occur?
- What is the probability that exactly n months will pass before at least a threshold number of disease incursions occur?

Where the time variable may be considered to be either discrete or continuous.

It can be seen that these questions are similar to those that may be addressed using the exponential distribution and, indeed, the probable cause for the lack of application amongst quantitative risk analyses conducted to date is also likely to be similar.

Conclusions

Both the gamma and erlang are probability distributions that have potential to be applied by import risk analysts to model a broad range of issues more searching than the traditionally reported 'release assessment' or 'exposure assessment'. Lack of familiarity and a desire for technical simplicity, components of the WTO's requirement for transparency (WTO, 1995; WTO, 1997a) have meant that these distributions have only been considered to date in theoretical descriptions in technical papers and texts. It is envisaged that with sufficient exposure, the erlang, gamma and other more complex probability distributions may be applied to model research questions specific to individual analyses.

2.1.4 General conclusions - statistical processes

The range of probability distributions that may be usefully applied in quantitative import risk analysis is far greater than the observed preference for the Bernoulli and binomial distributions would suggest. Indeed, the hypergeometric distribution, and each of the probability distributions that may be generated from the Poisson process, were virtually unrepresented amongst the identified analyses - even in the form of discussions that acknowledged their value or technical correctness and verified a decision to retain the simpler binomial model.

The reasons for the favour afforded to binomial distribution are difficult to state with certainty but probably include the suggestions that, A) the concept of repeated Bernoulli trials is simple and intuitive both to analysts and those with whom analysts must communicate the structure of a model, B) that the complexity of calculations based on the binomial distribution, while traditionally problematic, may be circumvented with statistical calculators, computer spreadsheets or statistical packages, and, C) that both the current standard for import risk, and a vast majority of existing analyses, are heavily orientated toward answering questions phrased in terms that invite the application of the binomial process. That is:

- What is the probability that at least one infected animal will be selected from an infected herd?
- What is the probability that testing will fail to identify an infected group of animals?
- What is the probability that disease agent will enter the importing country?
- What is the probability that susceptible animals will be exposed?
- What is the overall probability that importation of the commodity will result in a disease incursion(s)?

Each of these questions suggest the use of a model based on repeated Bernoulli trials and, while the validity of the binomial assumption that these trials are identical and independent may be questionable, the various forms of the binomial distribution nevertheless appear to be applied by default and without explanation.

In conclusion, I envisage that with repeated exposure and increasing familiarity, the less commonly applied hypergeometric distribution and the probability distributions of the Poisson process may appear more frequently in import risk analysis. It is also likely that considering more searching and specific questions may enhance quantitative models.

2.2 Conditional probabilities

Conditional probabilities are generally applied in quantitative risk estimation with one or more of the following broad objectives:

- To express the relevance of the position of a particular event, in a sequence or chain of events, to the probability being calculated
- To express the posterior probability of an event, given that additional information with which to refine its prior probability has been obtained
- To enable the calculation of a likelihood, where the algorithm to be used requires that the component probabilities be expressed in a particular conditional form

The first of these statements may be illustrated by considering 'the probability that an animal is infected' at each stage of an import risk analysis. Here it can be seen that at, for example, the fourth stage this probability will be conditional on the animal completing or passing through the preceding three stages, and may be expressed in abbreviated form as, P(infected at stage 4 | passed stages 1-3).

The second statement is more difficult to conceptualise, but most commonly refers to probability statements regarding the efficacy of testing, or otherwise detecting disease in animals or commodities. For example, the prior probability that an animal selected at random from a herd will be infected may be estimated by the prevalence of diseased animals in that herd. Accepting this, the posterior probability that an animal selected at random and tested-negative will be infected may be expressed as P(randomly selected animal will be infected | tested negative), or more simply P(D+|T-). This probability is described as 'posterior', since it represents a prior probability that has been modified by gaining additional information (in this case a test result) regarding the event (infection). Expressed in epidemiological terms this particular posterior probability is equivalent to the complement of negative predictive value (NPV) or, alternatively, (1-NPV). Finally, it should be stressed that the conditional probability given by P(D+|T-) is not the same as P(T-|D+), which in epidemiological terms expresses the complement of test sensitivity (Se), or (1-Se).

The third statement is the most difficult to illustrate using simple examples, but will be discussed at length in Section 2.2.2. Accepting this, it can be said that the reciprocal conditional forms for probabilities - that is, P(A|B) and P(B|A) - may be required in different circumstances within a quantitative model in order for the model's output probability to be calculated, and that it cannot be simply stated that one or other will be always be appropriate.

Table 9 summarises the use of conditional probabilities in the quantitative import risk analyses identified for review. This table will be used as a reference for each of the ensuing discussions.

Table 9: The reported use of conditional probabilities

Analysis	*Overall likelihood of entry and exposure*	*Release assessment*	*Exposure assessment*	*Stage-level likelihoods*
1992 Cassava AUS	0	0	-	0
1993 Garbage USA	0	-	-	1
1993 Pigs CAN	0	0	0	0
1994 Bluetongue CAN	0	1	1	1
1994 Piroplasm USA	0	0	1	0

Analysis	*Overall likelihood of entry and exposure*	*Release assessment*	*Exposure assessment*	*Stage-level likelihoods*
1994 Salmon1 NZ	0	1	1	0
1995 Bov Embryos BR	0	1	1	1
1995 Meat BR	0	1	-	1
1996 BSE NZ	0	-	-	0
1996 Camelids CAN	0	1	0	1
1996 Chicken AUS	0	-	-	-
1996 Hides BR	0	1	1	0
1996 Rabies USA	-	1	-	1
1996 Scrapie NZ	0	1	1	1
1997 CSF NL	0	-	-	-
1997 IBD NZ	0	1	1	0
1997 Rabies NZ	-	1	-	-
1997 Salmon2 NZ	0	1	1	0
1997 Swill USA	0	0	1	0
1998 Anthrax NZ	0	-	-	0
1998 PRRS2 NZ	0	1	1	1
Totals (n=21)	**n=0**	**n=12**	**n=10**	**n=8**

Legend

1 = Reported

0 = Not reported

\- = Probability not calculated

2.2.1 A conditional form for the overall likelihood of entry and exposure

According to the current OIE Code, release and exposure assessments should be carried out as independent investigations. Given this it will generally be helpful to combine these assessments to provide an overall measure of likelihood, before considering the outcome and deriving an integrated risk estimate. While this edition of the OIE Code does not provide any guidelines for combining quantitative likelihoods, the previous edition defined the overall likelihood of entry and exposure as:

$$Risk\ estimate = PAE \times PDE$$

Where the PAE and PDE are equivalent to release and exposure assessments, respectively.

Conditional forms for the release and exposure assessments are evaluated in the following sections, but if the results of these discussions may be stated pre-emptively, then the expression above can be expanded to give:

$$\begin{aligned} \text{Risk estimate} &= P(\text{agent entry and domestic exposure}) \\ &= P(\text{agent entry}) \times P(\text{domestic exposure} \mid \text{agent entry}) \end{aligned}$$

According to probability theory, the result of this equation is not considered a conditional probability and, indeed, it can be seen from Table 9 that none of the identified quantitative risk analyses expressed it conditionally. Given this, it is nevertheless difficult to establish a rule which states categorically that the risk estimated is an unconditional probability since it might, alternatively, be expressed as:

"... *The probability of an outbreak of disease X, given that the disease agent is imported according to the defined scenario and that susceptible animals in the importing country are adequately exposed to the disease agent* ..."

While an unusual phraseology, it can be seen that this valid statement for the risk estimate expresses a conditional probability.

The appropriate conclusion to draw from these observations is perhaps a pragmatic one stating that while a risk estimate may be expressed in a variety of forms, the OIE's simple mathematical definition provides a useful basis for its calculation. According to this definition, a risk estimate should be expressed verbally as the joint probability of the release and exposure assessments.

2.2.2 Conditional forms for release and exposure assessments

Having established a pragmatic solution for the overall likelihood of entry and exposure, it is also important to determine the most appropriate conditional form for release and exposure assessments. Two issues require investigation:

Should release and exposure assessments be expressed conditionally?

If so,

Which conditional form(s) is/are most appropriate?

These issues are addressed individually.

Conditional forms for the release assessment

Avoiding mathematical implications, the release assessment denotes the likelihood that a disease agent will enter a country as a result of trade in a given commodity. While it can be seen that this likelihood may be phrased in many ways it will generally describe two distinct 'events'. That is, that A) that the commodity is imported, and, B) the commodity is infected.

Probability statements regarding two events may be expressed in one of three forms.

1. The joint $P(A \cap B)$ $= P(A|B).P(B)$, where A and B are not independent events
   $\equiv P(B|A).P(A)$
   $= P(A) \times P(B)$, where A and B are independent events.
2. The conditional $P(A|B)$
3. The conditional $P(B|A)$

The first statement may be rewritten as the joint probability that commodity will be imported and infected and, since neither of the component probabilities are meaningful in isolation, will not be pursued. The second statement expresses the conditional probability that commodity will be imported given that it is infected, or **P(imported | infected)**, while the third statement equates to the reverse - that is, the conditional probability that commodity will be infected given that it is imported, or **P(infected | imported)**. It would seem that both forms are intuitively sensible and should be investigated further.

Table 10 summarises the conditional forms in which analysts expressed the release assessment. All 12 of the analyses in which the release assessment was reported conditionally calculated the P(imported | infected), although one (PRRS2 NZ) calculated both conditional forms.

Table 10: Conditional forms for the release assessment

Analysis	P(imported | infected)	P(infected | imported)
1994 Bluetongue CAN	1	0
1994 Salmon1 NZ	1	0
1995 Bov Embryos BR	1	0
1995 Meat BR	1	0
1996 Camelids CAN	1	0
1996 Hides BR	1	0
1996 Rabies USA	1	0
1996 Scrapie NZ	1	0
1997 IBD NZ	1	0
1997 Rabies NZ	1	0
1997 Salmon2 NZ	1	0
1998 PRRS2 NZ	1	1
Totals (n=12)	**n=12**	**n=1**

Legend

1 = Reported
0 = Not reported

In order to determine the most appropriate form in which to report the release assessment it was important to assess the extent to which they differ, and to investigate the factors that maximise or minimise differences.

Experiment 1 (see, Annex to Chapter 2) was carried out so as to meet these two objectives. In this experiment, a simple five-stage pathway depicting the importation of live animals was constructed, both as an event tree and as a deterministic spreadsheet model. The purpose of the exercise was A) to facilitate calculation of the two conditional forms of the release assessment, and, B) to enable primary[8] input variables to be assigned a range of values, such that a multivariate matrix of results might be derived for each conditional form.

The results and conclusions drawn from Experiment 1 are given in the Annex to Chapter 2. In

[8] **Primary input variable**: An input variable that is not derived from other existing input variables

answer to the first question, it was shown that where a model did not contain stages that included testing, quarantine, the use of sentinels, or other procedures that may result in animals or commodity units being rejected, then the two conditional forms will be equivalent. This situation arises quite frequently and, indeed, it was interesting to note that two of the 12 quantitative analyses in which a conditional release assessment was reported (IBD NZ; Swill USA) could have accurately phrased this probability as either P(imported | infected) or P(infected | imported). By the same logic, the second question was answered by observing that the results for each conditional form will diverge as the sensitivity of diagnostic procedures increases, the specificity decreases and the probability that each 'tested' unit is infected decreases. Given this, it can be seen that in practical import risk analysis, differences between the two probabilities may often be quite minor since the probability that an animal is infected at the point of testing is generally extremely low, test sensitivity is imperfect and test specificity is, by default, assumed to be one.

Accepting this practical point, the 'optimal' conditional form in which to report the release assessment should nevertheless be established. In order to accomplish this, the 'philosophical' and practical implications of each form will be considered in turn.

The philosophical difference between the P(infected | imported) and the P(imported | infected) can best be understood by considering the entire importation process to represent a single procedure, analogous to a single global 'test'. Given this, the P(infected | imported) represents the complement of the negative predictive value of the procedure, or (1-NPV), while the P(imported | infected) represents the complement of the sensitivity of the procedure, or (1-Se). From this model it can be seen that, as stated above, the two forms will be equivalent if the importation procedure does not incorporate 'testing' and, thus, the potential to reject commodity units. It can also be seen that where 'testing' is carried out, the first form, the P(infected | imported) will provide an assessment of the efficacy of the global importation procedure. This assessment will be based on the prior probability of disease in the population from which the commodity is drawn, and the global 'test' characteristics of the importation protocol. In contrast, the second form, the P(imported | infected), will only represent the ability of the importation procedure to detect and reject infected commodity.

These philosophical insights suggest that the first form, the probability that imported commodity is infected, is a more satisfactory conditional form in which to report the release assessment. Given this, the second form was also thought to provide the following practical benefits:

- Improved risk communication
- Access to more flexible units
- Access to a determination of acceptable import risk

Regulatory risk analysts appear to agree that stakeholders, decision makers and trading partners prefer to be provided with a release assessment expressed as the P(infected | imported)(Murray, 1998; AQIS, 1998a). Indeed, in an analysis of the risk of introducing PRRS into New Zealand with the importation of porcine semen (PRRS2 NZ), this author encountered substantial confusion from both regulatory personnel and industry groups with regard to the interpretation of the alternative conditional form.

The second practical advantage of reporting the P(infected | imported) is the fact that this form enables the expression of the release assessment in a range of units, both for the purpose of risk communication, and to allow the results of the analysis to be compared with analyses undertaken for similar commodities. An example of this was provided in the previously mentioned analysis of the risk of introducing PRRS into New Zealand (PRRS2 NZ), in which the authors reported both the risk per consignment or donor boar, and the annual risk of introducing this disease. The alternative form is expressed in terms of infected commodity and, without knowledge of the volume of infected commodity selected, it is difficult to manipulate the result into a sensible volume or time-based frame.

The final practical advantage that may be attributed to expressing the release assessment as the P(infected | imported) is that this form may be more easily assessed in terms of 'acceptability', whether alone or by combining it with an assessment of the consequence of the event. That is, the SPS Agreement requires that regulatory authorities base their judgement of acceptable risk on an estimate of the likelihood and consequence of an adverse event, not simply on the 'efficacy' of an import protocol or the role that production and processing will play in eliminating an organism. Thus the alternative conditional form, the P(imported | infected) is of academic interest, but should not be used as the basis for restrictive measures since it does not represent the likelihood that a particular volume or consignment of a commodity will be infected.

Calculation of the release assessment

Methods for calculating the P(infected | imported) were assessed in the Annex to this chapter. Here it was it was shown that the P(infected | imported) can be calculated cumulatively, by

moving through the model template and, where a stage is determined to be an intervention, calculating the complement of the negative predictive value. Alternatively, where a stage is a classified as 'simple', the probability derived from the previous stage is multiplied by the form of this probability that signifies the likelihood that the animal or commodity will remain infected after the said simple event. Simple events continue to be multiplied together until the next intervention occurs, whereupon the result is converted again into the posterior (1-NPV), etc. The final value from the algorithm - the P(infected | imported) - will be the final probability attained from this cumulative process.

It follows that the approach does not depend on the calculation and subsequent modification of the alternative conditional form of the release assessment, the P(imported | infected). In addition, it can be seen that this approach does not depend on the assumption that the specificity of each intervention is one, since specificity may be incorporated into the calculation of (1-NPV) without difficulty or added complexity. Finally, interventions may be reported during the initial specification of a model in the more intuitive conditional form given by the P(pass stage | infected) or, in epidemiological terms, one minus the sensitivity of that intervention. As the algorithm for the calculation of the release assessment moves through the pathway, this result will be combined with the probability of infection at that stage so as to derive the revised conditional form, the P(infected | pass stage), or one minus the negative predictive value of the intervention, which in turn is incorporated in the algorithm as described above.

Conditional forms for the exposure assessment

The exposure assessment differs fundamentally from the release assessment in that at least one imported commodity unit is assumed to be infected. This results in a likelihood expressed conditionally as 'the probability of exposure given disease entry', or P(exposure | disease agent entry).

The exposure assessment may be derived as a combination of two or more separate 'exposure scenarios', where each scenario represents a separate set of post-entry stages. This was illustrated in two similar analyses (Salmon1 NZ; Salmon2 NZ) in which a range of separate exposure pathways for the infection of domestic fish was modelled. Separate exposure pathways were then combined by considering the proportion of exposure attributable to each. This resulted in single overall estimates for the respective exposure assessments.

The procedure can be represented mathematically as shown below:

$$P(\text{Exposure}|\text{disease agent entry}) = \sum_{i=1}^{n} P(\text{Exposure}|\text{scenario}_i) \times P(\text{Scenario}_i)$$

In this equation, the P(exposure | scenario_i) represents the 'exposure assessment' specific to each exposure scenario, P(scenario_i) denotes the proportion of the total exposure that will be channelled through each scenario, and *n* describes the number of separate exposure scenarios. Given the above, it should be noted that in most cases there will be a single exposure scenario, and that the P(exposure | disease agent entry) will thus represent a single uncomplicated probability. Indeed, of the 12 quantitative analyses in which the exposure assessment was explicitly calculated, 10 reported it conditionally as the probability of exposure given disease agent entry, and seven of these reported a single exposure scenario.

2.2.3 Conditional forms for stage-level likelihoods

The objective of this discussion is to determine, A) whether stage-level probabilities should be reported conditionally, and, B) in which conditional form they should be expressed.

In order to answer the first of these questions, it will be helpful to categorise stage-level events as one of the following:

- *Interventions*: Stage-level or within-stage procedures such as tests, clinical examination, the use of quarantine or the application of quality assurance programs, each of which may lead to commodity units being rejected.

- *Simple stages*: Stage-level events, such as processing or storage procedures, or the shedding of infectious disease agent in milk or semen, which may influence the probability that a commodity unit is infected, but which will not lead to the rejection of that commodity unit.

From the definition of an *intervention*, it can be seen that probabilities associated with these events may be expressed conditionally as either the probability that commodity is infected given that it returns a negative 'test', or P(infected | tested negative), or the probability that commodity unit will return a negative 'test' given that it is infected, or P(test negative | infected). The first of these equates to the complement of the negative predictive value (NPV) of the 'test', or (1-NPV), while the second is the complement of the test's sensitivity, or (1-Se).

In contrast, it can be seen that it is difficult to express *simple events* conditionally, since without the analyst's knowledge of the outcome and the subsequent acceptance or rejection of the commodity, it is not possible to calculate a posterior probability. For the sake of convention, a phrase such as 'the probability that commodity will be infected given that it has passed the particular stage' is not technically incorrect but, by the same token, the probability that it will 'pass' the stage is obviously '1' and, thus, the conditionality is redundant.

Accepting these definitions it remains to determine the most appropriate conditional form in which to express those stages categorised as interventions. Since the release and exposure assessments represent such fundamentally different likelihoods, pre-export and post-entry interventions will be investigated independently.

Pre-export interventions

In determining the most appropriate conditional form in which to express probabilities associated with pre-export interventions, two criteria should be considered:

- The conditional form should facilitate the calculation of the release assessment
- The conditional form should be transparent and thus assist in effective risk communication

In Experiment 1 (see, Annex to Chapter 2) two alternative approaches to calculating the P(infected | imported) were evaluated. In order to calculate the release assessment according to the recommended algorithm, stage-level events considered to be 'interventions' must be expressed as the P(infected | passed stage) or, in epidemiological terms, the complement of negative predictive value (Martin et al, 1987). Given this, it was also shown in Experiment 1 that this conditional form will be calculated by applying Bayes' Theorem to the more simple P(pass stage | infected), and incorporating a knowledge of the probability of infection at that stage. That is, that in order to calculate the release assessment, *both* conditional forms will be derived for each intervention stage.

Since both conditional forms of pre-export interventions will be derived when calculating the release assessment, it remains to determine which will provide the better means of communicating the structure of the model. The simpler and more traditional P(pass stage | infected) is considerably easier to conceptualise and discuss and will probably provide the

information that most readers require regarding the potential efficacy of a risk-reducing intervention.

Post-entry interventions

The optimal conditional form for the exposure assessment was shown previously to be the P(exposure | entry of disease agent). In mathematical terms, this conditional form may be equated with the second and, ultimately, rejected form of the release assessment, the P(imported | infected) which, as explained in Experiment 1, is calculated from interventions expressed as P(pass stage | infected). Accepting this analogy, it follows that the PDE also will be calculated from interventions expressed in this simpler conditional form which, epidemiologically, is equivalent to the complement of the sensitivity of the 'test' applied at that stage.

Conclusions

In summary, the following conclusions were drawn in regard to the conditional forms for stage level events:

- Pre-export or post-entry stages in model templates may be classified as either interventions or simple events
- Probabilities associated with simple events may be expressed conditionally but can only be calculated as the P(infected | passed stage)
- Probabilities associated with pre-export interventions should be reported as the more intuitive P(pass stage | infected), although the alternative conditional form will be derived from this in order to calculate the release assessment
- Post-entry interventions should be expressed as the P(pass stage | infected), since this conditional form is both easy to communicate and is the form required for the calculation of the exposure assessment

2.3 Units for quantitative likelihoods

This section encompasses the group of issues surrounding the choice of 'unit' by which quantitative likelihoods are expressed. Since quantitative likelihoods are, in statistical terms, rates, this equates to the analyst's choice of metric for the numerator and denominator. In this discussion, any given combination of numerator and denominator is termed a 'unit'. While frequently overlooked, the choice of units is an important one, since for any given set of input

data values, it may alter an outcome variable by orders of magnitude.

Table 11 shows the units reported in the sample risk analyses. These can be summarised as shown below, although it should be noted that in many cases it was extremely difficult to determine the precise units that analysts had reported and, indeed, whether these were actually the units that were calculated in the model. In addition, it appeared that some analysts were inconsistent in the exact phraseology used to describe a risk estimate.

Numerator

- single commodity unit
- number of commodity units
- at least one commodity unit
- weight of commodity

Denominator

- single commodity unit
- number of commodity units
- weight of commodity
- unit time

Table 11: Units in which overall likelihoods, and those for the release and exposure assessments, were reported

Analysis	*Overall likelihood*		*Release assessment*		*Exposure assessment*	
	Numerator	*Denominator*	*Numerator*	*Denominator*	*Numerator*	*Denominator*
1992 Cassava AUS	-	-	Single unit	Unit weight	-	-
1993 Garbage USA	Unit weight	Unit time	-	-	-	-
1993 Pigs CAN	No. of import units	Unit time	-	-	-	-

Analysis	*Overall likelihood*		*Release assessment*		*Exposure assessment*	
	Numerator	*Denominator*	*Numerator*	*Denominator*	*Numerator*	*Denominator*
1994 Bluetongue CAN	No. of import units	Unit time	-	-	-	-
1994 Piroplasm USA	-	-	-	-	No. of import units	No. of import units
1994 Salmon1 NZ	No. of import units	Unit weight	No. of import units	Unit weight	No. of import units	Unit weight
1995 Bov Embryos BR	-	-	At least I unit	No. of import units	-	-
1995 Meat BR	-	-	At least I unit	Unit weight	-	-
1996 BSE NZ	Single unit	Single unit	-	-	-	-
1996 Camelids CAN	-	-	At least I unit	Unit weight	-	-
1996 Chicken AUS	-	-	At least I unit	Unit weight	-	-
1996 Hides BR	Single unit	Single unit	Single unit	Single unit	Single unit	Single unit
1996 Scrapie NZ	-	-	No. of import units	No. of import units	At least I unit	Unit weight
1997 CSF NL	-	-	-	-	-	-
1997 IBD NZ	At least I unit	Unit time	Single unit	Single unit	Single unit	Single unit
1997 Rabies NZ	-	-	No. of import units	No. of import units	-	-
1997 Salmon2 NZ	No. of import units	Unit weight	No. of import units	Unit weight	No. of import units	Unit weight
1997 Swill USA	At least I unit	Unit time	-	-	-	-

Analysis	*Overall likelihood*		*Release assessment*		*Exposure assessment*	
	Numerator	*Denominator*	*Numerator*	*Denominator*	*Numerator*	*Denominator*
1998 Anthrax NZ	At least I unit	Unit time	No. of import units	No. of import units	-	-
1998 PRRS2 NZ	At least I unit	Unit time	At least I unit	Unit time	-	-

2.3.1 Units for the overall likelihood of disease entry and exposure

It can be seen from Table 11 that 11 of the quantitative risk assessments reported overall likelihoods in units that could be clearly interpreted and that, within these, a range of approaches were used. This result is summarised below:

Unit	**Numerator**	**Denominator**
Single commodity unit	2	2
Number of commodity units	4	0
At least one commodity unit	4	0
Weight of commodity	1	2
Unit time	0	7
Total	11	11

It is difficult to evaluate the 'correctness' or, indeed, advantages and constraints of particular 'units', or combinations of metrics - that is, particular scenarios will simply demand or benefit from particular combinations. Given this, it was concluded that if the mathematics of calculations is correct then all the units themselves are likely to be acceptable.

2.3.2 Units for the release and exposure assessments

Table 11 shows that the following distribution of units was reported for the numerator and denominator of release and exposure assessments.

	Release assessment		Exposure assessment	
Units	**Numerator**	**Denominator**	**Numerator**	**Denominator**
Single commodity unit	3	2	2	2
Number of commodity units	4	4	3	1
At least one commodity unit	5	0	0	0
Weight of commodity	0	5	0	2
Unit time	0	1	0	0
Total	12	12	5	5

As above, the correctness or otherwise of the various combinations of these metrics could not be evaluated and it was again concluded that all 'units' are appropriate if the mathematics applied in their calculation is correct, and the assumptions upon which such mathematics are based clearly stated.

3 Issues specific to deterministic likelihood evaluation

3.1 Introduction

Deterministic risk estimation represents the more traditional approach to quantitative modelling in which the output is determined exactly by the individual quantities supplied as inputs (Averill andKelton, 1992). Given this, it should be stated that while the discipline of deterministic modelling *per se* may involve a host of complex mathematical techniques and, notably, the application of complex systems of differential equations (Osborne andWatts, 1977; Averill andKelton, 1992), this is not the case in the field of quantitative import risk analysis. Deterministic import risk analysis models are generally structurally identical to stochastic models, differing only in the fact that the analyst has elected to specify particular inputs as single values rather than probability distributions.

Given this, deterministic likelihood will involve each of the 'general issues' outlined above and aside from strategies for the management of uncertainty in model inputs, there appear to be few further issues or 'components' specific to the deterministic approach. The modelling of uncertainty is in fact the pivotal issue in the debate between import risk analysts who subscribe to the deterministic approach, and those who favour stochastic modelling. According to the deterministic view, the incorporation of probability distributions as a means by which to represent uncertainty in the value of model inputs is frequently unrealistic, and may mask or distort the

effect of true variability (Chicken AUS, 1996). Authors who subscribe to this approach suggest that in the absence of accurate information, analysts should model a scenario deterministically and assess the effect of particular inputs by purposively varying their value (Chicken AUS, 1996). The alternative (stochastic) view is that probability distributions, if chosen prudently, may be shaped to reflect the range of values for an input suggested by existing data or by expert opinion (Vose, 1996b). Sensitivity analysis may subsequently be performed to determine those variables that strongly influence the output and these may then be examined more closely and, if necessary, reassessed.

The debate cannot be resolved with yet another opinion one way or the other, and the important point is simply that aside from the issue of uncertainty there are few if any others specific to the deterministic approach. This contention was borne out in an assessment of the three deterministic assessments (Piroplasm USA; Chicken AUS; Anthrax NZ), and two stochastic assessments based on preliminary deterministic modelling (Scrapie NZ; Cassava AUS), none of which appeared to describe deterministic techniques or methodologies that required evaluation.

3.2 Sensitivity analysis in deterministic likelihood evaluation

Uncertainty can be managed in deterministic likelihood evaluation through the use of *sensitivity analysis*. Sensitivity analysis was in fact explicitly advocated in only one (Chicken AUS) of the five quantitative analyses that described deterministic modelling and, despite enthusiasm for its merits, this one paper did not utilise sensitivity analysis in the ensuing assessment. In addition, it appeared that the authors of the single deterministic assessment in which sensitivity analysis was actually employed (Piroplasm USA) did not formally report the procedure as such, but simply described it as a stage in the overall investigation of risk. This is unlikely to reflect a generally negative view of deterministic sensitivity analysis but, rather, the fact that most analysts who wished to assess the effect of uncertainty or natural variation tended to opt for the currently more familiar stochastic approach. Regardless, deterministic sensitivity analysis remains a valuable tool and one that may assume greater popularity as the demands and complexities of stochastic modelling become more widely acknowledged.

Deterministic sensitivity analysis can be seen to have two general objectives:

- To identify the variables within a model that are most influential in determining the magnitude of the final risk estimate (Averill andKelton, 1992; PRRS2 NZ, 1998)

- To determine the specific effect that purposive variation in a single variable or a group of variables will have on the final risk estimate (Chicken AUS, 1996)

The first objective describes the situation in which an analyst seeks to isolate particular variables likely to be most suitable as targets for risk-reduction measures, or those whose estimates should be the most robust. Given this, the second objective will generally be relevant where an analyst wishes to assess the robustness of the model's outputs to either natural variation in component variables, or to inherent uncertainty in their estimates.

3.2.1 Identifying influential variables

Influential variables may fall into one of two distinct groups:

- Within-stage *primary variables*: These have been defined previously as variables that are not derived from other variables, but which are used in the calculation of a stage-level probability. It has also been said that stages that contain within-stage primary variables are termed 'complex stages'

- *Stage-level variables*: These are either primary or secondary (ie calculated) variables expressing the probability associated with a stage

Issues associated with the identification of influential deterministic within-stage primary variables and stage-level primary or complex variables differ and therefore will be discussed separately.

Identifying influential within-stage primary variables

The identification of influential within stage primary variables is in fact a notably difficult procedure, and one that does not have any universally applicable solutions. That is, the influence of a primary variable on either the release or exposure assessment will depend upon its magnitude in relation to other variables, mathematical manipulation(s) within a given stage, the number of complex stages in which it is used and the means by which stage-level likelihoods are combined. Where a deterministic model involves even a moderate number of complex stages, it follows that the relative contribution of a single within-stage primary variable will be difficult, if not impossible, to determine.

The only apparent solutions to this problem are pragmatic rather than technical ones, in which the analyst restricts this form of sensitivity analysis to variables identified *a priori*. This may be based on particularly poor information regarding a variable(s) or a particular interest in its effect on the release or exposure assessments. Alternatively, it may be possible to systematically vary each of the primary variables and compile a structured assessment of the effect that this has on the outcome. This solution, always an arduous exercise, may become overtly problematic for reasons that will be discussed later in this section.

Identifying influential stage-level variables

An alternative approach to this aspect of sensitivity analysis is to identify the stage(s) most influential in determining either the release or exposure assessment. Where such stages are classified as 'complex', this will enable the analyst to look more closely at within-stage primary variables so as to determine whether the effect of inherent uncertainty or natural variation may need to be assessed systematically (see below). Alternatively, where the influential stages are simple, then the variable expressing the probability associated with that stage will itself be the primary variable of interest.

Given this, it remains to consider the specific algorithms used to calculate the release or exposure assessments and to determine whether the identification of influential stage-level estimates is feasible. As shown previously, calculation of the release assessment in the form, P(infected | imported), involves determining the probability that the commodity will be infected given that it has completed each given *intervention* stage, and the multiplication of the last of these in an importation pathway by any subsequent *simple* stage likelihoods.

Unfortunately, this potentially complex algorithm does not provide enough structure to derive generic rules to identify the stages within a pathway that will be most influential in determining the release assessment. That is, the contribution of each simple stage will be determined by its position in the pathway and its position with respect to each intervention stage, while the contribution of an intervention stage will be determined by its own position in the template, and by the sensitivity of the procedure it describes. Overall, it was not considered feasible to derive a set of rules that might enable an analyst to examine a deterministic model and conclude from its structure and the stage-level probabilities, the particular stages likely to be the most influential.

In contrast to the release assessment, the calculation of the exposure assessment is a relatively more straightforward procedure, generally involving the linear multiplication of stage-level

probabilities. Given this, it can be seen that since all stage-level probabilities are expressed on the same scale (0 to 1), their rank with regard to degree of influence on the exposure assessment will simply be their rank when arranged from lowest to highest.

Conclusions

It was concluded that the process of identifying influential variables in a deterministic model will be limited to ranking the influence of stage-level probabilities on the magnitude of the exposure assessment. The influence of within-stage primary variables on either the release or exposure assessment, and the influence of stage-level probabilities on the release assessment, will be determined by mathematical complexities which may be solved analytically in unusual cases, but for which it was not possible to derive generic rules.

Accepting this, it was concluded that the rank of each stage-level variable with regard to its influence on the exposure assessment will be equivalent to the rank of each stage-level probability when these are arranged from lowest to highest.

3.2.2 Assessing the sensitivity of outputs to particular variables

The alternative approach to deterministic sensitivity analysis is to investigate the effect of systematic variation in particular primary input variables on either the release or exposure assessments. It can be seen that since the objective of this approach is to investigate the robustness of a model to inherent uncertainty or natural variation in primary variables, both within-stage and stage-level primary variable should be considered. Given this, it remains to determine the most appropriate means by which to specify the degree of variation in each targeted input variable.

The simplest approach is that suggested in the single assessment that advocated this form of sensitivity analysis (Chicken AUS, 1996) and involves the analyst stating the 'likely range of values' that a variable may take, whether these reflect uncertainty or natural variation. A minor adaptation of this method is to consider that the said variable represents a distribution of values and to use the relevant probability density or mass function, or an approximation based on the Central Limit Theorem (Smith, 1994), to determine lower and upper percentiles for that variable. These may then be placed in the model in turn and the change in outcome recorded.

An alternative approach is to calculate lower and upper limits for a variable by considering

relative or absolute deviations from the original value (PRRS2 NZ, 1998). The objective of this approach is to standardise the degree of variation within input variable such that an output is obtained with each variable set at its 'expected' value, and subsequently with each variable raised and lowered by a given amount or by a given proportion of the original value. While this method has an intuitive advantage with regard to the systematic analysis of a group of primary variables, it can be seen that deviations based on absolute magnitude will tend to be unrealistic unless all such variables are measured on the same scale. Likewise, relative deviations based on a proportion of the original value may result in spurious results for variables with extreme (high or low) values.

In conclusion, the most sensible approach to the systematic variation of primary variables is to either specify a known range of likely values, or to select a suitable probability distribution for the variable, and use the corresponding probability density or mass function to determine percentiles. If the objective of a sensitivity analysis is to systematically examine variation in a group of primary variables, then an approach based on the distribution of each targeted variable is likely to be simple to administer and objective.

4 Issues specific to stochastic likelihood evaluation

4.1 Introduction

A preliminary assessment of the sample import risk analyses and allied disease risk analyses, the technical papers or texts, and the overviews of risk analysis (see, Introduction to Chapter 2) revealed a broad range of technical issues arising from the use of stochastic variables in quantitative likelihood evaluation. These were subsequently condensed into the categories shown below:

- Methods for calculating stochastic risk estimates
- Types of simulation
- Methods for Monte Carlo simulation
  - Random number generators
  - Sampling methods
  - Separating uncertainty and natural variation
  - Modelling dependencies in Monte Carlo simulation
  - Sensitivity analysis

- Probability distributions

Each of these topics entailed discrete groups of technical issues and will be evaluated independently.

4.2 Methods for calculating stochastic likelihoods

In a leading text on quantitative methods for risk analysis Vose (1996b) describes three alternative methods for obtaining an outcome distribution from a model in which at least one of the input variables have been described stochastically:

- The method of moments
- Exact algebraic solutions
- Simulation

4.2.1 Method of moments

According to this approach, the moment generating function for each random variable in a stochastic assessment is used to obtain the distribution's mean and variance. These may then be substituted into the model and the rules of basic probability theory used to derive the mean and variance of the output (Smith, 1994; Vose, 1996b).

The following are examples of commonly applied probability rules (Vose, 1996b):

- The mean of the sum of two variables is equal to the sum of their means
- The mean of the product of two variables is equal to the product of their means
- The variance of the sum of two variables is equal to the sum of their variances
- The variance of the product of two variables is equal to the product of their variances

The principal advantage of this approach is its inherent simplicity, both conceptually and with regard to its execution in a spreadsheet. The disadvantages, as categorised by Vose (1996b), include the following:

- It assumes all variables in the model are independent which, by extension, implies that no variables are correlated
- It assumes that the outcome is approximately normally distributed

- It assumes either that each input variable is approximately normally distributed, or that the model has a very large number of uncertain variables, none of which dominate the outcome
- It cannot easily cope with divisions, power functions, discrete variables, etc

Each of these constraints is likely to be problematic in the context of typical stochastic import risk analysis models. That is, A) input variables are frequently not independent, B) the outcome is often strongly left skewed and thus non-normal, input variables are rarely normally distributed, C) models may be dominated by particular input variables, and, D) input variables are frequently linked by complex mathematical formulae containing divisions, power functions, etc.

4.2.2 Exact algebraic solutions

The principle of this approach is to combine mathematically the probability density or mass functions for each input distribution, given that these will have been specified for each of the stochastic variables included in a model. While intuitively attractive, this approach will rarely be successful as the sole means of solving stochastic models for import risk analysis since exact algebraic solutions will be limited to a relatively small group of probability distributions and mathematical operations (Smith, 1994; Vose, 1996b). In addition to this, where more than two or three different stochastic variables are to be combined, the resulting arithmetic quickly becomes intractable, regardless of whether exact solutions for sub-sections of the model may theoretically be attained.

4.2.3 Simulation

While Vose (1996b) specifies Monte Carlo simulation, other available methods include discrete, continuous and mixed event simulation. The general purpose of simulation is to create a series of experimental 'iterations' or 'samples' which, when viewed together, may provide an indication of the behaviour of a model, given the expected behaviour of each input variable (Averill andKelton, 1992). Simulation therefore enables a system to be studied in a controlled environment and in either a protracted or compressed time frame. Alternatively, simulations may be time-independent, as will be shown to be the case for most stochastic import risk assessments.

In addition to these general properties, Vose (1996b) describes the following specific advantages of (Monte Carlo) simulation over the previous two methods for calculating output distributions:

- The distributions assigned to model variables do not have to be approximated
- Correlations and other interdependencies can be modelled
- Complex mathematics are not required to determine the outcome distribution
- Complex combinatorial algorithms can be included without additional mathematical considerations

The principal disadvantage of simulation has traditionally been the degree of skill in computer programming required to create such models. Recently however, software packages such as @Risk® (Palisade Corporation, Newfield, New York, USA) or Crystal Ball® (Decisioneering Inc, Colorado, USA) have been developed to enable Monte Carlo simulation to be performed within the environment of a computer spreadsheet. These packages are relatively simple to use, require little additional training beyond a general familiarity with computerised spreadsheets and yet are capable of producing complex Monte Carlo simulation models. The same cannot be said however for the development of tools for discrete and continuous event simulation and, despite the advent of various icon-based languages, these forms of simulation remain the domain of specialist simulation modellers.

4.2.4 Conclusions

Computer-aided simulation is the only realistic method for calculating an output from a stochastic model. The optimal type of simulation for stochastic import risk assessment - that is Monte Carlo, discrete event, continuous event or mixed event simulation - will be discussed in the following preliminary evaluation.

4.3 Types of computer-aided simulation

4.3.1 Discrete event simulation

Discrete event simulation involves the representation of a system using a model in which the state variables change instantaneously at separate points in time (Averill andKelton, 1992). Alternatively, this definition implies a system in which 'events' occur at a specified (deterministic or stochastic) rate. The principal advantage of discrete event simulation is that the occurrence of 'events' is an intuitive concept, and that the output may be analysed as though the simulation experiment was an observational study. In addition, continued advancements in high-level programming languages have meant that discrete event simulations may be designed and implemented more quickly and easily, and with less formal training and programming expertise.

In particular, icon-based languages such as Extend® (ImagineThat! Software Inc, CA, USA), Powersim® (Palisade Corporation, New York, USA), Ithink® (Palisade Corporation, New York, USA) or the currently prototypic, Alchemy (Cochrane, pers comm 1998)[9], enable comparatively inexperienced operators to specify a discrete event scenario which, if necessary, may be augmented by a specialist.

The principal limitations of the discrete event approach to simulation are that it is not suitable for scenarios in which events are extremely rare. Given this, it can be seen that models for the release assessment are likely to be problematic, since an event - the probability that imported commodity is infected - will commonly have an annual probability lower than 10^{-6}. Thus, in order to obtain results with any analytic power, huge numbers of iterations must be performed. Each of these may take at least a measurable period of processing time since discrete event simulation is, by virtue of the sequential nature of the programming commands, one of the slowest forms of simulation (Averill andKelton, 1992).

The problem is not reiterated for models of the exposure assessment. Here the 'events' to be modelled are the movements of viable organism through the stages of commodity processing and/or distribution in the importing country, and the opportunities for successful transmission or dissemination through a range of alternative mechanisms. Given this, it can be seen that discrete event models, while potentially complex and resource-intensive, will be well suited to these scenarios and, indeed, have been used successfully to model the spread of a number of key animal diseases. Of particular interest is a prototype of the Baseline Analysis System (BAS) developed by the United States Department of Agriculture as a global system for risk and consequence analysis (APHIS, 1997a). This system contains three separate modules one of which, the 'Epidemiologic Module', is a discrete event state-transition model designed to predict the spread of introduced diseases in the United States.

4.3.2 Continuous event simulation

In contrast to discrete event methods, continuous event simulation describes the modelling of a system by a representation in which the state variables change continuously with respect to time (Averill andKelton, 1992). This will typically involve the use of differential equations that provide relationships for the rates of change of state variables over time. If the differential

[9] Cochrane, TD: EpiCentre, Institute of Veterinary, Animal and Biomedical Sciences, Massey University, Palmerston North, New Zealand

equations are particularly simple, they may be able to be solved analytically. Alternatively, numerical analysis techniques such as Runge-Kutta integration (Averill andKelton, 1992) may be used.

Continuous event simulation is limited to the modelling of events that occur continuously with respect to time, such as economic fluctuations or biological models for the survival of a given species. Given this, the events considered in import risk analysis - that is, disease incursions and the exposure of susceptible species - are not generally continuous and these models are therefore unlikely to be of benefit. In addition, it can be seen that regardless of suitability, the methods required to represent or model a system continuously will be both mathematically and computationally complex and therefore unlikely to be practical as tools for most regulatory risk analysts.

4.3.3 Combined discrete/continuous event simulation

Combined event simulation is as the name suggests, simply the combination of the two methods described above, such that events whose behaviour changes with time may be optimally represented. Given this, the comments provided for each method need not be reiterated.

4.3.4 Monte Carlo simulation

Monte Carlo simulation has been defined as:

"*... a scheme employing random numbers, that is, U(0, 1) random variates, which is used for solving certain stochastic problems where the passage of time plays no substantive role ...*" (Averill andKelton, 1992)

or, alternatively,

"*... the random sampling of each probability distribution within a model to produce a series of independent scenarios ...*" (Vose, 1996b)

When applied in the context of a 'traditional' spreadsheet-based quantitative import risk analysis model, either definition simply implies the situation in which one or more of the point estimates provided for a deterministic model are replaced by randomly sampled distributions. This may be achieved by utilising the distribution functions provided in modern computer spreadsheets,

although it can be seen that for a large number of 'samples' this method will become difficult to administer. Alternatively, spreadsheet 'add-ins' such as @Risk® or Crystal Ball® may be used to generate a given number of random samples of each specified distribution and collect and display the results. These utility programs require little or no additional expertise beyond a familiarity with computerised spreadsheets and allow analysts to customise the simulation procedure by specifying the sampling method, the number of iterations to be used, the random number generator seed and other 'simulation parameters'. This not only provides a greater degree of flexibility for those who have a preference for particular methods, but enables analysts to experimentally vary simulation parameters or to replicate a simulation exactly.

The advantages of Monte Carlo simulation are thus its inherent suitability to the modelling of rare events and its comparative simplicity, given the relative ease by which deterministic spreadsheet models may be adapted to stochastic operation. Monte Carlo methods may also be used to model the behaviour of events that are not rare. That is, by retaining the probabilistic focus or by generating events and subjecting them to probabilistic conditions in a manner analogous to discrete event approach (Vose, 1997b). If there are any serious constraints to the use of Monte Carlo methods these are related to the ease with which they may be applied and the potential for complex mathematical issues, such as the representation of natural variation versus inherent uncertainty, to be overlooked (Vose, pers comm 1996). This problem has not been addressed in the published literature but was the subject of debate between regulatory risk analysts and a specialist risk analysis consultant at an international training course on import risk analysis (Risk Analysis and Animal Health, Zurich, Switzerland, 1996).

4.3.5 Conclusions

It can be seen that despite the potential for either high-level icon-based discrete event languages or purpose-built models to be adopted as a means of simulating the exposure assessment, neither are currently accessible to regulatory risk analysts without specialist training in simulation modelling, and neither are suitable for modelling rare events. Continuous and mixed event methods were also shown to be unsuitable and, accepting this, it follows that Monte Carlo simulation remains the single viable approach. Indeed, of the fifteen stochastic import risk analyses identified for review, all used Monte Carlo simulation to generate input distributions and calculate a stochastic output.

4.4 Methods for Monte Carlo simulation

4.4.1 Random number generators

All 20 of the stochastic quantitative risk assessments obtained for review used the commercial spreadsheet add-in @Risk® as the means by which to generate samples from stochastic variables. Communication with Palisade Corporation revealed that the random number generator used by @Risk® is a portable generator based on a subtractive algorithm in which the starting seed is either set manually or, where the user chooses 'zero', is clock (c/f machine) dependent[10] (Barrett, pers comm 1999)[11]. This algorithm should imply an infinite, or at least un-demonstrable, looping period, such that any repeated numbers that exist in an experimental series will not be followed by the same sub-series, as between the two repeats.

Aside from this, there were few other reported characteristics of subtractive random number generators which might apply to the system incorporated in @Risk®. The @Risk® random number generator was investigated systematically in Experiment 2 (see, Annex to Chapter 2) according to the generic properties required of all pseudo random number generators intended for use in Monte Carlo simulation modelling. That is, that in order to be considered adequate, a pseudo random number generator should provide:

- A source of independent and identically distributed uniform (0,1) random variates
- The facility to create replicate series by controlling simulation parameters - that is, the sampling method, the number of iterations and the random number generator seed
- A period greater than 5000 iterations

While a complete description of Experiment 2 will not be reiterated, it was noted in the discussion that the subtractive generator did appear to produce independent and identically distributed random variates from the uniform (0,1) distribution. That is, there was little visible or statistical evidence for deviation from either of these characteristics. It was also shown in Experiment 2 that the subtractive generator enabled the replication of a series of variates, although the role of the 'zero generator seed' as a means of instantiating a clock-based method for randomising seed selection *per se*, was not clearly documented in the software manuals or help files (Palisade Corporation, 1994). The implication of the zero seed was simply that any

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[10] **Clock dependent seed**: A random number generator seed determined by an algorithm which uses the time of the request as its parameter

[11] Palisade Corporation, Newfield, New York, USA

simulation based on this number could not be replicated since the seed actually inserted in the subtractive algorithm is not zero, but a separate number generated by an algorithm based on the computer's clock. Finally, while a subtractive pseudo random number generator should, theoretically, produce an infinite period (Press et al, 1986), it was nevertheless useful to demonstrate that there was no evidence of looping within the specified 5000 iterations of experimental variates.

4.4.2 Sampling methods

Sampling, in the context of Monte Carlo simulation, describes the process of obtaining a series of real numbers from the range of possible values that each stochastic variable may take (Press et al, 1986; Winston, 1996; Vose, 1996b). By extension, the probability that a given value will be obtained should thus correlate with the probability density or mass function for that variable (Smith, 1994). In practice, sampling is an extension of the process of generating and transforming independent and identically distributed uniform (0,1) random and regardless of the specific technique adopted, is based on the following principles (Averill andKelton, 1992; Bossel, 1994; Anon, 1997):

- The inverse function G(F(x)) is obtained by integration or approximated by numerical methods.
- To generate a random sample for the specified probability distribution, a random number (r) between zero and one is then obtained from the random number generator and substituted into the inverse function so as to determine the value to be generated for the distribution

$$G(r) = x$$

- The random number (r), known to be uniformly distributed between zero and one, provides equal opportunity for the generation of each value of x within any percentile range

This procedure may be illustrated using the simple case of an exponential distribution with parameter 8 = 2, and cumulative density function F(x) given by:

$$F(x) = 1 - e^{-2x}$$

Rearranging this with respect to (x) gives:

$$x = -½ \ln(1-F(x))$$

Thus, if F(x) is obtained by sampling a uniform (0,1) distribution, as explained in the previous section, then the value of x, from an exponential distribution with parameter $\lambda = 2$, may be obtained by substituting the uniform (0,1) variate into the expression above.

It can be seen that the method requires that a closed form integral for the probability density function f(x), or a summation of the probability mass function that has a finite and calculable solution (Smith, 1994; Anon, 1997). These will not always be available, and a number of alternative iterative and numerical techniques have been developed and implemented (Averill andKelton, 1992). In fact, many software packages that support the random sampling of predefined or customised distributions use such approximate procedures and, notably, procedures based on the 'envelope method' to sample distributions whose cumulative function have closed form integrals, simply because the procedures are relatively quick and reliable if programmed adeptly.

In summary, it can be seen from the outline above that distributions are generated in two stages. Firstly, samples of F(x) or its numeric equivalent are obtained as uniform (0,1) variates from the random number generator. Secondly, instances of the new variable (x) are obtained by considering the inverse function G(F(x)), or its numerical equivalent. While described briefly and in simple terms, an evaluation of the efficiency or accuracy of mathematical and computational algorithms for transposing uniform variates is beyond the scope of this discussion. Accepting this, it was nevertheless interesting to note that efficiency of a different type - *sampling efficiency* (Winston, 1996) - may be gained by creating a filtering stage between the generation of uniform variates and their transposition into variates of the required distribution. This stage has been described as 'Latin hypercube sampling' and differs from the traditional 'Monte Carlo' approach in several important respects.

Monte Carlo sampling

Monte Carlo sampling is the traditional approach to generating random variates in which the uniform variates are simply taken from the random number generator and transposed according to

mathematical or computational algorithms. The result of this procedure is that 'sampling error' may be obtained, since chance may dictate that an inordinate proportion of variates are generated from a particular region of the (0,1) interval (Vose, 1996b). It follows that with a sufficiently large number of iterations, uniformity should be adequately approximated and, thus, the generated random variates should fall in a distribution that approximates their theoretical probability distribution.

The principal advantage of Monte Carlo sampling is that the technique resembles true random sampling, and that any sampling error that may result can be viewed as evidence of objective random sampling, rather than as a technical aberration *per se*. The implication of this is that simulation experiments based on Monte Carlo sampling will satisfy the purist's desire to eliminate subjectivity and assess a result in which chance has deliberately played a role. An example of this is given in the field of queuing theory, where an analyst may wish to model Poisson arrival rates, but to allow the distribution of these rates to vary from the theoretical distribution according to chance, as they would in the 'real world' situations that they model. Unfortunately this is not the case for import risk analysts, who specify probability distributions principally to represent inherent uncertainty in particular estimates. Here it can be seen that having determined or defined an appropriate probability distribution for an uncertain variable, the overriding objective is to sample faithfully from that distribution so as to obtain an output that reflects the effect of the variable as accurately as possible.

It can thus be seen that the adequacy of a distribution obtained by Monte Carlo sampling will be directly related to the number of iterations used to derive it, a principal akin to the derivation of statistical estimates of a given precision from the random sampling of a population. Accepting this, it remains to determine whether Latin hypercube sampling, the alternative to Monte Carlo sampling, will produce an adequate distribution with fewer iterations - that is more 'efficiently'.

Latin hypercube sampling

Latin hypercube sampling is a randomised filtering procedure inserted between the generation of uniform variates and their subsequent transposition into variates of the desired probability distribution. Given this, Latin hypercube sampling utilises a procedure known as 'stratified sampling without replacement' (Palisade Corporation, 1994; Vose, 1996b), which proceeds systematically according to the stages shown below:

- The cumulative distribution of the desired random variate is divided into (n) categories, where (n) is the number of iterations to be performed. It should be stressed that categorisation is based on the cumulative probabilities (0-1) which, by extension, are equivalent to the uniform (0,1) variates obtained from the random number generator
- At each iteration, a category or stratum is selected by the random number generator. Once selected, a stratum will not be reused - that is, if the random number obtained indicates a previously sampled stratum, the procedure is repeated
- Once a stratum has been selected, a second random number is used to select a point, F(x), within that interval
- x = G(x) is then calculated, using calculus or one of the iterative or numerical techniques discussed above
- Stages 2 - 4 are repeated, noting that at each 'iteration', previously sampled strata are ignored

The advantage of Latin hypercube sampling is simply that the proportionality of the (0,1) interval will be maintained, regardless of the number of iterations performed. By extension, this implies that the procedure should be more efficient. Indeed, it can be shown using a simple simulation experiment that at a relatively low number of iterations, Latin hypercube sampling will result in a distribution which, while 'patchy', more closely resembles the superimposed outline of the theoretical distribution. As the number of iterations is increased, distributions obtained by the two methods converge although, even with 1000 iterations, 'sampling error' attributed to outliers is generally evident in the Monte Carlo histogram.

Conclusions

While Monte Carlo sampling will provide a simulation environment in which to replicate both the characteristics of a distribution and the random effects of 'sampling error', Latin hypercube sampling will be a more efficient means by which to obtain an accurate representation of a probability distribution, regardless of the type or shape characteristics of the distribution concerned. Accepting this, it follows that Latin hypercube sampling will generally be a more appropriate means by which to obtain the probability distributions specified in stochastic import risk analysis models.

4.4.3 Separating uncertainty and natural variation

Within the field of quantitative risk assessment, one of the interesting philosophical and

mathematical quandaries concerns 'inherent uncertainty' and 'natural variation', and the suggestion that these should be implemented differently in stochastic models (Hoffman, 1993; Vose, 1997b). Taken literally, 'uncertainty' describes the variation attributed to a model input which exists in the 'real world' as a single value or distribution, but for which information concerning either its value or distribution type or parameters is uncertain (Hoffman, 1993). Common examples of uncertainty attributed to a single value include disease point prevalence, or the probability that a particular procedure will inactivate a disease agent. Alternatively, examples of uncertainty arising from an unknown distribution include the size of cattle herds in an exporting country (which may be expected to vary within the bounds of a given Lognormal distribution) or the number of pigs in a quarantine centre (which may have upper and lower bounds and be distributed uniformly between these). It follows that where uncertainty represents lack of knowledge regarding a single value or a distribution, the uncertain variable will generally appear in a Monte Carlo model as a probability distribution whose type and parameters will have been estimated from data or from expert opinion.

Natural variation on the other hand is less well defined although generally refers to variation in variables derived within a model as a result of a stochastic process (Hoffman, 1993). A commonly-encountered example of this type of variable is the number of infected animals (x) to arise from repeated sampling of a population of size n and in which the disease prevalence is p. It can be seen that the 'natural variation' attributed to the number of infected animals x in this case represents the variance of a binomial distribution with parameters n and p. In other words, the natural variation is derived from a stochastic process rather than from the explicit knowledge of 'natural variation' in a real world variable. Alternatively, natural variation may be attributed to a variable that exists in the real world as a distribution, but for which both the parameters and type of distribution are 'known' and not estimated, as described above (Hoffman, 1993). An example of this is a variable such as 'annual salary', when obtained from census data. Here the population distribution for annual salary has been completely specified and thus the variance that sampling from this distribution will bring to the model will constitute 'natural variation'. It should be noted that examples of variables that exist as distributions but for which these distributions are completely 'known' are extremely rare in the field of animal health import risk analysis.

Applying modelling approaches to stochastic variables and processes

Stochastic models enable two fundamentally distinct modelling approaches to be used - Monte Carlo simulation and the calculation of direct or explicit algebraic solutions (Vose, 1996b). The

suggestion at this stage in the development of risk assessment methodology (Hoffman, 1993; Vose, 1997b; PRRS2 NZ, 1998) is that stochastic models may be optimised by combining the two methods. That is, by reserving Monte Carlo simulation for stochastic variables that represent uncertainty, and using exact algebraic solutions to model variables arising from stochastic processes. These issues have been examined in Experiment 3 (see, Annex to Chapter 2) and will be expanded systematically in the discussions below:

Modelling uncertainty

It has been suggested (Hoffman, 1993) that primary (un-calculated) variables, which may exist in reality as either uncertain point estimates or distributions with uncertain parameters, should be implemented in stochastic models as probability distributions suitable for Monte Carlo simulation. Listed below are four examples of such random variables. These were adopted from Experiment 3, a simple simulation experiment in which the effects of modelling approach on the characteristics of the output distribution were examined more closely (see, Annex to Chapter 2). The examples are arbitrary and are not intended to represent any real importation scenario. Regardless, they are realistic and serve to illustrate the range of random variables that, according to the ruling proposed in the previous section, represent fundamental uncertainty and should therefore be simulated rather than modelled explicitly by algebraic methods.

Herd Size (n)	~	Normal (25, 5) - constrained between 5 and 50
Herd Prevalence (p1)	~	Triangular (0.25, 0.50, 0.75)
Within-Herd Prevalence (p2)	~	Triangular (0.25, 0.50, 0.75)
Test Sensitivity(s)	~	Triangular (0.70, 0.75, 0.80)

Herd Size: This variable is interesting as it might conceivably have been derived to represent exact knowledge of the distribution of herd size in the exporting country or region and, were this the case, it would be unreasonable to consider the variation contributed to the stochastic model to represent 'uncertainty'. Accepting this however, it should be noted that in none of the stochastic analyses obtained for review were accurate census data used to derive with acceptable precision, probability distributions for variables that are known to exist in reality as distributions rather than as single values. Indeed, it would be more realistic to assume that this distribution was derived either from national industry statistics or from a combination of the latter and the opinion of experts. Given this, it follows that the stochastic variation contributed to the model represents uncertainty in the distribution type and/or parameters.

Herd Prevalence: The prevalence of infected herds in a country or region is also likely to occur as a distribution but, once again, is virtually never estimated with sufficient precision or accuracy for the result to be considered a representation of 'natural variation'. Indeed, a distribution for herd prevalence will commonly be derived from estimates based on national statistics or disease-specific surveys, and may be modified according to the perceived adequacy of veterinary services in that country or region.

Within-Herd Prevalence: Within-herd prevalence will frequently be difficult to estimate with accuracy, since it may vary dynamically within any given herd with the stage of an epidemic, between herds within a region or between herds in different regions, depending on the disease concerned and various other factors. Regardless, the shape and parameters of the probability distribution assigned to within herd prevalence may be based on disease-specific surveys, on national statistics or on the opinions of experts, and may be specific to herds in a given region or based on a national average.

Test sensitivity: Test sensitivity will generally be based on a conservative extrapolation of a point estimate provided by a diagnostic laboratory, or estimated directly as a beta distribution from trials investigating the test's ability to correctly identify infected and uninfected animals. This illustrates the fact that test sensitivity may be modelled as a distribution either to acknowledge uncertainty regarding a single 'true value', or to describe the range of values it is likely to take when performed under different conditions or by different laboratories.

Extrapolating from the general principles outlined in these examples it can be seen that primary variables which completely exclude uncertainty will be extremely uncommon. Since the adoption of exact algebraic methods (see below) will be based on the assumption that uncertainty does not contribute to variation in a given input, this supports the contention that all primary variables should be included in a model as representations of inherent uncertainty. Such variables should, by extension, be simulated rather than calculated explicitly.

This has in fact been the approach adopted by the authors of all stochastic analyses identified for review, although it is likely that in most cases, simulation was chosen on the basis of its simplicity and intuitiveness, rather than as a result of an analysis of the sources of variation. Regardless, it is pleasing to technically validate the decision to simulate variation in primary variables, since a need to consider exact algebraic solutions to calculations involving, for

example, variables that represent real world distributions, would greatly complicate the process of carrying out technically correct stochastic assessments.

Modelling natural variation

Natural variation was described in the opening comments as that portion of a model's variance that results from stochastic processes, and the variables so derived. The common example cited previously is the number of infected animals (x) that may arise if animals are selected randomly from a infected population or group. In this case, x has not been specified as a primary variable but, rather, is derived according to either the binomial or hypergeometric probability mass function.

The suggestion that natural variation should be modelled explicitly (ie. calculated directly rather than simulated) was also mentioned above. The implication is that variables such as the number of infected animals (x), as given in the example above, should not be specified in the usual Monte Carlo manner as a distribution to be simulated. Such variables should instead be incorporated into the model as a series of iterative combinations based on each possible value that the variable may take, and the probability that the given value will be observed. This point is best illustrated by example.

Consider that the objective of one stage of a risk assessment model is to determine the probability (Pr) that a test applied to a series or group of n animals selected from a large infected population with prevalence given by p, will fail to detect at least one of the infected animals (x) and, thus, identify the group as infected. Here it can be seen that x, the number of infected animals, will follow a binomial distribution with parameters n and P and, hence, the probability Pr may be calculated in two ways:

According to the first approach, Pr is determined by simulating the following expression:

$$\Pr = (1 - s)^{Bin(n,p)}$$

According to the second approach, Pr is determined by calculating the following expression:

$$\Pr = \sum_{x=1}^{n} \frac{n!}{x!(n-x)!} . p^x . (1-p)^{n-x} . (1-s)^x$$

It can be seen that if s, n and p were single point estimates, then the first expression would result in a distribution determined by the simulation of the series of n Bernoulli trials, while the second would lead to a single expected value for Pr. Likewise, if s, n and p were simulated primary variables, then both expressions would yield a distribution for Pr, but the first should result in a distribution with greater variance. This observation in fact illustrates the principal philosophical justification for the adoption of exact algebraic methods in the place of simulation, given the situation where variance contributed by a variable represents natural variation and not uncertainty (Hoffman, 1993). That is, that the introduction of simulation in the place of an exact calculation will create additional variation which, in turn, will inflate the variance of the output (Hoffman, 1993; Vose, 1997b).

This principle was investigated in Experiment 3, in which a simple stochastic model based on the group testing example shown above was used to determine the effect that the substitution of each expression for Pr would have on the characteristics of the outcome distribution. Here it was noted that even in a single stage stochastic model, the replacement of simulation with an exact calculation lead to a marked reduction in the variance of the outcome which, given the strongly left-skewed distributions, produced a difference in the 5^{th} percentiles of four orders of magnitude.

Accepting the benefit that may be accrued by modelling natural variation explicitly, it was also noted in Experiment 3 that the convenient algebraic reduction of the binomial summation shown above meant that the exact result could be implemented in a typical spreadsheet environment without undue difficulty. Were the algebraic reduction not available, and the number of selected animals large or the process itself based on a continuous (for example, Poisson) distribution, then it can be seen that the exact solution would have required either a lengthy and arduous manual summation, or the evaluation of a complex integral (Press et al, 1986; Armitage andBerry, 1994; Fishman, 1995). Given this, mathematical software packages such as Mathcad® (MathSoft Inc, Cambridge, Massachusetts, USA) are available for solving such reductions by finding exact solutions or by determining numerical approximations. These packages, however, are not designed for use by non-mathematicians and thus are likely to have limited application amongst regulatory import risk analysts. Given this, it is likely that exact solutions that prove too difficult to implement in a spreadsheet will be discarded in favour of the less precise but technically simple simulation-based alternative.

Conclusions

Partitioning uncertainty and true or natural variation

- Stochastic variation may represent either uncertainty or 'true' natural variation
- Primary (un-calculated) random variables may either represent 'real life' point estimates or distributions
- All primary random variables placed in a model to describe a stage or component of an importation scenario will incorporate some degree of uncertainty - whether they model point estimates or distributions
- Uncertainty may be represented in the choice of a probability distribution or its shape parameters
- 'True' or natural variation will thus be limited to secondary variables derived from primary variables as a result of a statistical (eg binomial, hypergeometric, Poisson, etc) process

Modelling uncertainty and true or natural variation

- Uncertainty in primary variables (whether they represent 'real life' distributions or single values) should be simulated
- Where possible, natural variation should be modelled explicitly by performing algebraic summations or integrations
- Natural variation may be simulated in the situation where algebraic solutions become impractical or intractable, given the option of mathematical software

4.4.4 Modelling dependencies in Monte Carlo simulation

Dependency between two (bivariate) or more (multivariate) random variables implies that values observed or generated are statistically associated (Smith, 1994). While dependency traditionally implies a single 'dependent' variable and one or more 'independent' variables, true multivariate associations - that is, associations described by a multidimensional covariance or correlation matrix - are also commonly observed (Armitage andBerry, 1994).

Dependencies may be expressed in a stochastic simulation by explicitly defining a variable in terms of one or more other variables, or by specifying a correlation between the iterated values of

two variables (Vose, 1996b).

Explicitly defining dependent variables

Here a variable is 'defined' explicitly by its relationship with one or more other variables. For example, body weight (BW) may be defined as height (H) multiplied by a constant (a) and then added to another constant (b), thus forming the typical simple linear regression equation,

$$BW = aH + b$$

It can be seen that in this situation, the distribution of the 'dependent' variable, BW, is defined entirely by the distribution of the variable H and the constants a and b.

The advantage of explicitly defining a new variable, in terms of the existing model variables, is the inherent modelling simplicity. This is particularly so in the case of spreadsheet-based simulation models that currently dominate the field of stochastic import risk analysis. Conversely, the disadvantage of this approach is that the relationship between two variables is seldom purely linear, curvilinear or otherwise defined by such a simplistic association. That is, while linear and other models are a useful means of investigating patterns or associations in observed data, the resulting equations describe least squares or maximum likelihood lines of best fit or, alternatively, the 'expected values' of a dependent variable in terms of the independent variable(s) (Armitage andBerry, 1994; Fishman, 1995). It can be seen that recreating a dependent variable by simulating independent variables and defining the relationship between these will result in the 'expected values' of the dependent variable, rather than the variable *per se*. Moreover, adding a random error term to the equation defining a dependent variable will simply create a distribution for the expected value of the dependent variable, rather than a distribution of the original variable (Smith, 1994).

Given the advantages and constraints inherent in explicitly specifying one variable in terms of another variable(s), it follows that this type of relationship will generally be reserved to describe interaction between the components of a 'system'. Whether this is a biological system, as was the case for the linear weight and height example, or any other system of fundamental components. Other common examples of systems-based models include economic models, sociological models, industrial models, etc.

Specifying correlations between variables

The second type of dependency that may be expressed in a stochastic model is fundamentally different to that described above in that while a relationship between variables is specified, one variable is not explicitly defined in terms of one or more other variables. The implication of this is that the two or more associated variables are simulated independently, and the iterated values arranged *post hoc* according to the degree of correlation between the variables (Vose, 1996b). While explicitly defined expressions of one variable in terms of another(s) are commonly used to describe associations between the elements of a system, the *post hoc* specification of correlation between the iterated values of two or more variables is generally reserved for logical relationships.

An hypothetical example of a logical relationship in the context of import risk analysis is the negative correlation that may occur between group size and the efficacy of daily clinical examination as a procedure for animal quarantine. Here it is conceivable that as the number of animals in quarantine increases, daily clinical examination may become less thorough. If this were thought to be the case, distributions obtained for the number of animals in quarantine and for the sensitivity of clinical examination might be negatively correlated, such that low values of one appear in the same iteration of the model as high values of the other. This principle was applied in one of the sample analyses (Salmonl NZ, 1994). Here the authors stated that as the prevalence of a particular disease of salmon increased, the effectiveness of inspection, grading and evisceration would be likely to increase. Given this, the author positively correlated these variables such that large values of one tended to occur in the same iteration as large values of the others.

The procedure used to generate *post hoc* associations between variables in a stochastic model is known as *rank order correlation*, and the statistic upon which it is based, as *Spearman's rank order correlation coefficient* (ρ) (Smith, 1994; Vose, 1996b). This statistic ranges between -1 and +1, is non-parametric and specifies linear correlation between the variables concerned. The advantages of using Spearman's rank order correlation coefficient are that it is simple and intuitive, and that the shape and parameters of each of the component distributions are preserved (Vose, 1996b). The disadvantage of the method is that it may be difficult to know exactly how much correlation to specify, since even where data illustrating a statistical relationship between variables is available, the accurate translation of this into a corresponding correlation coefficient may involve repeated iterative trials.

Rank order correlation remains the simplest means by which to specify a *post hoc* association between two or more variables. This is particularly so as it is available as a design tool within the simulation environment of @Risk®, the spreadsheet-based Monte Carlo software used by the authors of all identified stochastic import risk analyses. Despite this, the example cited above was the single identified instance in which rank order correlation, or any other *post hoc* means for correlating variables, was reported in the sample quantitative risk assessments. This may be because quantitative methods and, specifically, those pertaining to the structural aspects of quantitative models, remain at the limit of the technical expertise of many regulatory analysts. Alternatively, the specification of correlation between variables may be viewed as a trivial and potentially complex enhancement, rather than a worthwhile investment in time and other resources.

The effect of correlation was investigated in Experiment 4 (see, Annex to Chapter 2). In this experiment, the effect of simple mathematical operations performed on variably-correlated standard normal variables, and the more typical scenario in which a number of correlated random variables were incorporated in a complex algebraic expression, were examined. In brief, it was found that while the effect of rank order correlation was both predictable and significant when applied in a simple scenario, the same could not be said for the more complex algebraic model. In the latter case it was concluded that:

- Rank order correlation should be implemented in a model if the analyst believes it to represent the logic of the process being modelled
- The effect of rank order correlation on the mean and variance of the output should be evaluated by way of repeated sensitivity simulations

The logic behind correlated variables can only be determined through an intimate knowledge of the process and variables being modelled. The uncertainty arising from this evaluation of correlation thus illustrates the need for the thorough review of stochastic models by experts in the problem domain, prior to their simulation and to the publication of results. Finally, where the effect of rank order correlation on a model's output statistics is shown to be meaningful, the correlation coefficient specified should be reassessed. If necessary, further sensitivity simulations should then be carried out so as to ensure that an unrealistic degree of association is not detracting from the validity of the model.

Conclusions

Dependencies between random variables may be expressed in two fundamentally different ways. Firstly, a new variable may be created by explicitly defining a mathematical expression based on one or more existing variables - with or without the addition of a random error term. This approach is favoured when modelling interrelated elements within a 'system'. It should be noted however that where the expression has been derived from existing data, it will generally represent the 'expected values' of the new variable or, if an error term is added, the distribution of expected values of that variable.

The second approach to modelling dependencies is to incorporate rank order correlation, such that the sampled values of two or more variables are rearranged and incorporated into each iteration of the model according to a logical criterion. This approach is favoured where the values of the variables are related logically, and differs importantly to that described above in that no new variables are created. Rank order correlation was shown to have a substantial and predictable effect on the statistics of output distributions generated from simple operations involving identical input random variables. The effect of rank order correlation on the output statistics of more complex models will, however, be difficult to predict. Here it was concluded that while the procedure provides a valuable means by which logical relationships may be represented, sensitivity simulations using a range of suitable coefficients should be performed. Sensitivity simulations allow the effect of a rank order correlation coefficient to be assessed, and will enable the analyst to conservatively specify a value that does not alter the validity of the model.

4.4.5 Sensitivity analysis

From the evaluation of sensitivity analysis in the context of deterministic models (see Section 3.2), it was concluded that this procedure may entail either or both of the following objectives:

- To identify the variable(s) within a model that are most influential in determining the magnitude of the final risk estimate
- To determine the specific effect that purposive variation in a single variable, or a group of variables, will have on the final risk estimate

With regard to the first objective, it was shown that while systematically altering all primary variables in a deterministic model may lead to an understanding of their relative contribution to the outcome, this is likely to be both cumbersome and difficult to interpret. It was also shown that

while the contribution of each stage-level likelihood to the magnitude of the exposure assessment could be determined in a practical manner, the same could not be said for the release assessment whose derivation is likely to be more complex. With regard to the second objective, it was concluded that the effect of uncertainty (variation) in a particular primary variable could be investigated by specifying a known range of likely values, or specifying a suitable distribution for the variable and using the corresponding distribution function to determine suitable percentiles.

The application of sensitivity analysis to stochastic models differs importantly to the above, since primary variables will be simulated and the output will be a distribution rather than a discrete value. Thus, while the objectives of sensitivity analysis may remain as stated for deterministic, the solutions will be quite different.

Identifying influential variables

Of the 19 stochastic analyses obtained for review, only two (Salmon2 NZ, 1997; PRRS2 NZ, 1998) described a sensitivity analysis based on the identification of influential variables. Aside from these two reports, this form of sensitivity analysis was not discussed in any of the identified technical papers or texts specific to risk analysis. In fact, the only references to sensitivity analysis *per se*, were found in texts dedicated to simulation modelling (Osborne andWatts, 1977; Rasmussen, 1981; McCormick, 1981; Averill andKelton, 1992; Bossel, 1994; Fishman, 1995; Anon, 1997). Given this, the value of identifying influential variables, whether from the perspective of determining the most effective or cost-effective risk management procedures, or as a means of identifying those inputs for which information should be the most robust, is evident.

The authors of both analyses used the correlation-based sensitivity analysis routine provided within @Risk® to determine which of a subset of primary variables were the most important. The authors of the second analysis (PRRS2 NZ, 1998) subsequently enhanced this by carrying out sensitivity simulations for the significant variables, as will be discussed below. Sensitivity analysis may be performed in @Risk® by using one of two alternative approaches:

- Stepwise multiple regression
- Rank order correlation (Palisade Corporation, 1994)

Stepwise multiple regression

According to this procedure, the *standardised* distributions obtained from each of the model input

cells are regressed on the output distribution, and a multiple regression model thus derived. The partial regression coefficients obtained for this model subsequently indicate the degree to which a unit change in each of the standardised inputs will alter the output. Likewise, standard errors for the partial regression coefficients may be used to determine their precision. Finally, an R-squared statistic may be obtained as a means by which to estimate the extent to which the multiple regression model actually fits the data described by the output distribution (Smith, 1994; Armitage andBerry, 1994).

The difference between the stepwise procedure, and the alternative 'full model' approach, is that according to the former, inputs are entered into the model systematically according to the significance of their standardised partial regression coefficients when assessed with the existing model components. When the full model approach is used, however, the contribution of all variables is assessed at a single point (Armitage andBerry, 1994). The aim of the stepwise procedure is to allow variables that are strong 'predictors' of the outcome to be entered earlier, such that their coefficients will be less likely to be destabilised by any subsequently entered highly-correlated variables. The procedure is often augmented by specifying 'tolerance' values such that highly-correlated variables do not actually enter the model at all, or are removed at subsequent steps if their coefficients become unstable (Armitage andBerry, 1994). This modified approach may proceed in either direction (ie. starting with the complete model or with no model) and is known as step-down or step-up regression, respectively (Armitage andBerry, 1994). If the entry of variables into a stepwise model is not restricted, highly correlated variables with unstable coefficients may result. The principle of the algorithm, however, is that these may easily be separated from the strong predictor variables and the model re-run if required using the appropriate subset.

In the context of sensitivity analysis, unstable standardised partial regression coefficients derived from a stepwise procedure will be recognised by their small size, and the fact that they appear low in the significance ranking. Conversely, the larger standardised coefficients will also be those that most significantly contribute to variation in the output. This may be verified by collecting the distribution samples from @Risk®, running the sensitivity analysis in a statistical analysis software package and noting that the p-values of each coefficient increase as the standardised coefficients decrease. Finally, it follows that the rank for each variable obtained from this procedure will simply be the rank of its standardised regression coefficient.

Most analysts will be familiar with the principles and practice of multiple regression and, thus,

the stepwise procedure is intuitively attractive. However, it should be noted that there are two potential flaws. The first relates to the fact that this model assumes that the output can be adequately modelled by a linear additive combination of the input variables and coefficients. The release assessment was shown to be derived mathematically as a complex algorithm based on stage-level composite estimates, each of which may involve a similarly complex algebraic manipulation of primary variables. Likewise the exposure assessment, while a linear multiplicative combination of stage level estimates, is also obviously far removed from the simple linear additive model derived from the stepwise regression procedure. The result of this is the potential for a lack of fit for complex stochastic import risk analysis models. In addition, it is conceivable that the magnitude, rank and precision of partial regression coefficients derived from the additive multiple regression model may not be appropriate if extrapolated to the complex relationship that is *known* to have produced the output distribution.

The second constraint of the regression-based procedure is that the model is parametric and assumes that each input variable is at least approximately normally distributed, and at least approximately linearly related to the output distribution. One of the advantages of stochastic Monte Carlo models is that a huge range of probability distributions may be generated to represent uncertainty in the model's input variables and, given this, it follows that many inputs will be distinctly *non-normal.* Another advantage of Monte Carlo models, and particularly those created in the spreadsheet environment, is the fact that complex mathematical relationships between individual input variables can easily be described - by extension, this feature would suggest that inputs will seldom by linearly related to the output distribution. A lack of adherence to these principles may mean that the residuals from a sensitivity analysis based on the regression method are not independently distributed as normal (0,1) variates - the principal requirement for validating a least squares regression model (Armitage andBerry, 1994). Thus it follows that, in many cases, the results of a sensitivity analysis based on this approach should be reported with care.

Rank order correlation

The second approach to identifying influential variables involves the use of non-parametric rank order correlation. This technique has been described in the discussion of methods for modelling dependencies in Monte Carlo simulation but, to reiterate, is based on a process of sorting and ranking the iterated values for the input and output distributions, and calculating Spearman's rank order correlation coefficient (ρ) for each input-output pair. Correlation coefficients reflect the

degree to which high or low sampled values for each input are correlated with high or low values of the output. When considered *in toto*, the list of rank order correlation coefficients for a given model thus provide a measure of the degree to which each input 'appears' to be determining the output.

The advantage of rank order correlation is the fact that each coefficient, while dependent on others through the distribution of the output, is calculated independently. This means that highly correlated variables, or those that are derived from other variables, may be deleted from the sensitivity analysis without disturbing the remaining results. Likewise, a subset of variables of prior interest may be separated and examined in isolation. The disadvantages of rank order correlation are principally that the procedure is based on the strength of a linear association between the output variable and each given input, and that the precision of the Spearman's rank order correlation coefficient cannot be determined statistically.

A structured comparison between the rank order correlation and stepwise regression approaches to stochastic sensitivity analysis was undertaken in Experiment 5. Here it was noted that the ranks obtained from the two methods differed, both for a simple hypothetical import risk analysis model and a more complex model obtained from one of the identified analyses (PRRS2 NZ, 1998). It was also noted, however, that the ranks were not as different as might have been expected given the theoretical constraints of the regression based approach, as discussed above. In fact, a further rank order correlation analysis of the ranks obtained from the two procedures gave a Spearman's correlation coefficient of 0.90, which indicated that the results of the two methods, if not identical, were at least highly correlated.

Conclusions: Identifying influential input variables

Despite constraints regarding assumed linearity in the association between each input variable and the output distribution, and the fact that statistical tests are not available, Spearman's rank order correlation is theoretically more suitable as a means of determining the influence of each input than stepwise multiple regression. Accepting this, it was noted that when the two techniques were applied to stochastic models the ranks of input variables differed, although not to the degree that might be expected given the apparently serious theoretical constraints of the alternative regression-based approach.

Assessing the sensitivity of outputs to changes in particular input variables

The advantages and constraints of this aspect of sensitivity analysis, when applied in the context of deterministic models, have been discussed previously (see, Section 3.2). Here it was shown that the effect of uncertainty (variation) in a particular primary variable could be investigated by specifying a known range of likely values, or specifying a suitable distribution for the variable and using the corresponding distribution function to determine suitable percentiles. In the context of stochastic import risk analysis models, this approach is termed a 'sensitivity simulation', although is performed for the same reasons and carries the same inherent advantages and constraints. Given this, the most obvious difference between sensitivity simulations and the deterministic form of sensitivity analysis is that sensitivity simulations involve specifying a range of alternative distribution parameters, or completely different probability distributions, whereas the deterministic approach simply involves specifying alternative data points.

Two fundamentally different questions may be answered through carefully conducted sensitivity simulations:

- Do the revised input variables alter the outcome distribution to a measurable degree?
- Do the revised input variables alter the output distribution such that it is no longer acceptable?

Comparing the original and re-simulated distributions

The first of these questions equates to an assessment of the robustness of the model to extreme values in particularly influential variable(s). This approach was undertaken in one of the sample analyses (PRRS2 NZ, 1998), the single stochastic risk analysis to report sensitivity simulations. In an annex to this analysis, the authors identified influential variables for each of four stochastic models using a rank order correlation based screening analysis. The direction in which each influential variable would have to deviate in order to increase the risk estimate was determined and each variable subsequently raised or lowered to the maximum extremes considered realistically possible. The altered variables were then replaced, the modified model re-simulated and the 50^{th} and 95^{th} percentiles recorded. These statistics were chosen for the sensitivity simulation as they were reported in the original analysis.

Having completed the simulation and reporting, the authors were required to choose a measure by which to interpret the degree of difference between the output obtained from the original simulation, and that derived from the altered model. Both the 'absolute difference' in the

recorded percentiles and the 'proportional change' were tabulated. This was undertaken to illustrate the authors' documented supposition that, where the outcome distribution is a probability with values in the order of 10^{-6}, significant absolute differences are also likely to be extremely small and may thus be overlooked. Given this, it was observed that the same negligible[12] absolute differences, when expressed as proportional changes, were often in the order of 10^{3} and that the results of the sensitivity simulation analysis could thus be interpreted in a different light.

This issue was further investigated in Experiment 5 (see, Annex to Chapter 2). In this experiment, a similar approach was taken to identifying an influential variable, specifying alternative distributions and re-running the sensitivity simulations. Likewise, statistics were gathered and tabulated for each simulation and, absolute differences and proportional changes were documented. The results of Experiment 5 showed that the absolute difference between the mean obtained from the original simulation, and that obtained when the influential variable was raised, was ostensibly negligible (5.81×10^{-5}), while the ratio of the same statistics was in contrast quite substantial (0.30). The danger of misinterpreting a low absolute difference was further highlighted by the highly significant p-value ($p<0.0001$) for a non-parametric t-test carried out on the means of the two distributions. The conclusion reached in this stage of Experiment 5 was that 'subjective' assessments of the difference between distributions obtained from an original model, and those which may arise from sensitivity simulations, while valuable, should be undertaken with care. It was stressed that, in the absence of statistical tests, several measures (absolute difference, proportional change, etc) should be derived and assessed simultaneously.

Determining the acceptability of an output from a modified distribution

Aside from assessing the degree to which a sensitivity simulation has altered the output distribution, it may also be important to determine whether the latter remains 'acceptable', where acceptability represents an arbitrary cut-off below which a given percent or statistic from the risk estimate should fall. This quandary was also discussed in the annex to PRRS2 NZ, where the authors sought to determine whether modifying influential distributions in an unfavourable direction and to an extreme degree might cause the distribution for the risk estimate to become unacceptable to the regulatory authority concerned. The approach adopted by these authors was to simply re-run the models and re-record the 95th percentiles, which were subsequently compared with the level of risk considered to be acceptable. In Experiment 6, the process

[12] A probability in the order of 10^{-6} is commonly considered to be 'negligible'

undertaken was similar although the entire cumulative distributions for the original results and those obtained from each sensitivity simulation were superimposed on a plot that also indicated the arbitrary level of acceptability. While the conclusion from this hypothetical example is unimportant, it was noted that the use of the cumulative distributions led to a greater understanding of the behaviour of the modified output and enabled a more insightful decision as to the acceptability of the risk estimate.

Finally, it should be noted that while not undertaken in either PRRS2 NZ or Experiment 5, a statistical hypothesis testing approach might also be adapted to this aspect of sensitivity analysis. That is, the sampling distribution for the mean or median might be used to compare these statistics to the proposed level of acceptability. Whether this approach would yield information more insightful than the cumulative distribution plots is doubtful, although there is some intuitive gain to decision making in the provision of statistical tests.

Conclusions: Assessing the sensitivity of outputs to changes in particular input variables

Sensitivity simulations differ from the equivalent iterative changes made to deterministic models in that they are based on the specification of alternative distributions and/or distribution parameters, rather than on single values. Sensitivity simulations can also be used to answer two discrete questions - that is, A) whether changes in the value of influential distributions significantly altered the output distribution, and, B) whether the same changes detracted from the acceptability of the risk estimate. When considered together, these issues describe the robustness of the model to extreme values of its influential variables. In answer to the first question, it was noted that care should be taken in choosing the form of comparison and the statistics used. Specifically, it appeared that absolute differences might be misleading unless accompanied by the appropriate statistical test. In answer to the second question, statistics could once again be tabulated and compared with an acceptable limit, although it was noted in Experiment 5 that cumulative distribution plots provided better insight into the behaviour of the modified risk estimate.

EVALUATION IV

Consequence assessment

Contents

1 Introduction

Consequence assessment is currently one of the least developed aspects of import risk analysis. Consequence assessment has the potential to become at least as technical and/or resource intensive as the estimation of likelihood and, indeed, numerous assessments of the potential economic, social and other 'consequences' of disease incursions were identified for review (Quarantine AUS, 1991; Avocado USA, 1993; Irradiation USA, 1993; Nursery plants USA, 1994; Salmon econ AUS, 1994; Pseudorabies USA, 1994; ASF USA, 1994; Exotic2 AUS, 1995; Brucellosis USA, 1997). It will be shown later in this discussion, however, that detailed consequence assessments tended to have been undertaken independently of a risk analysis *per se*, and that benchmarks or guidelines for the conduct of these studies within a regulatory framework remain in an early stage of development.

2 Approaches to consequence assessment

2.1 Consequence assessment in the OIE Code

According to the OIE Code, consequence assessment is the process of "*describing the relationship between specified exposures to a biological agent and the consequences of those*

exposures". The OIE Code goes on to say that "*a causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the likelihood of them occurring*". These statements are important since they not only stress the need to determine the ways in which the effects of a disease incursion may be manifested in the importing country, but also the *likelihood* that each of these effects will be realised. That is, consequence assessment, as described in the OIE Code, should involve a form of adjustment or weighting, such that the seriousness of each outcome is interpreted realistically. This approach is not dissimilar to the concept of 'expected monetary values', or EMVs, in which the net expected cost or benefit of a decision is determined by summing the products of each monetary outcome and its probability of occurrence. Methods by which the concept of expected consequence can be implemented practically will be discussed later in this section.

The OIE Code describes potential consequences as either 'direct' or 'indirect'. Examples of direct consequences include the infection of animals, disease and production losses. Examples of indirect consequences include surveillance and control costs, compensation costs, potential trade losses and any adverse consequences to the environment. Despite the mention of socioeconomic effects in the introductory statements, these do not appear to have been included as a potential indirect consequence. The socioeconomic effects of rural disasters such as drought, fire and flood are well recognised, as are the effects of livestock slaughter programs and/or movement and marketing controls. Thus, while the lists of direct and indirect consequences provided in the OIE Code are clearly labelled as 'examples', it is evident that the potential socioeconomic effects of a disease incursion should be included in an assessment of its consequences.

Finally, the OIE Code clearly specifies that consequence assessments may be either qualitative or quantitative, and does not place a higher value on either approach. It will be shown later in this evaluation that quantitative consequence assessments carried out as a component of a risk analysis are relatively uncommon. This is because quantitative consequence assessments are inherently complex, and require significant technical expertise to carry out and interpret. One solution to this quandary is to carry out structured semi-quantitative consequence assessments in a similar format to the semi-quantitative likelihood evaluations discussed in a previous evaluation (see Evaluation III Part I). This approach is discussed in Section 2.4.

2.2 Consequence assessment in the OIE Aquatic Code

The OIE Aquatic Code states that in assessing the consequences of an aquatic disease, *"the adverse consequences affecting aquatic animal health, human health, aquatic ecology and ecosystems and the environment must be described and quantified*". The OIE Aquatic Code goes on to say that *"the scope of the adverse effects to wild populations could entail a whole range from minor to irreversible alteration to the aquatic environment and ecology*".

These definitions are, for several reasons, notably different to those in the OIE Code. Firstly, the definition is didactic, stating that analysts 'must' examine each of the identified consequences. This is unfortunate phraseology, since it is clear that the requirements of consequence assessments will differ between commodities and importing countries. From this perspective, the 'examples' provided in the OIE Code are a preferable format. Aside from this, the list of consequences does not include socioeconomic effects, effects on trade or compensation and disease control costs. Each of these are likely to be pertinent in a broad range of scenarios. The third point is that the OIE Aquatic Code does not appear to recognise the assessment of the likelihood of each consequence as an important component of the consequence assessment. Assessing and interpreting the likelihood of a consequence is unlikely to be a trivial exercise but will nevertheless ensure that importing countries do not inflate the importance of potentially catastrophic disease effects when considering the riskiness of an import proposal. Finally, the OIE Aquatic Code specifies that consequences should be evaluated quantitatively. While there may be merits in the quantitative approach, it is considerably more resource-intensive and is unlikely to be practical for all import risk assessments.

2.3 Consequence assessment in the sample import risk analyses

It was shown in Evaluation I that 16 of the 55 import risk analyses identified for review included a consequence assessment. Of these, only one (CSF NL, 1997) quantitatively modelled the outcome. This analysis was limited to a single disease agent and was carried out in an academic institution as an exercise in stochastic economic modelling. The remaining 15 analyses either qualitatively or semi-quantitatively assessed the consequences of disease incursions. Twelve reports described the effect of diseases on susceptible animals in the importing country, while only two appeared to consider public health. These outcomes are classified as the direct consequences of a disease incursion. The result was surprising given the importance of public health to a country's biosecurity measures, and may reflect the fact that relatively few analyses were based on zoonotic diseases.

The remaining outcomes were classified as indirect consequences. Surveillance costs and the cost of compensation were difficult to separate, since some analysts classified this aspect more loosely as, for example, 'disease control'. Given this, disease control costs were considered in 11 of the 16 analyses. The effect on trade was also commonly described, with 13 analyses reporting this as a criterion for consequence assessment. Only six analyses reported environmental effects and four the effects on a country's socioeconomic status. Both environmental and socioeconomic effects will be difficult to gauge with any accuracy, but should nevertheless be considered important areas for potential damage.

While not tabulated, it was also noted that none of the analyses appeared to factor the *likelihood* of any given consequence into the assessment, nor recognised that the likelihood associated with the direct and indirect consequences are fundamentally different. Indeed, during the process of reviewing import risk analysis literature and available analyses, I did not encounter a reference to this aspect of consequence assessment, aside from the OIE Code (or documents that cited the OIE Code) and the group of specific economic assessments. It was noted that internal guidelines produced by the Australian and the New Zealand regulatory authorities either quoted the OIE Code or described an approach to consequence assessment that was based on the phraseology in the OIE Code. Given this, Australian or New Zealand analyses produced after the circulation of these documents did not appear to consider the likelihood of each consequence criterion and thus derive the 'expected' consequences alluded to in the OIE Code.

This statement is not intended as a criticism, since it will seldom be practical to undertake a detailed assessment of the consequences of each disease, let alone determine their likelihoods. The statement does however support the need to develop a practical means by which to carry out structured and transparent consequence assessments that comply with the OIE guidelines. One such means is illustrated in the following section.

Table 12: Consequence assessment in the sample import risk analyses

Analysis	Approach (Qualitative / Quantitative)	Criteria for consequence assessment						
		Direct costs		Indirect costs				
		Animal infection	Public health	Surveillance and control costs	Compensation costs	Potential trade losses	Adverse effects on Environment	Socioeconomic effects
Qualitative likelihood assessments								
1990 Exotic AUS	Qualitative	0	0	1	0	0	0	1
1994 Salmon1 NZ¥	Qualitative	1	0	1	1	1	0	0
1995 Aquatic1 AUS¥	Qualitative	0	0	1	0	0	1	1
1995 Exotic IRE	Qualitative	1	0	0	0	1	0	1
1997 Lobster AUS¥	Qualitative	1	0	0	0	1	0	1
1997 Ratites NZ	Qualitative	1	0	1	1	1	1	0
1997 Salmon2 NZ¥	Qualitative	1	0	0	0	1	0	0
1998 Fibre NZ	Qualitative	1	0	1	1	1	0	0
1998 Psittacines NZ	Qualitative	1	0	0	0	1	1	0
1999 Chicken NZ	Qualitative	1	1	1	1	1	0	0
1999 Crocodiles AUS	Qualitative	1	1	1	0	1	1	0
1999 Porcine semen AUS	Qualitative	0	0	1	0	1	1	0
Totals (n=12)	**n=12**	**n=9**	**n=2**	**n=8**	**n=4**	**n=10**	**n=5**	**n=4**
Quantitative likelihood assessments								
1996 Camelids CAN	Qualitative	1	0	1	0	0	0	0
1996 Scrapie NZ	Qualitative	1	0	0	0	1	0	0
1997 CSF NL	Quantitative	0	0	1	0	1	0	0
1997 IBD NZ	Qualitative	1	0	1	1	1	1	0
Totals (n=4)	**n=3**	**n=3**	**n=0**	**n=3**	**n=1**	**n=3**	**n=1**	**n=0**
Overall totals (n=16)	**n=15**	**n=12**	**n=2**	**n=11**	**n=5**	**n=13**	**n=6**	**n=4**

2.4 An alternative semi-quantitative approach to consequence assessment

It was shown above that relatively few regulatory analysts have attempted to carry out comprehensive consequence assessments, and that none have done so in a manner that satisfies recommendations in the OIE Code. In a previous evaluation (see Evaluation III Part I), a semi-quantitative method for likelihood evaluation was proposed. This method utilised six categories of likelihood, with probability ranges that collectively spanned the 0-1 interval for probabilities. The method also supported the concept of multiple exposure scenarios, and allowed partial probabilities of exposure to be calculated.

If this approach is continued, it can be seen that the challenge is to formulate a practical means by which to evaluate the consequence of exposure when susceptible animals are exposed by each identified exposure scenario. As described in the OIE Code, this evaluation should incorporate both direct and indirect consequences, and should be based on an estimate of the likelihood that each consequence will occur at a given magnitude. One practical and transparent means by which this may be achieved is to consider the range of discreet 'outbreak scenarios' that may result from the exposure of susceptible animals by a given route, or exposure pathway. Outbreak scenarios commonly result from natural phenomena. For example, environmental factors such as temperature and rainfall may cause a pathogenic agent to become established more quickly or to spread more effectively. Outbreak scenarios may also stem from the nature of the human response to the outbreak, such as early diagnosis and rapid containment, or late diagnosis and disease establishment and spread, etc.

It is important that outbreak scenarios considered for each exposure pathway are clearly identified and likely to be associated with measurably different consequences, since over-specification at this point may lead to an analysis that is unnecessarily complex and, therefore, less transparent. In some situations, the severity of an outbreak will be more intuitively associated with a continuous spectrum, than discrete scenarios *per se*. Where this is the case, it will be necessary to form a workable number of categories, ensuring that the boundaries of these categories can be clearly identified.

Once the range of possible outbreak scenarios for each exposure pathway has been described, it will be necessary to assign a qualitative likelihood to each. These qualitative likelihoods are conditional, in that they assume that the exposure of susceptible animals has occurred by a particular exposure pathway. According to this method, qualitative likelihoods should be assigned using the nomenclature based on probability ranges described in the previous evaluation (Table

4).

Having established a range of outbreak scenarios, it will be necessary to provide for each an estimate for the impact of the disease agent on specified direct and indirect consequence criteria. Whether the list of suggested criteria provided in the OIE Code is adopted as written, or altered by the analyst, is not important to the method itself. It will, however, be critical for regulatory authorities to justify the particular criteria assessed, and to ensure consistency both within and between analyses. The impact of a disease agent may be measured using any clearly described and unambiguous qualitative or monetary descriptors.

The following terms and definitions were derived as an example, and will be adopted to illustrate the remaining stages of the assessment:

Negligible: The impact on a given criterion is likely to be minor to directly affected parties. The impact is unlikely to be discernible at any other level

Low: The impact on a given criterion is likely to be recognised within affected zones, and significant to directly affected parties. It is not likely that the impact on the given criterion will be recognised at the national level.

Moderate: The impact on a given criterion is likely to be recognised at a national level, and significant within affected zones. The impact is likely to be highly significant to directly affected parties

High: The impact on a given criterion is likely to be significant at a national level, and highly significant within affected zones. This classification implies that the impact would be of national concern. The serious effect on economic stability, societal values or social wellbeing would, however, be limited to a given zone

Extreme: The impact on a given criterion is likely to be highly significant at the national level. This classification implies that national economic stability, societal values or social wellbeing would be seriously affected

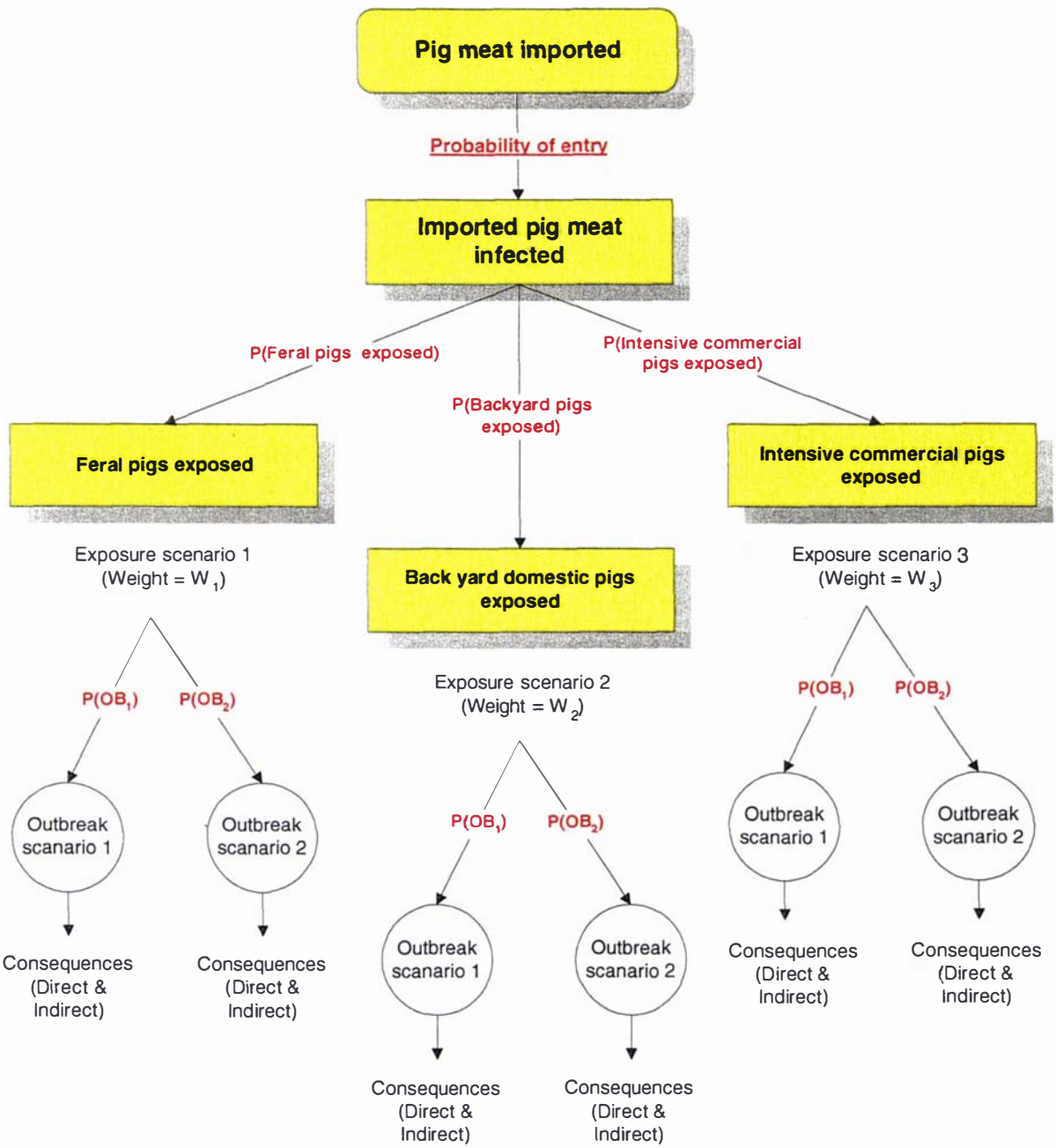
The final stage in this method for consequence assessment is to combine estimates of the impact of a disease agent on each consequence criterion, to give an overall consequence estimate for

each identified outbreak scenario. If the assessment were truly quantitative, this process would be undertaken using a complex summation in which the impact on each criterion was reported in a standard form (for example, monetary loss). The method is not, however, quantitative, but is simply intended to provide a practical and yet structured and transparent approach for regulatory analysts. As such, a set of 'rules' for obtaining an overall estimate of the magnitude of loss associated with each outbreak scenario, was derived. These rules are mutually exclusive, and should be addressed in the order that they appear in the list. For example, if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered, and so forth until one applies.

1. Where the impact on any direct or indirect criterion is 'extreme', the overall consequence is also considered 'extreme'
2. Where the impact on more than one criterion is 'high', the overall consequence is considered 'extreme'
3. Where the impact on a single criterion is 'high' and the impact on each remaining criterion is 'moderate', the overall consequence is considered 'extreme'
4. Where the impact on a single criterion is 'high' and the impact on remaining criteria is not unanimously 'moderate', the overall consequence is considered 'high'
5. Where the impact on all criteria is 'moderate', the overall consequence is considered 'high'
6. Where the impact on one or more criteria is 'moderate', the overall consequence is considered 'moderate'
7. Where the impact on all criteria is 'low', the overall impact is considered 'moderate'
8. Where the impact on one or more criteria is considered 'low', the overall impact is considered 'low'
9. Where the impact on all criteria is 'negligible', the overall consequence is considered 'negligible'

The components of this structured semi-quantitative approach are illustrated schematically in Figure 9. This illustration continues the hypothetical example of imported pig meat introduced in Evaluation III Part I, and shows that two outbreak scenarios have been identified for each of the three exposure pathways.

Figure 9: Components of the structured semi-quantitative consequence assessment



It can be seen that this structured and transparent approach will provide a qualitative estimate for the impact of a disease agent on each identified outbreak scenario. The method will also provide an estimate for the likelihood that each outbreak scenario will occur. The final stage in the assessment will be the combination of these estimates with the likelihood of entry and likelihood of exposure. This process is described in the OIE Code as 'risk estimation', and is the subject of the next evaluation.

3 Conclusions

Consequence assessment remains the least developed and least applied aspect of import risk analysis. Regardless, both the OIE Code and SPS Agreement specify that risk assessment should incorporate an assessment of the consequences of a disease incursion. More specifically, the OIE Code states that direct and indirect consequences should be considered. The OIE Code also maintains that a consequence assessment should include an evaluation of the likelihood that consequences occur at a given magnitude. This concept was described as the need to estimate the 'expected loss' associated with a disease incursion.

Quantitative methods may be employed to assess the likely consequences of exposing susceptible animals to a disease agent. These methods will not generally be practical for routine import risk analyses. To answer this difficulty, a structured semi-quantitative approach was proposed. This approach generates a series of outbreak scenarios for the identified exposure pathways and, for each, provides an estimate of the impact of a disease agent and an estimate of the likelihood that each scenario will occur. These estimates may be utilised in risk estimation, as discussed in the following evaluation.

EVALUATION V

Risk estimation

Contents

1 Introduction

In discussions of likelihood evaluation (see Evaluation III Part I and Evaluation III Part II) it was concluded that the release and exposure assessments should be based on clearly identified biological pathways, and that these pathways should in turn be based on clearly delineated steps. Whether the evaluation is quantitative or qualitative is less important than the need to create and adhere to a structured model of importation and exposure scenarios. It has also been shown (Evaluation IV) that consequence assessments should be based on a consideration of direct and indirect consequence criteria and the likelihood that a disease agent will impact on each at a given magnitude.

The challenge of *risk estimation* is to combine information regarding likelihood and consequence to give a global estimate of 'risk'. The underlying requirements are that the estimate reflects the real risk associated with a given agent as accurately as possible, and that it be conducted in such a way as to be transparent and repeatable.

2 Approaches to risk estimation

2.1 Risk estimation in the OIE Code

The OIE Code does not provide comprehensive guidelines for risk estimation but, rather, makes some suggestions regarding the quantitative form that the risk estimate may assume. These suggestions are in fact confusing, since they appear to describe the output of the quantitative exposure model rather than a structured approach to combining the likelihood of an event and its consequences. The preceding paragraphs of the OIE Code clearly outline the various categories of 'consequence', and it is surprising that these were not considered in the subsequent description of risk estimation.

It was suggested in the discussion of frameworks for import risk analysis that the integration of likelihood and consequence assessments may be another example of the trend according to which countries tend to adhere more closely to the precise requirements of the SPS Agreement. If this is the case, it seems unfortunate that the official guidelines do not provide analysts with a more comprehensive outline of an approach to this difficult and potentially contentious procedure.

2.2 Risk estimation in the sample import risk analyses

It was shown in Evaluation I that only three (Fibre NZ, 1998; Crocodiles AUS, 1999; Porcine semen AUS, 1999) of the 55 sample analyses undertook to combine likelihood and consequence assessments. Of these three analyses, one (Crocodiles AUS, 1999) cited rules by which the categorical likelihood and consequence assessments were combined, another (Porcine semen AUS, 1999) described a 'risk estimation matrix', while the third (Fibre NZ, 1998) simply made reasoned inferences from the reported likelihood and consequence assessments. The two formal approaches will be examined in further detail.

In the first analysis (Crocodiles AUS, 1999), the release assessment, exposure assessment and consequence assessments were reported as though integrated in a single step. This was unusual since all other identified analyses combined release and exposure assessments to give a single likelihood, or calculated a single likelihood without first considering the probability of entry and/or exposure. When the analysis was examined more closely however, it became clear that the author had assigned the same consequence to all identified diseases, and had subsequently ignored this when calculating the 'integrated risk estimate'. This observation is not intended as a criticism, since there are no templates for carrying out integrated risk estimation, and the draft

analysis report was evidently circulated for comments regarding this and other procedural issues. It was also noted that the author did not distinguish between direct and indirect consequences, and that a global consequence assessment score was inserted into the risk estimation algorithm.

The second analysis (Porcine semen AUS, 1999) reported a slightly confusing approach to risk evaluation. In this analysis, it was stated that "*the relationship between likelihood of entry, establishment and spread and the consequences is used in deciding whether specific risk management options are required*". This is a sensible statement, and consistent with the SPS Agreement, and yet the author then reports that "*for agents with potentially catastrophic consequences, importation would not be permitted if the risk of establishment, after application of any risk management measures deemed necessary, were higher than negligible*". That is, the author appears to carry out two separate risk evaluations, each involving the consequence assessment - firstly to determine whether risk management is necessary and secondly to determine whether the managed risk is acceptable. This is also consistent with the SPS Agreement. It was, however, unclear as to how the independently reported release and exposure assessments were combined to give the overall 'risk of exposure', or how risk management specifically effects each and therefore modifies this risk.

Risk estimation in Porcine semen AUS (1999) was illustrated in this analysis using a 'risk estimation matrix' (Table 13). This is simply a cross-tabulation of likelihood and consequence, such that the cells represent the 'expected loss' associated with a given disease agent. In the matrix used in this analysis, cells were labelled 'yes' and 'no', representing an 'acceptable' or 'unacceptable' level of risk, respectively. The risk estimation matrix provides a transparent and intuitive means by which 'rules' describing the combination of likelihood and consequence can be displayed. It remains difficult, however, to understand exactly how the author obtained the 'likelihood of establishment', or how this was modified by any ensuing risk management.

Table 13: Risk estimation matrix cited in an assessment of the risks associated with importation of porcine semen into Australia (Porcine semen AUS, 1999)

Probability of establishment	Negligible	Low	Moderate	High	Extreme
Extreme	*Yes*	*No*	*No*	*No*	*No*
High	*Yes*	*No*	*No*	*No*	*No*
Moderate	*Yes*	*Yes*	*No*	*No*	*No*
Low	*Yes*	*Yes*	*Yes*	*No*	*No*
Very low	*Yes*	*Yes*	*Yes*	*Yes*	*No*
Negligible	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*

Consequence of establishment

Legend

Yes = Risk considered to be acceptable
No = Risk considered to be unacceptable

Issues associated with the definition of acceptable risk will be discussed in the next evaluation. It can be seen, however, that there are neither official guidelines for deriving a risk estimate from estimates of likelihood and consequence, nor published analyses in which this has been carried out in a methodical and transparent manner. Given this, the semi-quantitative method of probability ranges described in Evaluation III Part I and Evaluation IV was examined to determine whether it might be successfully applied to risk estimation.

2.3 An alternative semi-quantitative approach to risk estimation

According to this novel semi-quantitative approach, risk estimation should be carried out in three steps:

- For each identified outbreak scenario, the likelihood that, A) disease agent will enter the importing country, B) exposure will occur by the relevant pathway, and, C) that exposure will lead to that outbreak scenario, should be determined
- For each identified outbreak scenario, the probability defined above should be combined with the estimate of the impact of consequence relevant to that scenario, to give a *partial*

risk estimate

- The partial risk estimate obtained for each outbreak scenario should be combined to give a measure of the overall (restricted or unrestricted) 'risk' associated with proposed importation

The components required for risk estimation are illustrated in the scenario tree in Figure 9. It can be seen that there are three successive levels or 'branches' which, in combination, lead to each identified outbreak scenario.

The first step in this approach to risk estimation is undertaken by following the branches in Figure 9 and combining the probabilities specified for each. The first of these is the probability of entry, as obtained during the release assessment (see Evaluation III Part I). According to this semi-quantitative approach, the probability of entry will have been expressed at the close of the release assessment as a qualitative score ('negligible', 'very low', 'low', 'moderate', 'high', 'extreme'). This probability should be rephrased for risk estimation as the precise quantitative probability obtained from the multiplication of component step-level estimates. For example, if 2.19×10^{-5} was the result obtained from the multiplication of the midpoints of step-level estimates, then this probability should be retrieved as the probability of entry.

The second branch represents the partial probability of exposure for the given exposure scenario. This partial probability, and those for other exposure pathways, will have been derived during the exposure assessment (see Evaluation III Part I). In the example of imported pig meat used to illustrate multiple exposure scenarios (Table 6), hypothetical partial probabilities of exposure were calculated for scenarios representing the exposure of feral pigs, domestic backyard pigs and intensively raised commercial pigs.

The final branch is the conditional probability that each identified outbreak scenario will occur. This will have been estimated and reported as a component of consequence assessment. In the example in Figure 9, the probability associated with each of the outbreak scenarios identified for a given exposure scenario, is written as $P(OB_1)$ and $P(OB_2)$(see Evaluation IV).

The three probabilities are combined by simple multiplication, and the result rephrased as a qualitative likelihood ('negligible', 'very low', 'low', 'moderate', 'high', 'extreme') using the nomenclature outlined in Table 4 (see Evaluation III Part I). This result expresses the partial probability of entry and establishment for a particular outbreak scenario, and is the probability

that should ultimately be combined with the consequences of that scenario to obtain a partial risk estimate. This final step in risk estimation is achieved using the risk estimation matrix in Table 14 below.

The 'rules' represented in this matrix are not derived through any formal manipulation of the two components but, rather, from a consideration of the expected loss that would most intuitively be associated with each combination of likelihood and consequence. Likewise, while cells have been shaded (yellow, green and red) so as to illustrate practical aspects of the application of this approach, boundaries are entirely arbitrary and have simply been assigned in a manner that is intuitively sensible.

In this matrix, cells shaded either green or yellow are associated with an 'acceptable' level of risk, while those shaded red are considered 'unacceptable' (the issue of acceptability will be pursued in following evaluation of approaches to risk management). Were this method adopted, the rules and/or designation of acceptable risk might be altered according to the user's requirements.

Table 14: Risk estimation matrix

Probability of entry and establishment	Consequence of entry and establishment				
	Negligible	Low	Moderate	High	Extreme
Extreme	Moderate	High	Extreme	Extreme	Extreme
High	Low	Moderate	High	Extreme	Extreme
Moderate	Negligible	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Low	Moderate	High
Very low	Negligible	Negligible	Negligible	Low	Moderate
Negligible	Negligible	Negligible	Negligible	Negligible	Low

Finally, having obtained partial risk estimates for each outbreak scenario, it will be necessary to combine these to give an estimate of the overall unrestricted risk of entry. Partial risk estimates are combined by applying the rules described below. These rules are mutually exclusive, and should be addressed in the order that they appear in the list. For example, if the first set of

conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered, and so forth until one applies.

1. Where the partial risk for any outbreak scenario is 'extreme', the overall risk is also considered 'extreme'
2. Where the partial risk for all outbreak scenarios is 'high', the overall risk is considered 'extreme'
3. Where the partial risk for any outbreak scenario is 'high' and the partial risk for each remaining outbreak scenario is 'moderate', the overall risk is considered 'extreme'
4. Where the partial risk for any outbreak scenario is 'high' and the partial risk for remaining outbreak scenarios is not unanimously 'moderate', the overall risk is considered 'high'
5. Where the partial risk for all outbreak scenarios is 'moderate', the overall risk is considered 'high'
6. Where the partial risk for one or more outbreak scenarios is 'moderate', the overall risk is considered 'moderate'
7. Where the partial risk for all outbreak scenarios is 'low', the overall risk is considered 'moderate'
8. Where the partial risk for one or more outbreak scenarios is considered 'low', the overall risk is considered 'low'
9. Where the partial risk for all outbreak scenario is 'negligible', the overall risk is considered 'negligible'

3 Conclusions

Risk estimation is an inherently complicated process, as it ties together estimates of the likelihood and consequences of a disease incursion resulting from trade in an animal or animal product. While the elements of risk estimation (likelihood and consequence) are described in the OIE Code, comprehensive technical guidelines are not provided. Likewise, risk estimation was not pursued methodically in any of the identified risk analyses.

Given the above, a semi-quantitative method was proposed which tied together similar semi-quantitative approaches outlined in the evaluations of likelihood evaluation and consequence assessment. This method provided a structured and transparent approach to risk estimation, and was considered to be compliant with the requirements for risk estimation outlined in the OIE

Code. While not stated previously, it is also evident that the method can be adapted to the situation where one or more components of likelihood or consequence have been evaluated quantitatively. This is likely to be a substantial advantage, since while a complete quantitative likelihood and consequence model will generally be impractical, it is not uncommon that one or more of these components will be suited to quantitative modelling.

EVALUATION VI

Risk management

Contents

1 Introduction

The OIE Code provides disease-specific guidelines for the importation of live animals or genetic material, and a series of standards for common practices such as semen collection and storage, embryo transfer or animal transport. In addition, the OIE Manual provides a reference of internationally recognised diagnostic techniques. These standard risk management practices may be applied to a proposed import without being justified using a scientific risk assessment. Risk management other than that specified in the OIE Code or OIE Manual must be based on a transparent assessment of the unrestricted risk, and must not be more trade restrictive than is necessary to satisfy the importing country's appropriate level of protection, the so-called ALOP.

2 Approaches to risk management

2.1 Risk management in the OIE Code

Risk management is defined in the current OIE Code as "*The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk*". From the definition of 'risk', it follows that risk management may thus involve either a reduction in the likelihood of direct or indirect consequences, or reduction in their magnitude. This is an interesting

perspective, since practical risk management is generally limited to efforts to reduce the release assessment. Exceptions include the post-entry management of zoo animals, or the management of biologicals in secure facilities, but these are unusual and outside of the general perspective on animals and animal products.

The OIE Code also describes the principles of risk management. These are essentially the principles described in the introductory comments (see above), and are orientated largely on the notion of a country's ALOP. Appropriate level of protection is described in the SPS Agreement as "*the level of protection deemed appropriate (as a sovereign right) by the Member establishing or reviewing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory*". A country's ALOP is thus a societal value judgement, and is not the sole responsibility of the regulatory authority. The role of the regulatory authority is to provide stakeholders with technical information and advice. The resulting ALOP will be based on this, and the stakeholders' trade-off between maximal protection and the need to comply with international trade regulations. According to the WTO principle of equivalence, previous or existing quarantine decisions are considered a suitable benchmark for determining a country's ALOP.

The OIE Code lists four components of risk management - risk evaluation, option evaluation, implementation and monitoring and review. Risk evaluation describes the process of comparing the unrestricted risk with the importing country's ALOP. That is, determining whether the unrestricted risk is considered to be acceptable. The difficulty with this central theme of risk assessment is that neither the ALOP nor the risk estimate itself is expressed in terms that are concrete, unambiguous or indeed directly comparable with either the current risk estimate or that obtained from other similar analyses. Indeed, the system appears to be based on a conceptual model in which all estimates are quantitative and all are measured and reported on the same scale. The application of this system in practical risk assessment will be discussed below. Suffice it to say that it is difficult to understand how a risk analysis, however technical or carefully undertaken, can act as the scientific basis for trade conditions when the pivotal process of interpreting risk and acceptability remains virtually hypothetical.

Option evaluation, the second OIE component of risk management describes the process of evaluating the efficacy and feasibility of various risk management alternatives. Evaluation of efficacy will be a more concrete task, since the degree of risk reduction can be determined by the same methods as used to determine the unrestricted risk. While not described in the OIE Code, a

related concept is that of 'efficiency'. Where a quantitative approach has been followed, decision analysis may be used to identify the most cost-effective means of risk reduction. As stated, risk reduction may be achieved by reducing either the likelihood of the direct or indirect consequences, or their magnitude. This flexibility should be borne in mind when selecting risk management alternatives, and measures other than those designed to reduce the release assessment should be considered.

The implementation and monitoring of risk management are critical procedures, but largely unrelated to this evaluation of risk analysis.

2.2 Risk management in the OIE Aquatic Code

Risk management is described in the OIE Aquatic Code as the application of 'risk reduction factors'. The description is not remarkable, except for the fact that the first risk reduction factor is considered to be the choice of exporting country. According to the WTO trade principles it is obviously unacceptable to rule out exporting countries without following the prescribed risk estimation/risk management path. The suggestion does apply to the situation in which the importers are free to source a commodity from a range of countries and as such can be viewed as a sensible code of practice rather than a risk management alternative.

2.3 Risk management in the sample import risk analyses

As shown in the preliminary evaluation of frameworks for import risk analysis, only 14 of the 55 sample analyses reported risk management as a separate procedure. Seven of these were relatively recent Australian or New Zealand analyses, carried out after the circulation of internal guidelines (AQIS, 1998a; Murray, 1998) in which the approach to risk management outlined in the OIE Code was recommended. Three of these analyses (Ratites NZ, 1997; Porcine semen AUS, 1999; Crocodiles AUS, 1999) cite ALOP as the criterion upon which the decision to apply risk management should be based. None of these three analyses, however, explicitly describe either their country's ALOP, or the means by which it is objectively compared with the integrated risk estimate. This illustrates the difficulty with this pivotal component of the import risk analysis procedure.

It was also noted that one of the analyses (Crocodiles AUS, 1999) documented the OIE's sequential components of risk management. Risk evaluation was undertaken, although not with

direct reference to Australia's ALOP, and a list of disease agents for which the unrestricted risk was considered to be unacceptable was compiled. Option evaluation subsequently identified the available risk management alternatives. Option evaluation did not, however, discuss the efficacy of each procedure, as suggested in the OIE Code, although it did encompass post-entry measures designed to reduce the exposure assessment. The analysis was a preliminary policy document and did not therefore describe the implementation or monitoring of specific import requirements.

2.4 An alternative approach to ALOP and risk management

It was shown in the discussions above that the principal difficulty in applying risk management in accordance with the OIE guidelines is that a country's ALOP will not generally be defined in concrete terms. However, if the SPS Agreement is examined more closely it is evident that the critical issue is that regardless of the level of import risk purported to be acceptable, countries should be consistent, such that particular commodities or exporting countries are not treated more restrictively. Indeed, it is specifically pointed out in an Annex to the SPS Agreement that a country may establish *any* level of protection, providing that this level is applied to all (animal- and plant-based) import proposals.

By adopting the highly structured and rule-based method proposed in preceding evaluations (see Evaluation III Part I and Evaluation IV), likelihood, consequence and risk itself would be assessed identically in all situations. Likewise, by adopting the same method for risk estimation, 'risk' would be interpreted according to the standardised level of protection shown in the risk estimation matrix in Table 14. It follows that were the same method adopted and utilised during risk management, then import risk would be treated consistently and the quandary of ALOP would largely be circumvented.

The risk estimation matrix contains a diagonal series of cells that have been shaded green. These cells represent an example of a standardised ALOP. Where a restricted risk falls below this line of cells (ie in one of the cells shaded yellow), then according to the SPS principles, the importing country may be considered too trade restrictive. Alternatively phrased, the importing country may be applying a level of protection that is greater than the level it has stated to be 'appropriate'. Of course it will not always be possible to determine precisely the effect of a risk management procedure on the risk estimate. Likewise, the exporting country might consider a risk management procedure that provides a level of protection considered overly restrictive to be more practical, or efficient, than one that meets exactly the ALOP. These are operational issues that

should be discussed during the drafting of import requirements.

Given the above, it can be seen that the system does not require ALOP to be defined in concrete terms, but does allow countries to demonstrate a consistent risk attitude when considering proposals for the importation of animals or animal products. Definitions and rules used throughout the system, including the positioning of the band of cells designating ALOP, could be modified at the discretion of the importing country. Once established, however, definitions and rules should be maintained both within and between analyses.

While it will not be discussed in this thesis, it can also be shown that the system can be applied in an identical fashion to import proposals for plants and plant products. Here the SPS Agreement holds equally, although guidelines for import risk analysis are compiled by the IPPC rather than the OIE. This result is particularly appealing since it would allow countries to improve consistency both within and between animal and plant based analyses.

3 Conclusions

It is evident that risk management is a critical component of risk analysis. It is also evident that risk management should be applied in a manner that demonstrates a risk attitude that is consistent, both within and between analyses. This system hinges on a country's determination of an acceptable level of protection, or ALOP. While the OIE Code provides guidelines for a systematic approach to risk evaluation and option evaluation, it does not indicate how ALOP should be defined. The most intuitive approach is to perform a retrospective study of quarantine decisions, so as to determine the level of risk that has historically been considered acceptable. The difficulty in this process is that likelihood, consequence and 'risk' itself will have been estimated and expressed using a range of metrics, and that most existing qualitative assessments will not be sufficiently transparent to provide a clear impression of ALOP.

The alternative to this approach is to institute a system that will ensure that a consistent ALOP is used in quarantine decision making, but which does not require the importing country to determine and state its level of protection in concrete terms. This system would enable the importing country to meet its international obligations in a practical and transparent manner. The semi-quantitative system for likelihood evaluation, consequence assessment and risk estimation described in previous evaluations provides a means by which risk can be estimated consistently, and risk management applied in accordance with the OIE Code. The system allows for

procedures to be shown to be overly restrictive, and thus supports the notion that ALOP is a specific level, rather than simply a delimitor between what is acceptable and what is unacceptable.

EVALUATION VII

Risk communication

Contents

1 Introduction

Risk communication refers to two discrete groups of issues. The first concerns the range of protocols or systems adopted by individual analysts or regulatory authorities in order to effectively communicate the methods or results of analyses to interested parties. Protocols for risk communication may be national policies, as is the case, for example, for the Australian Quarantine and Inspection Service (AQIS)(AQIS, 1998b). Alternatively, protocols may represent the individual strategies and sentiments of the principal analyst(s), as has tended to be the practice, for example, of New Zealand's Ministry of Agriculture and Forestry (MAF). There are no consistent advantages or constraints to either approach. There is, however, a considerable volume of research dealing with the sociological and psychological aspects of risk communication, or dictating industrial or agency-level policies for risk communication (Ibrekk and Morgan, 1983; Auld, 1990a; Auld, 1990b; Fisher, 1991; Rowan, 1991; Broughton, 1991; Fisher et al., 1994; Rowan, 1994). These issues are beyond the scope of the thesis, although it is recognised that analysts or agencies should consider the relevant principles before instituting blanket systems or protocols that determine their approach to risk communication.

The second and more technical aspect of risk communication concerns the available methods by

which risk analysis methods and results can be presented to stakeholders or decision-makers. In the light of the WTO requirement for transparency, these issues are a particularly important consideration.

2 Approaches to risk communication

2.1 Risk communication in the OIE Code

The OIE Code describes six principles of risk communication. The first four concern the principles behind effective communication with stakeholders and decision-makers and, as stated above, will not be discussed further in this document. The fifth principle describes a need to communicate the assumptions and uncertainty in a risk analysis model, as well as the model inputs and risk estimates. Although these points appear to be focussed on quantitative analyses, they do convey the need to present analysis methods and results in a transparent manner. Approaches that have been adopted for communicating technical components of risk analyses will be discussed below. The final principle stresses the requirement for peer review as a routine step in the risk analysis process.

2.2 Risk communication in the sample import risk analyses

Four methods were commonly adopted for the presentation of technical issues.

- Written discussion
- Tabulated reports
- Path diagrams
- Distribution plots

The distribution of analyses in which each method was adopted is shown in Table 15.

Table 15: Methods for presenting technical components of risk analyses

Analysis	*Written discussion*	*Tabulated reports*	*Path diagrams*	*Distribution plots*[1]
Qualitative analyses				
1988 Anseriforms NZ	1	0	0	-
1990 Exotic AUS	1	0	0	-
1991 Meats NZ	1	0	0	-
1991 Hides NZ	1	0	0	-
1993 Milk AUS	1	1	0	-
1993 Salmon1 AUS¥	1	0	0	-
1994 Salmon1 NZ¥	1	1	0	-
1995 Aquatic1 AUS ¥	1	0	0	-
1995 Aquatic2 AUS ¥	1	0	0	-
1995 Exotic EU	1	0	0	-
1995 Exotic IRE	1	0	0	-
1995 PRRS1 NZ	1	0	0	-
1996 Baitfish NZ ¥	1	0	0	-
1996 Salmon2 AUS ¥	1	1	0	-
1997 Bees USA	1	0	0	-
1997 Fish products NZ ¥	1	0	0	-
1997 Goat embryos CAN	1	1	0	-
1997 Lobster AUS ¥	1	0	0	-
1997 Ostrich SA	1	0	0	-
1997 Passerines NZ	1	0	0	-
1997 Pork CAN	1	0	0	-
1997 Ratites NZ	1	1	0	-
1997 Salmon2 NZ ¥	1	0	0	-
1997 Sheep and goat meat NZ	1	0	0	-
1997 Sheep/goats ME	1	0	0	-
1997 Shrimp USA ¥	1	0	0	-
1997 Wildlife SA	1	0	0	-
1998 Equines/semen NZ	1	0	0	-
1998 Fibre NZ	1	1	0	-
1998 Psittacines NZ	1	0	0	-
1999 Chicken NZ	1	0	0	-

Analysis	*Written discussion*	*Tabulated reports*	*Path diagrams*	*Distribution plots*[1]
1999 Crocodiles AUS	1	1	0	-
1999 Porcine semen AUS	1	1	0	-
1999 Scrapie AUS	1	0	0	-
Totals (n=34)	***n=34***	***n=8***	***n=0***	***n=0***
Quantitative analyses				
1992 Cassava AUS	1	0	0	0
1993 Garbage USA	1	0	1	1
1993 Pigs CAN	1	1	1	1
1994 Bluetongue CAN	1	0	0	0
1994 Piroplasm USA	1	1	0	0
1994 Salmon1 NZ ¥	1	1	0	1
1995 Bov Embryos BR	1	1	0	1
1995 Meat BR	1	1	0	1
1996 BSE NZ	1	1	0	0
1996 Camelids CAN	1	0	1	1
1996 Chicken AUS	1	1	0	0
1996 Hides BR	1	1	1	1
1996 Rabies USA	1	1	0	0
1996 Scrapie NZ	1	1	0	0
1997 CSF NL	1	0	0	0
1997 IBD NZ	1	0	0	0
1997 Rabies NZ	1	0	0	0
1997 Salmon2 NZ ¥	1	1	0	1
1997 Swill USA	1	1	0	1
1998 Anthrax NZ	1	0	0	0
1998 PRRS2 NZ	1	1	1	1
Totals (n=21)	**n=21**	**n=13**	**n=5**	**n=10**
Overall totals (n=55)	**n=55**	**n=21**	**n=5**	**n=10**

Legend

¥ Import risk analyses for aquatic animals or animal products (13 of 55 sample analyses)

[1] Distribution plots = only applicable to quantitative likelihood evaluation

Written discussion and tabulated reports are self evident as methods of presentation and do not require further discussion. Path diagrams and distribution plots will be examined more closely.

2.2.1 Path diagrams

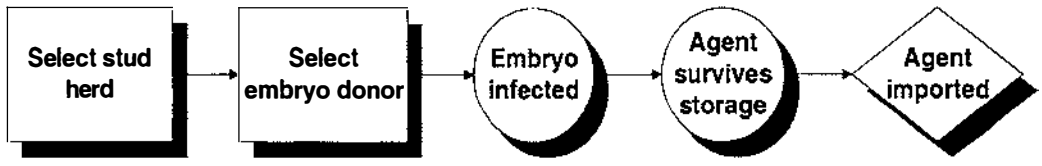
This method of presentation encompassed influence diagrams, event trees, scenario pathway diagrams, decision trees and various other permutations of the path diagram principle. This group of graphical tools generally served two purposes:

- To provide pictorial means by which the structure of an importation and/or exposure pathway can be communicated
- To assist in, or simply illustrate, the derivation of a qualitative, semi-quantitative or quantitative final result

Influence diagrams

These are the simplest of the path diagrams. According to the discipline of decision theory, influence diagrams should consist of 'nodes', joined by arrows that illustrate the flow of events through a model. Nodes may represent decisions (square by convention), probabilities (circular) or an outcome (diamond shaped) and, thus, may be used to describe a logical sequential process such as an importation or exposure pathway (Figure 10). A single analysis was identified in which an influence diagram was provided (PRRS2 NZ, 1998). Here the authors used the diagram to illustrate the sequence of stages in the importation of pig semen. Nodes of varying shapes display either risk management decisions, probabilities or outcomes.

Figure 10: Sample influence diagram - abbreviated stages in the importation of embryos



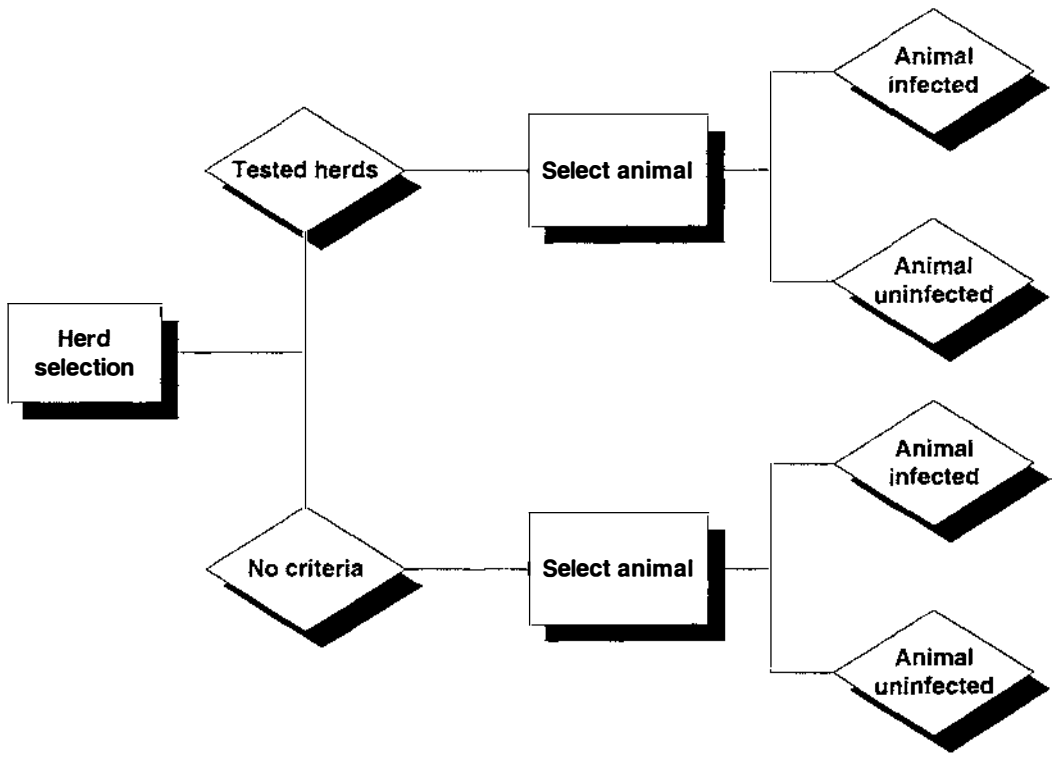
The advantage of influence diagrams is their inherent simplicity - that is, the ability to convey structural information regarding the essential stages in a model template without complicating

this with issues stemming from complex stages. The limitation of influence diagrams is that essential information will inevitably be hidden from the reader if the stages depicted by individual nodes contain complex decision-based procedures. This will be pertinent where an analyst seeks to document a range of alternative strategies that might be applied at given stages of an importation scenario so as to determine the most appropriate or efficient importation protocol. Here an influence diagram can display, for example, a quarantine node, but cannot illustrate the range of alternative procedures that might be undertaken during quarantine. This was in fact the case for the single cited example of an influence diagram (PRRS2 NZ, 1998), in which the authors simultaneously examined many alternative quarantine procedures, and other risk management strategies. In this example, a single influence diagram was used to describe the sequence of stages, and various other forms of display adopted to communicate specific stage-specific risk management options.

Decision trees

Decision trees (Figure 11) also arise directly from decision theory and are therefore based upon the same schematic nodal system as described above. Give this, the principal difference between influence diagrams and decision trees is that decision nodes are expanded so as to produce a separate branch for each alternative action, probabilistic event and outcome. It can be seen that where a number of stages have been included in a single pathway, the resulting tree may become extremely complex. In an analysis of various alternative protocols for importing porcine semen, Beckett and Morris (PRRS2 NZ, 1998) obtained 135 separate risk estimates from a relatively simple six stage release assessment. This was in fact the only identified example of a decision tree, which may suggest that this approach is best suited to the relatively unusual situation in which a large number of alternative importation protocols are being investigated concurrently.

Figure 11: Simplified decision tree for an animal selection procedure



While the decision tree may be used in a simplistic manner as a means by which to illustrate branching alternatives and outcomes, it arose within the field of economics and was originally designed as a pictorial or graphical aid to the calculation of conditional expected monetary values (EMV) (Anon, 1997). In order to achieve this, 'Bayesian Revision' is applied at each level of the tree and the latter 'folded back' to produce posterior probabilities for the final branch-level outcomes. Where even a moderate number of stages are involved, however, the procedure is potentially complex and generally performed with the assistance of software designed for specifically for decision analysis, for example DPL® (Applied Decision Analysis, Price-Waterhouse-Coopers, USA) or DATA® (Tree-Age Software, Williamstown, MA, USA). While this is attainable in an academic context, the technical difficulties inherent in both conducting and interpreting complex decision analyses have meant that the procedure has never, to my knowledge, been applied in a quantitative sense within the field of import risk analysis.

Scenario trees

In a seminal important review of techniques for quantitative import risk analysis (APHRAN, 1996), Morley points out that scenario trees are essentially equivalent to the event trees defined

by Rasmussen (1981) and McCormick (1981). Indeed, it was difficult to determine concrete differences between event trees identified as such in the literature (Vose, 1997b), and those described as scenario trees (Miller et al., 1993; Garbage USA, 1993; Pigs CAN, 1993; APHRAN, 1996; Camelids CAN, 1996; Hides BR, 1996; PRRS2 NZ, 1998). Scenario or event trees, as shown in Figure 12, are an alternative means by which the physical or conceptual flow of events within a model may be described simultaneously with their respective probabilities and outcomes.

Scenario trees begin with an 'initiating failure event' (such as the selection of a diseased herd). From this point, the probability that an animal or commodity destined for importation remains infected (that is, remains in the 'initial state') is mapped by a series of 'branch points', probabilities and 'end states'. Accordingly, a 'scenario' as such is simply one complete branch of the tree, starting with the initiating failure event and finishing at a designated end state.

Figure 12: Simplified scenario tree depicting events in the importation of a live animal

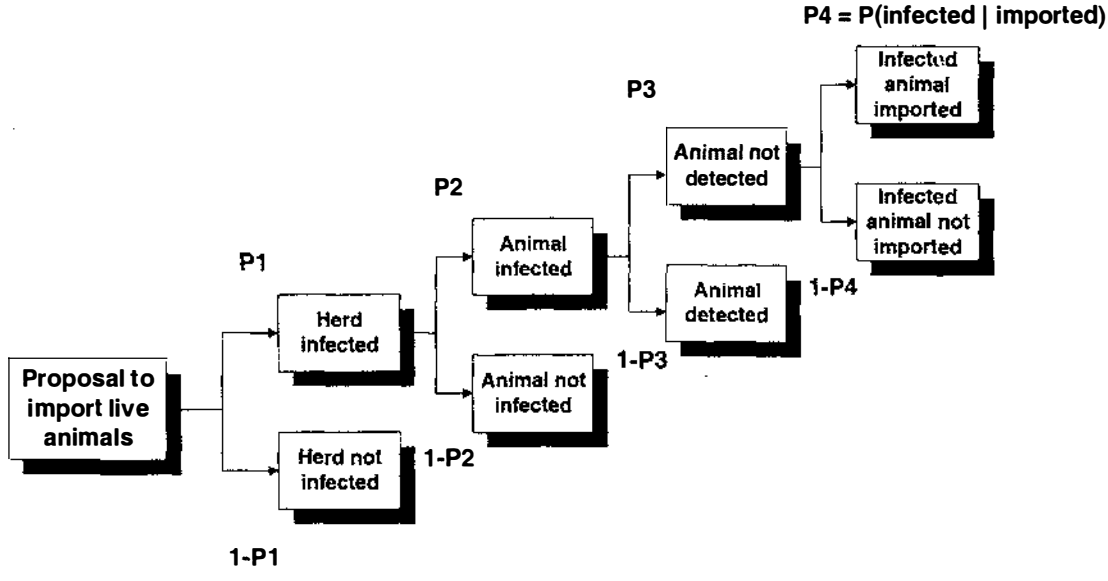


Figure 12 shows that for most scenario trees used in import risk analysis, a branch point will either lead directly to an end point, or will represent the continuation of an undetected but infected commodity unit or animal within the importation scenario. The focus of a scenario tree is thus to describe the movement of infection through an importation procedure, and not to determine the likelihood that commodity at any point is in fact infected. Aside from differences in general construction and conventions, this would appear to be the principal difference between

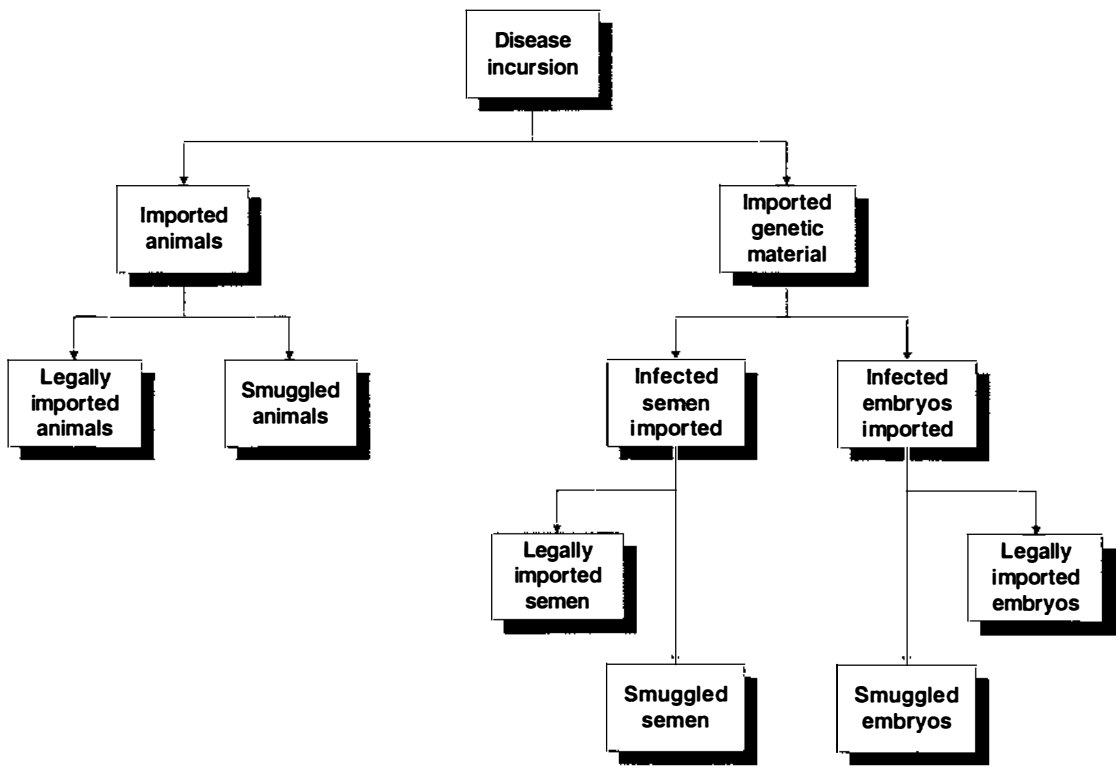
scenario trees and decision trees. Indeed, each branch in a scenario tree describes the probability that the scenario will continue in that particular direction. In the context of import risk analysis, this is generally expressed as the probability that the animal or commodity will remain infected and undetected. The final result is thus the ability to follow a route from the initiating failure event to a particular outcome (generally importation or successful exposure). By linear multiplication of component branch point probabilities, it will also be possible to determine, for example, the probability that infected commodity will be imported.

This is a fundamentally different approach from that undertaken in constructing and calculating traditional decision trees, where posterior probabilities are calculated by folding back the tree, and where end point probabilities represent the cumulative result for a given branch of the tree. Moreover, the conditional form resulting from a decision tree will be the reverse of that obtained by linear multiplication of events described in a scenario tree. That is, where the latter was shown to yield the probability that infected animals or commodity will be imported, the former in fact describes the probability that imported animals or commodity will be infected.

Fault trees

Fault trees (Figure 13) are in effect scenario or event trees drawn in reverse (APHRAN, 1996). That is, fault trees start with the outcome - for example, a disease incursion - and work back through each of the possible scenarios that might have led to that outcome. Fault trees have been applied in import risk analysis (APHRAN, 1996) although they appear to be better suited to situations in which an analyst wishes to qualitatively explore possible pathways for disease entry or exposure. That is, fault trees would seem to be well suited to preparatory studies or investigations of the possible 'background risk' to an animal population, but less so to import risk analyses per se, in which a particular importation scenario is to be examined.

Figure 13: Simplified fault tree depicting events leading to the incursion of an hypothetical disease

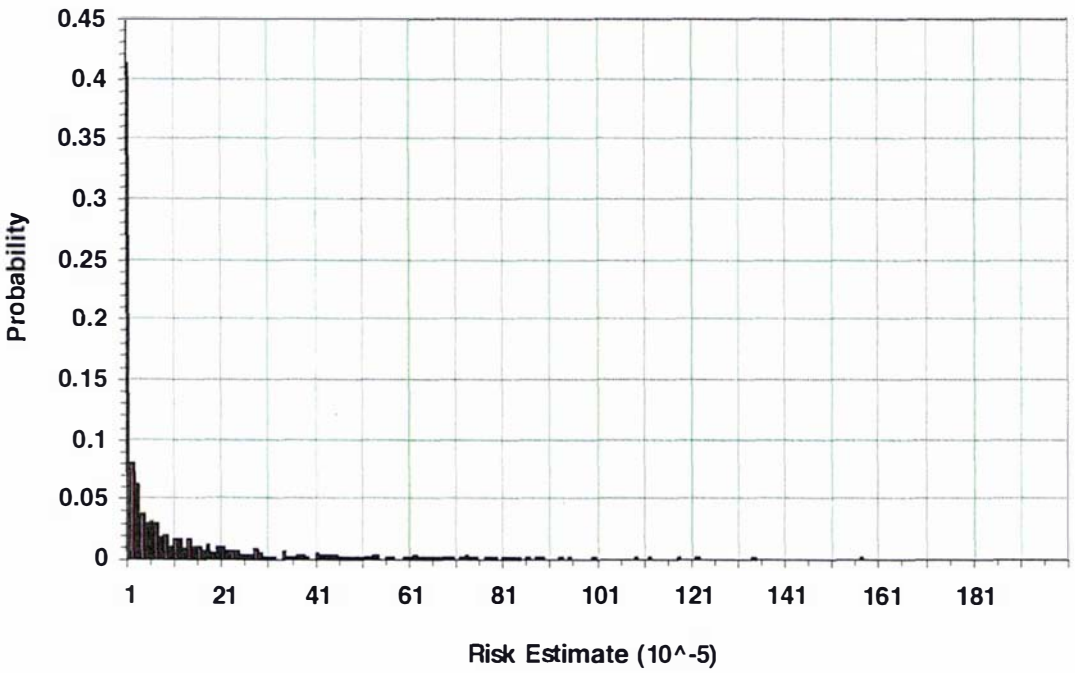


2.2.2 Distribution plots

Histograms

Histograms (Figure 14) are obtained by categorising the output, which is generally a probability and thus limited between the values zero and one, and determining the proportion of the total number of iterations that fall into each category. The number of categories chosen will depend upon the number of iterations in the simulation. A large number of categories for a small set of results will result in very few values in each category and information that is difficult to interpret with any confidence. The reverse will lead to the compression of information and, ultimately an inability to make inferences regarding the true distribution of results. A useful rule is to divide the number of iterations by 10 and to use this value as the number of categories. For example, if 2000 iterations were used and results ranged from zero to one, then 200 categories would be derived, each of width ten units. This rule is obviously a guide only and may be modified such that the observed range is divided by a number that will not result in a fraction.

Figure 14: Sample histogram



Cumulative probability plots

Cumulative probability plots (Figure 15) illustrate the percentage of observed values lower than each given point in the range of observed values. Cumulative probability plots may thus be based either on the categories defined for the histogram, or on the original values, where the latter have simply been ranked and plotted against the cumulative probability that each observed value will be less than or equal to itself.

Figure 15: Sample cumulative probability plot

3 Conclusions

These discussions illustrate the advantages and constraints of the various forms of path diagrams and distribution plots. The adoption of one or more of these techniques to display technical aspects of the methods and/or results of an analysis will depend upon whether the assessment is qualitative or quantitative and on the experience and personal preference of each analysts. The only criterion for the selection and application of risk communication strategies is that the methods chosen enhance the transparency of the analysis, and therefore enable it to be thoroughly and objectively critiqued.

ANNEX TO Chapter 2

Demonstrations and Experiments

Contents

1 Experiment 1: Conditional forms for the release assessment

1.1 Research questions

The objective of this experiment was to determine the extent to which the two common conditional forms for the release assessment (see, Evaluation III Part II: Section 2.2.2) differ and to investigate the factors that maximise or minimise differences. While much of this information could be gained from a careful dissection of the algebraic derivation of either form, it was considered beneficial to construct a spreadsheet in which inputs may be systematically varied and the formulae made clearly visible, and to utilise this as the basis for discussion. To reiterate, the two conditional forms examined in the experiment include:

- The probability that commodity will be infected, given that it has been imported, or P(infected | imported)
- The probability that commodity will be imported, given that it is infected, or P(imported | infected)

Factors likely to alter these two forms disproportionately included:

- The prior prevalence of infection in the population
- The sensitivity and specificity of any diagnostic 'tests' - that is, any intervening procedures that may lead to the rejection of commodity on the basis of infection status

The means by which these were incorporated into a sample model template is described below.

1.2 Methods

A spreadsheet model was considered the most flexible and transparent means by which variation in inputs, and the structural formulae or calculations within a sample importation pathway might be investigated. The scenario chosen for the exercise was an hypothetical importation of live animals and, in particular, the pre-exportation events which when combined constituted the release assessment. The pathway, although deliberately simplistic, represented a reasonably typical live animals importation scenario, and contained both *simple stages* and *interventions*.

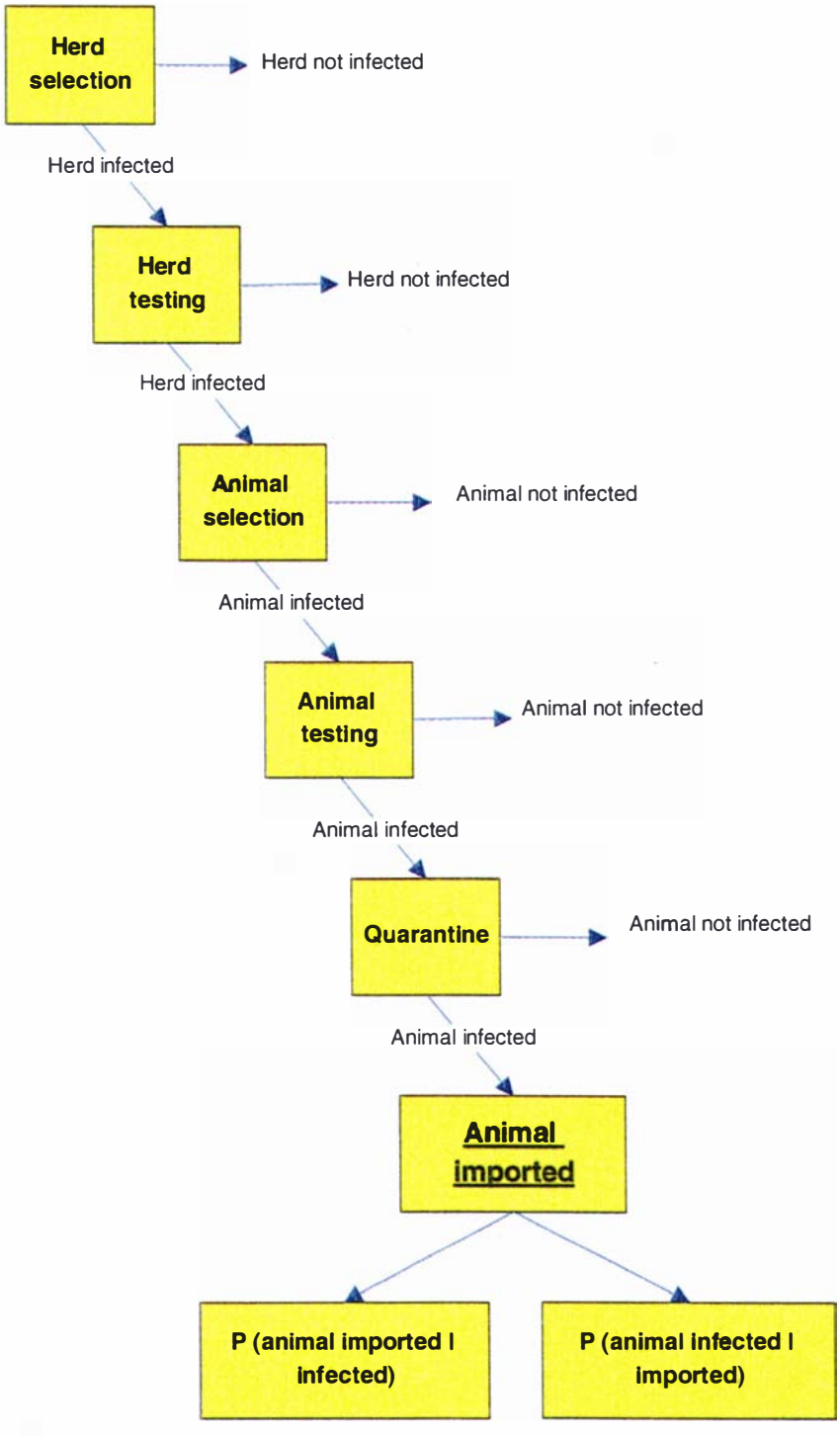
Interventions are events such as tests, quarantine protocols or quality assurance procedures that may lead to animals or animal-derived commodity being purposively rejected from the importation. Simple events, by comparison, are phenomena that may alter the likelihood that an animal or commodity unit is infected, but over which the analyst or observer has neither control nor a means by which to determine the outcome of the event. Common examples of simple events include the probability that disease agent will survive storage or the probability that infectious disease agent will be shed in the semen of an infected donor.

The five stages described in the hypothetical model included:

- Herd selection
- Herd testing
- Animal selection
- Animal testing
- Quarantine

These are shown in the event tree in Figure 16.

Figure 16: Simplified event tree for the importation of live animals



The spreadsheet model was based upon two groups of variables - that is, 'primary' variables that required direct data for enumeration, and 'secondary' or calculated variables that were obtained

from the latter through algebraic manipulations.

The following primary variables were included in the model:

- Herd prevalence (HP)
- Within herd prevalence (IP)
- Herd test sensitivity (Herd Se)
- Herd test specificity (Herd Sp)
- Individual test sensitivity (Ind Se)
- Individual test specificity (Ind Sp)
- Quarantine sensitivity (Quar Se)
- Quarantine specificity (Quar Sp)

Herd prevalence described the proportion of infected herds in the (arbitrary) exporting country, while within herd prevalence represented the expected proportion of diseased animals. The product of these two measures provided an estimate of the 'prior probability' of selecting an infected animal (Armitage andBerry, 1994). Each of the sensitivities (Se) and specificities (Sp) are self-evident, providing the usual estimates for the ability of 'test' procedures to correctly identify diseased and non-diseased animals or herds. Many analysts (Marchevsky et al., 1989; Finkel, 1990; Martin et al., 1992; PRRS2 NZ, 1998) utilise the binomial probability mass function and basic probability theory to derive a measure for 'herd test sensitivity'. For the sake of brevity and simplicity, this issue has been abbreviated with a single value.

Given the above, it follows that differences between the two calculated conditional forms for the release assessment must arise from particular values or combinations of values given to the primary variables. This relationship may be investigated by systematically varying these variables so as to create a multivariate matrix of results. Primary variables were assigned the following values:

Prevalence (herd and individual)

low = 0.10

moderate = 0.50

high = 0.90

Test characteristics (sensitivity, specificity)

low = 0.60

high = 0.95

The range of values assigned to between- and within-herd prevalence was considered sufficiently broad to detect the role that this variable may play in determining the extent of differences between conditional forms. Likewise, typical low and high values were assigned to both sensitivity and specificity. In order to remove the ability of the three 'tests', or interventions, to lead to the rejection of animals from the importation protocol, sensitivity was also modelled as zero and specificity as one.

The two conditional forms for the release assessment were calculated as follows:

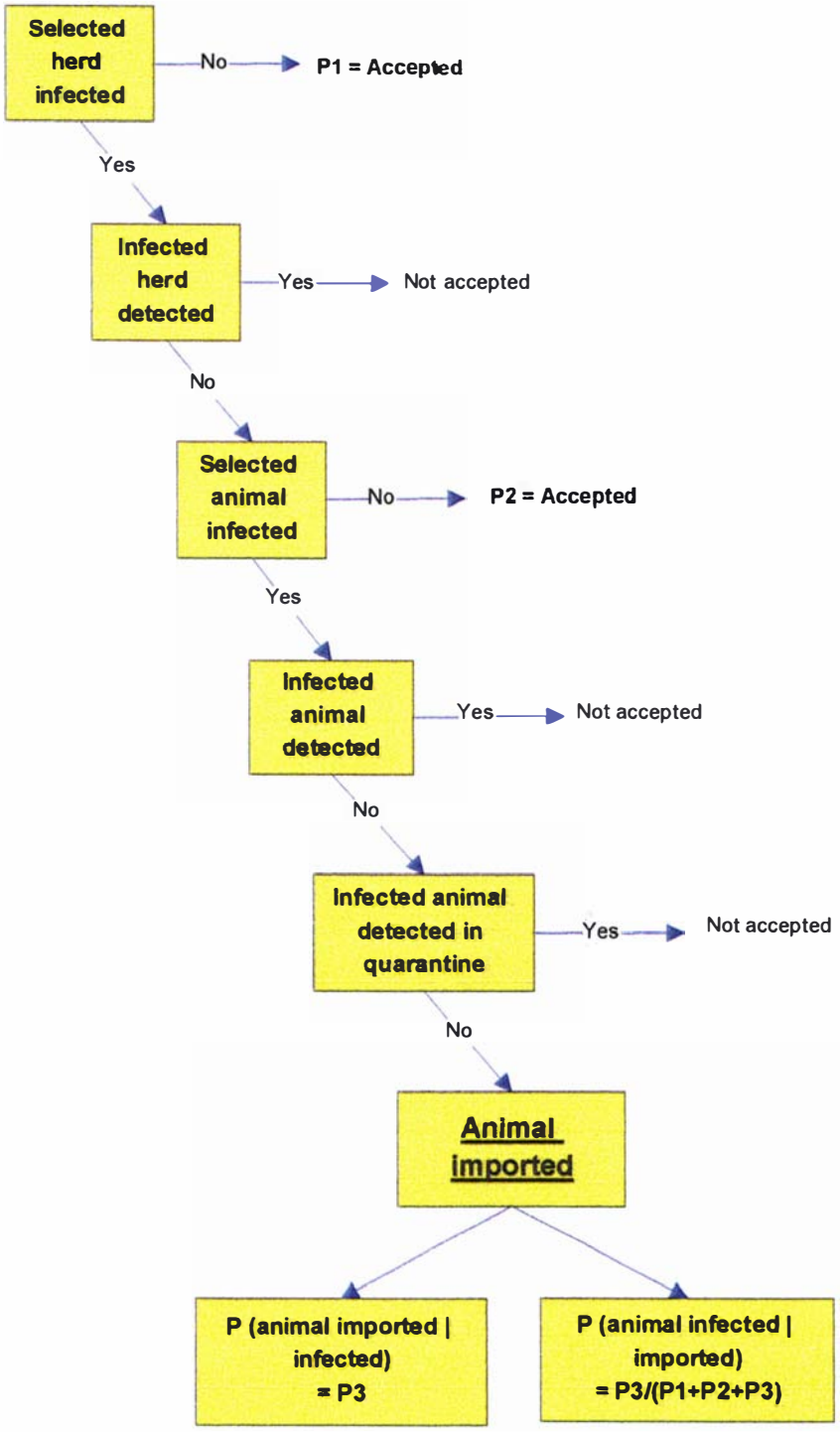
P(imported | infected): This conditional form of the release assessment is calculated by multiplying together the likelihoods derived for each component stage. Component likelihoods should, in turn, be expressed as the probability that infection will not be detected at a given stage (the complement of stage-level sensitivity) or the probability that infection will persist after a given stage. Since the calculation is the product of a series of components, it could, theoretically, be performed in any order. However, permutations of the binomial mass function are often utilised to determine the sensitivity of group tests, and since these will generally be based upon prevalence or the probability of disease at a given stage, it follows that calculations must be performed in the order dictated by the importation pathway.

P(infected | imported): Calculation of the P(infected | imported) is one of the more complex issues encountered in quantitative likelihood evaluation. After a search of sample analyses and technical documents, it appeared that two methods are available.

In the first case (Vose, 1997b) the P(imported | infected) - as described above - is modified by dividing it by the sum of the probabilities attached to all alternative pathways by which the animal or commodity may have been 'accepted' or imported. For example, if a stage dictated the survival of an organism with storage of the commodity, then attached to this stage would be the probability that the organism was killed, the commodity uninfected and, thus, accepted or imported. It follows that this method is a simplification of reality, since it assumes that the specificity of test procedures or other interventions is one. While this is never the case, the simplification does provide a conservative estimate for the P(infected | imported) and is thus unlikely to jeopardise the security of an import decision.

This method is illustrated in the event tree in Figure 17.

Figure 17: Calculation of the P(infected | imported) as described by Vose (1997b)



The second method (PRRS2 NZ, 1998) is based on the clear distinction between two distinct types of stages:

- Interventions
- Simple events

This method follows a fundamentally different approach from that described by Vose (1997b) in that the P(infected | imported) is calculated 'cumulatively' with each stage of the model. This is achieved by considering that interventions, by virtue of the fact that they modify prior knowledge of infection status, give rise to posterior probabilities (Armitage andBerry, 1994). One of these is 'the probability that an animal or commodity unit is infected, given that it is tested negative or designated as uninfected by some other means'. In epidemiological terms, this is the complement of the negative predictive value (NPV) of that intervention, or (1-NPV) (Martin et al, 1987). Unlike sensitivity and specificity, predictive values are heavily dependent upon the prior probability of disease (or prevalence) and, thus, their calculation in the order specified by the model template is paramount.

Given this, the P(infected | imported) is determined by moving through the model template and, where a stage is determined to be an intervention, calculating the complement of the negative predictive value. Alternatively, where a stage is a classified as 'simple', the probability derived from the previous stage is multiplied by the form of this probability that signifies the likelihood that the animal or commodity will remain infected after the said simple event. Simple events continue to be multiplied together until the next intervention occurs, whereupon the result is converted again into the posterior (1-NPV), etc. The final value from the algorithm - the P(infected | imported) - will be the final probability attained from this cumulative process.

It can be seen that this approach does not depend on the calculation and subsequent modification of the P(imported | infected). In addition, the approach does not depend on the assumption that the specificity of each intervention is 1, since specificity may be incorporated into the calculation of (1-NPV) without difficulty or added complexity. Indeed, while the second method may involve more calculation, it is based on logic which, in my opinion, simplifies the extremely un-intuitive issue of posterior probabilities, negates the need for event trees except as aids to description, and minimises the potential for confusion.

These advantages led me to conclude that the second method was more appropriate, particularly given that one of the central criteria for this group of exercises is the derivation of methodologies that might be applicable to an automated expert system. Accepting this, the calculation of the P(infected | imported) as it applies to the simple template for importing live animals is shown in the spreadsheet in Table 16 below.

Table 16: Calculation of the P(infected | imported) (adapted from Beckett and Morris, 1998)

Stage	Definition	Derivation	Sample values
Herd selection	Herd prevalence (HP)	P(Herd D+)	0.10
	1-HP	P(Herd D-)	0.90
Herd testing	Herd test Se (HSe)	P(T+|Herd D+)	0.85
	1-HSe	P(T-|Herd D+)	0.15
	Herd test Sp (HSp)	P(T-|Herd D-)	0.90
	1-HSp	P(T+|Herd D-)	0.10
	1-Herd NPV = P(Herd D+|T-)	P(T-|Herd D+)*P(Herd D+) / {P(T-|Herd D+)*P(Herd D+) + P(T-|Herd D-)*P(Herd D-)}	0.02
	Herd NPV = P(Herd D-|T-)	P(T-|Herd D-)*P(Herd D-) / {P(T-|Herd D-)*P(Herd D-) + P(T-|Herd D+)*P(Herd D+)}	0.98
Animal selection	Probability select an infected animal	P(w/i D+)*P(Herd D+|T-) = P(Ind D+)	0.00
	Within herd prevalence (w/i Herd P)	P(w/i D+)	0.15
	Probability don't select an infected animal	P(Ind D-)	1.00
	1-w/i Herd P	P(w/i D-)	0.85
Animal testing	Test Se (Se)	P(T+|Ind D+)	0.95
	1- Se	P(T-|Ind D+)	0.05
	Test Sp (Sp)	P(T-|Ind D-)	0.90
	1-Sp	P(T+|Ind D-)	0.10
	1-Ind NPV = P(Ind D+|T-)	P(T-|Ind D+)*P(Ind D+) / {P(T-|Ind D+)*P(Ind D+) + P(T-|Ind D-)*P(Ind D-)}	0.00
	Ind NPV = P(Ind D-|T-)	P(T-|Ind D-)*P(Ind D-) / {P(T-|Ind D-)*P(Ind D-) + P(T-|Ind D+)*P(Ind D+)}	1.00
Quarantine	Probability tested animal infected (P)	D+ = P6.1	0.00
	1-P	D- = P6.2	1.00
	Quarantine Se (QSe)	P(Quar+|D+)	0.95
	1-QSe	P(Quar-|D+)	0.05
	Quarantine Sp (QSp)	P(Quar-|D-)	0.90
	1-QSp	P(Quar+|D-)	0.10
	1-Quar NPV = P(D+|Quar-)	P(Quar-|D+)*P(D+) / {P(Quar-|D+)*P(D+) + P(Quar-|D-)*P(D-)}	0.00
	Quar NPV = P(D-|Quar-)	P(Quar-|D-)*P(D-) / {P(Quar-|D-)*P(D-) + P(Quar-|D+)*P(D+)}	1.00
PAE calculations	P(imported | infected)	HP*(1-Herd Se)*IP*(1-Ind Se)*(1-Quar Se)	5.63E-06
	P(infected | imported)	Final model probability = (1-Quar NPV)	8.44E-06

1.3 Results

Systematic variation of between- and within-herd prevalence led to the results shown in Table 17. The most fundamental observation to be drawn from this table was the fact that the second conditional form - that is P(infected | imported) - always provided a higher or more conservative estimate for the release assessment. In addition to this it was noted that, for any given combination of sensitivity and prevalence, the P(imported | infected) did not alter with changing specificity. Conversely, under stable conditions of prevalence and sensitivity, increasing specificity tended to lower the P(infected | imported), while the relative difference between these measures appeared to be most evident when specificity was low, regardless of sensitivity or prevalence. Finally, Table 17 showed that when specificity is fixed at 1, as is often the assumption in import risk assessments, the principal effect of decreasing the prior prevalence of

infection and increasing the overall sensitivity of diagnostic procedures, is to decrease both forms of the release assessment.

Table 17: Systematic results from the 'importation of live animals' sample model template for each conditional form of the release assessment

Prior prob.		Test characteristics																	
		Se 0	Sp L	Se 0	Sp H	Se 0	Sp 1*	Se L	Sp L	Se L	Sp H	Se L	Sp 1*	Se H	Sp L	Se H	Sp H	Se H	Sp 1*
Herd P	L	1.00×10^{-2}	1.00×10^{-2}	1.00×10^{-2}	6.40×10^{-4}	6.40×10^{-4}	6.40×10^{-4}	1.25×10^{-6}	1.25×10^{-6}	1.25×10^{-6}									
Ind P	L	4.22×10^{-2}	1.16×10^{-2}	1.00×10^{-2}	3.08×10^{-3}	7.50×10^{-4}	7.38×10^{-4}	6.38×10^{-6}	1.61×10^{-6}	1.38×10^{-6}									
Herd P	L	5.00×10^{-2}	5.00×10^{-2}	5.00×10^{-2}	3.20×10^{-3}	3.20×10^{-3}	3.20×10^{-3}	6.25×10^{-6}	6.25×10^{-6}	6.25×10^{-6}									
Ind P	M	1.91×10^{-1}	5.77×10^{-2}	5.00×10^{-2}	1.56×10^{-2}	4.04×10^{-3}	4.47×10^{-3}	3.20×10^{-5}	8.08×10^{-6}	6.93×10^{-6}									
Herd P	L	9.00×10^{-2}	9.00×10^{-2}	9.00×10^{-2}	5.26×10^{-3}	5.26×10^{-3}	5.26×10^{-3}	1.13×10^{-5}	1.13×10^{-5}	1.13×10^{-5}									
Ind P	H	3.13×10^{-1}	1.03×10^{-1}	9.00×10^{-2}	2.86×10^{-2}	7.83×10^{-3}	6.33×10^{-3}	5.78×10^{-5}	1.46×10^{-5}	1.25×10^{-5}									
Herd P	M	5.00×10^{-2}	5.00×10^{-2}	5.00×10^{-2}	3.20×10^{-3}	3.20×10^{-3}	3.20×10^{-3}	6.25×10^{-6}	6.25×10^{-6}	6.25×10^{-6}									
Ind P	L	1.56×10^{-1}	5.65×10^{-2}	5.00×10^{-2}	1.82×10^{-2}	5.38×10^{-3}	4.68×10^{-3}	5.38×10^{-5}	1.39×10^{-5}	1.20×10^{-5}									
Herd P	M	2.50×10^{-1}	2.50×10^{-1}	2.50×10^{-1}	1.60×10^{-2}	1.60×10^{-2}	1.60×10^{-2}	3.13×10^{-5}	3.13×10^{-5}	3.13×10^{-5}									
Ind P	M	5.58×10^{-1}	2.76×10^{-1}	2.50×10^{-1}	1.00×10^{-1}	2.99×10^{-2}	2.60×10^{-2}	2.78×10^{-4}	7.10×10^{-5}	6.10×10^{-5}									
Herd P	M	4.50×10^{-1}	4.50×10^{-1}	4.50×10^{-1}	2.53×10^{-2}	2.53×10^{-2}	2.53×10^{-2}	5.63×10^{-5}	5.63×10^{-5}	5.63×10^{-5}									
Ind P	H	7.81×10^{-1}	4.87×10^{-1}	4.50×10^{-1}	2.00×10^{-1}	6.06×10^{-2}	5.25×10^{-2}	5.16×10^{-4}	1.31×10^{-4}	1.12×10^{-4}									
Herd P	H	9.50×10^{-2}	9.50×10^{-2}	9.50×10^{-2}	6.08×10^{-3}	6.08×10^{-3}	6.08×10^{-3}	1.19×10^{-5}	1.19×10^{-5}	1.19×10^{-5}									
Ind P	L	2.23×10^{-1}	9.93×10^{-2}	9.00×10^{-2}	4.00×10^{-2}	1.50×10^{-2}	1.34×10^{-2}	3.11×10^{-4}	9.20×10^{-5}	8.01×10^{-4}									
Herd P	H	4.65×10^{-1}	4.65×10^{-1}	4.65×10^{-1}	3.04×10^{-2}	3.04×10^{-2}	3.04×10^{-2}	5.94×10^{-5}	5.94×10^{-5}	5.94×10^{-5}									
Ind P	M	7.10×10^{-1}	4.78×10^{-1}	4.63×10^{-1}	2.50×10^{-1}	1.04×10^{-1}	9.33×10^{-2}	1.89×10^{-3}	5.30×10^{-4}	4.59×10^{-4}									
Herd P	H	9.03×10^{-1}	9.03×10^{-1}	9.03×10^{-1}	5.75×10^{-2}	5.75×10^{-2}	5.75×10^{-2}	1.13×10^{-4}	1.13×10^{-4}	1.13×10^{-4}									
Ind P	H	9.38×10^{-1}	8.29×10^{-1}	8.10×10^{-1}	6.00×10^{-1}	3.05×10^{-1}	2.77×10^{-1}	4.34×10^{-3}	1.13×10^{-3}	9.68×10^{-4}									

Legend

Results (table cells): Upper value = P(imported | infected)
Lower value = P(infected | imported)

Prevalence: Low (L) = 0.10
Moderate (M) = 0.50
High (H) = 0.90

Test characteristics: Low (L) = 0.60
High (H) = 0.95
* Sp = 1 (general import risk assessment assumption)

1.4 Discussion

The second conditional form of the release assessment - the probability that imported commodity

will be infected - always produced a higher or more conservative result. It was also noted that decreasing the combined measure of prevalence and increasing the sensitivity of diagnostic procedures decreased the results for both forms. Finally, the relative difference between the forms appeared to be most evident when specificity was low, regardless of sensitivity and prevalence.

In order to understand these observations, the algebraic basis for each conditional form was reexamined:

$$P(imported \mid infected) = HP \times (1\text{-}Herd\ Se) \times IP \times (1\text{-}Ind\ Se) \times (1\text{-}Quar\ Se)$$

$$P(infected \mid imported) = \text{the final cumulative calculation - that is}$$

$$= (1 - \text{negative predictive value for quarantine})$$

It can be seen that the first form is dependent on measures of prevalence only so as to establish the prior 'probability of infection' (Armitage andBerry, 1994), and that following this, the release assessment depends solely on the sensitivities of diagnostic procedures. Conversely, the second form, whilst also utilising the prior probability of infection, bases each stage of the model template on a posterior calculation of the probability that the commodity will be infected, given that it has satisfied the requirements of that stage. When it is shown that the general form for this probability - the complement of negative predictive value, or (1-NPV) - is calculated as:

$$1 - NPV = P(T\text{-} \mid D+) \times P(D+) / \{P(T\text{-}|D+) \times P(D+) + P(T\text{-}|D\text{-}) \times P(D\text{-})\}$$

$$= (1\text{-}Se) \times P(D+) / \{(1\text{-}Se) \times P(D+) + Sp \times (1\text{-}P(D+))\}$$

and it is stressed that the 'probability of disease' or P(D+) is in fact the same posterior result but from the preceding stage, it can be seen that both prior probability of infection and the various test characteristics contribute conjointly at each stage in the model. When a model template consists of a series of interventions (tests, quarantine, the use of sentinels, etc) and simple probabilistic events (storage, the persistence of an organism in a commodity, etc), the result of this process will be difficult to predict without explicit modelling. Given this, it stood to reason that the general trends observed in this trial will hold in all cases.

1.5 Conclusions

This experiment examined two research questions:

- Will the two conditional forms for the release assessment ever be equivalent?
- What conditions will determine the degree of difference between them?

The answer to the first question may be inferred from the logic above and is simply that where there are no stages that represent interventions and, thus, no chance that animals or commodity will be rejected, then the two forms will be equivalent. This situation arises quite frequently and, in fact, two of the quantitative analyses that reported conditional release assessments (IBD NZ, 1997; Swill USA, 1997) could have accurately phrased it as either the P(imported | infected) *or* the P(infected | imported). By the same logic, the second question may be answered by considering that the results for each conditional form will diverge as the sensitivity of interventions increases, the specificity decreases and the probability that each 'tested' unit is infected decreases. Given this, it can be seen that in practical import risk analysis, differences between the two probabilities may often be quite minor, since the probability that an animal is infected at the point of testing is generally extremely low, test sensitivity is imperfect and test specificity is, by default, assumed to be 1.

2 Experiment 2: Properties of the @Risk random number generator

2.1 Research questions

The principal objective of this experiment was to investigate the suitability of the random number generator incorporated in @Risk (Palisade Corporation, New York, USA), the Monte Carlo add-in package, for spreadsheet-based simulations. To some extent the experiment was unnecessary, since one would assume that Palisade Corporation software developers would have satisfied themselves that the random number generator is suitable for the software. Given this, one of the overall project objectives was to use the results of the evaluations presented in the chapter to design and implement a generic expert system for import risk analysis. In completing this objective, a suitable random number generator will be required. The simulation module within @Risk® is the obvious choice since it can be extracted and used in other applications. If the module is going to be used however, it was considered mandatory that its random number generator be evaluated. Experiment 2 was therefore designed both to meet this objective and provide the material for an academic discussion of the principles of random number generation.

Specifically, three issues were investigated:

- Does the algorithm provide IID uniform (0,1) random variates?
- Can a series of random numbers be replicated by controlling the parameter(s) of the algorithm?
- Is the period between repetition of random numbers likely to be greater than 5000 iterations?

2.2 Methods

2.2.1 Research question 1

The first of these issues contained two separate hypotheses:

- That the variates provided by the algorithm are distributed uniformly (0,1)
- That the variates are independent

The first hypothesis was investigated by generating n = 5000 uniform (0,1) variates, using a random number generator seed of 1 and Monte Carlo sampling. Convergence was not used. The samples were collected, ranked and categorised according to k = 100 bins of equal width. The number (f_i) and proportion (p_i) in each category were tabulated (Table 18) and examined graphically, as shown in Figure 18 below. Proportions were tested statistically using a chi-squared goodness-of-fit test, with (k-1) = 99 degrees of freedom.

The chi-squared test was defined as (Averill andKelton, 1992):

$$\chi^2 = \frac{k}{n}\sum_{j=1}^{k}\left(f_i - \frac{n}{k}\right)^2$$

The principal ramification of independence to validate in an investigation of a random number generator is auto-correlation at a lag of one (Averill andKelton, 1992). Thus the second hypothesis was investigated by determining the correlation between the sample of 5000 variates (x) and the series obtained when the first of these was removed and each iterated value moved up one rank. That is, the correlation between $X=x_i$ and $X=x_{i-1}$.

2.2.2 Research question 2

In order investigate the ability to exactly replicate a series of random numbers, the simulation parameters used to obtain the first series were re-entered and a second series of 5000 uniform (0,1) variates obtained. These were compared with the original series on a record-by-record basis.

2.2.3 Research question 3

The third question required the period of the random number generator to be greater than 5000 iterations, since this was considered to be the maximum number likely to be generated by most import risk analysts. The random number generator used by @Risk was a portable generator based on a subtractive (cf. linear congruential) algorithm. One of the theoretical properties of this algorithm is an infinite period, such that 'looping', as observed for linear congruential algorithms, should not occur.

In order to test for looping and a finite period, the observed values were sorted and each value subsequently subtracted from that which occurred above it in the series. Where the result of this subtraction equalled zero, a duplicate existed and this was traced to the unsorted series to determine the number of iterated values that occurred between replicates.

2.3 Results

2.3.1 Research question 1

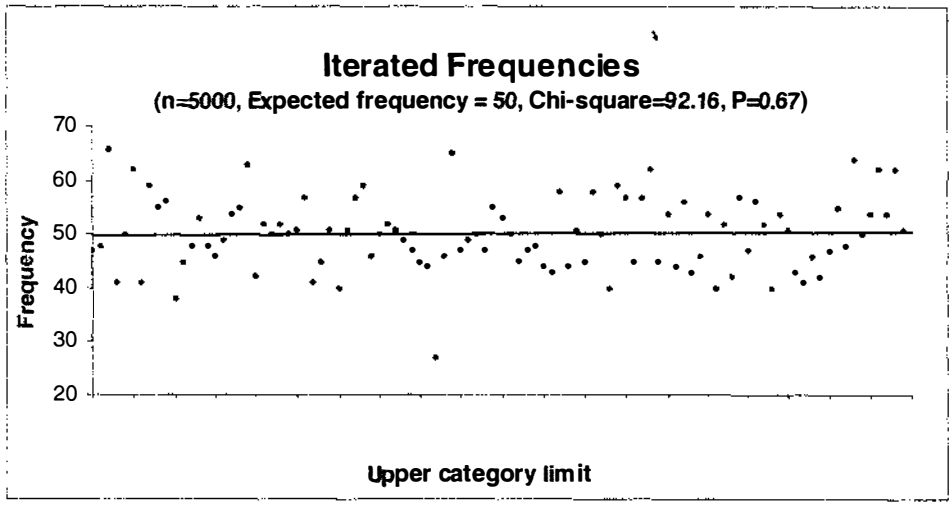
The frequency and proportion of uniform (0,1) variates each category are shown in Table 18. It can be seen that there is general adherence to the expected frequency of 50 (proportion 0.10).

Table 18: Frequency and proportion of uniform (0,1) variates as generated by @Risk

Upper limit	Frequency	Proportion
0.01	47	0.0094
0.02	48	0.0096
0.03	66	0.0132
0.04	41	0.0082
0.05	50	0.0100
0.06	62	0.0124
0.07	41	0.0082
0.08	59	0.0118
0.09	55	0.0110
0.1	56	0.0112
0.11	38	0.0076
0.12	45	0.0090
0.13	48	0.0096
0.14	53	0.0106
0.15	48	0.0096
0.16	46	0.0092
0.17	49	0.0098
0.18	54	0.0108
0.19	55	0.0110
0.2	63	0.0126
0.21	42	0.0084
0.22	52	0.0104
0.23	50	0.0100
0.24	52	0.0104
0.25	50	0.0100
0.26	51	0.0102
0.27	57	0.0114
0.28	41	0.0082
0.29	45	0.0090
0.3	51	0.0102
0.31	40	0.0080
0.32	51	0.0102
0.33	57	0.0114
0.34	59	0.0118
0.35	46	0.0092
0.36	50	0.0100
0.37	52	0.0104
0.38	51	0.0102
0.39	49	0.0098
0.4	47	0.0094
0.41	45	0.0090
0.42	44	0.0088
0.43	27	0.0054
0.44	46	0.0092
0.45	65	0.0130
0.46	47	0.0094
0.47	49	0.0098
0.48	50	0.0100
0.49	47	0.0094
0.5	55	0.0110
0.51	53	0.0106
0.52	50	0.0100
0.53	45	0.0090
0.54	47	0.0094
0.55	48	0.0096
0.56	44	0.0088
0.57	43	0.0086
0.58	58	0.0116
0.59	44	0.0088
0.6	51	0.0102
0.61	45	0.0090
0.62	58	0.0116
0.63	50	0.0100
0.64	40	0.0080
0.65	59	0.0118
0.66	57	0.0114
0.67	45	0.0090
0.68	57	0.0114
0.69	62	0.0124
0.7	45	0.0090
0.71	54	0.0108
0.72	44	0.0088
0.73	56	0.0112
0.74	43	0.0086
0.75	46	0.0092
0.76	54	0.0108
0.77	40	0.0080
0.78	52	0.0104
0.79	42	0.0084
0.8	57	0.0114
0.81	47	0.0094
0.82	56	0.0112
0.83	52	0.0104
0.84	40	0.0080
0.85	54	0.0108
0.86	51	0.0102
0.87	43	0.0086
0.88	41	0.0082
0.89	46	0.0092
0.9	42	0.0084
0.91	47	0.0094
0.92	55	0.0110
0.93	48	0.0096
0.94	64	0.0128
0.95	50	0.0100
0.96	54	0.0108
0.97	62	0.0124
0.98	54	0.0108
0.99	62	0.0124
1	51	0.0102
Total	**5000**	

These results are displayed graphically in Figure 18, where it can be seen that 'random' variation about the trend-line set at a frequency of 50 is minimal.

Figure 18: Distribution of the uniform (0,1) variates



The results were tested statistically using the chi-squared test described above. Here it was found that a $\chi^2_{(DF=99)}$ of 92.16 was associated with a p-value of 0.67 and, thus, there was little reason to reject the hypothesis that variates generated were distributed uniformly within the (0,1) interval.

The second aspect of Research Question 1 concerned the auto-correlation (lag = 1) of pseudo random uniform (0,1) variates. Here it was found that auto-correlation was equal to 0.01 and, likewise, there was little reason that this aspect of statistical independence had been violated.

2.3.2 Research question 2

Replication of the series was undertaken and it was shown that where the simulation parameters were identical, every record was duplicated exactly. It should be noted however that this random number generator requires the generator seed to be non-zero if replication is to be obtained. Where the seed is set to zero, the algorithm interprets this as the analyst's wish to impose further 'randomness' and obtains a seed independently by reference to the computer's clock. Given this, no two simulations based on random number seeds of zero can be identical.

2.3.3 Research question 3

Here it was found that while one value was duplicated in the series (n=5000), the interceding pseudo random numbers were not reiterated after the second observation of the value and, thus, looping did not appear to be occurring.

2.4 Discussion

For the portable random number generator used by @Risk to be suitable for Monte Carlo simulation experiments in the field of import risk analysis it should provide the following:

- A source of IID uniform (0,1) random variates
- The facility to create replicate series by controlling simulation parameters
- A period that is at least sufficiently long as to negate the risk of looping within 5000 iterations

It can be seen from these discussions that the subtractive generator does appear to produce independent and identically distributed random variates from the uniform (0,1) distribution - that is, there was little visible or statistical evidence for deviation from either of these characteristics. The generator also allowed for the replication of a series of variates, although the role of the 'zero generator seed' as a means of instantiating a clock-based method for randomising seed selection per se, was not clearly documented in the software manuals or help files.

2.5 Conclusions

It was concluded that the portable, subtractive, pseudo random number generator used by @Risk is appropriate for the purpose of Monte Carlo simulation experiments as carried out in stochastic risk assessments. If required, this random number generator could be adopted for use in the proposed expert system for import risk analysis.

3 Experiment 3: Methods for modelling natural variation

3.1 Research question

The variance of secondary or derived variables stems from 'natural variation' rather than 'uncertainty', since these variables simply result from stochastic statistical processes. Given this, it has been suggested that natural variation should not be simulated since this will introduce an unnecessary inflation in the variance of the output (Hoffman, 1993). The objective of this experiment was to demonstrate the degree to which the variance of the output of a simple stochastic model may be influenced by algebraically calculating, rather than simulating, a single

secondary random variable.

3.2 Methods

In order to illustrate the comparative effect of an exact algebraic solution and the traditional simulation-based approach, a simple stochastic model was created. This model described the probability that a test applied to a series of animals selected from a large infected population will fail to detect at least one of the infected animals and, thus, identify the group as infected. Animals to be tested have been selected from an infected herd which, in turn, has been selected from country or region.

The primary variables and their probability distributions in this model were thus:

- The probability that a selected herd will be infected (p1 ~ Triangular (0.25, 0.50, 0.75))
- The probability that a selected animal will be infected (p2 ~ Triangular (0.25, 0.50, 0.75))
- The number of selected animals (n ~ Truncated normal (25, 5, 5, 50))
- The sensitivity of the test (s ~ Triangular (0.70, 0.75, 0.80))

It can be seen that if x represents the number of infected animals in the selected group, then x will follow a binomial distribution with parameters n and $p3$ (where, p3 = p1 × p2). Given this, it follows that the outcome probability (Pr) may be calculated in two ways:

1. By simulating the following expression:

$$\Pr = (1 - s)^{Binomial(n,p3)}$$

2. By calculating the following expression:

$$\Pr = \sum_{x=1}^{n} \frac{n!}{x!(n-x)!} . p3^{x} . (1 - p3)^{n-x} . (1 - s)^{x}$$

Fortunately the summation above, which would be problematic to implement in a spreadsheet environment, may be simplified by following the following algebraic steps:

The generic expression below represents a finite binomial summation from $x = 0$ to $x = t$,

$$(A+B)^t = \sum_{x=0}^{t} \frac{t!}{x!(t-x)!} A^x B^{t-x}$$

This expression may be adjusted as shown below to represent the binomial summation from $x = 1$ to $x = t$,

$$(A+B)^t - B^t = \sum_{x=1}^{t} \frac{t!}{x!(t-x)!} A^x B^{t-x}$$

The calculation for Pr may be re-arranged into the general form of the binomial summation above,

$$\Pr = \sum_{x=0}^{t} \frac{t!}{x!(t-x)!} . (p3(1-s))^x . (1-p3)^{t-x}$$

From this, the binomial terms $A = p3(1-s)$ and $B = (1-p3)$ may be extracted and the equation re-written in the simplified form below,

$$\Pr = (1-p3s)^t - (1-p3)^t$$

Since Pr is conditional on the herd being infected, it is necessary to adjust the binomial sum to remove the term $x = 0$. This is achieved as shown below by dividing by the sum of the distribution (Bayes Theorem),

$$\Pr = \frac{[(1-p3s)^t - (1-p3)^t]}{(1-(1-p3)^t)}$$

Each model was simulated 1000 times using @Risk®, the spreadsheet-based Monte Carlo simulation program. The iterated results were collected and graphed (see Figures 19 and 20), using the following (upper) category boundaries:

- $\Pr \leq 1 \times 10^{-10}$
- $\Pr \leq 1 \times 10^{-9}$

- $Pr \leq 1 \times 10^{-8}$
- $Pr \leq 1 \times 10^{-7}$
- $Pr \leq 1 \times 10^{-6}$
- $Pr \leq 1 \times 10^{-5}$
- $Pr \leq 1 \times 10^{-4}$
- $Pr \leq 1 \times 10^{-3}$
- $Pr \leq 1 \times 10^{-2}$
- $Pr \leq 1 \times 10^{-1}$
- $Pr \leq 1$

3.3 Results

From the line graphs in Figures 19 and 20 it can be seen that the calculation of (x), the number of infected animals selected, has led to a substantially smaller variance than that which resulted when (x) was simulated.

Figure 19: Probability distributions obtained by exact algebraic and simulation methods

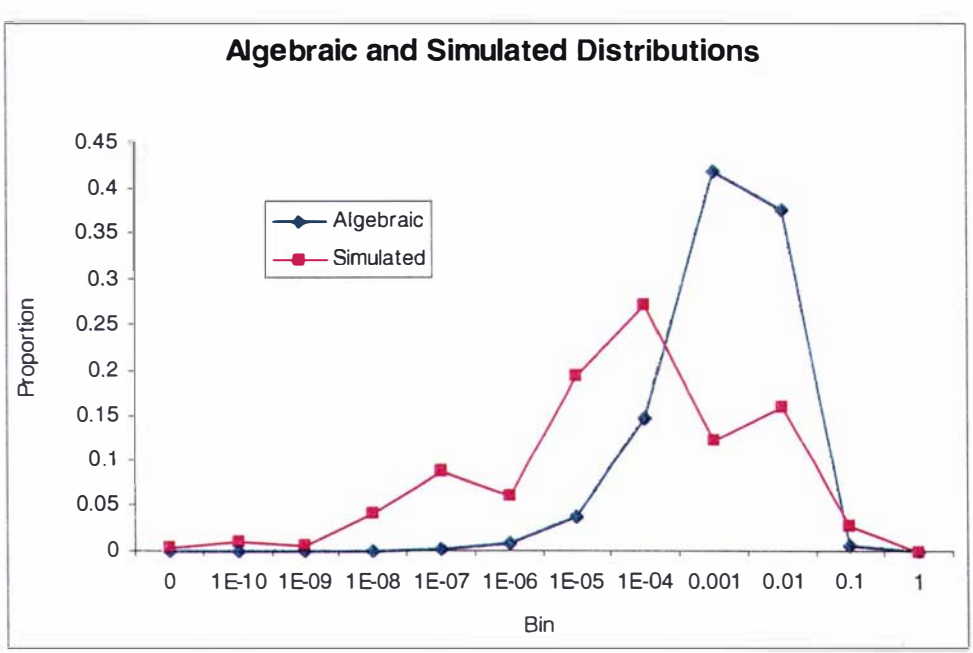
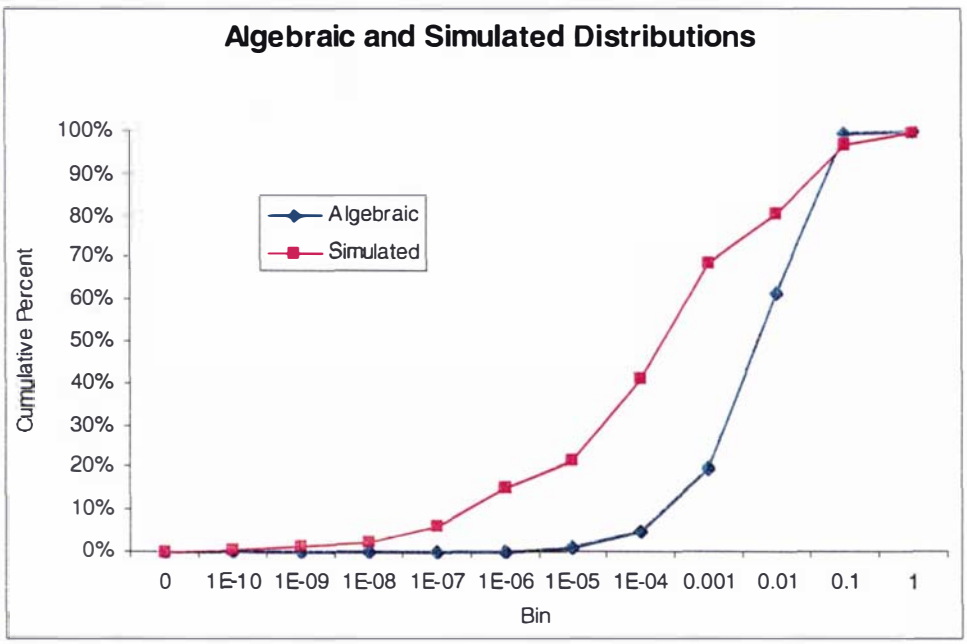


Figure 20: Cumulative distributions obtained by exact algebraic and simulation methods



These results were summarised in the distribution statistics provided in Table 19. Here it can be seen that while the means are similar, the variance in the simulated model is an order of magnitude larger. Likewise, it was interesting to note that the strongly left-skewed distributions had similar 95th percentiles but markedly differing 5th percentiles.

Table 19: Statistics from comparative stochastic models in which natural variation was calculated directly or simulated

Statistic	Simulation	Algebraic calculation
Mean	1.34×10^{-2}	2.17×10^{-2}
Variance	9.74×10^{-3}	3.22×10^{-4}
5th percentile	8.07×10^{-8}	1.05×10^{-4}
95th percentile	7.22×10^{-2}	5.45×10^{-2}

3.4 Discussion

At each iterated value of the primary variables in the model, the algebraic calculation of the

expected value of Pr minimised variance in the output. Specifically, it was noted that the strongly left-skewed distributions had similar means and 5^{th} percentiles, but markedly differing 95^{th} percentiles. These statistical results were reinforced in the superimposed line graphs for each model.

The implication of these results is that where practicable, secondary variables derived as a result of statistical processes should be modelled using exact algebraic approaches. It can be seen that the general binomial 'group testing' formula, as used in this model and in many published quantitative (stochastic and deterministic) analyses, has a convenient binomial summation and, thus, may be implemented easily in a spreadsheet.

Given this, the permutations of binomially-based algebraic forms that have been applied in quantitative risk analysis models are virtually endless and, on this basis, it is difficult to state unequivocally that in every case there will be a convenient means by which to abbreviate the spreadsheet. Of particular concern are large sample sizes, or the situation in which the integration of a continuous (eg Poisson-based) form was required. In such cases, mathematical packages such as Mathcad® (MathSoft Inc, Cambridge, Massachusetts, USA) may be of use to determine exact or numerical solutions.

3.5 Conclusions

It was concluded that simulating secondary (calculated) inputs whose variance represents the 'natural variation' conveyed by the statistical process from which they arise will inflate the variance of the output to a measurable and unnecessary degree. Given this, it follows that such variables should where possible be incorporated in the model using exact algebraic representations - in many cases the latter will be complex summations or integrations and these may either be reduced using common mathematical results, or by using software designed for performing such mathematical reductions. In some cases reduction will not be practical and here the analyst should either create the summation manually or, if impractical, should simulate the variable and describe the difficulty in the analysis report.

4 Experiment 4: The effect of rank order correlation on the output of a simple stochastic model

4.1 Research questions

The objective of this experiment was to determine the extent to which various degrees of rank order correlation between variables in a simple stochastic model altered the distribution and statistics model's output.

The following questions were asked:

- How do varying degrees of correlation effect the sum of two standard normal (0,1) distributions?
- How do varying degree of correlation effect the product of two standard normal (0,1) distributions?
- Given answers to the questions above, how do varying degrees of correlation affect the output from a simple stochastic model?

4.2 Methods

Two separate spreadsheet-based simulation experiments were performed.

4.2.1 Trial I

In the first trial, two normal (0,1) distributions were specified. These were subsequently summed and multiplied, with rank order correlations of -1, -0.5, 0, 0.5 and 1 specified for each operation. The outputs from each simulation were collected and plotted as line graphs of frequency and cumulative frequency distributions. Statistics generated from each output distribution were summarised and documented (Table 20).

4.2.2 Trial II

In the second trial, the simple group testing model developed in Experiment 3 was modified. Test sensitivity was replaced with a uniform distribution for the sensitivity of a clinical examination (s ~ uniform (0.70, 0.90)), and the model simulated with varying degrees of negative correlation between the sensitivity of clinical examination and group size (0, -0.25, -0.50, -0.75, -1.0).

In both trials, 1000 samples were generated using Latin hypercube sampling and a random number generator seed of 1.

4.3 Results

4.3.1 Trial I

The results of the first trial are shown in Figures 21-24, and Table 20. Specifically, Table 20 shows that adding either positive or negative correlation to the sum of the normal (0,1) distributions resulted in a mean closer to the expected mean of zero. In contrast however, while strong negative correlation greatly reduced both the variance and the two reported percentiles, strong positive correlation achieved the opposite.

When the product of the normal (0,1) distributions was calculated, positive and negative correlation increased and decreased, respectively, the mean of the resulting distribution by an equivalent degree. Positive or negative correlation increased the variance by the same degree, and this was reflected in the difference between each percentile and its corresponding mean.

Table 20: Output from two summed or multiplied standard normal distributions, when the rank order correlation (ρ) between iterated values varied between -1.0 and +1.0

Rank Order Correlation	Summed normal (0,1) distributions				Product of normal (0,1) distributions			
	Mean	Var	5th %	95th %	Mean	Var	5th %	95th %
-1	-9.22×10^{-5}	9.19×10^{-5}	-3.87×10^{-3}	3.67×10^{-3}	-1	2.03	-3.86	-4.0×10^{-3}
-0.5	-9.22×10^{-5}	1.02	-1.65	1.72	-0.49	1.28	-2.65	0.69
0	7.20×10^{-4}	2.01	-2.41	2.33	5.56×10^{-3}	1.05	-1.68	1.76
0.5	-9.22×10^{-5}	3.02	-2.78	2.71	0.51	1.36	-0.59	2.53
1	-9.22×10^{-5}	4.01	-3.29	3.28	1	2.03	3.89×10^{-3}	3.82

These results are reiterated in Figures 21-24. Here it can be seen that the frequency distributions for the summed normal (0,1) variates (Figure 21) become progressively flatter as the correlation moves from -1 through zero to +1, and that the mean appears stable throughout. Likewise, it is evident from the cumulative frequency distributions (Figure 22) that increasing positive

correlation increases the variance of the summed normal (0,1) distributions while increasing negative correlation has the reverse effect. The cumulative distributions also quite clearly illustrate the relationship between increasing variance and increasing percentiles, as evident in Table 20.

Figure 21: Probability distributions obtained from summed standard normal (0,1) distributions

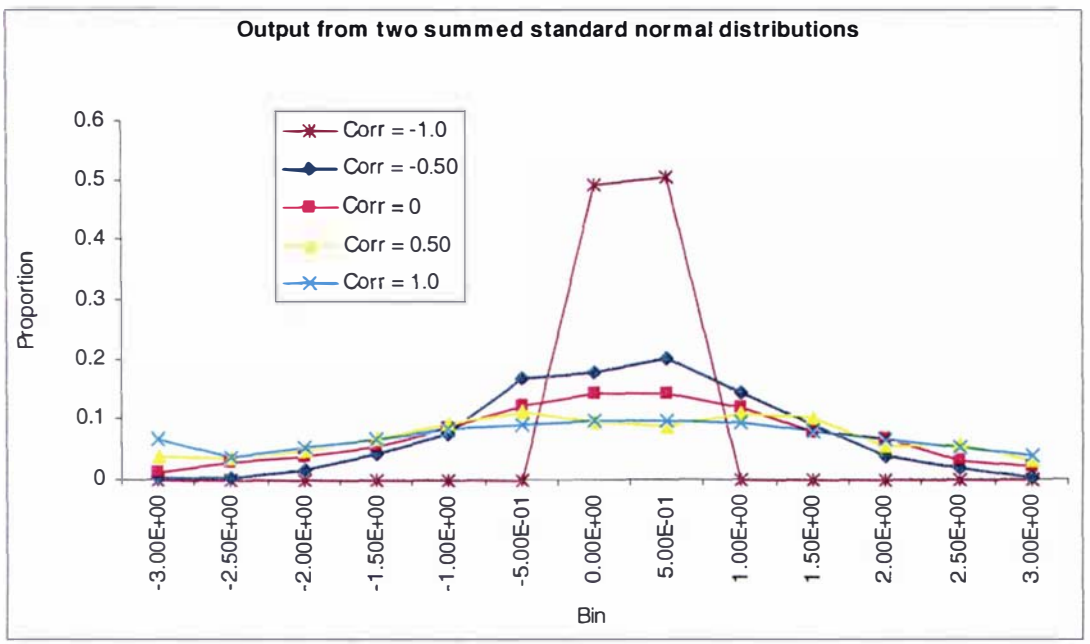


Figure 22: Cumulative distributions obtained from summed standard normal (0,1) distributions

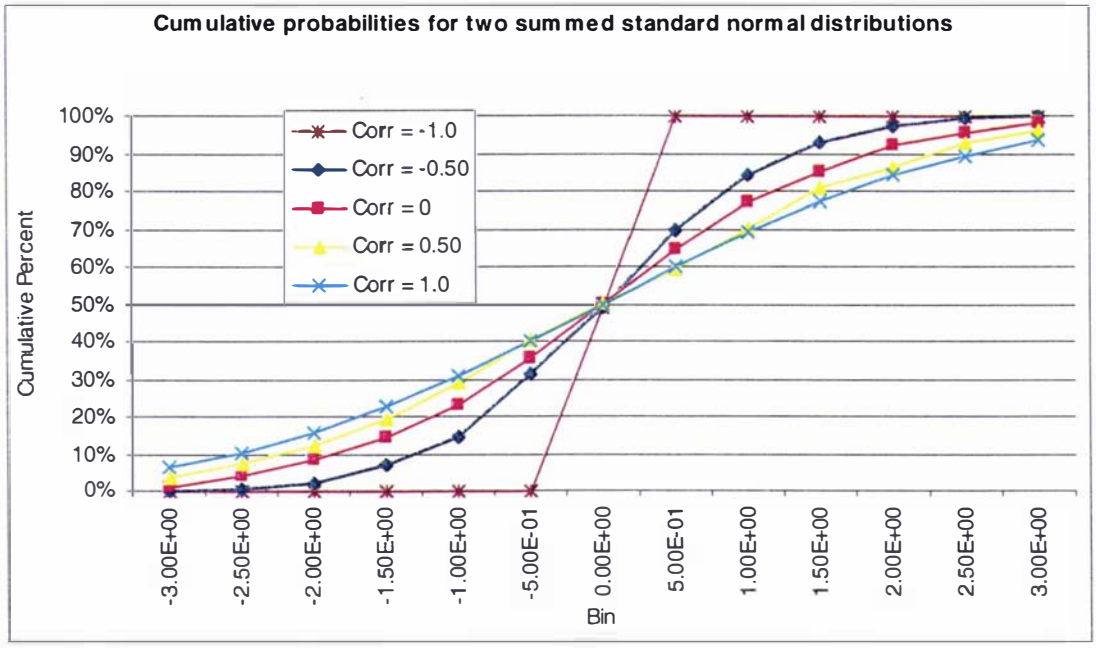


Figure 23: Probability distributions obtained from the product of two standard normal (0,1) distributions

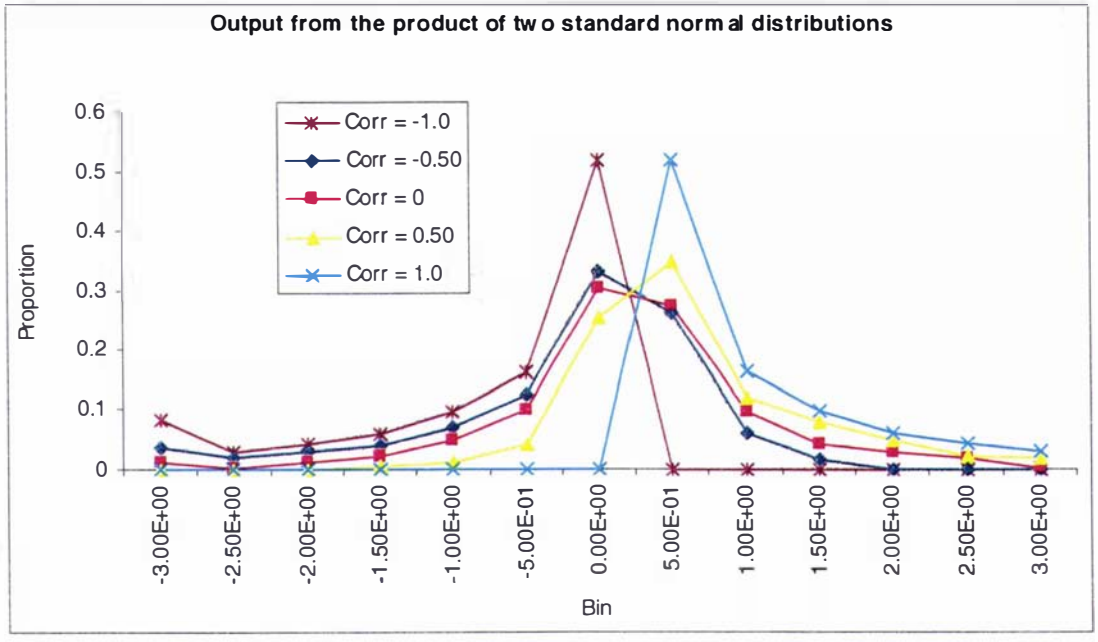
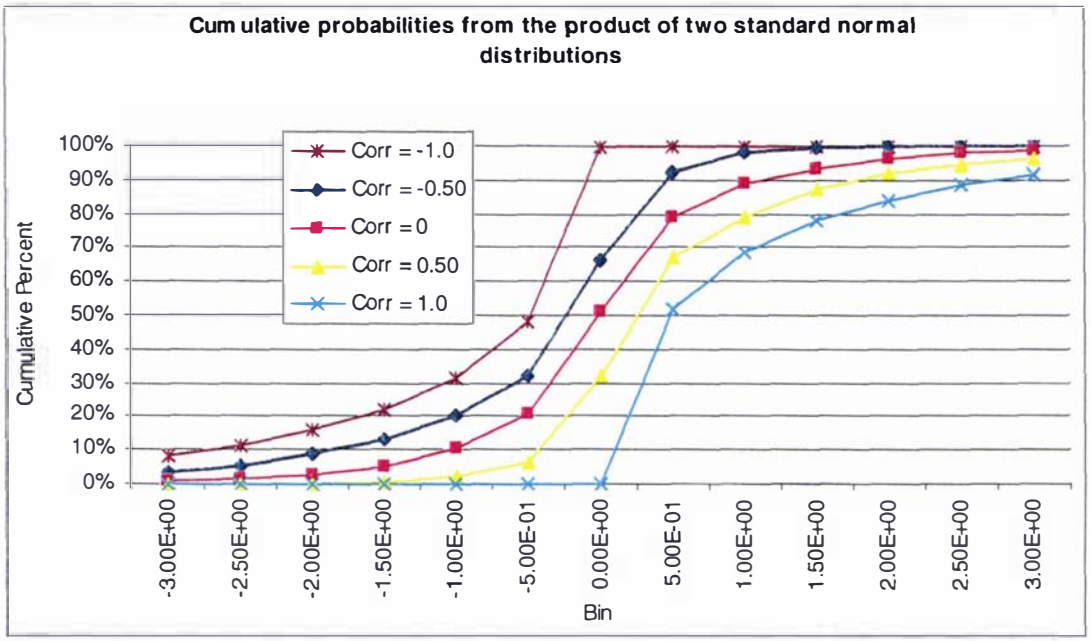


Figure 24: Cumulative distributions obtained from the product of two standard normal (0,1) distributions



The second group of figures reiterate the effect of positive and negative rank order correlation on the product of two normal (0,1) distributions, as described in the summary of Table 20. Briefly, it can be seen from Figure 23 that as correlation increases from -1 through 0 to +1, the mean of the product of the distribution shifts on the x-axis from approximately -1 to approximately 1. As might be expected, a similar effect is seen with the percentiles, although this is modified to a degree by the increase in variance with the absolute value of rank order correlation. Figure 24 reiterates the shifting mean and, in addition, shows the degree to which percentiles are modified both by the lateral shift in each distribution and the changing variance.

4.3.2 Trial II

In contrast to the results described for Trial I, the effect of negative rank order correlation, when varied between -0.25 and -1.0, was minimal. Given this, Table 21 shows that increasing negative correlation was associated with a steadily decreasing variance and a negligibly decreasing mean. Likewise, the 5th percentiles steadily increased and the 95th percentiles appeared to decrease as negative correlation increased. These results are illustrated in the frequency distributions and cumulative frequency distributions shown in Figures 25 and 26, respectively, although their small size confounds the graphical interpretation.

Table 21: The effect of negative rank order correlation between group size and the sensitivity of clinical examination on the probability that an infected group will be detected by this means

Rank order correlation	Statistic			
	Mean	Variance	5^{th} %	^{95th} %
Corr = 0	8.72×10^{-4}	1.46×10^{-5}	3.22×10^{-9}	4.09×10^{-3}
Corr = -0.25	8.82×10^{-4}	1.70×10^{-5}	3.37×10^{-9}	4.45×10^{-3}
Corr = -0.50	7.38×10^{-4}	9.12×10^{-6}	4.20×10^{-9}	3.84×10^{-3}
Corr = -0.75	6.14×10^{-4}	4.66×10^{-6}	6.99×10^{-9}	3.23×10^{-3}
Corr = -1.0	5.58×10^{-4}	3.67×10^{-6}	1.01×10^{-8}	2.85×10^{-3}

Figure 25: Probability distributions for the group testing model when rank order correlation is set to 0, -0.25, -0.50, -0.75 and -1.0

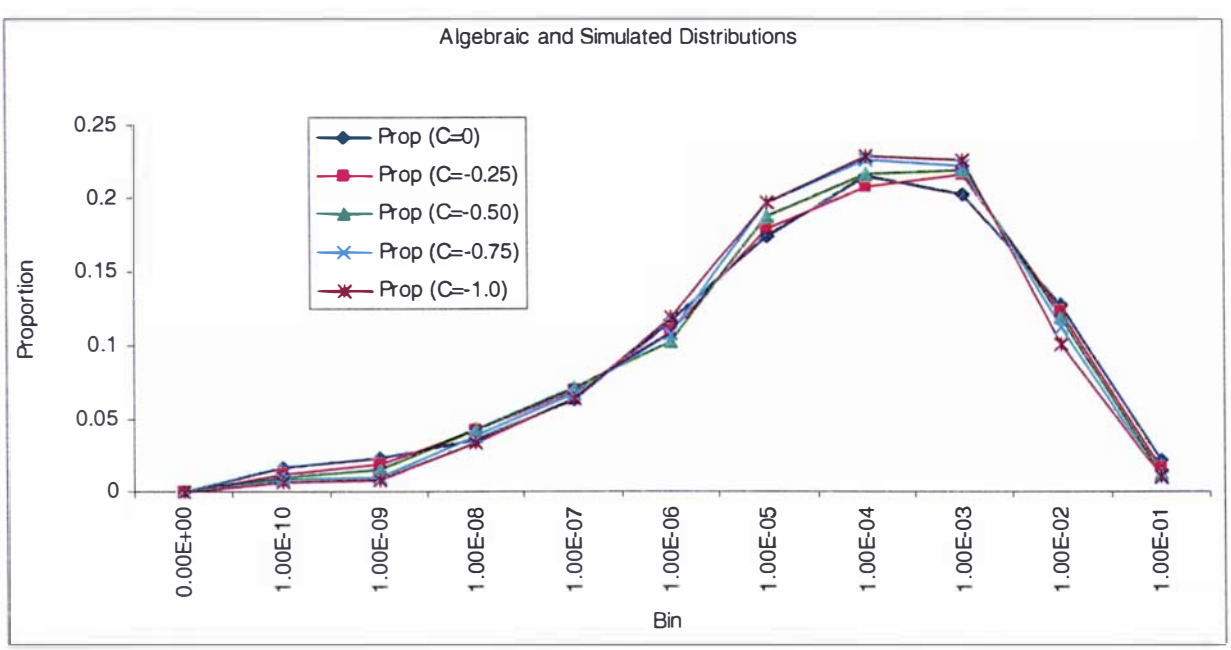
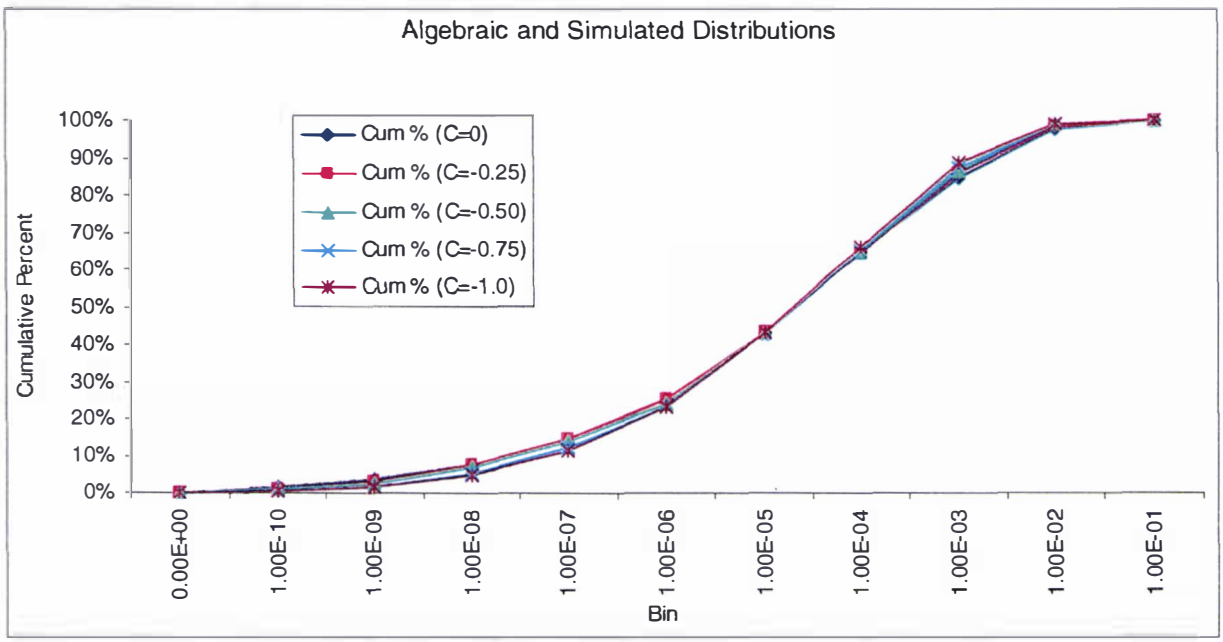


Figure 26: Cumulative distributions for the group testing model when rank order correlation is set to 0, -0.25, -0.50, -0.75 and -1.0



4.4 Discussion

Before interpreting and discussing the results of these experiments it is important to note that Spearman's non-parametric rank order correlation coefficient, the metric upon which this form of correlation is based, is not equivalent to Pearson's product moment correlation coefficient (r). The latter is a parametric statistic defined by the following equation:

$$r = \frac{Cov(X,Y)}{Var(X).Var(Y)}$$

Where Cov(X,Y) is the covariance between the random variables X and Y, and Var(X) and Var(Y) are their corresponding variances. Likewise the probability axioms governing the addition and multiplication of dependent random variables cannot be applied when rank order (c/f parametric product moment) correlation has been applied.

Given this, the results of the first two trials can be interpreted by considering the mechanics of the rank order procedure. Rank order correlation is achieved in Monte Carlo simulation by generating

the series of random variates for each distribution, sorting and ranking the values by magnitude, and applying a correlation based on the ranks. To illustrate, where the correlation was specified as +1, the largest value for variable X would appear in the same iteration of the simulation as the largest values for variable Y, and so on through the ranks of each variable. Likewise, where the correlation is -1, the largest value of variable X would appear with the smallest value of variable Y, etc. Where the correlation is zero, no attempt is made to match large-and-large or large-and-small ranks and where the correlation lies between -1 and +1 (excluding zero), the ranks are correlated to the degree specified by the correlation coefficient.

It can thus be seen that where, for example, two theoretically identical variables with a rank order correlation of +1 are summed, large values are added to large values and small values to small values. This results in an increase in the variance of the resulting distribution, and an increase in the spacing of percentiles. The mean, however, remains the sum of the component means. Likewise, where a correlation of -1 has been applied to two summed identical variables, large values will be added to small values and vice versa, and the resulting distribution will have a smaller variance and more closely spaced percentiles. As above, the mean will simply be the sum of the component means.

While more difficult to conceptualise, the same approach may be used to interpret the results of the summed variables and, likewise the two intermediate correlations of +0.5 and -0.5. It can thus be seen that rank order correlation is essentially a logical procedure but nevertheless one which, with a sufficient number of iterations, should produce results that follow theoretical axioms for the addition and multiplication of dependent variables. For example, if X and Y are two dependent random variables, the addition rule states that:

$$E(X_1 + X_2 + \ldots + X_n) = \sum_{i=1}^{n} E(X_i)$$

$$Var(X_1 + X_2 + \ldots + X_n) = \sum_{i=1}^{n} Var(X_i) + 2\sum_{i<j} Cov(X_i, X_j)$$

It can be seen that E(X+Y) - the mean of the sum of X and Y - was, in Trial I, approximated by the sum of their means (in this case, zero). Alternatively, the Cov(X,Y) may be approximated using the formula stated at the start of this discussion. Here the correlation coefficient is specified (for example, +1), and inserted with the simulated statistics Var(X) (1.02) and Var(Y) (1.00) into

the expression for the Cov(X,Y). Once Cov(X,Y) has been calculated, the Var(X+Y) may be solved using the expression above.

In this example, the variance of the sum of the distributions is approximately equal to:

$(1.02 + 1.00) + (2 \times 1.02) = 4.06$

This is in fact close to the iterated value for the variance of the sum of X and Y - that is, 4.01.

Unfortunately however, while the results for simple operations performed on identical distributions may be predicted or interpreted relatively easily, the effect of positive or negative rank order correlation when applied to variables within a typical stochastic model may not be as consistent. This was seen in Trial II, in which group size and the effectiveness of clinical examination were negatively correlated to varying degrees without substantially altering the overall probability of identifying an infected group. In this case, the algorithm used to calculate 'the probability that at least one infected animal will be detected' involved several mathematical permutations of prevalence and the effectiveness of clinical examination, each raised to the power of group size. This represents a comparatively complex combination of ranked iterated values, and yet the calculation would typically form just a single stage in a stochastic import risk analysis model. Given this, it is evident that the effect of correlation between component variables on the mean, variance or percentiles of the output from an entire model will be virtually impossible to predict, whether by analytic approximations or by logical deductions from a knowledge of the rank order correlation procedure.

Accepting the above, it follows that while the validity and logical interpretation of rank order correlation appears to be adequate, 'sensitivity simulations' should nevertheless be performed so as to assess the effect of the each specified correlation. Where correlations lead to substantial changes in the output statistics, the coefficients specified should be re-evaluated and, if estimated from negligible data or from expert opinion, further simulations should be performed with a range of alternative values. That is, rank order correlation is a useful but nevertheless approximate non-parametric procedure and analysts would be advised to adopt a conservative approach to it's application in risk analysis models.

4.5 Conclusions

While the effect of rank order correlation on the mean, variance and percentiles of an output distribution could be predicted and interpreted when examined in simple isolated examples, the same could not be said for more complex models. Given this, it will be important to consider any correlations between input variables where these are believed to exist. Where this is the case, the effect of correlation on the mean and variance of the output should be evaluated by way of repeated sensitivity simulations. If the effect of rank order correlation on a model's output statistics is shown to be meaningful the correlation coefficient should be reassessed and, if necessary, further sensitivity simulations carried out. This will ensure that an unrealistic degree of association is not detracting from the validity of the model.

5 Experiment 5: Sensitivity analysis for stochastic models

5.1 Research questions

The overall intent of this experiment was to illustrate systematically the common objectives, procedures and outputs obtained when sensitivity analysis is performed on a stochastic Monte Carlo simulation model. In Evaluation III Part II it was shown that sensitivity analysis has two broad objectives - the identification of influential variables and the assessment of the effect of changes in these or other variables on the model's output. In view of this, the following research questions were considered:

- How do the results of a sensitivity analysis based on stepwise multiple regression and rank order correlation compare?
- What are the alternative ways in which the results of sensitivity simulations may be compared with those obtained from simulating the original model?

5.2 Methods

In order to investigate these research questions, the simple deterministic model for the importation of live animals developed in Experiment 3 was adapted, such that the primary input values were represented as probability distributions. The probability distributions and algebraic formulae resulting from this process are show in the spreadsheet in Table 22.

Table 22: Spreadsheet for stochastic sensitivity analysis

Stage	Description	Derivation	Model inputs
Herd selection	**Herd prevalence (HP)**	**P(Herd D+)**	**Betapert (0.10,0.15,0.25)**
	1-HP	P(Herd D-)	0.842
Herd testing	**Herd test Se (HSe)**	**P(T+lHerd D+)**	**BetaPert (0.80,0.90,0.95)**
	1-HSe	P(T-lHerd D+)	0.108
	Herd test Sp (HSp)	**P(T-lHerd D-)**	**BetaPert (0.80,0.90,0.95)**
	1-HSp	P(T+lHerd D-)	0.108
	1-Herd NPV = P(Herd D+lT-)	P(T-lHerd D+)*P(Herd D+) / {P(T-lHerd D+)*P(Herd D+) + P(T-lHerd D-)*P(Herd D-)}	0.022
	Herd NPV = P(Herd D-lT-)	P(T-lHerd D-)*P(Herd D-) / (P(T-lHerd D-)*P(Herd D-) + P(T-lHerd D+)*P(Herd D+)}	0.978
Animal selection	Probability select an infected animal	P(w/i D+)*P(Herd D+lT-) = P(Ind D+)	0.005
	Within herd prevalence (w/i Herd P)	**P(w/i D+)**	**BetaPert (0.1,0.25,0.3)**
	Probability don't select an infected animal	P(Ind D-)	0.995
	1-w/i Herd P	P(w/i D-)	0.767
Animal testing	**Test Se (Se)**	**P(T+lInd D+)**	**Uniform (0.85,0.95)**
	1 - Se	P(T-lInd D+)	0.100
	Test Sp (Sp)	**P(T-lInd D-)**	**Uniform (0.75, 0.85)**
	1-Sp	P(T+lInd D-)	0.200
	1-Ind NPV = P(Ind D+lT-)	P(T-lInd D+)*P(Ind D+) / {P(T-lInd D+)*P(Ind D+) + P(T-lInd D-)*P(Ind D-)}	0.001
	Ind NPV = P(Ind D-lT-)	P(T-lInd D-)*P(Ind D-) / {P(T-lInd D-)*P(Ind D-) + P(T-lInd D+)*P(Ind D+)}	0.999
Quarantine	Probability tested animal infected (P)	D+ = 1-Ind NPV	0.001
	1-P	D- = Ind NPV	0.999
	Quarantine Se (QSe)	**P(Quar+lD+)**	**Uniform (0.85,0.95)**
	1-QSe	P(Quar-lD+)	0.100
	Quarantine Sp (QSp)	**P(Quar-lD-)**	**Uniform (0.75, 0.85)**
	1-QSp	P(Quar+lD-)	0.200
	1-Quar NPV = P(D+lQuar-)	P(Quar-lD+)*P(D+) / {P(Quar-lD+)*P(D+) + P(Quar-lD-)*P(D-)}	8.19E-05
	Quar NPV = P(D-lQuar-)	P(Quar-lD-)*P(D-) / (P(Quar-lD-)*P(D-) + P(Quar-lD+)*P(D+)}	1.00E+00
PAE	**P(infected | imported)**	***Final model probability = (1-Quar NPV)***	**8.19E-05**

The stochastic model described above was subsequently iterated 1000 times, using Latin hypercube sampling and a random number generator seed of 1. Output distribution samples and statistics were stored in a separate spreadsheet.

5.2.1 Research question 1

In order to answer the first question, sensitivity analyses were performed using the stepwise multiple regression and rank order correlation options available within @Risk®. Results were compared to those obtained using Statistica® (Statistica version 5.1, StatSoft Inc, Tulsa, USA), a statistical analysis software package. Finally, the ranks obtained for each input variable, when the correlation and regression based procedures were used, were compared both visually and statistically.

5.2.2 Research question 2

In order to answer the second question, sensitivity simulations were undertaken in which the input variable with the highest rank order correlation was systematically varied by specifying alternative distributions both above and below its former limits. Having specified these distributions, the model was re-run using the original simulation parameters - random number

generator seed, sampling method and number of iterations. Two alternative sets of distribution samples and statistics were derived. The alternative distributions were subsequently compared to the results of the original simulation using each of the following approaches:

- Absolute differences and proportional changes in the maximum and minimum iterated values, mean, standard deviation, variance, 5^{th}, 50^{th} and 95^{th} percentiles were tabulated
- The statistical significance of absolute differences in the means and variance were obtained using non-parametric t-tests and F-tests, respectively
- The probability of observing values at least as high as the "acceptable risk" - arbitrarily set to at 10^{-4} - was determined from the cumulative distributions of each of the alternative extreme simulations

5.3 Results

5.3.1 Research question 1

The results obtained from the stepwise multiple regression and rank order correlation procedures are shown in Table 23. Here it can be seen that while input variables with high ranking on the Spearman's rank order correlation coefficient scale tended also to have high rankings on the regression based scale, the two systems did not produce identical results. Indeed, a parametric Pearson's correlation analysis of the two sets of ranks showed that while correlation was both high and significant, it was not exact ($r^2 = 0.90$, $P = 0.037$).

Closer examination of the input variables showed that the sensitivity of quarantine ($\rho = -0.56$) was ranked as the most influential variable on the rank order correlation scale, while the sensitivity of the individual diagnostic test had the highest standardised partial regression coefficient ($\beta = -0.50$) and was therefore ranked the most important on the regression scale. When the distribution samples obtained from the simulation were exported to Statistica® and both forms of sensitivity analysis repeated, the results were identical to five decimal places.

Table 23: Results of sensitivity analyses based on stepwise multiple regression and Spearman's rank order correlation

Input variable	Regression-based analysis		Rank-order-correlation-based analysis	
	Partial regression coefficients	Rank	Rank Correlation Coefficient	Rank
Quarantine sensitivity	-0.4983588	2	-0.56	1
Individual test sensitivity	-0.5000817	1	-0.54	2
Herd test sensitivity	-0.4232278	3	-0.46	3
Herd prevalence	0.3484458	4	0.29	4
W/I herd prevalence	0.2640357	5	0.29	5
Quarantine specificity	-0.05303028	7	-0.09	6
Herd test specificity	-0.04853355	8	-0.06	7
Test specificity	-0.0698401	6	0.00	8

5.3.2 Research question 2

The use of rank order correlation in stochastic risk analysis was shown in Evaluation III Part II to be based on a more sound theoretical footing. This scale was adopted as the more appropriate for the purpose of screening the model for influential input variables. It was stated above (and illustrated in Table 23) that when this scale was used, the sensitivity of quarantine appeared to be the most influential variable. It can also be seen from Table 23 that there was little difference between the rank order correlation coefficients obtained for quarantine sensitivity and either individual test sensitivity (ranked 2nd) and herd test sensitivity (ranked 3rd). Had this example been a genuine assessment, all three variables should have been retained for sensitivity simulations.

Regardless, the objective here was to examine methods that may be used to interpret the results of sensitivity simulations and, as such, the distribution for quarantine sensitivity alone was systematically altered so as to result in sampled values both above and below its former limits. Once again the specific procedure adopted for this exercise, while intuitively sensible, was carried out as an arbitrary example and was not intended to represent any particular quarantine scenario. Accepting this, the original and modified distributions are shown below:

- Original distribution for quarantine sensitivity ~ Uniform (0.85, 0.95)
- Upper extreme distribution ~ Uniform (0.95, 0.99)
- Lower extreme distribution ~ Uniform (0.75, 0.85)

Table 24 provides a summary the original results, and those obtained when the model was re-simulated with each of the modified distributions for quarantine sensitivity alternatively substituted. It can be seen from this table that raising the values for quarantine sensitivity tended to lower the output distribution - in this case the release assessment - as should logically be the case. Likewise, lowering the value for quarantine sensitivity tended to raise the probability that imported commodity will be infected.

Given this, it can also be seen that there are many ways in which the results of the sensitivity simulations might be interpreted. Some of these are presented in Table 24 and will be discussed in the following section. Likewise, the cumulative distributions obtained from each of the three simulations are superimposed in Figure 27, where the arbitrary upper "acceptable" limit for the release assessment shows the relative security afforded and lost when quarantine sensitivity is systematically raised and lowered, respectively.

Table 24: Output from the stochastic live animals model, including original results and those obtained from the two sensitivity simulations

Statistics	Original simulation	Raised values for quarantine sensitivity[1]	Lowered values for quarantine sensitivity[2]
Minimum	1.13×10^{-5}	1.79×10^{-6}	3.01×10^{-5}
Maximum	3.20×10^{-4}	1.32×10^{-4}	5.63×10^{-4}
Mean	8.30×10^{-5}	2.49×10^{-5}	1.65×10^{-4}
Std Deviation	4.88×10^{-5}	1.63×10^{-5}	8.48×10^{-5}
Variance	2.38×10^{-9}	2.67×10^{-10}	7.18×10^{-9}
5^{th} percentile	2.61×10^{-5}	6.56×10^{-6}	6.18×10^{-5}
Mode	4.96×10^{-5}	1.91×10^{-5}	1.17×10^{-4}
95^{th} percentile	1.74×10^{-4}	5.44×10^{-5}	3.23×10^{-4}

Legend

1. Statistics for the output distribution obtained when quarantine sensitivity was modelled as uniform (0.95, 0.99)
2. Statistics for the output distribution obtained when quarantine sensitivity was modelled as uniform (0.75,

0.85)

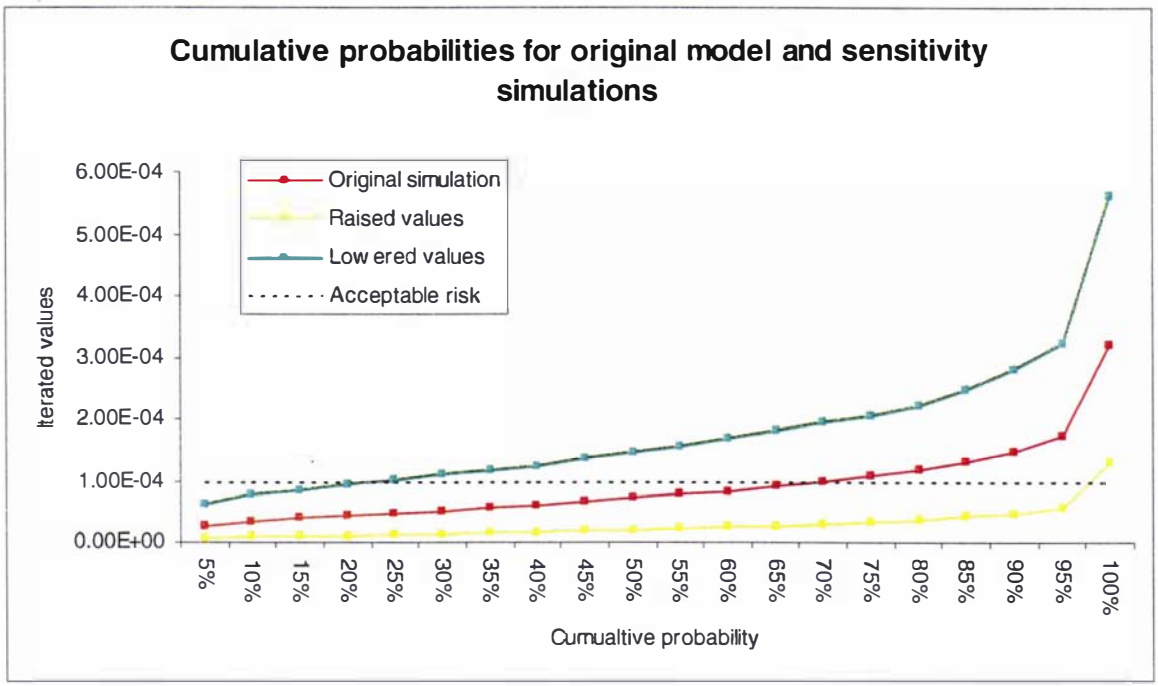
Table 25: A comparison between the results of the original simulation and those obtained when values for quarantine sensitivity were systematically raised and lowered

Statistics	Absolute difference[1]		Proportional change[2]	
	Raised - original values	**Lowered - original values**	**Raised/original values**	**Lowered/original values**
Minimum	9.51×10^{-6}	1.88×10^{-5}	0.16	2.66
Maximum	1.88×10^{-4}	2.42×10^{-4}	0.41	1.76
Mean	5.81×10^{-5} ($p<0.0001$)	8.24×10^{-5} ($p<0.0001$)	0.30	1.99
Std Deviation	3.25×10^{-5}	3.60×10^{-5}	0.34	1.74
Variance	2.11×10^{-9} ($p<0.0001$)	4.80×10^{-9} ($p<0.0001$)	0.11	3.02
5^{th} percentile	1.95×10^{-5}	3.58×10^{-5}	0.25	2.37
Mode	3.05×10^{-5}	6.78×10^{-5}	0.39	2.37
95^{th} percentile	1.19×10^{-4}	1.49×10^{-4}	0.31	1.86

Legend

1. The absolute value of the difference between the summary statistics derived for the original output distribution, and those obtained when quarantine sensitivity was modelled as either uniform (0.95, 0.99) or uniform (0.75, 0.85)
2. The proportional change in summary statistics between those derived for the original output distribution, and the statistics obtained when quarantine sensitivity was modelled as either uniform (0.95, 0.99) or uniform (0.75, 0.85)

Figure 27: Cumulative probabilities obtained from the simulation of the original model and from each of the two sensitivity simulations



5.4 Discussion

5.4.1 Research question 1

The supposition that differences might arise between the outcome of regression and rank order correlation based sensitivity analyses was borne out in results obtained for the first research question. The regression based procedure ranked each input variable according to its standardised partial regression coefficient, which is equivalent to a ranking based on the statistical significance of unstandardised partial coefficients when all the variables are simultaneously in the model. While useful as a data analysis tool, the disadvantage of this method in the context of import risk analysis model is the fact that it builds a linear additive model for the relationship between input and output variables and, furthermore, assumes that inputs are normally distributed. It can be seen that most import risk analysis models are multiplicative, or based or more complex algorithms, and that input distributions are often distinctly and deliberately non-normal.

The rank order correlation method, on the other hand, compares the sampling distributions obtained for each input variable with the distribution of the output, and ranks the inputs according

to the absolute magnitude of the Spearman's rank order correlation coefficients so obtained. The method is non-parametric and thus does not require inputs to be normally distributed. In addition, this method does not make any assumptions regarding the structure of the relationship between input and output variables. If there is a noticeable disadvantage to rank order correlation, it is the fact that no measures for the significance of each coefficient are provided.

Given the above, two key observations arose from this stage of the experiment. Firstly, it was noted that the @Risk® report for sensitivity analysis, while listing both partial regression coefficients and rank order correlation coefficients, bases its ranking on the former and does not draw attention to the fact that ranks derived from the correlations will be different. Obviously the tornado graphs generated by either method will illustrate the differences, but few analysts would derive two sets of graphs and may simply assume that the ranks obtained from each will be identical. The second key observation concerns the fact that while the ranks derived by each procedure were different, they were in fact quite highly correlated ($\rho = 0.90$). To further investigate this result, the complex model used for the analysis presented in PRRS2 NZ (PRRS2 NZ, 1998) was obtained, and the results of sensitivity analyses based on regression and rank order correlation once again compared. In this example, the correlation between the ranks obtained from either procedure was less ($\rho = 0.82$) but still substantial and an interesting result given the markedly different approaches and the fact that the PRRS2 NZ model was not only markedly non-linear, but contained a large number of heavily-skewed non-normal input variables.

Finally, the regression analysis was repeated for both the simple example model and the more complex PRRS2 NZ model using various approaches to multiple regression - that is, stepwise, step-up, step-down and full model analysis. While the results for this exercise were not tabulated, it appeared that the procedure used by @Risk® is based on the standard 'stepwise' multiple regression algorithm. This algorithm does not use 'tolerance' or an equivalent statistic as a means by which to select a subset of the original variables. This is an important result if the regression-based procedure is elected, since highly correlated or non-significant covariates with unstable partial regression coefficients are likely to be entered into the model, and may thus detract from the precision of the existing coefficients.

Conclusions: Research question 1

The conclusion to be drawn from this subgroup of demonstrations is that rank order correlation must be considered the most correct procedure to use for sensitivity analysis, given the

characteristics of most import risk analysis models. Accepting this, if sensitivity analyses are based on the multiple regression procedure, then the ranks obtained are likely to be similar to those obtained by rank order correlation.

5.4.2 Research question 2

In this stage of the experiment, input variables identified as 'influential' were included in the sensitivity simulations. It would appear from Table 23 that the input variables ranked 1-5 on either scale contributed similarly to the output and that the last three variables are less markedly significant. Quantitative methods are not generally used to determine the importance of variables in a sensitivity analysis although, for the regression-based analysis, the significance of t-tests for partial regression coefficients could be examined. Given this, p-values for the first five partial regression coefficients were less than 0.05, while those for the remaining three would not have been considered significant at this level.

Table 24 shows the statistics as obtained from @Risk® and it can be seen that, as expected, raising the sensitivity of quarantine has lessened the probability that imported commodity will be infected, and vice versa. Given this, the questions that must be answered however are either:

- Does raising or lowering quarantine sensitivity really alter the output from this model to a meaningful extent?
- Does raising or lowering quarantine sensitivity actually alter the acceptability of the importation scenario?

These questions will be discussed independently.

Comparing output distributions

In this situation, the analyst will be seeking the most appropriate means by which to compare the original distribution with that obtained by sensitivity simulation(s). It can be seen from Table 25 that a comparison may be based on demonstrating, A) that the absolute difference in particular statistics is negligible, or, B) that the ratio of a statistic derived from the original distribution to that derived from the sensitivity simulation(s) is not meaningfully different from 1. The choice of statistic cannot be standardised for all scenarios since in some cases analysts will be particularly interested in lower or upper percentiles, while in other cases means or other measures of central tendency may be reported. It should be noted, however that while statistical tests based on the

difference between means or variances may be performed with little difficulty, the sampling distributions for percentiles and for the range of ratios obtained when 'proportional change' is examined are less well known or documented. Given this, statistical tests for these measures will be more difficult to carry out and interpret.

An important subjective issue discussed in Evaluation III Part II and illustrated in Table 25 is the fact that in the absence of statistical tests, the various comparative measures may highlight or mask real differences between distributions, particularly if their values are extreme. For example, Table 25 shows that the absolute difference between the mean obtained from the original simulation and that obtained when quarantine sensitivity was raised was ostensibly negligible (5.81×10^{-5}), while the ratio of the same statistics is in fact quite substantial (0.30). The danger of misinterpreting a low absolute difference was further highlighted by the p-value (< 0.0001) for a non-parametric t-test carried out on the two distributions, which clearly indicates that the means of the distributions are indeed different. Other examples of this are evident in Table 25, illustrating the value of generating alternative comparative measures and carrying out statistical tests where practicable. Finally, the choice of a non-parametric statistical test was based on the observation that neither of the distributions was normal and the fact that their variances had been shown to differ significantly.

The conclusion reached was that 'subjective' assessments of the difference between the output of an original model and that obtained from sensitivity simulations should be undertaken with care. In the absence of statistical tests, several measures (absolute difference, proportional change, etc) should be derived and assessed simultaneously.

Using sensitivity simulations to determine the acceptability of an import protocol

In this situation, the objective of the analyst will be to determine whether raising or lowering the values of a particularly influential input variable(s) will alter the acceptability of an importation protocol. Two approaches may be adopted to answer this objective. In the first case, one-tailed statistical tests may be employed to determine whether the mean, mode or other statistics are significantly higher than the pre-determined 'acceptable risk'. This approach will be constrained by the difficulty inherent in conducting significance tests for percentiles, and the fact that percentiles are often favoured for reporting risk estimates over measures of central tendency as the shape of output distributions for risk estimates are generally unpredictable and heavily skewed.

The alternative to statistical tests is to plot the cumulative distributions for the original simulation and sensitivity simulation(s), and determine graphically the proportion of iterations that were less than or equal to the given acceptable limit. However, this approach, while intuitively sensible and easily undertaken, introduces a second level of subjectivity since analysts must determine the percentile below which the line of acceptability should fall. Typically, this will be the percentile reported for the original simulation, as was the approach adopted by the authors of the single identified stochastic analysis in which sensitivity simulations were reported (PRRS2 NZ, 1998). It can be seen, however, that there is no clear administrative boundary between, for example, the 5^{th} percentile and the 10^{th} percentile, and were the acceptable risk to lie above the 5^{th} percentile, it may be difficult to objectively declare the protocol or importation scenario to be too 'risky'.

The cumulative distribution method was illustrated in Figure 27. Here it was noted that while raising the sensitivity of quarantine led to a release assessment that was acceptable for at least 98 percent of the model's iterations, lowering the same variable implied that the risk would only be acceptable in approximately 25 percent of iterations. Indeed, in this example, were the 95^{th} percentile reported as a conservative statistic for the outcome risk, the results of the original simulation would not have been considered acceptable.

Conclusions: Research question 2

Many aspects of classifying input variables as influential or otherwise, and subsequently conducting and interpreting sensitivity simulations, are based on the subjective assessments of the individual analyst, and a need to determine the specific requirements of a given import risk analysis. Accepting this, the clear tabulation of results and the graphical display of cumulative distribution functions will aid in the transparency of the sensitivity analysis and, indeed, should enable analysts to carry out a sensible and valid investigatory procedure.

Chapter 3

Development and specification of a computerised expert system for import risk analysis

Contents

1 Introduction

In Chapter 2, aspects of import risk analysis were evaluated in the light of the changing trade environment, prevailing international guidelines and the range of approaches that have been developed by individuals or teams of analysts. These evaluations led to conclusions regarding the most robust approaches and methods, and those that are most consistent with the requirements of the WTO.

This chapter describes the design and implementation of HandiRISK (for Help with ANimal DIsease RISK analysis), an expert system for import risk analysis. Where possible, the approaches and methods represented in HandiRISK are based on the conclusions drawn from Chapter 2. HandiRISK was intended, however, to be a system that could be employed immediately by New Zealand MAF and, with minimal adjustment, by regulatory authorities worldwide. Given this, methods or approaches derived from new ideas or from experimental work carried out during this project were simplified, or substituted for the more familiar alternatives. It will be shown, however, that HandiRISK has a modular design and can be

upgraded or extended without significant disturbance to either the code or database design. It is envisaged that as new or experimental methods are peer reviewed they will be incorporated in the software, and will either replace the more simple approaches or be made available as alternatives.

In designing HandiRISK, the key objectives were to create a system that might enable analysts to carry out analyses efficiently and in a structured and methodologically sound manner, and to provide outputs that would help users to meet the WTO's requirement for transparency. In meeting these objectives, the most significant challenge was to design a system that was sufficiently generic as to allow analysts to model the importation of a wide range of animals and animal products. The system should also be sufficiently intelligent to enable import risk analyses to be carried out without the operator's personal interpretation of the many technical issues pertaining to import risk analysis.

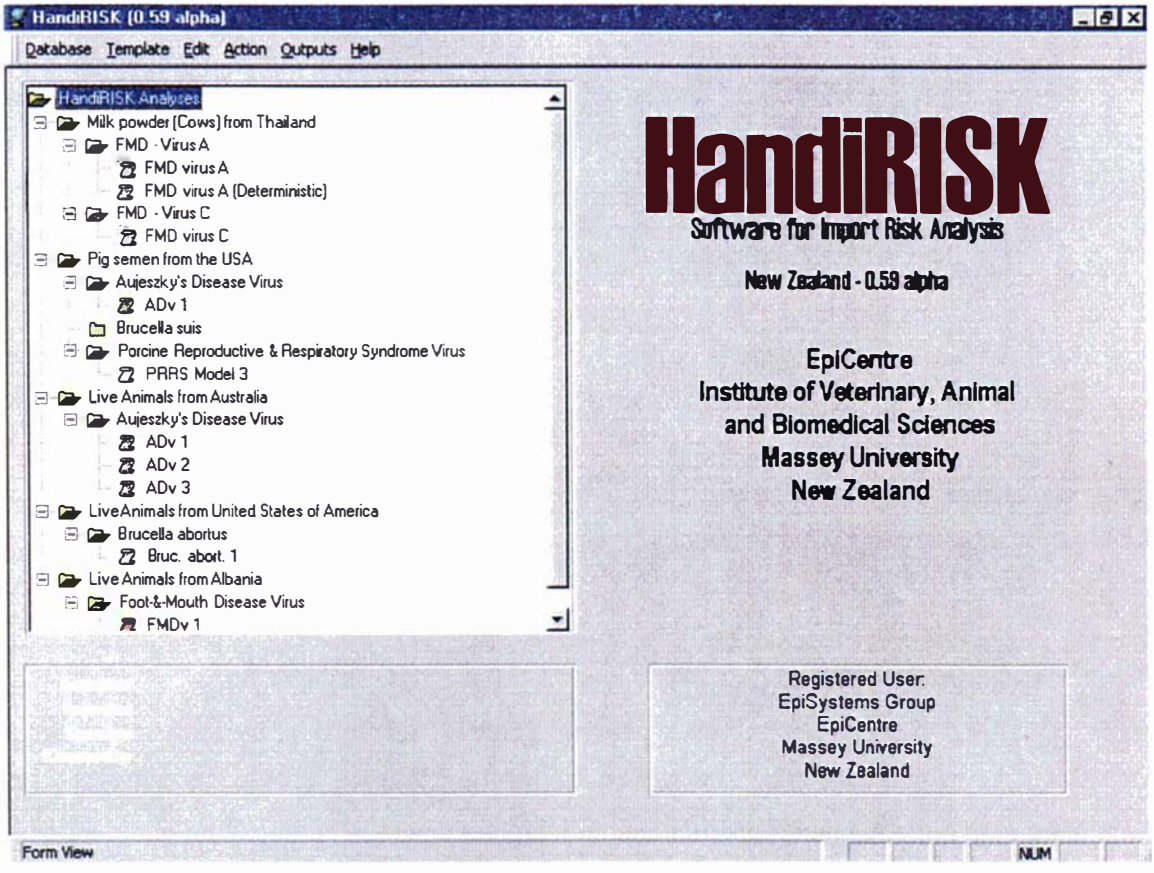
2 Interface elements

The user-interface or 'front end' of HandiRISK was designed to enable analysts to undertake import risk assessments in a structured, objective and repeatable manner, and to minimise the need to follow instructions or design 'wizards'. The user-interface is characterised by a single 'Home Screen' that contains the following interrelated functional systems:

- The model management system (MMS)
- The menu system
- The question-window interface

These elements are shown in the screen capture in Figure 28. The MMS rests in a scrollable window to the left of the screen, the pull-down menus appear at the top of the screen and the HandiRISK logo fills up the currently inactive question-window interface.

Figure 28: HandiRISK Home Screen - The model management system, menus and the question-window interface



2.1 The model management system

The MMS fulfils two fundamental roles in the functionality of the HandiRISK Home Screen. Firstly, it provides a structural representation of the libraries of model templates and import risk analyses available within the HandiRISK database. Secondly, the MMS provides a platform of primary 'selectable' objects from which the context-sensitive menus may be generated and the system's operational features performed.

The MMS was designed to resemble and operate in a similar manner to the standard Windows™ expanding and collapsing 'tree and branch' folder system. This structural representation is shown in the screen capture in Figure 28. Where a branch's end point is a model instance, the icons described below indicate whether that model instance is qualitative or quantitative, whether data entry has been completed, and whether the model has been 'run'. This feature was intended to aid the general philosophy that the Home Screen should at all time be interpretable to analysts,

without the use of help-files or manuals:

- A red scroll indicates that data entry for the selected model is incomplete
- A blue scroll with an asterisk above a indicates that data entry for the selected model is complete, but that the model has not been run
- A green scroll indicates that data entry for the selected model is complete and that the model has been run

Where the definitive final unit is a model template, the icon will always be a yellow scroll. Whenever a functional unit of the MMS has been selected, a brief description of that unit appears in the summary screen at the base of the MMS window.

2.2 The menu system

Two systems of context-sensitive menus have been implemented in the Home Screen of HandiRISK:

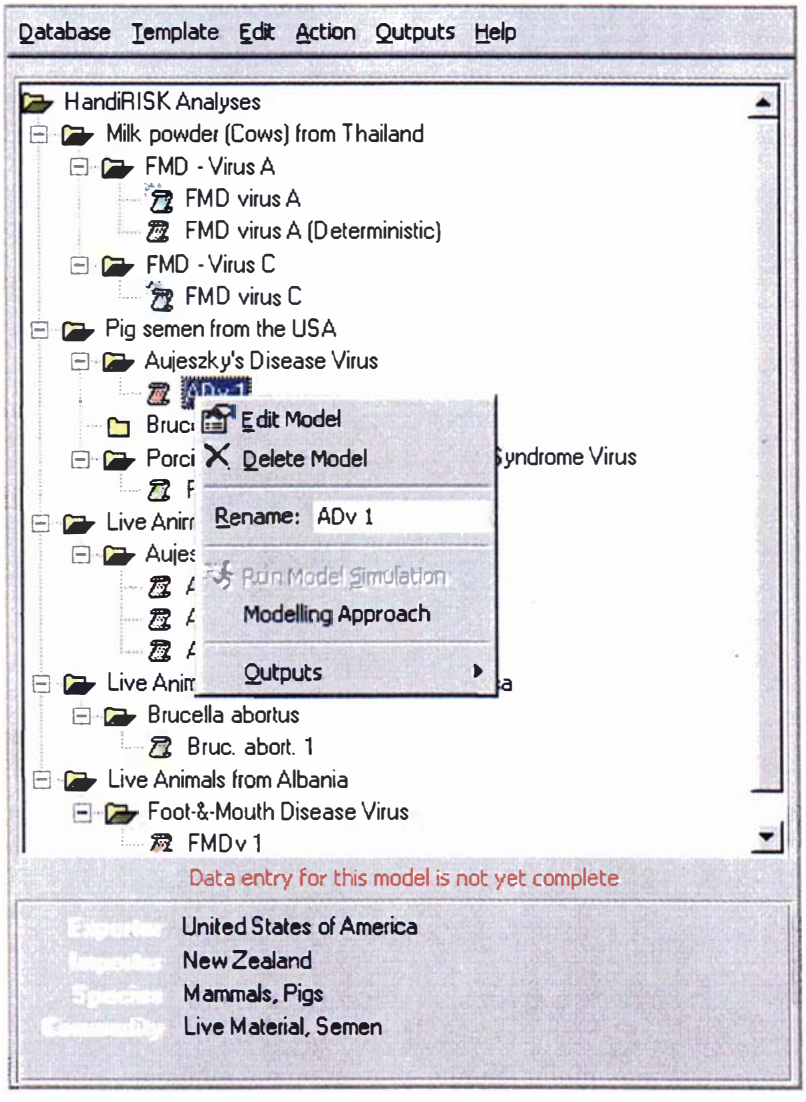
- Right-mouse-click menus
- Pull-down menus

While the range of functions performed by each of these groups of menus is essentially the same, they operate from different but complementary perspectives and, as such, enable operations to be carried out in an environment that is maximally intuitive.

2.2.1 Right-mouse-click menus

These menus are generated by selecting an item within the MMS, and using the usual Windows™ right click convention. An example of a right-mouse-click menu is shown in the screen capture in Figure 29.

Figure 29: Right-mouse-click menu generated when an incomplete model is selected from the model management system (MMS)



The range of right-mouse-click menus is shown below.

Model template branch

Select .. TEMPLATES

3 New template

3 Import template

3 Close

Select .. PAE/PDE

3 New template

3 Close

Select .. QUANTITATIVE/QUALITATIVE

3 New template

3 Close

Select .. BATCHED COMMODITY/INDIVIDUAL UNITS

3 New template

3 Close

Select .. INDIVIDUAL TEMPLATE

3 Edit template

3 Rename template

3 Delete template

3 Export template

Import risk analyses branch

Select .. ANALYSIS

3 Expand analysis / Collapse analysis

3 Add new agent(s)

3 Delete analysis

3 Rename analysis

Select .. 3 Outputs

Select .. 3 Reports

Select .. 3 Comprehensive Report

3 All agents and models

3 Specify agents and models

Select .. 3 Summary Report (where at least one quantitative model run)

3 All agents and models

3 Specify agents and models

Select .. AGENT

3 Expand agent / Collapse agent

3 Add new Model

3 Delete agent

3 (Add / Edit) consequence analysis

Select .. 3 Outputs

Select .. 3 Reports

Select .. 3 Comprehensive Report

3 All models

3 Specify models

Select .. 3 Summary Report

3 All models

3 Specify models

Select .. MODEL (QUALITATIVE)

3 Edit model

3 Delete model

3 Rename model

3 Run model simulation

3 Modelling approach

Select .. 3 Outputs

Select .. 3 Reports

3 Comprehensive Report

Select .. 3 Pathway diagrams

3 Influence diagram

3 Decision pathway diagram

3 Scenario pathway diagram

Select .. MODEL (QUANTITATIVE)

3 Edit model

3 Delete model

3 Rename model

3 Run model simulation

3 Modelling approach

Select .. 3 Outputs

Select .. 3 Tabulated reports

3 Comprehensive Report

3 Summary Report

Select .. 3 Pathway diagrams

3 Influence diagram

3 Decision pathway diagram

3 Scenario pathway diagram

Select .. 3 Output distributions

3 Probability density plot

3 Cumulative density plot

Select .. 3 Sensitivity analysis

Select .. 3 Correlation

3 Statistics

3 Tornado diagram

Select .. 3 Regression

3 Statistics

3 Tornado diagram

2.2.2 Pull-down menus

Based on their function, the pull-down menus in HandiRISK may be divided into two groups. The first group provides users with an alternative means for creating and modifying analyses, disease agents and individual models and for generating the various outputs provided by HandiRISK. These features are identical to those of the right-mouse-click menus of the MMS. The second group are utility menus, designed to be similar to the 'File' and 'Edit' menus commonly found in Windows™ applications, and allow the user to open and close databases, import templates, edit text, control printer setup features, etc.

The six pull-down menus available in HandiRISK include:

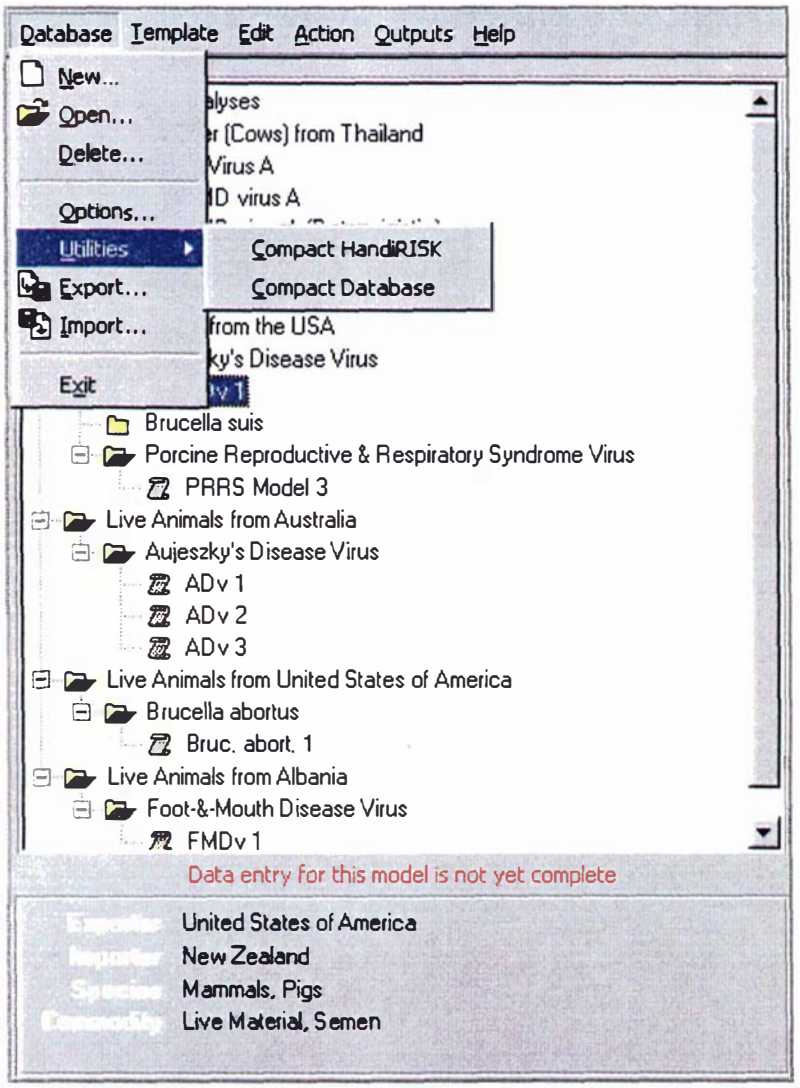
- Database

- Template
- Edit
- Action
- Outputs
- Help

Database menu

The Database menu is designed to replace the File menu. The File menu is featured in most Windows™ applications and controls many of the top-level properties or features of the active 'file'. In HandiRISK, the active file is the database of model templates and risk analyses. The Database menu (Figure 30) enables users to create new databases, to open or delete a database, to import or export a database, and to perform various system maintenance tasks such as compacting and repairing a database, should they be required.

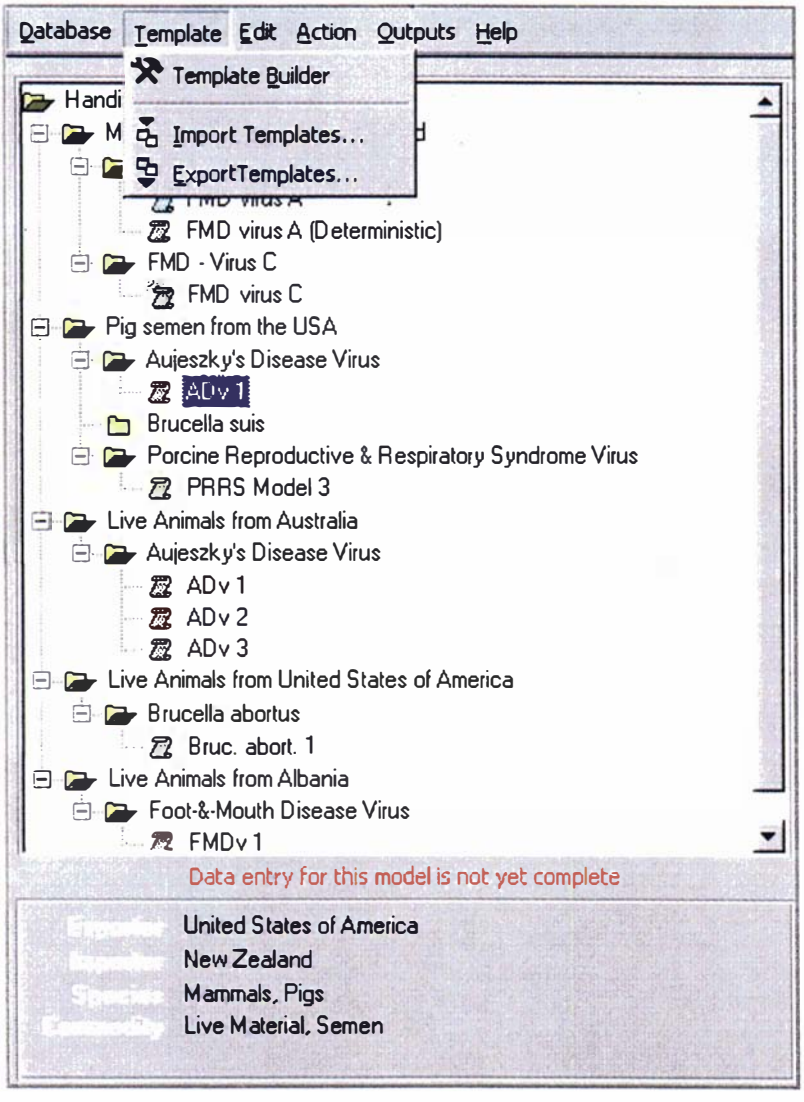
Figure 30: Database pull-down menu



Template menu

The Template menu (Figure 31) gives the user access to the template-building engine (see, Section 3.2.2) and enables the import and export of model templates. The Template menu is context-sensitive and gives the user access to functions available from each level of the template branch of the MMS. Context-sensitivity is displayed by substituting key words in the menu options and by greying out those not applicable. The alternatives available to user at each level of the template branch of the MMS are identical to those described in the preceding discussion.

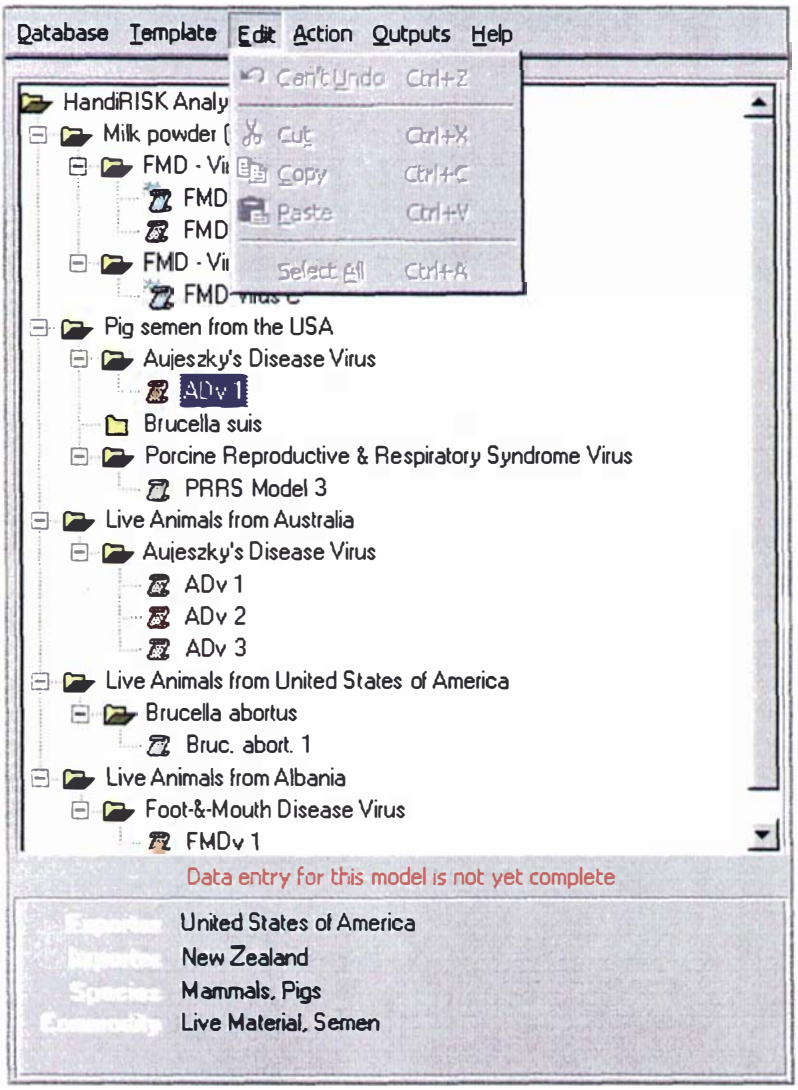
Figure 31: Template pull-down menu



Edit menu

The Edit menu (Figure 32) is the least specific to HandiRISK and, in many respects, is included to continue the interface characteristics that Windows™ users expect to see. That is, the Edit menu enables the user to cut, copy or paste text and to perform the usual select and undo procedures.

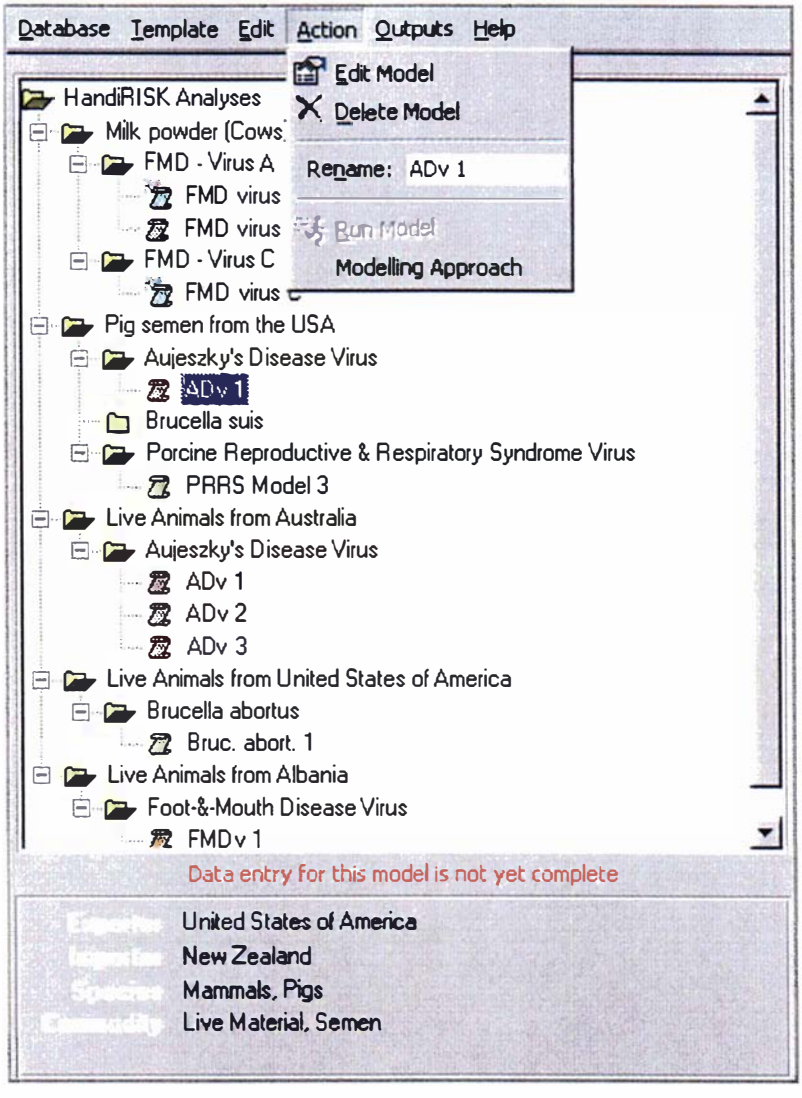
Figure 32: Edit pull-down menu



Action menu

The Action menu (Figure 33) is context-sensitive and enables the user to perform operations on analyses, agents or individual models. Context-sensitivity is linked to the level of the MMS selected when the menu is opened, and is displayed by substituting key words in the menu options and by greying out those not applicable. Alternatives available to the user when each level of the MMS is selected are identical to those described for the MMS in the preceding discussion.

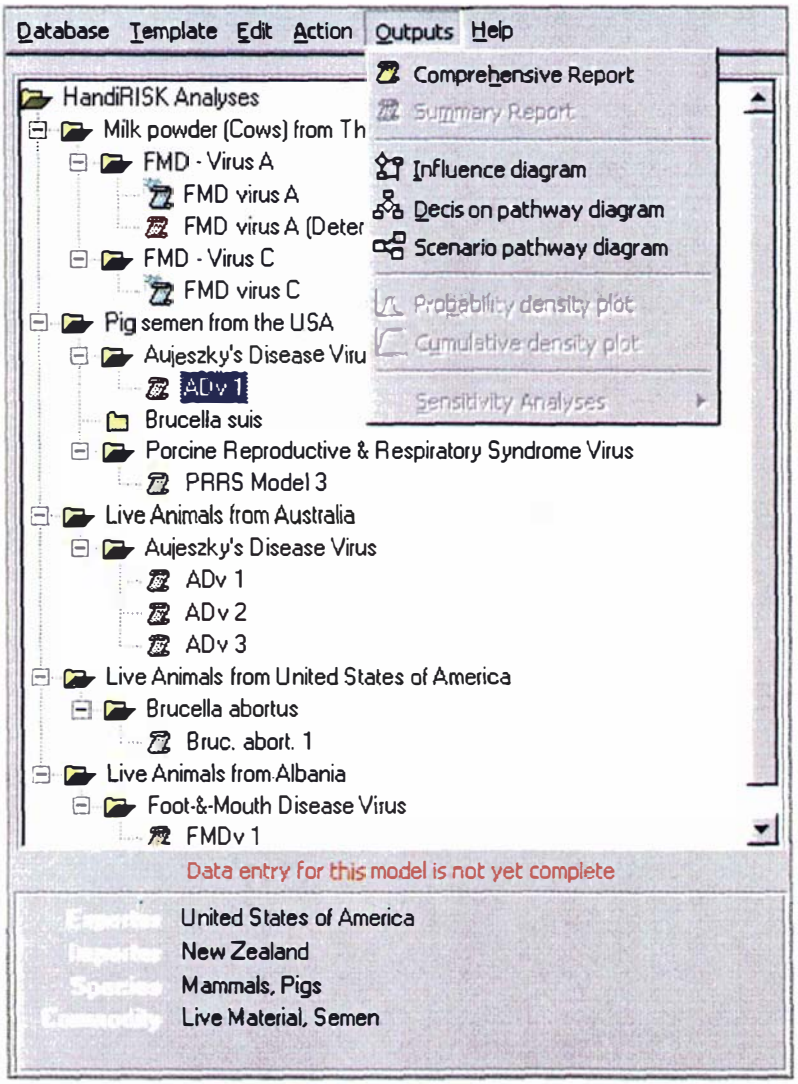
Figure 33: Action pull-down menu



Outputs menu

The Outputs menu (Figure 34) is also context-sensitive and is used to generate the outputs available when various components of the MMS are selected. Context-sensitivity is achieved by greying out unavailable menu options and, as above, the alternatives available to the user when each level of the import risk analysis branch of the MMS is selected are identical to those described in the previous section.

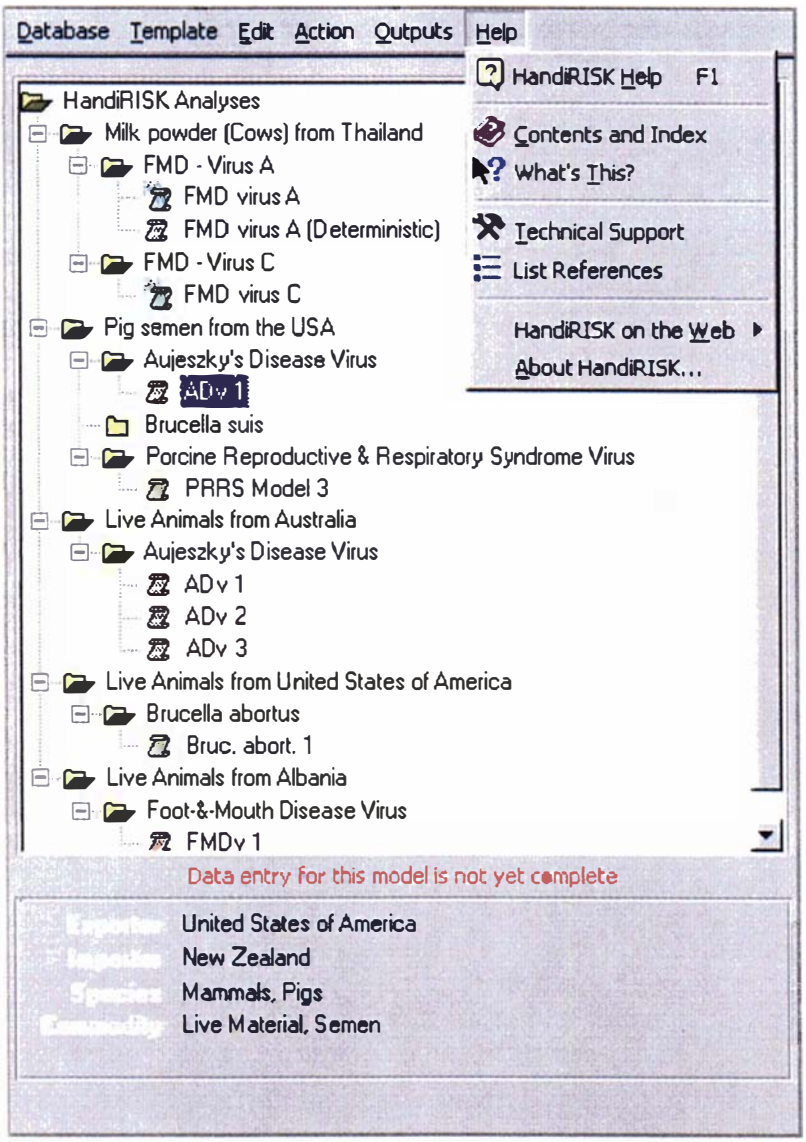
Figure 34: Outputs pull-down menu



Help menu

The help menu (Figure 35) provides the user with further information about the program. The Help menu will be extended to include a table of contents, search features and context-sensitive help, as the program is adapted for a wider group of users.

Figure 35: Help pull-down menu



2.3 The question-window interface

The question-window interface is the dynamic area on the right hand side of the Home Screen in which most operations are performed. Typically these include the systematic completion of each phase undertaken in defining and carrying out an import risk analysis, or the activities generated by the wizard-based environment within which model templates are created or edited. When the system is inactive, as it is in the screen captures in the figures above, the question-window interface simply contains summary information regarding HandiRISK.

3 System design

HandiRISK was implemented in the database environment provided by Access 97 (Microsoft Corporation, Redmond WA, USA). The system was modelled using the object-orientated paradigm (Yourdon, 1994; Lano, 1995), although implemented procedurally using the tables, queries, code modules and macros supported by Access 97.

3.1 Database design

The schematic design diagram shown in Figure 36 illustrates the fundamental components of the HandiRISK system database. The system engines are coded routines that enable the knowledge base and data tables to interact and thus carry out the essential functions of HandiRISK. For example, the model running engine collects the data entered for a particular model instance and creates a text string which, if the model is stochastic, is subsequently passed to the simulation engine. Once the simulation has been completed, the model running engine collects the simulation results, stores them in the simulation results table and signifies to the MMS that the model instance has been 'run'. The icon denoting this model instance is then changed from a blue scroll with an asterisk to a green scroll, as described in the preceding section.

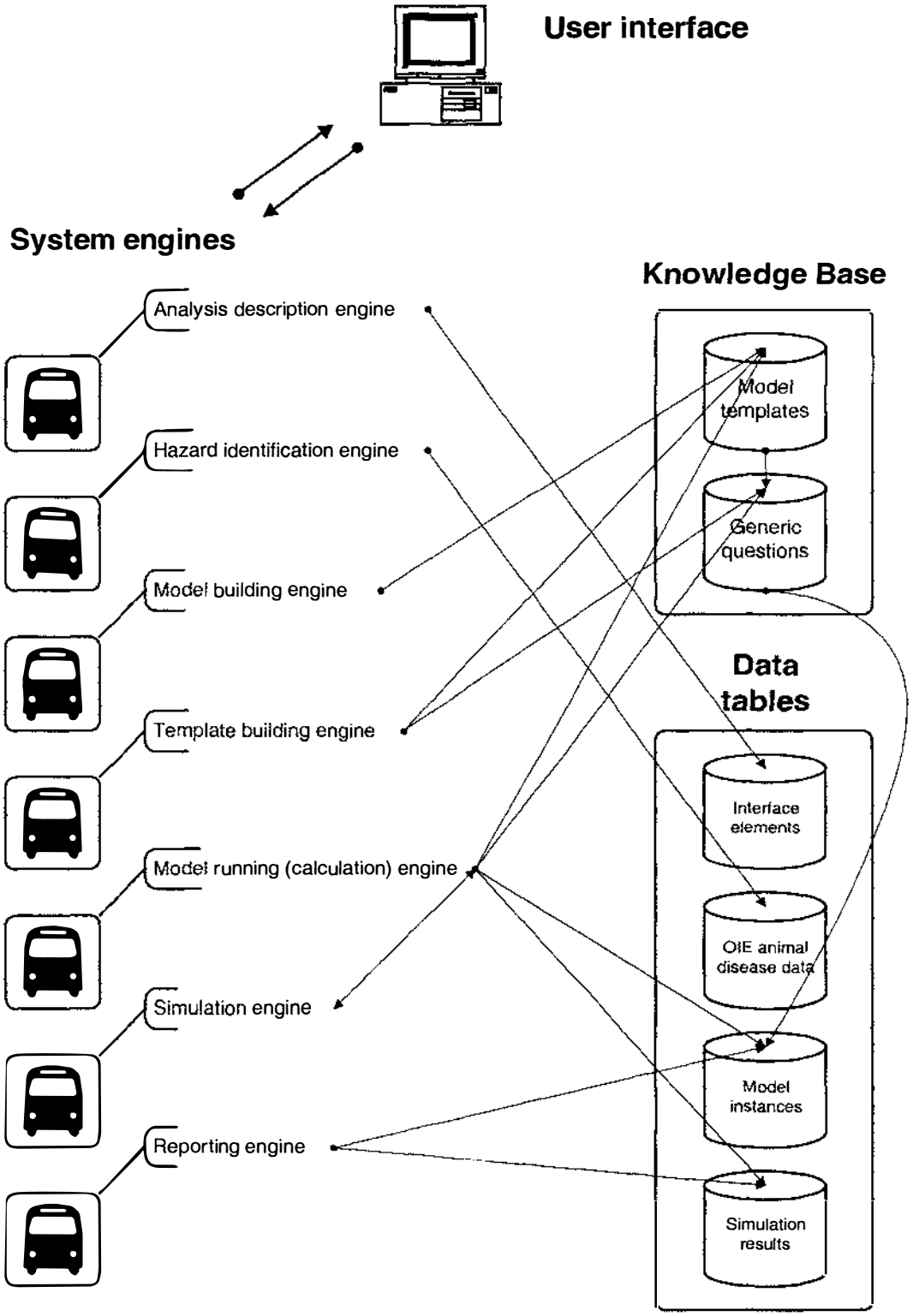
HandiRISK is an expert system and, as such, must contain a 'knowledge base' (Beerel, 1987; Sallis et al, 1993). The HandiRISK knowledge base entails two separate entities; the generic questions and the model templates. With the assistance of various system engines, these two functionally distinct units interact with each other and enable the analyst to produce individual risk analysis models.

Finally, HandiRISK contains a large number of data tables in an integrated relational database. These tables enable either the temporary or permanent storage of information, including expert knowledge, the data collected for individual model instances and the results obtained from models that have been run. HandiRISK also contains an extensive range of minor system tables that contain, for example, substituted text strings, global variables and animal-health data from the OIE.

In summary, HandiRISK is based on functional elements linked in a system that, although conceptually simple, performs many very complex functions. The specification and implementation of each functional element were extremely complex processes. It is not the objective of this thesis to describe in detail these technical aspects of HandiRISK, and suffice it to

say that the system contains various utility features that enable the user to interact with the knowledge base and produce highly structured and technically sound import risk analyses.

Figure 36: Design of the HandiRISK system database



3.2 Knowledge based design

Knowledge representation has been defined (Beerel, 1987) as:

"*... a way of structuring the knowledge in a knowledge base in a manner that suitably replicates human problem solving ...*"

Where a knowledge base was, in turn, considered to be:

"*... the information held in an expert system that constitutes its expertise ...*"

In the context of HandiRISK, the knowledge base equates to the components of the system, which contain information regarding standardised procedural approaches and methodologies for import risk analysis.

One of the concerns expressed early in the conceptualisation and development of this computerised system was the fact that importation scenarios are extremely diverse. In order for such a system to be useful, it must therefore be flexible enough to enable an analyst to model scenarios at least as accurately as could be achieved by the conventional manual approaches (MacDiarmid, pers comm 1997). In order to achieve this degree of flexibility, it was determined that the HandiRISK knowledge base should include the following facilities:

- The ability to choose between the use of flexible 'generic model templates' and constructing models from first principles using 'model-building tools'
- The ability to specify separate approaches to modelling the release and exposure assessment
- The ability to model an importation scenario quantitatively or qualitatively
- The ability to consider importation scenarios based on either batched commodities or individually handled units

The HandiRISK knowledge base was constructed from two fundamental and interrelated entities:

- Generic questions
- Model templates

While these elements were implemented procedurally in the HandiRISK database as data tables

linked by coded modules, both were designed and specified in accordance with the principles of the object-orientated paradigm (Pressman, 1992; Yourdon, 1994; Lano, 1995). This approach dictates that objects belong to a hierarchical system of classes, such that those in any one class share a set of attributes and methods and automatically pass these to objects in a lower class - a principle termed inheritance. Furthermore, objects may be characterised as discrete encapsulated units that may be altered without impacting on remaining elements in the system (Yourdon, 1994; Lano, 1995).

Considered together, the principles of object-orientated representation imply that information may be efficiently represented in a system with a minimum of repetition, and may be modified or extended in a modular fashion without damaging the logic of the code (Yourdon, 1994). These characteristics are very important to an expert system such as HandiRISK which was designed to demonstrate the potential for a computerised approach to import risk analysis, and was constructed iteratively through a series of prototypes - features which translate to a fundamental requirement for ease of adaptability.

3.2.1 Generic questions

The term 'generic question' was coined to denote an encapsulated and self-contained object within the knowledge base, that could generate interface elements. These elements could be used to prompt the user to provide information regarding a discrete issue (for example, quarantine, the selection of animals from a herd, testing of groups of animals, etc) and to store the data as a labelled record in a data table. Interface elements could also be used to perform any calculations required and to interact with other questions or the model template so as to facilitate the completion of model instance. Generic questions may be *instantiated*, or activated, by a message sent from either a model template or from another generic question and, in turn, may instantiate other generic questions in order to obtain the data they require.

As a simple example, the 'TEST1' question collects the name and characteristics of a diagnostic test. In order to complete this task however, the TEST1 question twice calls the 'VALUE' question (through which all numeric data is entered), which in turn calls the REF question since all data entered in HandiRISK must be referenced. The result of the procedure is that test sensitivity and specificity, and references for each, are obtained from the user and stored within each question's data table. Where this data was requested by another question (as is the case for both the TEST1 question and each instance of the VALUE question) that original question simply

stores a reference to the record number of the question table in which the data resides.

This system may be conceptualised as a pool of discrete units which are sufficiently intelligent to interact with each other, or with a model template, in a manner that can be mapped retrospectively as a single model instance. The system is unique, and given the huge number of permutations and combinations that may be described by even a relatively small number of generic questions, is evidently a very powerful means by which the level of flexibility required by import risk analysts may be obtained. In addition to this, the fact that each question is discrete and encapsulated implies that it may be altered or updated as required without seriously disturbing the system and, likewise, that new questions may be added.

In accordance with object-orientated terminology, each generic question was considered to be derived from the following fundamental attributes and methods:

Attributes

- A form, which describes the question's class-specific elements and is necessary for visual display and data entry
- A data table, which is implemented in a separate section of the data base but linked directly to the question

Methods

- A state machine which is essentially a routine or list of sequenced methods and logical operations, is stored as an Access module and is performed by the question

In addition to object-orientated properties, the generic questions coded in HandiRISK contain embellishments that enable the system's knowledge base to operate more efficiently, and with more intuitive user-interface elements. These features included:

- Global flags
- Substituted text strings
- Substituted key words
- Substituted variables
- Question classification

Global flags

Global flags are pieces of code attached to model templates (as described in the following section) which, when selected, populate a global variables table that may be referenced by each question so as to inform it as to whether the current model is qualitative or quantitative. Most generic questions have both qualitative and quantitative components. While, the extent of differences between these components will in some cases be minor, it will always be imperative that the question is able to 'look up' the global variables table and determine the nature of the current model instance, if only so as to phrase data entry or decision questions to the user in a form that is appropriate for either qualitative or quantitative models. Examples of the use of global flags and difference between qualitative and quantitative question statements and calculations are provided in the annex to this chapter.

Substituted text strings

Some generic questions require substituted text strings to be sent from the instantiating question or the model template. These strings are inserted into existing text fields and appear in the statements posed to users on-screen, and in the responses cited in the comprehensive report. Notably, the 'VALUE' question, the means by which both quantitative and qualitative data is entered and stored in HandiRISK, prompts the user using text strings sent by the instantiating question.

Substituted key words

In addition to substituted text strings, many of the generic questions contain substituted key words or phrases which enable the question prompts presented to users to be maximally relevant to each importation scenario. Key words are stored in a table within the HandiRISK database which may be cross-referenced with the characteristics of the current model template, thus enabling each instantiated generic question to obtain a word relevant to the given importation scenario. This approach was chosen so as to reduce textual ambiguity, to increase the general ease of working through a computerised analysis and to enhance the transparency of the various outputs generated by the system.

Examples key words are provided in Table 26 below. Taking the first of these - the key word 'AGENT' - as an example, it can be seen that through this system, an instantiated question is able to present to the user a question prompt that includes the precise disease-causing agent for which

the model has been created. This will be considerably more intuitive than a statement including the words 'disease-causing agent', particularly since the user will be required to answer many such questions through the course of completing a given model instance. Extending the principle to other key words such as 'ANIMAL' or 'GROUP' will illustrate the power of the system as a means by which the truly 'generic' questions in the HandiRISK knowledge base can also be truly specific.

Table 26: Key words included in the HandiRISK knowledge base

Key word	Definition
AGENT	Designates the name of the disease-causing agent (eg PRRS-virus, FMD-virus etc)
ANIMAL	Designates the global name of the species to be imported or from which a commodity (eg genetic material) will be derived (eg PIG, COW etc)
COMMODITY	Designates the commodity to be imported (eg semen, ova, live animals etc)
COMMODITY_UNIT	Designates the individual unit to be imported (eg a 'straw of semen')
COMMODITY_BATCH	Designates the collective term for a batch of import units (eg 'straws of semen)
EXP_COUNTRY	Designates the exporting country
IMP_COUNTRY	Designates the importing country
DISEASE	Designates the common name for the disease produced by the agent (eg PRRS)
DONOR	Designates the gender-specific term for the donors genetic material to be imported (eg BOAR, COW etc)
FEMALE	Designates the female of the species described by ANIMAL
GROUP	Designates the collective name for a given species (eg HERD, FLOCK)
GROUP2	Designates a special instance such that the name given to any group of animals is determined not by their species, but by their location (eg QUARANTINE GROUP, COLLECTION CENTRE GROUP, GROUP OF RECIPIENTS etc)
HANDLING	Designates whether the commodity is handled as a 'batched consignment' or as 'independent units'
MALE	Designates the male of the species described by ANIMAL
RECIPIENT	Designates the gender-specific term for the recipient of genetic material (eg COW, SOW etc)
SYSTEM	Designates whether the production system is group (eg herd) -based, or based on the 'small-holder' village system where animals are either managed individually or in small groups

Substituted variables

Substituted variables are abbreviated and intuitive strings that describe variables likely to be referenced frequently during data entry for a given model. Generic questions that require commonly referenced variables (for example, the number of units in a batched consignment) contain methods that enable them to search the 'substituted variables table' for the relevant entry and, if available, to substitute it as the answer for a given sub-question. Where the required variable has not previously been provided, the generic question prompts the user, collects the response, labels it using the standard string and stores it in the substituted variables table. Subsequent instances of this or any other question may obtain the result and substitute it automatically without the user re-entering the data. In addition, since all data entered in HandiRISK must be referenced, this information is also stored in the substituted variables table with the link to the data intact.

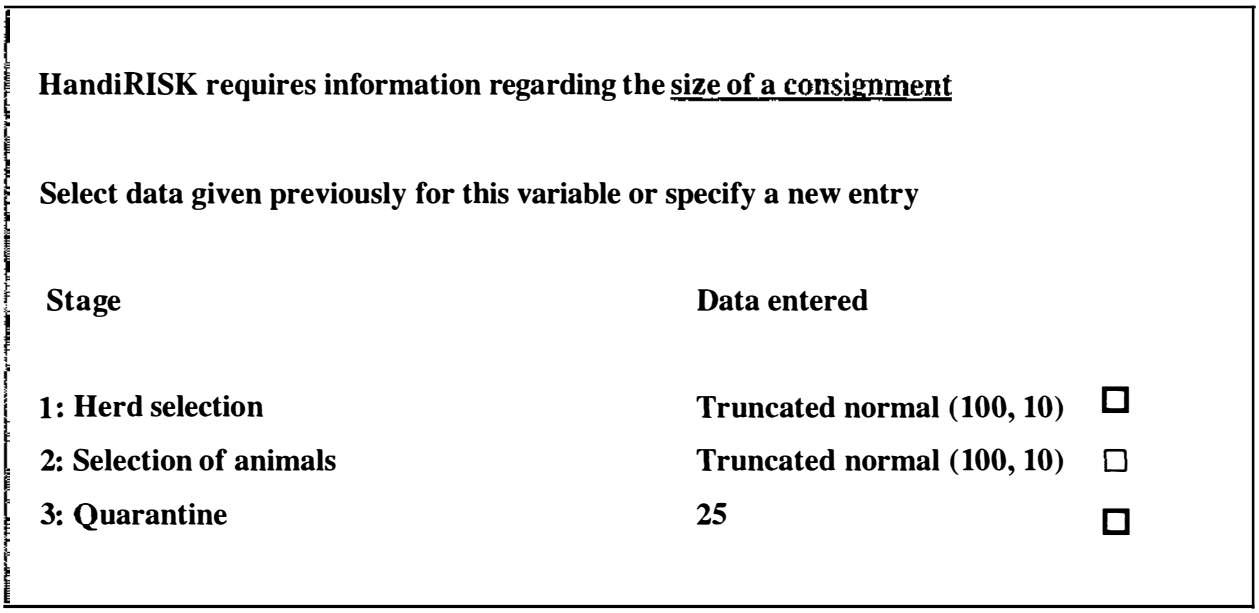
Substituted variables thus enable HandiRISK to perform the following functions:

- Minimise data entry and the risk of data entry errors (particularly with regard to bibliographic references)
- Decrease the potential for users to accidentally describe a single variable differently at various stages of a model
- (*stochastic models*) Allow a simulation to run using a sample taken from a single random variable (cf replicated sampling of a variable wherever it appears in a model)

HandiRISK never substitutes a local variable as a question response without first notifying the user and allowing the logic to be overridden with an independent data entry. Furthermore, where a variable has been overridden, both the new value and that entered previous are stored and displayed to the user when the local variable is next required.

An example of the format and information presented to the user is shown in Figure 37. The quantitative local variable is called 'BATCH_SIZE-quant', and describes the number of individual units in a consignment. It can be seen that the variable was first entered during stage 1 (Herd selection) and reused in stage 2 (Selection of animals). At stage 3 (Quarantine), however, the variable was altered and thus the user now is presented with two options:

Figure 37: The user interface for substituted variables



In addition to these fields, the substituted variables table records the identification of each instance of a question or sub-question that either enters or requests a piece of data. These references enable the 'calculation engine' (see, Section 3.1) to read a model instance and create necessary links such that a given piece of data need not be replicated unnecessarily. In the case of quantitative stochastic models, this means that the simulation module will only receive a single set of distribution parameters for a given variable. Calculations will be performed by referring across all questions to this variable. In effect, this recreates the familiar 'cell referencing' system adopted in spreadsheet-based simulations.

Substituted variables stored and referenced in HandiRISK are shown in Table 27.

Table 27: Substituted variables stored and referenced by HandiRISK

Variable name	Description	Instantiating question(s)
CLINIC_SENS-quant	The probability that an animal infected with disease will be detected during clinical examination	CLINIC1.1
CLINIC_SPEC-quant	The probability that an animal not infected with disease will be declared uninfected following clinical examination	CLINIC1.2
CLINIC_SENS-qual	The likelihood that an animal infected with disease will be detected during clinical examination	CLINIC1.3
CLINIC_SPEC-qual	The likelihood that an animal not infected with disease will be declared uninfected following clinical examination	CLINIC1.4
BATCH_SIZE-quant	The number of animals in a consignment	CLINIC2.1 GROUP2.2 INDIV2.1 SMALL_HOLD2.2 TEST2.1
BATCH_PREV-quant	The prevalence of infected animals in a consignment	CLINIC2.2 INDIV2.2 TEST2.2
GROUP_PREV-quant	The prevalence of infected animals in a GROUP	INDIV1.1
NO_RECIPS-quant	The number of recipients of genetic material from a given donor	INF_RECIP1.1
TEST_SENS-quant	The probability that a test will fail to correctly classify an infected animal	TEST1.2
TEST_SPEC-quant	The probability that a test will fail to correctly classify an uninfected animal	TEST1.3
TEST_SENS-qual	The likelihood that a test will fail to correctly classify an infected animal	TEST1.4
TEST_SPEC-qual	The likelihood that a test will fail to correctly classify an uninfected animal	TEST1.5
TEST_BATCH-qual	The likelihood that a test will correctly classify an infected batch	TEST2.6

Question classification

Question classification is, as the name suggests, a means by which the discrete classes of generic questions may be identified. The class system forms an integral component of object-orientated knowledge representation as it enables common characteristics (attributes and methods) to be inherited from a parent object to subsequent 'offspring' - that is, new questions of that class

(Yourdon, 1994; Lano, 1995). This is in fact a central advantage from the perspective of implementation since the specification of a question class and the implementation of a single parent question implies that subsequent questions may be created from this shell relatively quickly and easily. Indeed, if each of the generic questions encoded in this prototype of HandiRISK were to have been implemented without the use of question shells, the process would probably have been considered untenable, given the allocated resources and time frame.

Four question classes were encoded in HandiRISK Version I (Table 28):

- Interventions (I)
- Simple probabilistic questions (S)
- Composite questions (C)
- Utility questions (U)

In addition to object-orientated considerations, the categorisation of generic questions provided a means by which the 'model-running engine', as described briefly in the previous section, could recognise questions of a given class and adjust its calculation algorithm accordingly.

Table 28: The name, description and classification of generic questions included in HandiRISK Version I

Question name	Question objective	Question classification1 (I/C/S)
CLINIC1	To record or estimate the probability that an ANIMAL infected with DISEASE will not be identified by clinical examination	I
CLINIC2	To obtain the information necessary to determine the PROBABILITY that a consignment of ANIMALS infected with DISEASE will not be identified as such following clinical examination	I
CLINIC3	To obtain the information necessary to determine the PROBABILITY that a group of independently selected and handled ANIMALS, in which at least one is infected with DISEASE, will not be identified as infected following clinical examination	I
COLL_CENT1	To obtain the information necessary to determine the likelihood that procedures within a controlled semen collection centre will fail to identify infection within a group of DONORS	I

Question name	Question objective	Question classification1 (I/C/S)
COLL_CENT2	To obtain the information necessary to determine the likelihood that procedures within a controlled embryo collection centre will fail to identify infection within a group of DONORS	I
COLL_CENT1_PRELIM	To record details regarding the assumptions on which the effectiveness of procedures applied within a semen collection centre are based	U
COLL_CENT2_PRELIM	To record details regarding the assumptions on which the effectiveness of procedures applied within an embryo collection centre are based	U
EMB_CONT1	To obtain the data necessary to determine the probability that at least one embryo from an individually selected DONOR will be contaminated	C
EMB_CONT2	To obtain the data necessary to determine the probability that at least one embryo from a batch of DONORS will be contaminated	C
GROUP1	To obtain the information necessary to determine the PROBABILITY that a source group of ANIMALS is infected, given each specific choice of GROUP-selection strategy	C
GROUP2	To obtain the information necessary to determine the PROBABILITY that at least one infected GROUP will be selected while obtaining ANIMALS for the consignment	C
GROUP_PRELIM1	To determine the appropriate group-selection strategy for the given country or region	U
GROUP_PRELIM2	To determine the appropriate group-selection strategy for the given country or region	U
INDIV1	To obtain the information necessary to determine the PROBABILITY that at least an ANIMAL selected at random from a GROUP is infected	C
INDIV2	To obtain the information necessary to determine the PROBABILITY that at least one ANIMAL selected from a GROUP is infected	C
INF_RECIP1	To obtain an estimate for the probability that at least one recipient will in turn be infected and develop clinical signs of disease	C
INF_RECIP2	To obtain an estimate for the probability that at least one recipient of commodity from an infected consignment will in turn be infected and develop clinical signs of disease	C
MEAT_PROC	To obtain the information necessary to estimate the probability that AGENT within meat or meat products will not be inactivated by processing	S

Question name	Question objective	Question classification1 (I/C/S)
MONIT1	To obtain the information necessary to determine the PROBABILITY that monitoring will fail to detect DISEASE in a single recipient GROUP	C
MONIT2	To obtain the information necessary to determine the probability that the monitoring will fail to detect infection in at least one recipient GROUP	C
POST_ENTRY1	To obtain information necessary to determine the PROBABILITY that post-entry certification of infected ANIMALS will fail to detect infection	C
POST_ENTRY2	To obtain information necessary to determine the PROBABILITY that post-entry certification will fail to detect an infected consignment of ANIMALS	C
POST_ENTRY3	To obtain information necessary to determine the PROBABILITY that post-entry certification will fail to detect an infected batch COMMODITY_UNITS	C
PRE-PROC	To obtain the information necessary to estimate the PROBABILITY that pre-processing chilling and storage will fail to inactivate AGENT	S
PRE-SLAUGHT	To obtain the information necessary to determine the PROBABILITY that pre-slaughter clinical examination and/or testing will not detect an infected ANIMAL	S
PROPH_TREAT	To obtain the information necessary to estimate the probability that prophylactic treatment of processed genetic material (semen or embryos) will fail to inactivate infectious AGENT	S
QUAR	To obtain the information necessary to determine the PROBABILITY that quarantine will fail to identify infection within a group of ANIMALS	C
QUAR_PRELIM	To record details regarding the assumptions on which the effectiveness of quarantine is based	U
REF	To obtain information necessary for generating references in the comprehensive report	U
RISK_EST	The RISK_EST question is instantiated when a user 'runs' a model	C
SEM_CONT	To obtain the information necessary to estimate the PROBABILITY that semen will become contaminated with infectious AGENT during the process of collection	C
SENT	To obtain the information necessary to determine the PROBABILITY that housing or managing an infected group of ANIMALS with susceptible sentinels of the same species will not lead to the detection of infection	I

Question name	Question objective	Question classification1 (I/C/S)
SHED_SEMEN1	To obtain an estimate for the Probability that infectious AGENT will be shed in the semen of an individually selected DONOR at the time of collection	S
SHED_SEMEN2	To obtain an estimate for the probability that infectious AGENT will be shed in the semen of at least one DONOR from an infected consignment, at the time of collection	S
SMALL_HOLD1	To obtain the information necessary to determine the PROBABILITY that at least one infected small-holder production unit will be selected while selecting an animal	C
SMALL_HOLD2	To obtain the information necessary to determine the PROBABILITY that at least one infected small-holder production unit will be selected while obtaining animals for the consignment	C
STORE	To obtain an estimate for the probability that AGENT will remain infectious and viable following pre-export storage	S
SURV	To obtain the information necessary to determine the PROBABILITY that surveillance of the national GROUP in IMP_COUNTRY will fail to detect early cases and prevent a generalised outbreak of DISEASE	I
TEST1	To obtain the information necessary to determine the PROBABILITY that a test applied to a single infected ANIMAL will fail to identify it as infected	I
TEST2	To obtain the information necessary to determine the PROBABILITY that a test applied to an infected consignment of ANIMALS will fail to identify that consignment as infected	I
TEST3	To obtain the information necessary to determine the PROBABILITY that a test applied to an infected group of independently selected ANIMALS will fail to identify that group as infected	I
TEST4	To obtain the information necessary to determine the PROBABILITY that a test applied to an infected cluster of COMMODITIES will fail to identify that cluster as infected	I
TISS_INF1	To obtain the information necessary to determine the probability that meat or meat products derived from the tissues or organs of an individually-selected are infected	S
TISS_INF2	To obtain the information necessary to determine the probability that meat or meat products derived from the tissues or organs of at least one ANIMAL in a consignment are infected	S

Question name	Question objective	Question classification1 (I/C/S)
VALUE	To obtain from the user a 'value' - whether a number, a PROBABILITY, a PROBABILITY distribution or a semi-quantitative rank	S
VECT	To obtain information necessary to determine the PROBABILITY that spread of DISEASE in IMP_COUNTRY will occur despite vector control or the restriction of importations to periods when vectors are limited	S

Legend

C = Composite question
I = Intervention question
S = Simple question
U = Utility question

3.2.2 Model templates

Model templates form the second component of the HandiRISK knowledge base. Model templates are in some respects simpler then the generic question objects, both conceptually and from the perspective of implementation. That is, model templates are required only to convey information regarding the sequence of stages in an importation scenario, the name of each stage and the probability or qualitative likelihood it models and the top-level generic question that will be instantiated to collect the appropriate information from the user. This top-level question will often instantiate others in order to gather the information it requires. An important design feature of this system is that once the top-level question is instantiated, the template does not need to be aware of any subsequent processes. It simply waits for the signal that the top-level question's coded modules, and those of any subsequently instantiated questions, have completed their tasks and obtained the necessary information, then moves to the next stage. The underlying principle is that each of the objects retains its independence, communicating through a single instantiating command. This concept continues the theme and advantages of object-orientated system design, since it enables both groups of objects to be updated or altered with minimal disturbance to the system's functionality and, likewise, provides an environment in which new templates (and questions) may be added and the knowledge base thus extended.

As was the case for generic questions, model templates may also be classified according to the

three groups of dichotomous criteria shown below:

- Model segment (events in either the exporting or importing country)
- Modelling strategy (quantitative or qualitative)
- Commodity handling strategy (batched consignments or individually handled units)

These criteria are illustrated in Table 29, where it can be seen that each specified importation[1] may be associated with up to eight different model templates. Alternatively, it can be seen that the knowledge base will contain eight groups or classes of templates which will differ only with regard to the importation scenario they model. This point is important from the perspective of implementation, since it enables a parent template from each class to be used as a shell from which new templates of that class may be cloned and subsequently customised. Once again, this illustrates the object-orientated property of inheritance, as the characteristics of the parent shell will be required to persist within each new member of its class. It can be seen that this system provides an efficient and relatively error-free means by which new templates may be created.

Table 29: Schema illustrating the requirement for eight similar templates per specified importation

	Model segment	Quantitative	Qualitative
Batch	**Release assessment**	Template 1	Template 5
	Exposure assessment	Template 2	Template 6
Individual selection	**Release assessment**	Template 3	Template 7
	Exposure assessment	Template 4	Template 8

Finally, and while not a class distinction as such, model templates in the HandiRISK knowledge base exist in two broad groups; generic model templates and user-constructed model templates. Generic templates are those that have been pre-built as system components and, as such, may not be modified by users of the system. User-constructed templates are created by the analyst using the template-building engine (as described later in this discussion) and are structurally identical to generic templates in every respect other than the fact that they may be edited.

[1] **Specified importation**: The combination of importing and exporting country or countries, the commodity to be imported and the animal species from which the commodity was derived

Generic model templates

HandiRISK was intended to be a useful product but not a final version of this system and, as such, generic templates were included for the following importation scenarios:

- Live animals: Cattle, sheep, pigs and goats (all exporting and importing countries)
- Genetic material (semen and ova): Cattle, sheep, pigs and goats (all exporting and importing countries)
- Meats and meat products: Cattle, sheep, pigs and goats (all exporting countries)

In order to allow users the flexibility to describe importations based on batched or individually selected commodities, and to model events in the exporting and importing countries using either qualitative or quantitative models, eight different templates were created for each of the live animals and genetic materials scenarios. It was not considered feasible however to construct generic model templates that would represent the huge range of post-entry events in an importation scenario for meats or meat products. Thus, these templates were limited to the four combinations (ie $2^2 = 4$) relevant to the calculation of the release assessment.

Examples of generic model templates are provided in the Annex to this chapter.

User-constructed model templates

The facility by which users of HandiRISK could construct their own model templates was considered another of the design feature that enabled the system to attain the degree of flexibility required by regulatory analysts. While it would have been considerably simpler to restrict HandiRISK to the generic templates and questions described above it was also recognised that analysts would encounter importation requests for unusual commodities, and that an entirely pre-modelled system might not be able to accommodate these situations.

Given this, the 'template building engine' was designed as a means by which model templates could be created from their class-specific shells (as described above) by following a wizard-based system. This system, which will be illustrated in Section 4, enabled the user to replicate tasks that would otherwise have been performed by a computer programmer. The end result of the process is a model template with the same level of class-specificity as the generic templates, which at each stage is capable of interacting with a designated top-level generic question in the manner of

generic templates. Indeed, user-created templates are essentially identical to the generic templates with the exception of the fact that they may be edited (if no model instances have been created from them) and may be exported to other users.

Finally, user-created model templates are stored with information regarding the original author and date of creation, as well as summary information regarding subsequent modifications. Thus a model template that is derived by copying an existing user-created template and modifying various stages will contain this information, and any model instances derived from it may report the information in its Comprehensive Report (see, Section 4.6.1).

3.2.3 Conclusions

The innovative, object-orientated design of the HandiRISK knowledge base has enabled the system to attain the level of flexibility required by regulatory analysts, while retaining an efficient and easily manipulated data structure. Flexibility was imparted by a combination of intelligent generic questions, a group of generic model templates for commonly encountered importation scenarios and a facility that allowed users to create model templates which interact with generic questions and may be manipulated using the usual mechanisms. In addition to this, sophisticated extras such as the global flags and the substituted text strings, key words and variables, produced an interface that is intuitive, unambiguous and, ultimately, a unique means by which truly specific interface elements can be generated from the truly generic database objects.

Aside from the issue of flexibility, the object-orientated design enables individual elements within the HandiRISK knowledge base to be modified or updated with little disturbance to the system's functionality. By the same mechanism, new elements may easily be added to the system. These facilities were considered essential, both to the successful completion of an iterative implementation life cycle (see, Section 5.2) and to envisaged upgrading of HandiRISK Version I following a structured process of peer review.

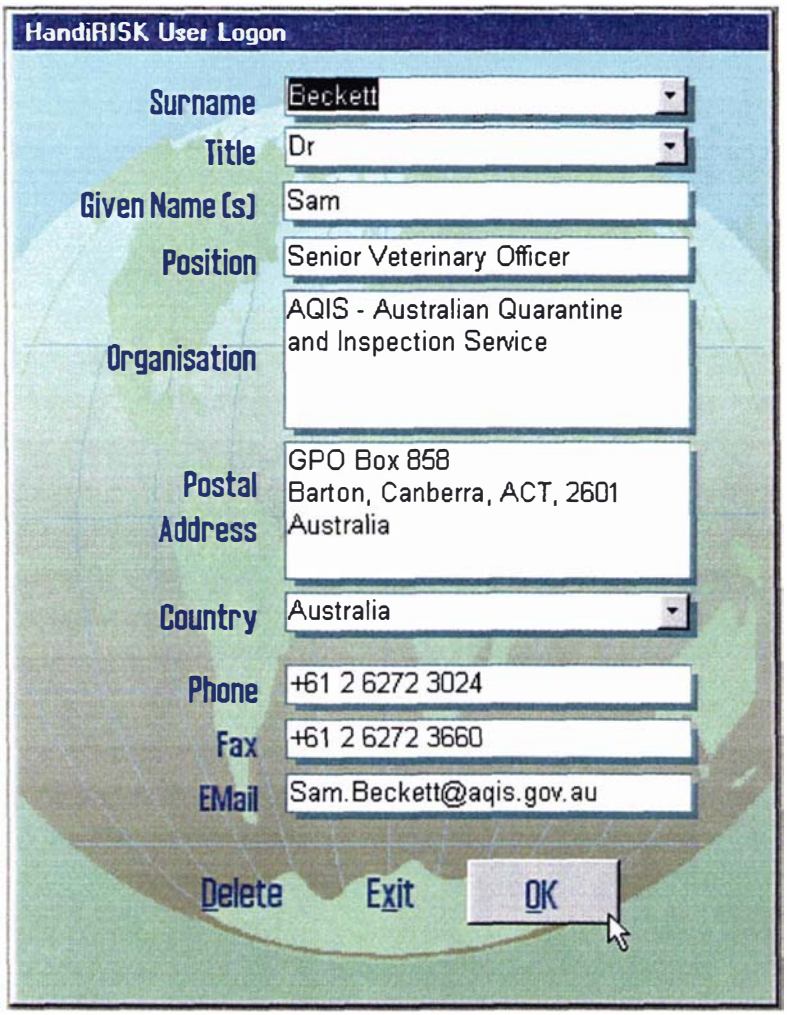
Finally, it was observed that the application of the object-orientated class system enabled empty question or template shells to be created and their characteristics passed down to 'offspring' through a process of inheritance. This in turn facilitated the relatively rapid representation of expert knowledge.

4 Implementation of an automated approach to import risk analysis

4.1 Phase 1: User log-on

The user log-on is achieved through a single data entry window (Figure 38), presented to the user immediately following the instantiation of program files, and before the appearance of the MMS and pull-down menus. The purpose of the log-on screen is to register a new or existing user such that their details may be entered automatically into any reference fields declared to be his or her 'personal opinion'. Personal details will also be associated with any new analyses, model instances or model templates compiled by that user (see, Section 3.2.2). Existing users are displayed in a list box. Users may be removed from this list by selecting and activating the 'Delete User' button. This will not remove the user's details from the system storage table, since these may be required as references for models or analyses in the database, but will flag that person as 'not current'.

Figure 38: The HandiRISK user log-on procedure



Once logged-on, the user is required to open a database. This is achieved by selecting the Database pull-down menu, designating 'Open/Database' and choosing from the list of databases that appears. By default, HandiRISK will contain a single database and, when starting a newly-installed system for the first time, the user will be required to provide a name and to specify whether password security is required.

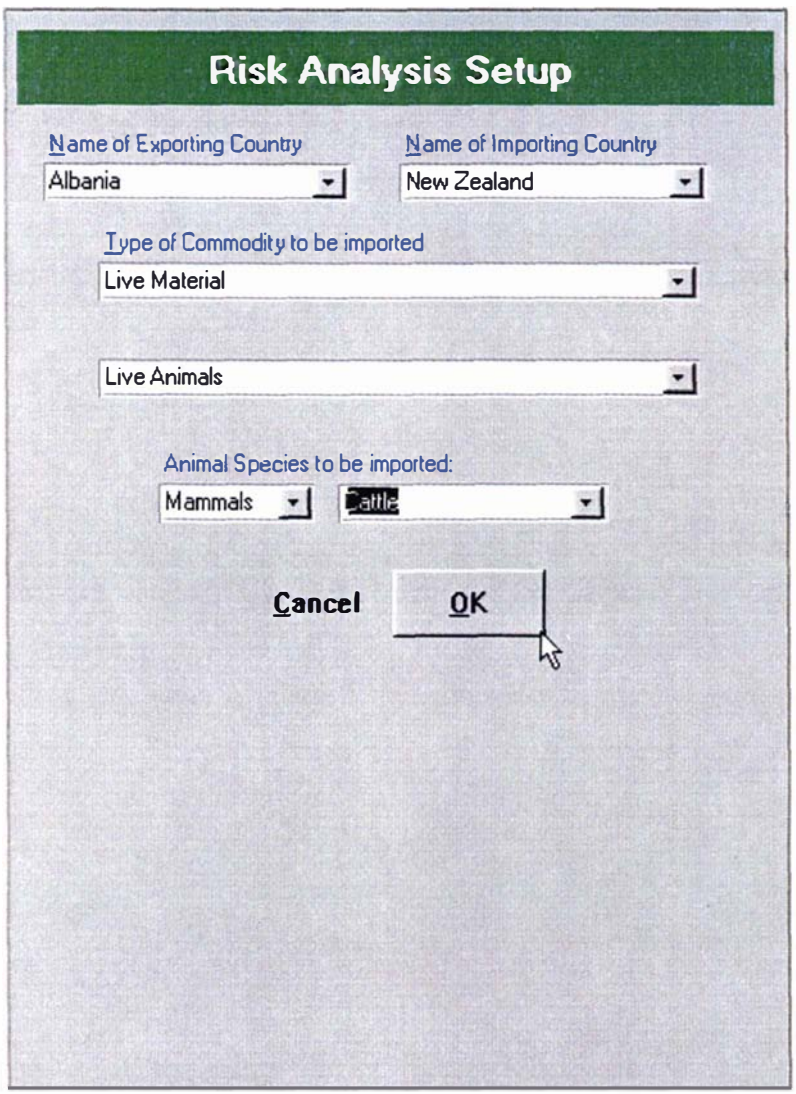
The user log-on is not designed to be a security measure. The confidentiality of a database is ensured in HandiRISK by an optional password. Any new analyses, templates or model instances, or changes made to existing components will be registered in the name of the (currently logged on) user.

4.2 Phase 2: Describing an import scenario

This preliminary phase was implemented through the series of list boxes shown in Figure 39. The design of this screen was linked closely to the subsequent requirements of the hazard identification phase, and the fact that the latter was centred upon the user's option to utilise HandiSTATUS, the OIE's database management tool, as a means by which to generate a list of disease agents. Hazard identification is discussed in further detail in Section 4.3. It should be noted, however, that the fields and field names were designed to obtain information that, if required, would be compatible with HandiSTATUS.

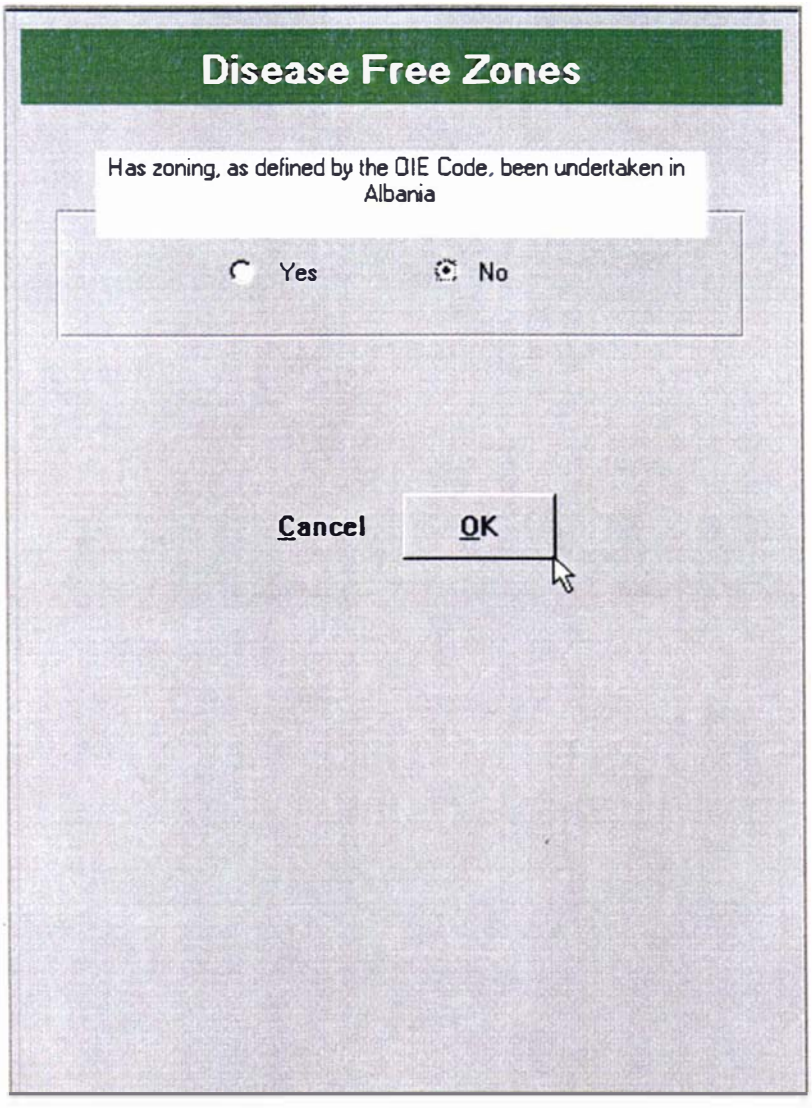
A new analysis will typically be initiated by selecting the root node of the import risk analyses branch of the MMS, applying a right mouse-click and choosing 'New Analysis' from the menu that appears. Alternatively, the root node might be selected and 'New Analysis' chosen from the Analysis pull-down menu at the top of the opening screen. Either of these approaches will generate the import description window shown in the screen capture below.

Figure 39: Description of an importation scenario



Having completed these fields and, in doing so, satisfied the requirements of HandiSTATUS, HandiRISK determines whether the exporting country is one in which a disease free zone (or zones) has/have been declared and advised to the OIE. If this is the case, the user is prompted to state whether exportation will be limited to animals or animal products from a given zone. The WTO policy of risk avoidance can only be truly advocated and practised if zones with different disease risks are recognised. The procedure for obtaining information regarding zones and regions is shown in Figure 40.

Figure 40: Specification of zones and regions



Information regarding zoning is stored in data-tables describing the importation and, where it has been specified that exportation will be limited to a specific zone or type of zone, any text statement containing the name of the exporting country is automatically modified. This facility serves both to remind the user of the constraint that has been placed on the analysis, and to provide those reading or viewing any outputs with the information required to correctly interpret the analysis or implement a policy statement from it.

4.3 Phase 3: Hazard identification

In Chapter 2 it was concluded that hazard identification should be undertaken as a two step

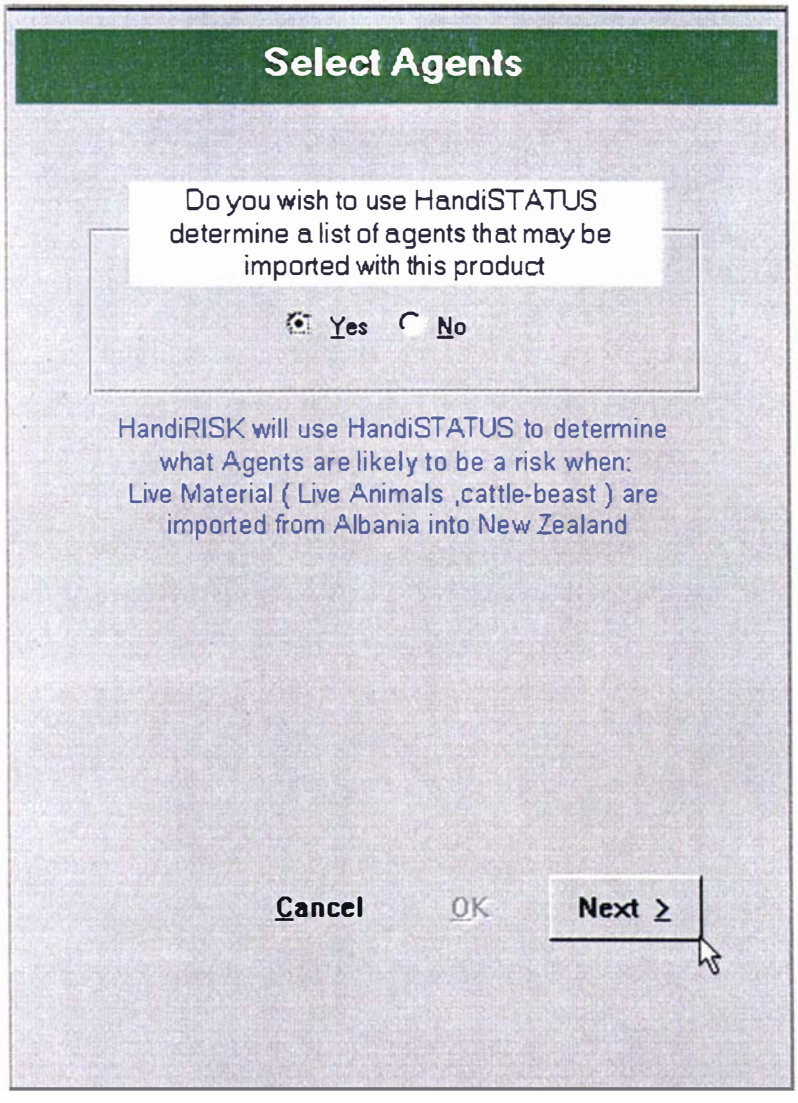
process involving preliminary hazard identification and hazard refinement. Preliminary hazard identification simply describes the identification of disease agents relevant to the animal species from which the commodity is to be derived. This initial list may be minimised by considering only disease agents that are known to be transmitted via the commodity, although there was some concern that this judgement should be reserved for the risk assessment. Hazard refinement is a screening procedure applied to the preliminary list of disease agents, so as to limit the ensuing risk assessment to diseases that may realistically pose a risk.

These two sub-procedures are undertaken independently in HandiRISK. The criteria for hazard refinement are those suggested by the New Zealand Ministry of Agriculture and Forestry, since this agency was a partner in the development of the software. Given this, the hazard refinement module is encapsulated and can thus be customised for other importing countries, or to reflect only the criteria that appear in the OIE Code.

4.3.1 Phase 3.1: Preliminary hazard identification

HandiSTATUS, the OIE's database management software, provides a useful means by which some or all of the criteria above may be used to generate a preliminary list of hazards. While this list will only be as complete as the country- and commodity-specific information within the OIE's animal health database, it may nevertheless provide analysts with a useful starting point before conducting further literature searches or consulting experts in the given field(s). This decision is shown in Figure 41.

Figure 41: Options for determining a preliminary list of hazards



If the analyst answers 'Yes' to this question, HandiRISK searches the OIE data files for disease agents which may be carried in or on the commodity to be imported, and which are capable of infecting the animal species from which it was derived. In future versions of both HandiSTATUS and HandiRISK, it will be possible to download these data files from the OIE's Internet web-site and insert them in HandiRISK in the place of existing files. Because HandiSTATUS is a DOS-based program, it cannot readily communicate with HandiRISK, which operates in the Windows™ environment. Hence, epidemiological logic governing the process of hazard identification in HandiSTATUS was extracted from queries within this program and inserted directly into HandiRISK. That is, when generating a HandiSTATUS list of diseases, users view a reproduction of the HandiSTATUS 'splash screen' (Figure 42) while the query of the OIE data

files is actually run entirely from within HandiRISK. This approach allowed full credit for the query logic to remain with HandiSTATUS and the OIE, while enabling HandiRISK to function efficiently within the environment of its own database.

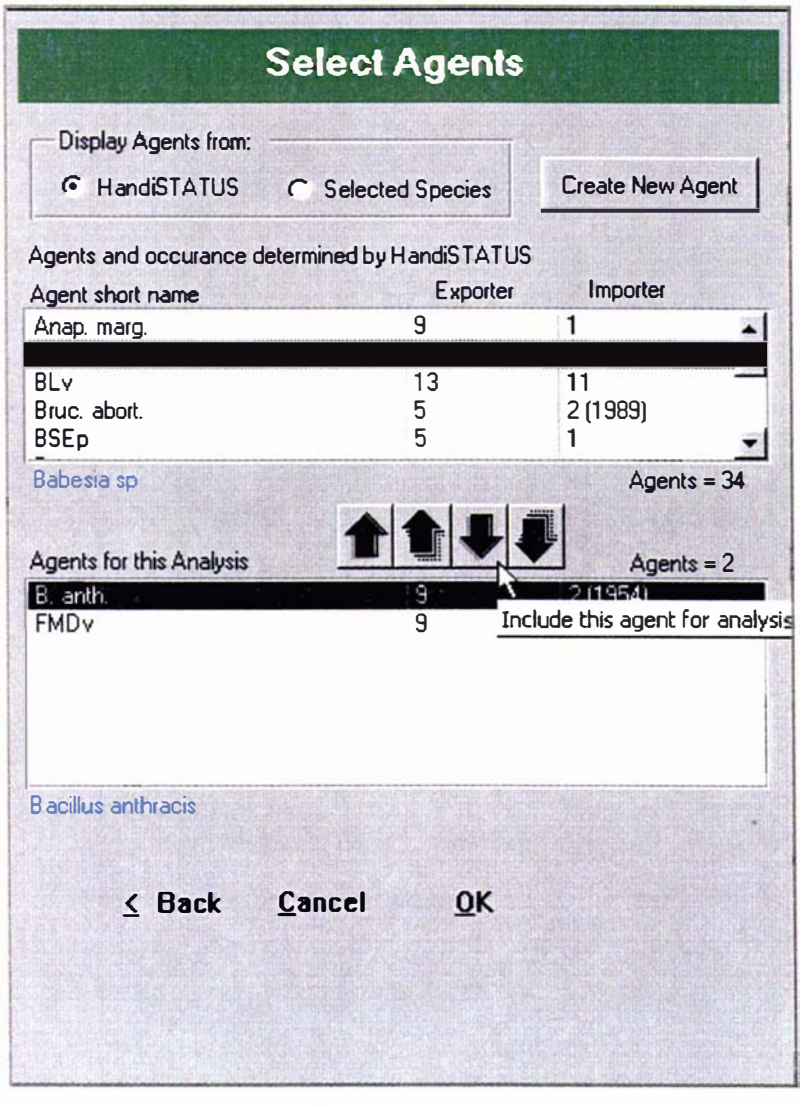
Figure 42: Display of the HandiSTATUS splash screen as HandiRISK performs the search query of the OIE's data files

Having obtained a list of diseases from an HandiSTATUS query, HandiRISK allows the user to edit this by adding or removing individual agents. This is achieved by providing two list boxes, the first containing those diseases obtained from the query and the second a recipient box to be populated by selecting diseases from this list and/or adding others of particular interest. The procedure of disease selection and transfer is illustrated in the screen capture in Figure 43. Here it can be seen that two disease agents (*Bacillus anthracis* and foot-and-mouth-disease virus) have been selected from the 34 agents provided by HandiSTATUS and placed in the separate list of agents to included in the ensuing analysis. It can also be seen that the analyst is in the process of selecting '*Babesia sp*', and may either intend to include this agent or to use the right mouse-click

menu to determine the agent's occurrence information. Some of the disease agent abbreviations displayed in this form are inconsistent with the formal biological naming convention. This problem arose as a result of an interim solution to errors in the original OIE data files, and will be addressed in further versions of HandiRISK.

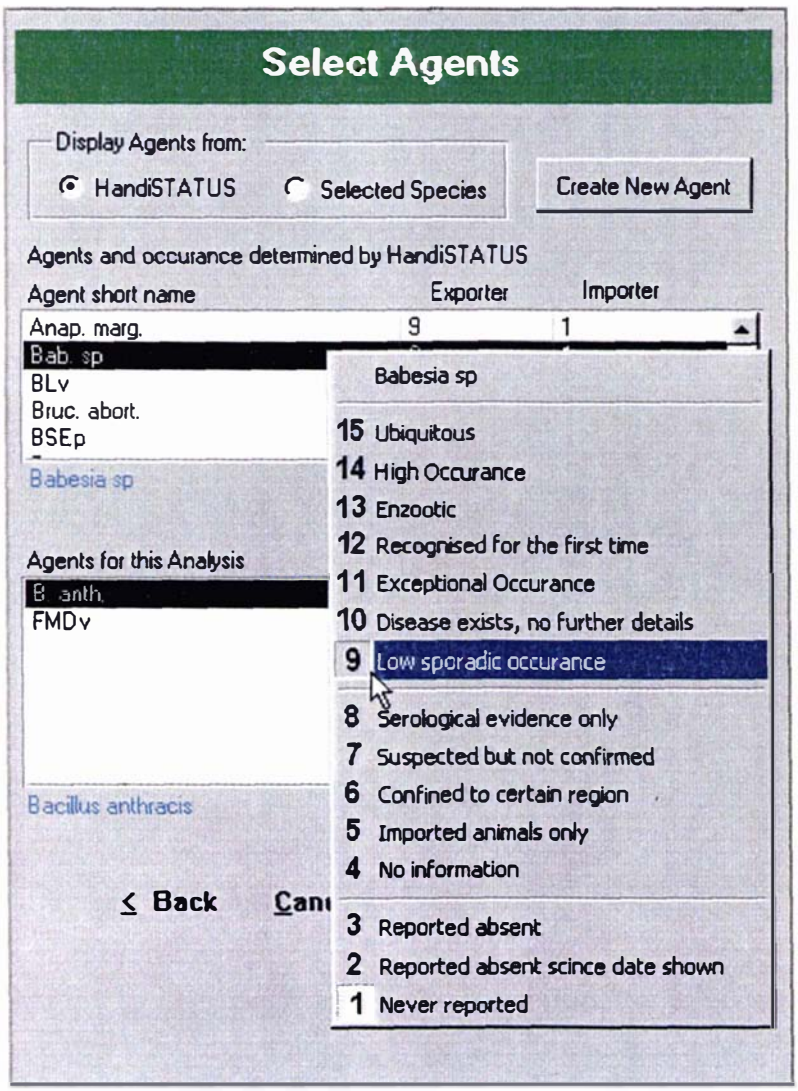
Finally, toggles are provided at the top of the screen that allow the agent to switch dynamically between the list of disease agents produced by the HandiSTATUS commodity-based query, and the OIE species-specific list. If this expanded list does not contain a particular disease of concern, the analyst may request to specify a 'new disease', as shown in Figure 43.

Figure 43: Results of the HandiSTATUS query



The HandiSTATUS query also generates a series of 'occurrence codes', which give specific information regarding the prevalence and distribution of each listed agent. HandiRISK converts the occurrence codes provided by HandiSTATUS into numerical codes, which are listed in separate columns for the importing and exporting country, adjacent to each identified disease. The result is shown in the screen capture in Figure 44, where it can be seen that *Anaplasma marginale* has a low sporadic occurrence in the exporting country, and has never been reported in the importing country.

Figure 44: Occurrence codes and their interpretation, as displayed by HandiRISK in the results of a HandiSTATUS query

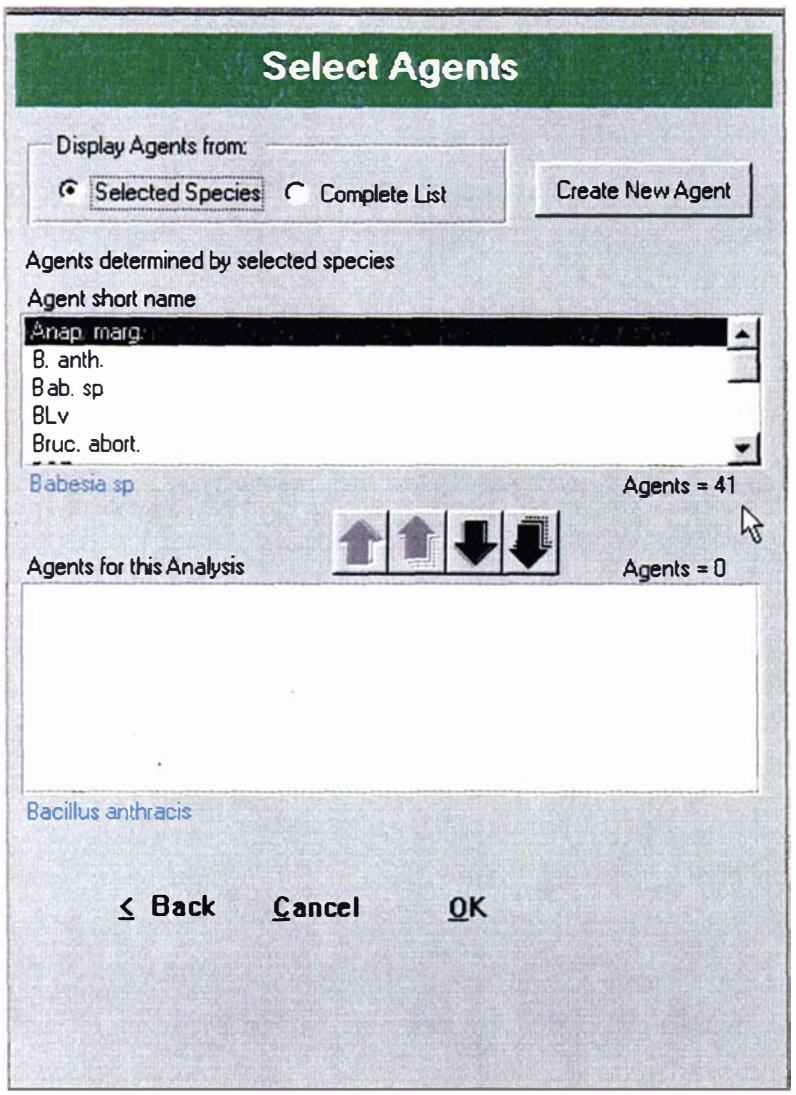


Where the user wishes to include diseases which do not appear in the results of a HandiSTATUS

query, he/she may either request the complete OIE species-specific list of animal diseases and transfer any number of these to the recipient list box, or may simply describe diseases from first principles. Both options are available directly from the query results window shown in the screen capture in Figure 44.

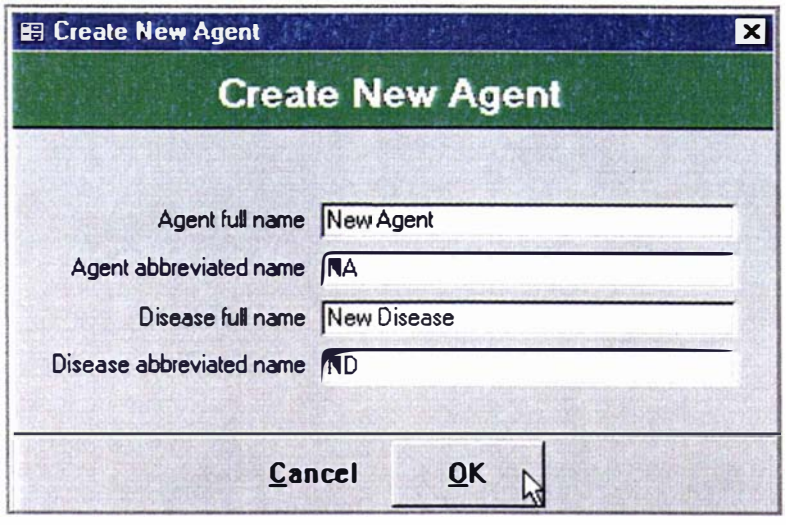
Alternatively, users may not have requested a HandiSTATUS query when this question was posed at the start of the hazard identification. Where this is the case, the screen shown in Figure 45 is generated and the user may view either the OIE's species-specific disease list or a complete list of diseases in the OIE's animal disease database. The results of a species-specific search are shown in Figure 45. It can be see that there are 41 disease agents in this list - seven more than were present in the results of the commodity/species specific HandiSTATUS query described above.

Figure 45: The results obtained when HandiRISK directly queries the OIE data files for a list based on the imported animal species (cattle)



Finally, users who have elected to specify diseases from first principles will be presented with the data entry window shown in Figure 46. It should be noted that regardless of whether HandiRISK obtains details regarding diseases and their agents through a selection process based on OIE data files, or from information entered directly into these data entry windows, the system requires each of the four descriptors shown in the screen capture. This is due to the fact that each of the various forms of disease and agent name are used as text substitutions in question statements and system outputs so as to ensure that the system's interface is as unambiguous as possible.

Figure 46: Specification of a 'new disease' - that is one that does not appear in the OIE's animal disease data files

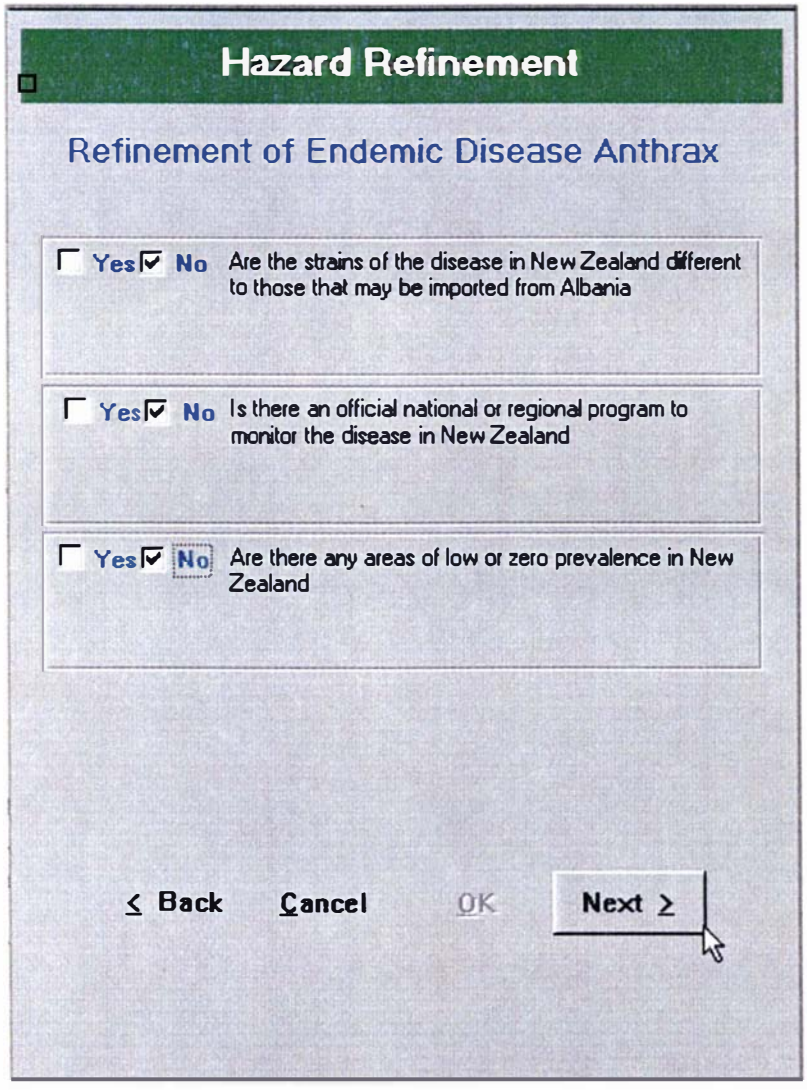


4.3.2 Phase 3.2: Hazard refinement

When viewed as an integrated unit, the process of hazard refinement is essentially equivalent to a standardised and self-contained semi-quantitative risk assessment. The results of this assessment are automatically interpreted and individual disease agents retained for further analysis or discarded from the preliminary list.

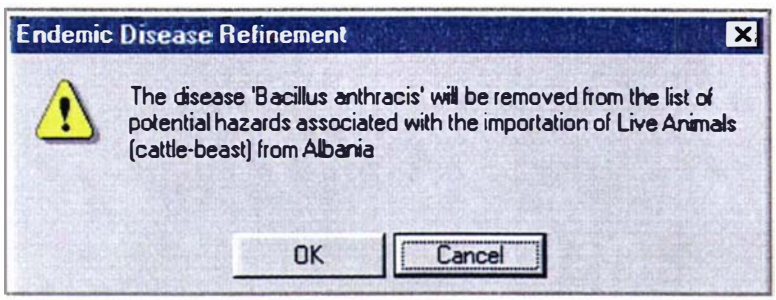
Once the user has requested hazard refinement, he or she must first identify any diseases on the preliminary list that are endemic in the importing country. Having marked the endemic diseases, the user is prompted to complete a series of question that will determine whether each is to be discarded from the list or retained for further assessment. These questions are shown in Figure 47, where it can be seen that if all are answered "No" then Anthrax will be deleted from the list of potential hazards and the questions reiterated for the next identified endemic disease.

Figure 47: Hazard refinement for endemic diseases



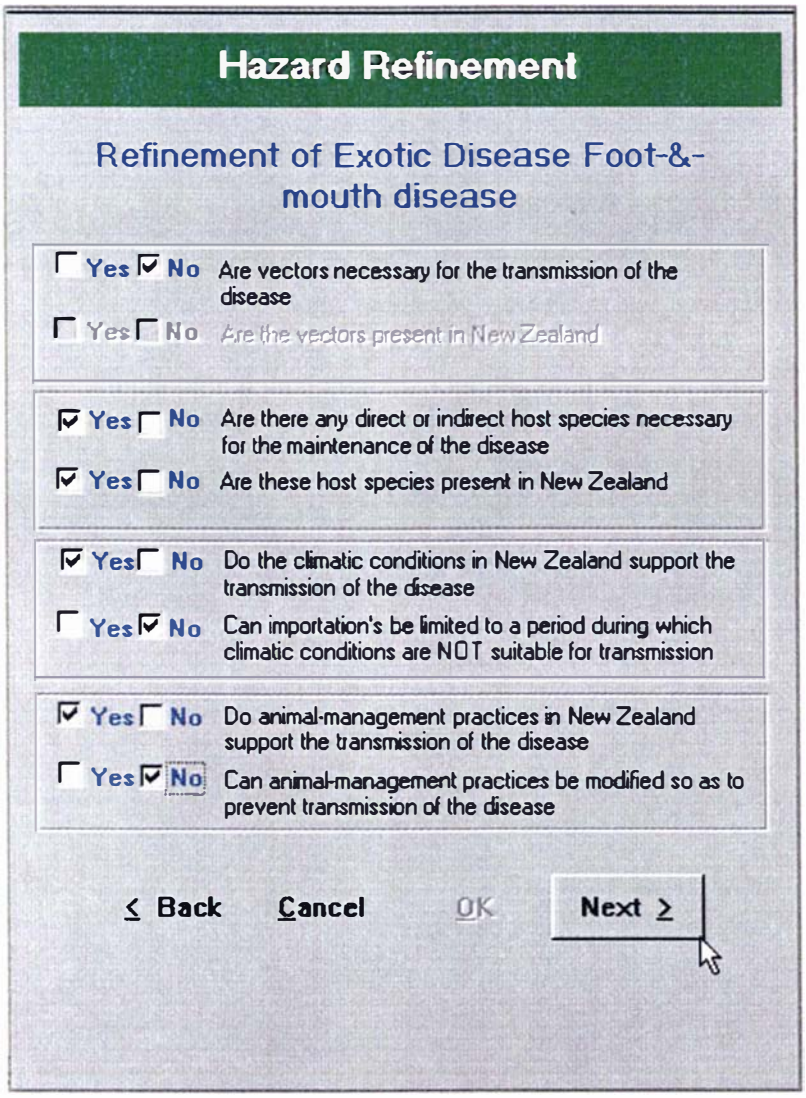
Diseases will never be removed from a list without warning. It can be seen from the screen capture in Figure 48 that HandiRISK has recognised that the consistent series of 'No's provided in the previous screen suggest that *B. anthracis* should be removed from the list. At this point the analyst is given the opportunity to accept or reject the system's logic.

Figure 48: Removal warning for screening hazard identification



Once screening of endemic diseases has been completed, HandiRISK returns to the list of exotic diseases and, for each disease identified as a potential hazard, prompts the user to provide two groups of responses. The first of these (Figure 49) concern the logistics of transmission and establishment of the disease in the importing country.

Figure 49: Hazard refinement for exotic diseases (I) - The ability of the proposed agent to become established in the importing country



The disease agent is removed from the list if any of the following conditions are met:

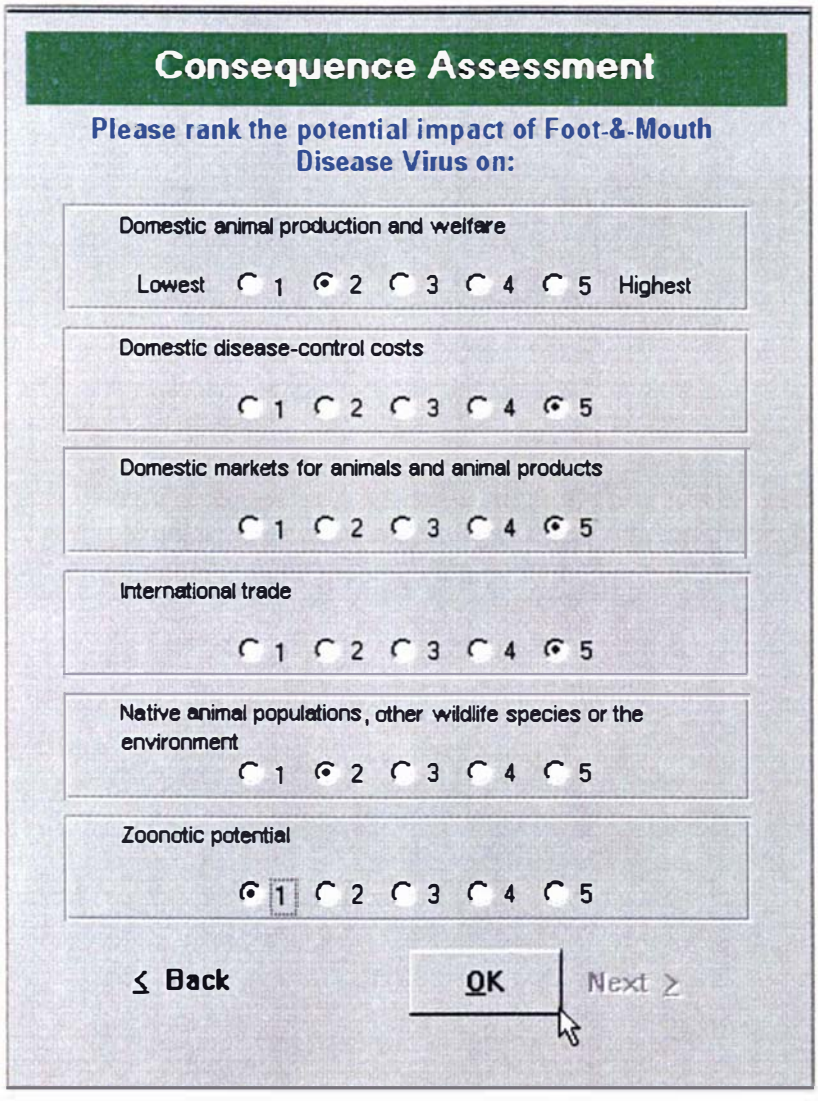
- Answer 1 (vectors) is 'Yes' and sub-answer 1 is 'No'
- Answer 2 (host species) is 'Yes' and sub-answer 2 is 'No'
- Answer 3 (climatic conditions) is 'Yes' and sub-answer 3 is 'Yes', OR, answer 3 is 'No'
- Answer 4 (animal management practices) is 'Yes' and sub-answer 4 is 'Yes', OR, answer 4 is 'No'

The second group of questions, which essentially forms a superficial semi-quantitative

consequence assessment based on scores of 1 to 5, is illustrated in Figure 50. The rule adopted for this assessment is simply that if the answer to any of these five questions is greater than '1', then the disease concerned is retained in the list of hazards for consideration in a subsequent risk analysis. If the answer to all five questions is '1', the disease agent is discarded. Accepting these rules, it can be seen that foot-and-mouth-disease virus will remain on the list of hazards.

This system was adopted in favour of a more rigorous, but as yet experimental, approach based on outbreak scenarios that was proposed in Chapter 2. The need for simple and well-established approaches to be represented in this initial version of HandiRISK was discussed in the introduction. The modular design of HandiRISK has also been discussed and, in view of this, it can be seen that the consequence assessment module can be modified without difficulty to accommodate minor alterations to definitions or scores, or to support the more technical approach proposed in Chapter 2.

Figure 50: Hazard refinement for exotic diseases (II) - Consequence assessment for the selected disease agent



4.4 Phase 4: Risk assessment

It was concluded in Chapter 2, that risk assessment should describe three distinct sub-phases:

- Likelihood evaluation (release and exposure assessment)
- Consequence assessment
- Risk estimation

4.4.1 Phase 4.1: Likelihood evaluation

It was concluded in Chapter 2 that likelihood evaluation, whether qualitative or quantitative, should be carried out according to the following principles:

- Likelihood evaluation should be based on the consideration of biological pathways for disease entry and exposure, and these should in turn be described by series of sequential steps or stages
- The likelihood of disease entry and exposure should be evaluated independently
- Where likelihood evaluations are to be based on a more than one exporting country (so-called, 'generic' evaluations), analysts should group these countries with respect to country factors and thus carry out a discrete series of secondary evaluations, or demonstrate that country factors do not contribute significantly to the likelihood of entry

In addition to these common principles, conclusions were drawn regarding the current role of quantitative likelihood evaluation:

- Quantitative likelihood evaluation may be used to enforce the concept of structured importation and exposure pathways
- Quantitative likelihood evaluation may be used as a means by which to conduct sensitivity analysis
  - to enable risk management to be targeted and efficient
  - to identify stages for which information should be most reliable
  - to determine whether country-specific stages in the importation pathway are significant determinants of the likelihood of disease entry
- Quantitative likelihood evaluation may be limited to either the release or exposure assessment, or may be used to enhance stage-level likelihoods within a qualitative model

Finally, it was suggested that if analysts or decision-makers felt uncomfortable interpreting quantitative results, there might be some benefit in converting these to qualitative or semi-quantitative likelihoods.

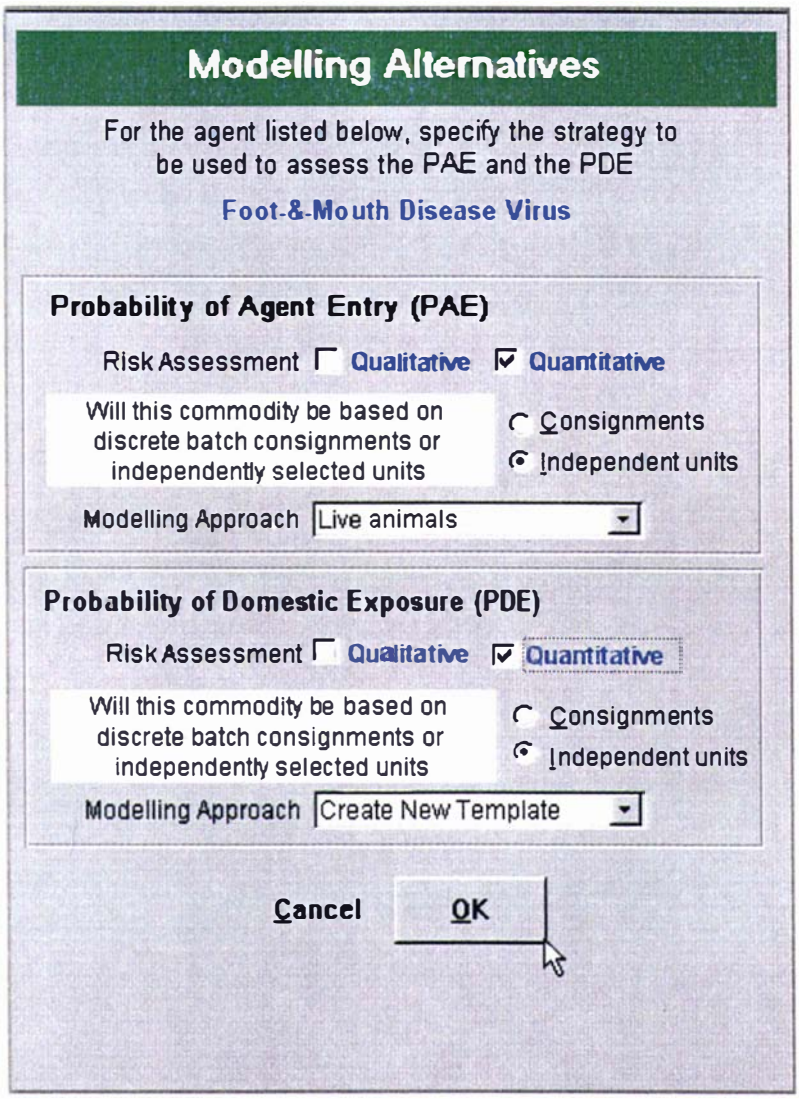
The modelling facilities available in HandiRISK are illustrated in Figure 51. Here it can be seen

that the release and exposure assessments (termed PAE and PDE[2] respectively) are modelled separately. It can also be seen that each of these assessments may be qualitative or quantitative, may refer to commodities handled as batched consignments or independent units, and may be based on an existing (generic or user-created) model template or on a template to be 'purpose-built' using the template building engine. In the example shown in the screen capture, the user has elected to model the release assessment quantitatively and as batched consignments, and to base this model on the generic template termed 'Live Animals'. The exposure assessment is to be modelled quantitatively and as independent units and, for this section of the overall model, the user has decided to create a new template.

Having made these selections, the user clicks 'OK' and in this case is moved directly to the interface of the template building engine. If the user had elected to base both assessments on existing model templates, then he/she would have been returned to the MMS where a red scroll (see, Section 2.1) would indicate that a new and, as yet incomplete model has been created. From this point the user may either right-mouse-click on the still selected model and elect to enter the data required to complete it, start a new model with a different strategy, start a new model for a different agent, or perform any other task.

[2] At the time when HandiRISK was developed, the OIE terms for release and exposure assessments were PAE and PDE, respectively.

Figure 51: Modelling alternatives available in HandiRISK



By requesting a 'new template', the user instantiates the wizard-based 'template building engine' (see, Section 3.2.2) which guides them through the template-building procedure using a series of interactive screens. The first of these is shown in Figure 52 where it can be seen that the user has named the template "*Sams One*", and defined it to be a qualitative template based on the post-entry events relevant to the importation of live animals, where these are managed as independent units. It can also be seen that a series of three 'tabs' are provided on the lower half of the form in which the user may specify the importing countries, commodities and species for which the template may be used. The important point here is that although the template has been generated for a particular model, which itself belongs to a particular importation scenario, it will be stored in the knowledge base with the generic templates and other user-created templates. The template

will thus be made available for any subsequent models that comply to the specifications provided in this form.

Figure 52: Template building tool - Opening screen

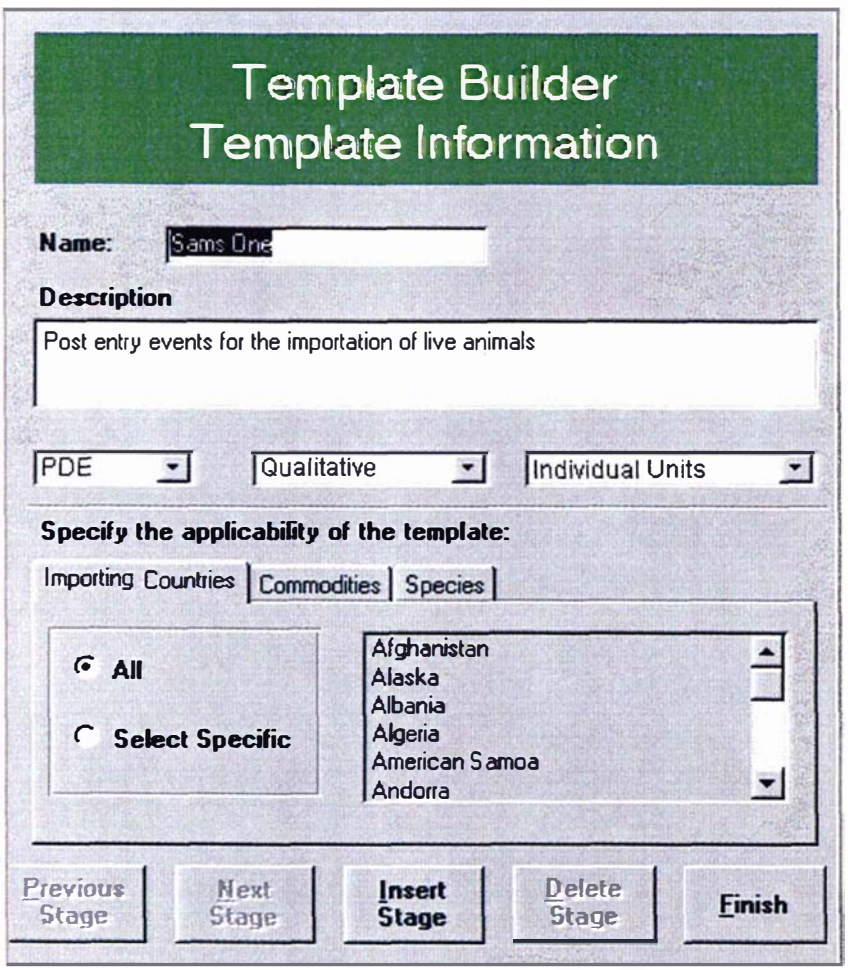
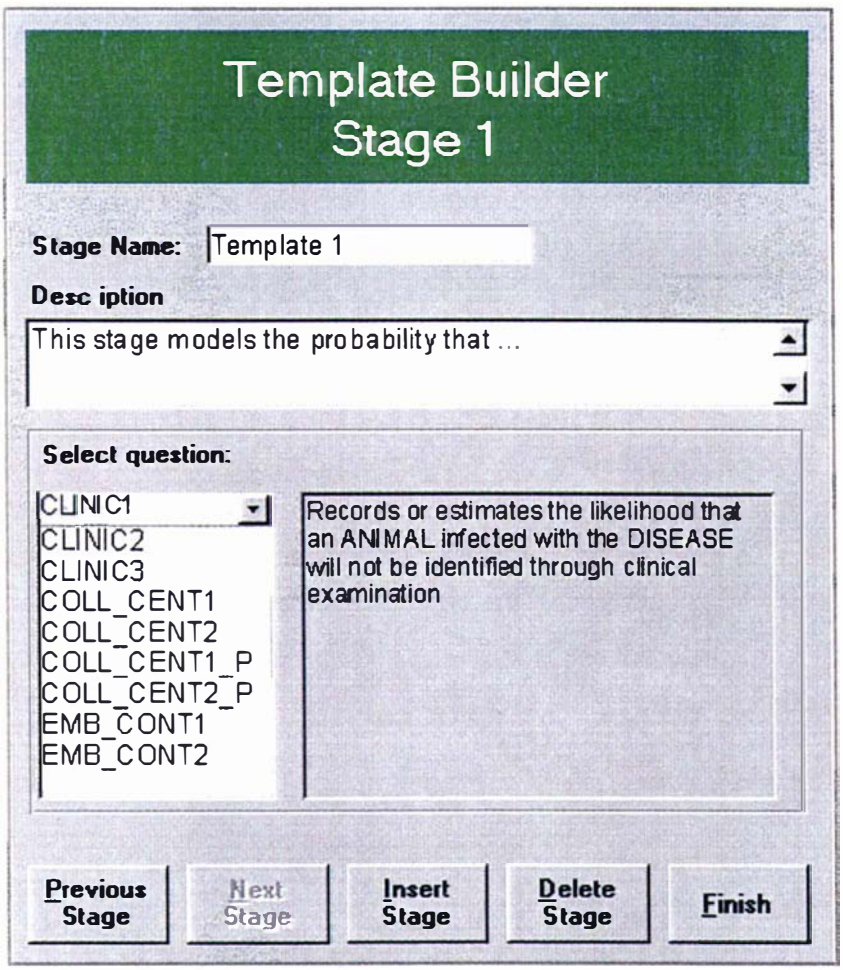


Figure 53 shows the fields required for the specification of the first stage of the new template. Here it can be seen that the user is required to enter a stage name and description, and to use the *combo box* provided to select the 'top level' question that this stage will call or instantiate (see, Section 3.2.2). Once these fields have been provided, the user selects 'Next Stage' and the process is repeated. This cycle continues until all of the required post-entry stages in the new template have been specified, at which point the user clicks 'Finish' to save the template and return to the MMS.

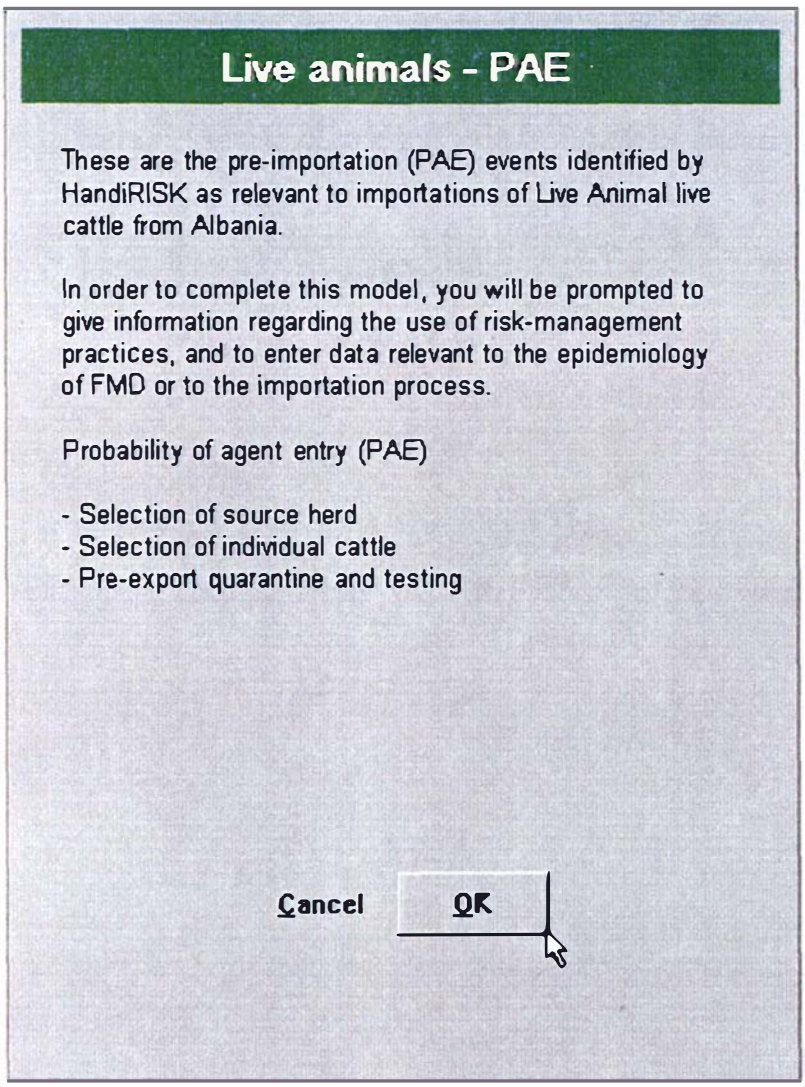
Figure 53: Template building tool - Stage 1



Having specified an approach to modelling release and exposure assessments, and having defined any new model templates, it remains to create individual model instances. In this hypothetical importation scenario, the release assessment was quantitative and the exposure assessment qualitative.

Figure 54 shows the screen presented to the user at the start of either the release or exposure assessment. In order to complete either assessment, the analyst simply works through these stages, answering question prompts regarding risk management alternatives or entering data. The screens that appear for qualitative versus quantitative assessments are obviously different, however, and thus the two approaches will be described independently.

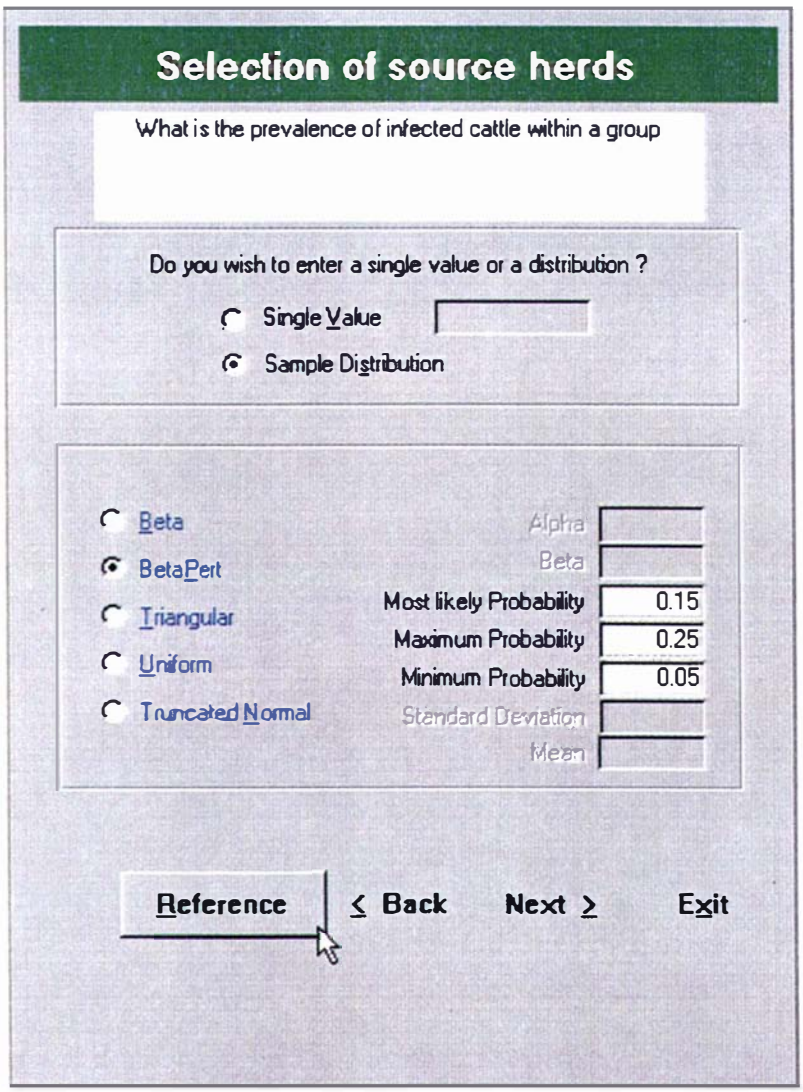
Figure 54: Preliminary descriptive screen for the release assessment (PAE)



Quantitative likelihood evaluation

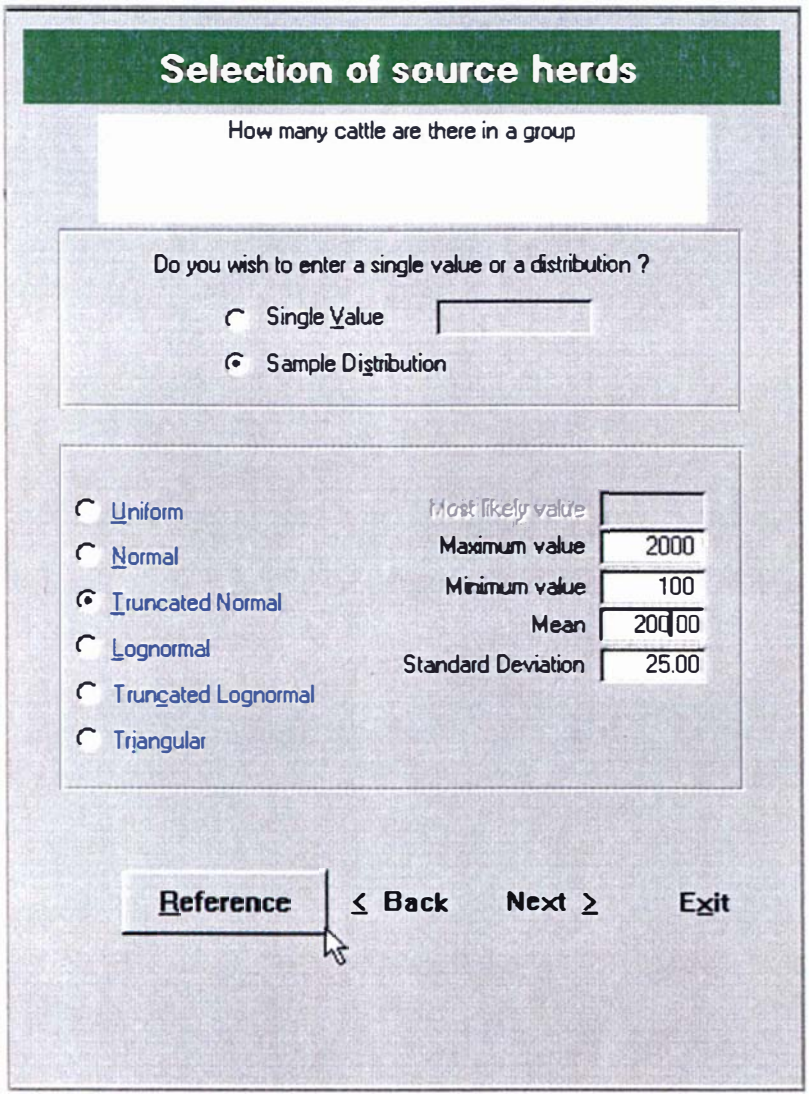
Quantitative data is entered through the screen generated by the quantitative form of the generic 'VALUE' question. As shown in Figure 55, either single values or distributions may be entered. Single values represent the deterministic approach to quantitative modelling, although it should be stressed that the two approaches may be combined in a single model. For example, the number of pigs in a quarantine group may be fixed at 20, whereas test sensitivity may be considered a stochastic variable and modelled using a beta distribution.

Figure 55: Quantitative data entry for a proportion, prevalence or probability



Where the distribution option is selected, HandiRISK determines whether the variable is a proportion, prevalence or a probability and should thus be limited between 0 and 1. Where this is the case (Figure 56), HandiRISK provides a selection of distributions that are either inherently bound within this range, or which may be truncated. Where none of these 'key words' appear in the text string sent to the 'VALUE' question (Figure 56), HandiRISK determines that the variable need not be bounded and provides an alternative list of distributions.

Figure 56: Quantitative data entry for an unrestricted value



Finally, all data entered in HandiRISK must be referenced before the analyst can move to the next data entry screen or model stage. The referencing procedure is shown in Figures 57-58. The user is first asked to specify whether the information has been published or not. If so, then the options shown in Figure 57 are generated. If not, then the user is presented with the alternative range of options (Figure 58). Users may provide multiple references.

Figure 57: Data entry for a published reference

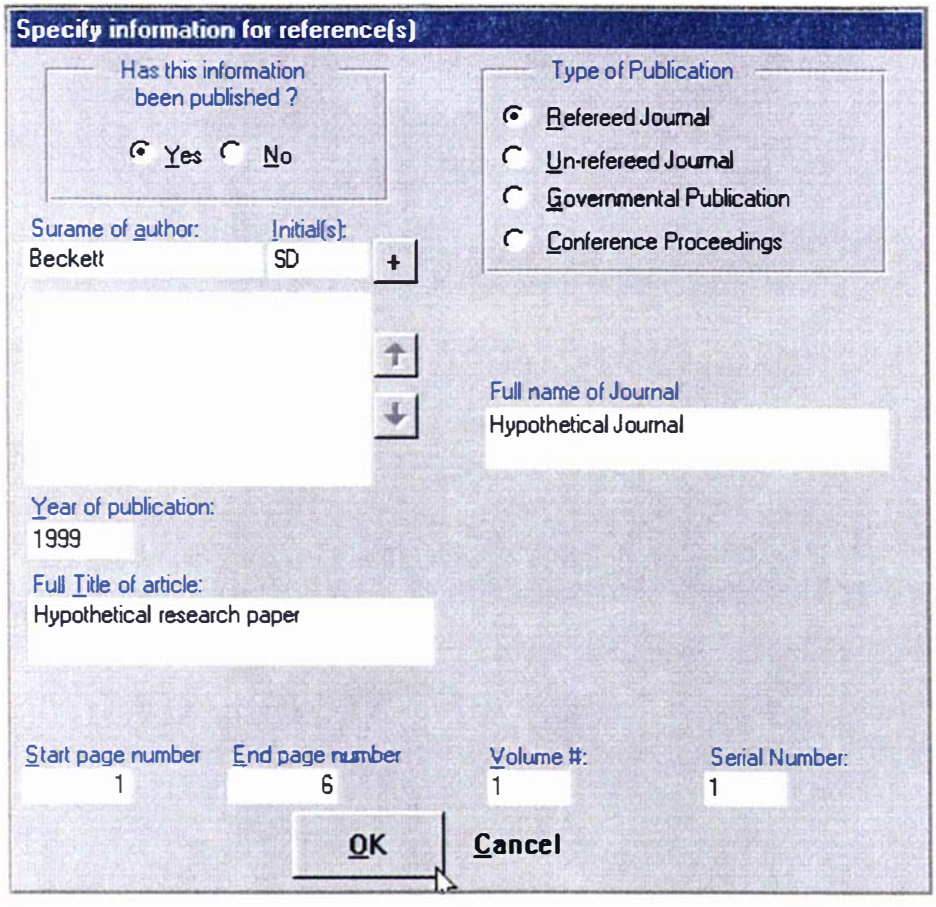
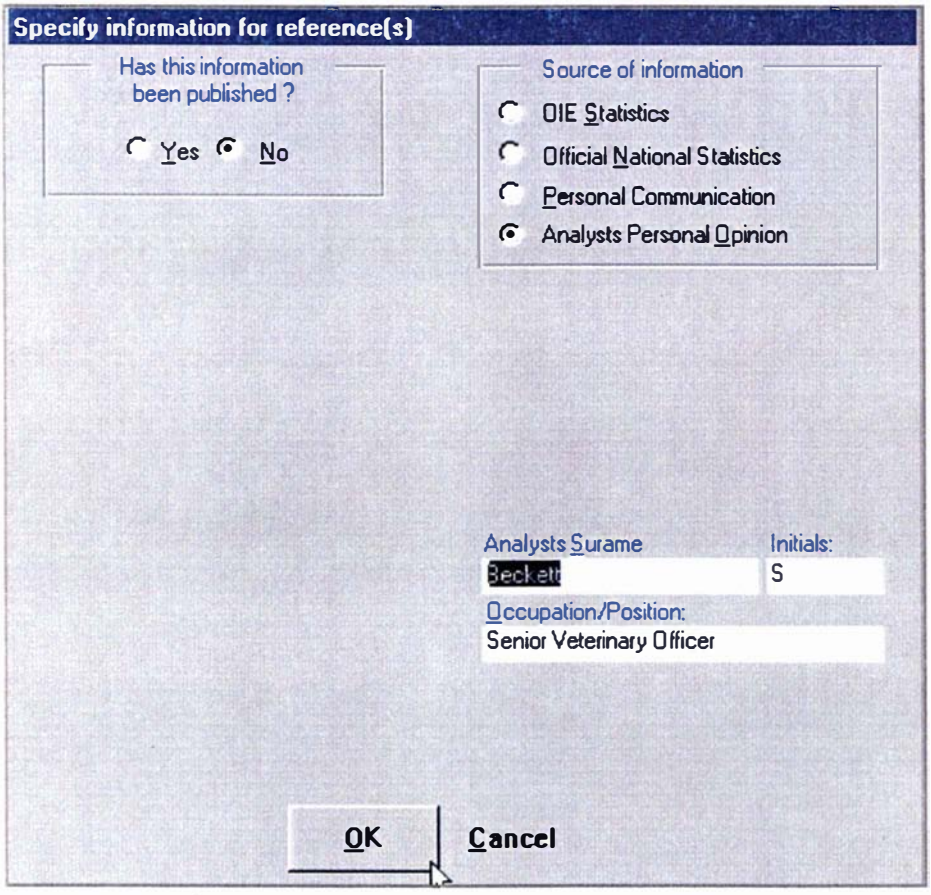


Figure 58: Data entry for an unpublished reference



Once data entry for a release and/or exposure assessment has been completed, that model or sub-model may be 'run' and the corresponding likelihood(s) evaluated. Not surprisingly, this is achieved by the 'model running engine'. The model running engine uses the model template to identify the relevant data tables, collects data for the given model instance and performs any algebraic manipulations. This data is stored as a single text string. Where the model is entirely deterministic (ie contains no random variables) the text string will also include the single quantitative output for the model - that is, a single value for either the release or exposure assessment.

Given this general overview of the model running procedure, a number of the more sophisticated features should be described. The statistical processes described in Chapter 2 were incorporated in the mathematical formulae used to calculate stage-level likelihoods. In particular, those questions involving *interventions*, such as testing or clinical examination (see, Section 3.2.1), which contained complex binomial summations that avoided the need to approximate in the

situation where without-replacement random samples were taken from a small group. Summations were enhanced by enabling analysts to generate models based on either batches or independent commodity units. The mathematics behind these summations is explained in Chapter 2.

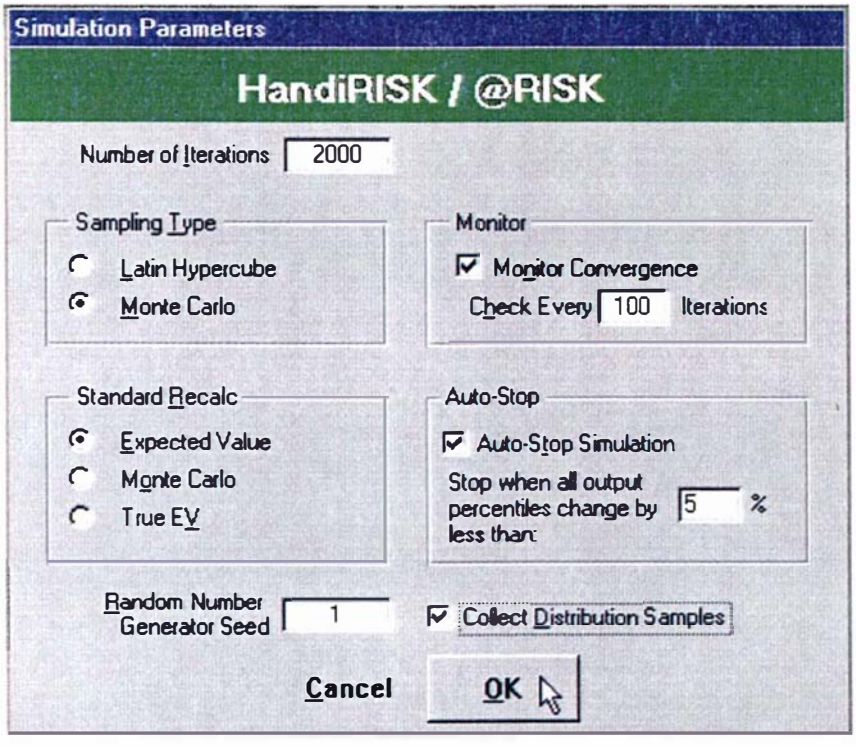
In addition to within-stage calculations, the model-running agent is able to delineate between a release and exposure assessment and calculate the appropriate conditional form for each. Conditionality is also discussed in Chapter 2, and will not be reiterated except to say that calculation of the release assessment is a highly complex procedure. Indeed, the development of an automated algorithm that enables this probability to be calculated in any situation was considered to be one of the most significant technical achievements. Once calculated, the release assessment was enhanced by allowing analysts to express it as either the 'risk per commodity unit', or the 'annual risk'. Where an annual risk is requested, the analyst is prompted to provide the volume of commodity to be imported annually. Once calculated, the release and exposure assessments are simply multiplied together to yield an overall likelihood of entry and exposure. Where the release or exposure assessment is qualitative, the overall likelihood cannot be calculated and the two are reported independently (see, Section 4.6.1).

Deterministic sensitivity analysis may also be performed in HandiRISK, although is limited to the ability to edit individual inputs within a completed model and either save these changes into the model or rename it as a second model. In either case, the edited model may be re-run and the output compared to that obtained from the original inputs. Through this process, the effect of variation in particular inputs may be determined, or each of the deterministic inputs examined systematically. Editing and saving models is a quick and simple procedure, and each new model may be named in the MMS so as to identify clearly its particular characteristics. Finally, a summary report may be used to generate a list of summary statistics for each of the edited deterministic models, sorted by name or by any of the reported statistics. Alternatively, a comprehensive report may be used to describe each model and thus display the altered inputs. Each of these reports is described in further detail in Section 4.6.1.

Where the model is stochastic, the component probability distributions and their parameters are stored in the text string and sent in this form to the 'simulation engine'. The simulation engine in HandiRISK is in fact the pre-built @Risk 'Risk Developer's Kit', or RDK (Palisade Corporation, New York, USA). This is the simulation module used by @Risk, a popular spreadsheet-based Monte Carlo simulation package and, as such, supports both Monte Carlo and Latin hypercube

sampling. The benefits and constraints of each of these approaches were discussed in Chapter 2. The RDK also enables the analyst to specify the random number generator seed, and thus replicate simulations, and to determine the number of iterations. These facilities are collectively termed 'simulation parameters' (Figure 59).

Figure 59: Simulation parameters for stochastic models



Where possible, HandiRISK uses the analytical method rather than simulation to model natural variation that arises from a secondary (calculated) input variable. It was shown in Chapter 2 that this approach avoids the inflated variance commonly associated with models that rely on simulation as a means by which to represent both uncertainty and natural variation. Exact analytical solutions are most pertinent to the intervention stages, and are provided by the binomial summations discussed above.

HandiRISK was also designed to enable users to specify rank order correlations between primary variables. This was to have been achieved by generating an editable rank order correlation matrix of a model's primary variables, in which each cell was given the default value of zero (no correlation). Users could then modify this matrix (prior to running a model) by specifying rank

order correlation coefficients between minus and plus one. This feature, while consistent with that which may be achieved manually using the spreadsheet-based simulation add-in @Risk has, however, proved difficult to implement through the @Risk RDK and may not be included as a fully-operable component of Version I.

Stochastic sensitivity analysis is implemented in HandiRISK as a *post hoc* statistical procedure performed on the stored distribution samples for each model instance. That is, the facility for sensitivity analysis available as an option within the @Risk RDK, is ignored. The principal reasons for running the sensitivity analysis independently of the @Risk RDK were, A) to enable better control over the selection of variables to be included in the analysis, and, B) to obtain results in a form that could immediately be displayed in graphs or inserted into reports. Each of these procedures could have been achieved through manipulating the @Risk RDK although it was simpler, more transparent and computationally faster to implement them separately.

Given the above, sensitivity analysis may be performed on any stochastic model that has been successfully run. Influential variables can be identified by carrying out a rank order correlation analysis. Sensitivity analysis may be based on all primary variables in the model, or on a subset of those specified by the analyst. Rank order correlation was chosen over the regression-based alternative for the reasons discussed in Chapter 2. The results of the analysis may be displayed in tabular form or using tornado diagrams (Figure 60 and 61, respectively). In the examples below it can be see that the variable "Quarantine sensitivity" is particularly influential, with a rank order correlation coefficient of approximately -0.83. ELISA sensitivity and ELISA specificity were also important variables, with coefficients of approximately -0.64 and 0.51, respectively.

Figure 60: Tabulated correlations obtained from a sensitivity analysis

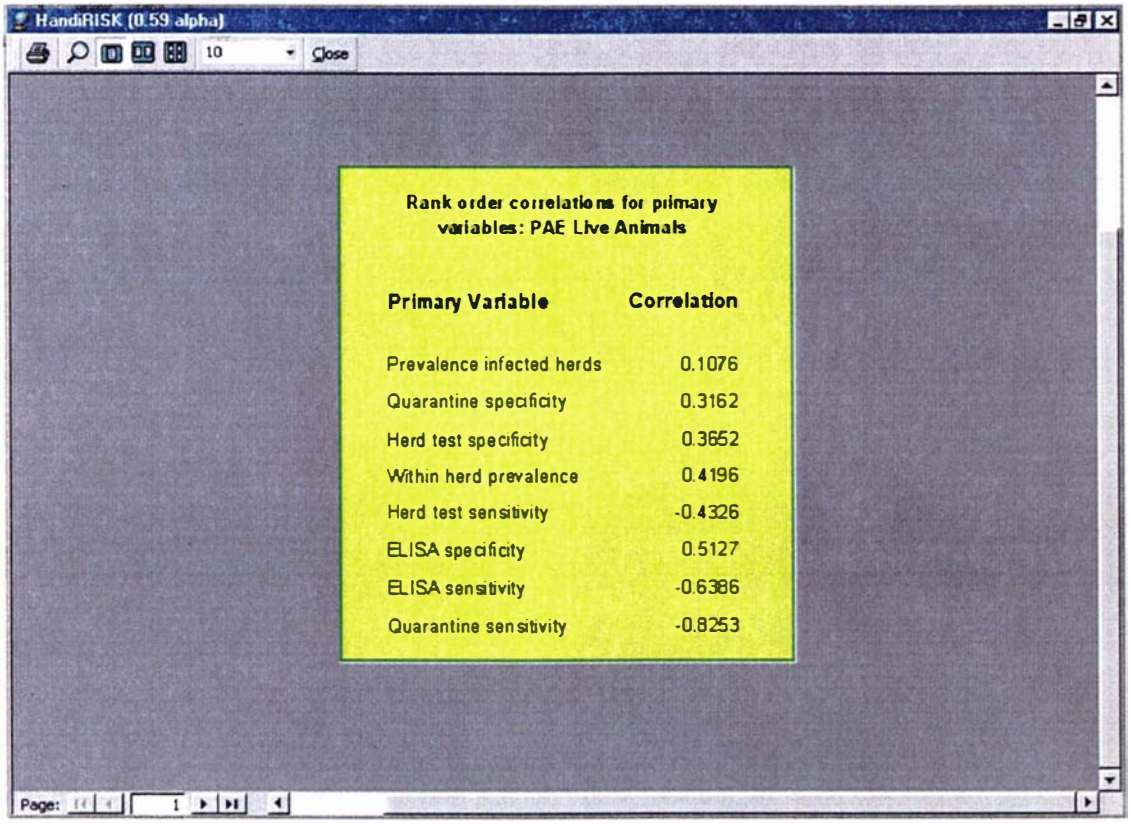
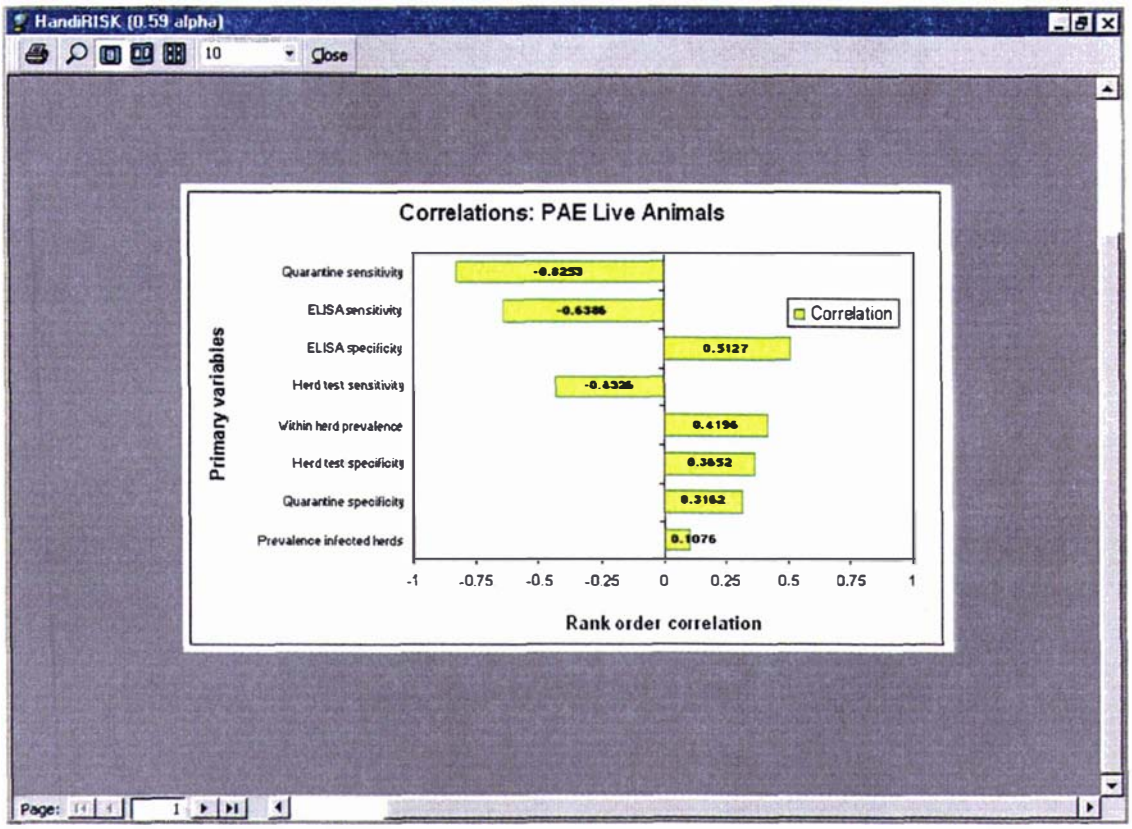


Figure 61: Tornado diagram obtained from a sensitivity analysis



Once identified, influential variables may be modified by editing the model and either saving the new setting or saving the model to a new name. The latter would be recommended in the context of sensitivity analysis, since this procedure may then be repeated iteratively so as to derive a series of related models, and the results of the group generated for comparison as a single summary report. Alternatively, a comprehensive report for the group of models could be produced so as to illustrate exactly the changes that were made and to provide a detailed analysis of the resulting outputs (see, Section 4.6.1).

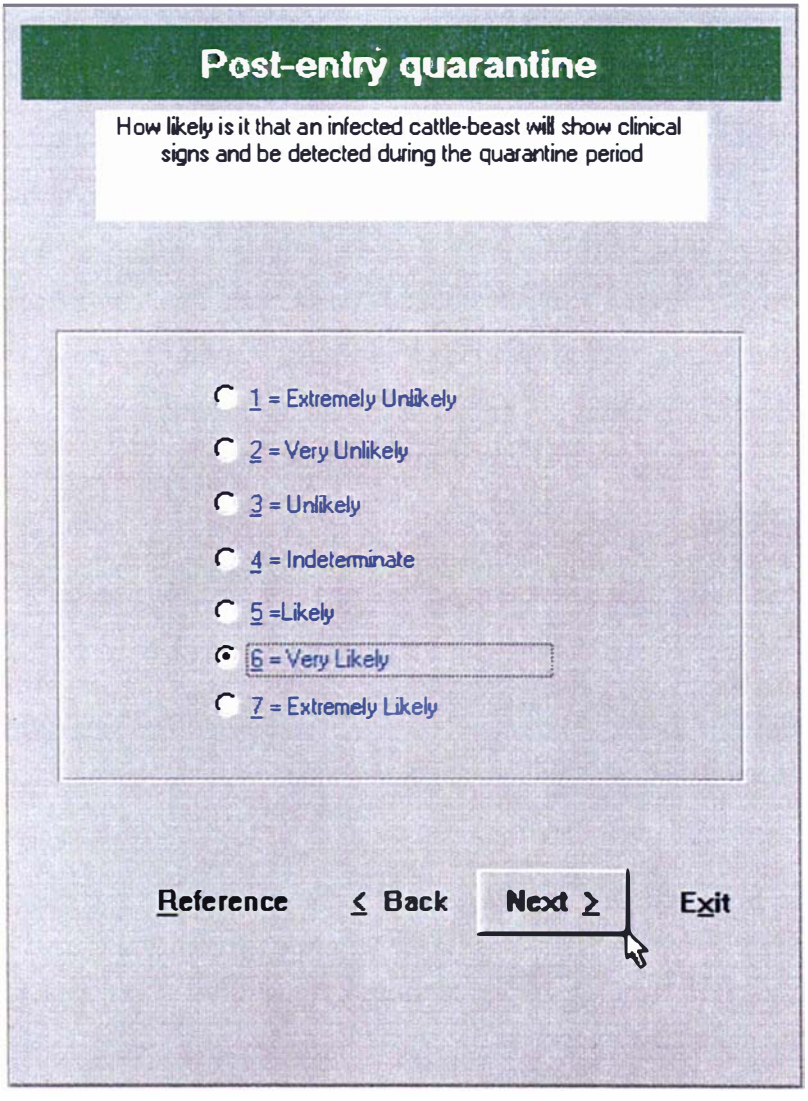
Qualitative likelihood evaluation

With the exception of specially designed qualitative data entry screens, the general procedure of qualitative likelihood evaluation is (at least from the user's perspective) identical to that described for the quantitative approach. An example of a data entry screen for qualitative responses is shown in Figure 62. Having selected a semi-quantitative score, the analyst is required to provide a reference - if only to specify that the information is his or her personal opinion. Referencing for qualitative models is identical to that for the quantitative approach discussed previously.

It can be seen that the data entry screen in Figure 62 uses seven semi-quantitative scores. Although not visible, it should also be noted that once data entry for a qualitative release or exposure assessment is complete, the model can be run in the same manner as outlined for quantitative models. That is, the model running engine visits data tables in the relevant generic questions and collects qualitative 'data' for the model. Qualitative data equates to stage-level qualitative likelihoods. Qualitative likelihoods are combined according to the 'smallest value' algorithm derived in Chapter 2. Where both release and exposure assessments are qualitative, these are subsequently combined according to the same algorithm to yield an overall qualitative likelihood of entry and exposure. The reporting of qualitative release and/or exposure assessments will be described in the following section.

This system for qualitative likelihood evaluation is considerably simpler than the structured semi-quantitative approach based on probability ranges proposed in Chapter 2. The system also uses seven rather than six categorical scores. As explained previously, the system adopted for this and other components of the risk analysis process were those that were amenable to New Zealand MAF, or which would be unlikely to be considered by other regulatory authorities to be controversial or experimental. It has also been explained that the modular design of HandiRISK will enable the approach to qualitative likelihood evaluation to be modified following the peer review of the more technical semi-quantitative procedure. This would either lead to the replacement of this simple approach, or the facility for analysts to customise their approach to likelihood evaluation.

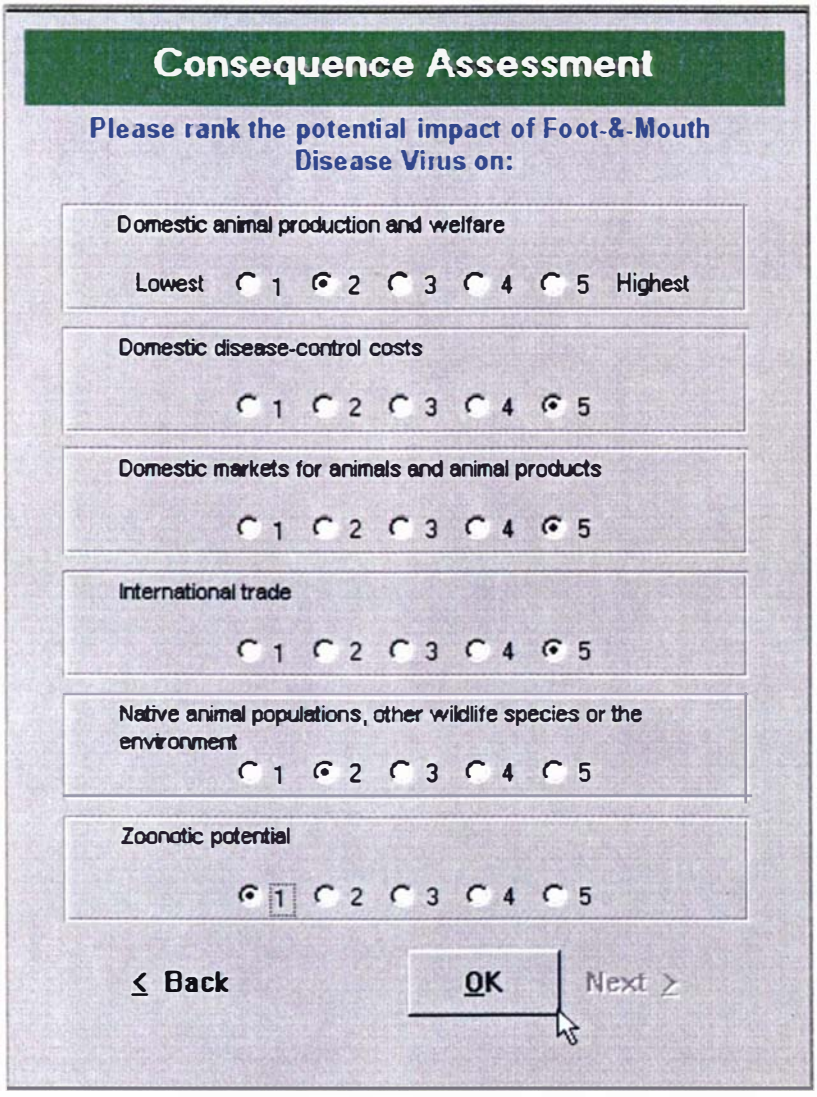
Figure 62: Qualitative data entry



4.4.2 Phase 4.2: Consequence assessment

The simplified consequence assessment module was described briefly in the discussion of hazard refinement (Section 4.3.2). Likewise, the ability for this module to be modified so as to support the more rigorous experimental approach proposed in Chapter 2 was also mentioned. Given this, it can be seen that the screen shot of the formal consequence assessment module (Figure 63) is identical to the screen shot of the abbreviated consequence assessment carried out for exotic diseases as a component of hazard refinement (Figure 50). Although not visible, the algorithm for deriving a consequence assessment from the data entered in this screen is also identical.

Figure 63: Consequence assessment in HandiRISK



4.4.3 Phase 4.3: Risk estimation

Risk estimation was shown in Chapter 2 to involve the integration of likelihood and consequence assessments so as to gain an overall measure of 'risk'. It was also shown in Chapter 2 that despite the clear need for integration of likelihood and consequence assessments, this aspect of risk analysis remains relatively under-developed, or at least underrepresented in the import risk analyses obtained for review. A structured approach to risk estimation was proposed in Chapter 2. This approach was based on a risk estimation matrix, and can be adopted for either quantitative or qualitative assessments, or for assessments that use a combination of the two methods. The approach was, however, experimental and for this reason was not implemented in this version of

HandiRISK.

In fact, given the reluctance for analysts to formalise a procedure for risk estimation, and the complete absence of official guidelines, this phase of risk assessment was not represented in HandiRISK in any form. Instead, the reporting facilities (see, Section 4.6) were designed so as to enable analysts to display aspects of likelihood evaluation and consequence assessment in a clear and consistent manner, and to use these to derive and implement their own approaches to risk estimation. It has been explained at various points in this document that HandiRISK has a modular structure. Given this, a risk estimation module can be included in later versions without disturbing the database design or system code.

4.5 Phase 5: Risk management

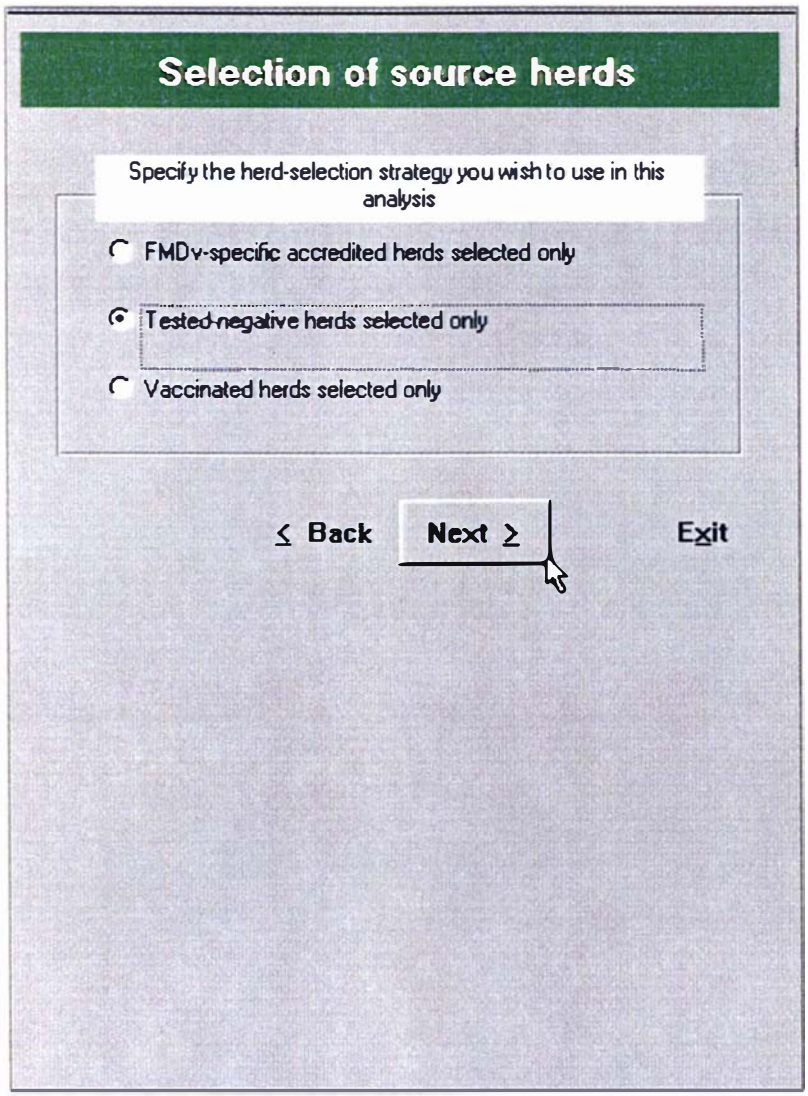
As a discrete process within risk analysis, risk management can be divided into two phases. The first is the need to classify unrestricted risk estimates as acceptable or otherwise. The second entails the identification and evaluation of alternative risk management strategies for risks considered unacceptable in their unrestricted form. The procedure of classifying unrestricted risks is closely linked to risk estimation (as described above) and is not represented in this version of HandiRISK. The reasons for this have been discussed. In contrast, the procedure for evaluating alternative risk management strategies is considered one of the most comprehensive features of HandiRISK.

Firstly, sensitivity analysis, as described in Section 4.4.1, may be used to identify the particularly influential stages or primary variables and thus enable risk management to be focussed and efficient. Secondly, model templates may be created or edited using the template-building tool so as to add risk management stages to an existing model template or rearrange the sequence in which they are performed. Finally, the generic questions incorporated in HandiRISK each support a wide range of risk management alternatives.

An example of the last of these facilities is provided in Figure 64, where the generic herd-selection question has been instantiated and the user presented with three separate risk management choices. By selecting the second choice (as shown) the user generates one of the TEST questions and so initiates the process of completing a model in which only tested-negative source herds will be permitted. When it is considered that virtually all of the generic questions coded in the HandiRISK knowledge base describe alternative pathways similar to that shown in

the herd selection example, it can be seen that a huge number of different model instances can be generated from a single model template. Indeed, since it is envisaged that analysts will wish to explore the efficacy of various risk management strategies, the summary report (see, Section 4.6.1) was designed specifically to provide an efficient means by which the results of similar models could be viewed concurrently.

Figure 64: Risk management options generated by the generic herd-selection question



4.6 Phase 6: Risk communication

It was concluded in Chapter 2 that tabulated reports, path diagrams (influence diagrams, decision pathway diagrams and scenario trees) and distribution plots (histograms and cumulative

probability plots) were all valuable means by which the methods and/or results of an import risk analysis could be communicated to stakeholders or decision makers. Each of these was subsequently implemented in HandiRISK.

4.6.1 Tabulated reports

Two groups of tabulated report were implemented in HandiRISK:

- Comprehensive report
- Summary report

Comprehensive report

The principal objective of the comprehensive report is to ensure that import risk analyses carried out using HandiRISK are completely transparent. That is, that the structure of all models, all quantitative data and mathematical formulae, all decisions and all references are adequately described. If this is achieved, then policy makers, stakeholders and trading partners alike can see how any given risk estimate was derived and, if desired, may replicate the analysis manually. This satisfies the official requirements of the WTO and, in many respects, removes the 'black box' phobia that frequently surrounds computerised systems.

The comprehensive report is designed to be a reference document and may be cumbersome if generated for an entire analysis, particularly where this has examined the risks associated with a large number of disease agents. From this point of view, it is expected that analysts will generally produce comprehensive reports for particular models or, at most, for a small number of different models created to determine the risks associated with a particular disease agent.

The comprehensive report is the more universal of the tabulated reports as it may be generated for an entire analysis, a group of models constructed for a single disease agent, or for an individual model, regardless of whether quantitative or qualitative or of the state of completion (See, Section 2.2.1). The comprehensive report is based at the level of individual models, although for each of these that are described, the relevant 'parent' disease agent(s) and analysis(es) are also cited. The comprehensive report is thus a systematic expansion of information pertaining to the tree of models, agents and analyses described in the MMS, and contains as many of these elements as follow from the component selected in the MMS when the report is requested.

The specific information displayed in the comprehensive report will depend to some degree on whether the component models and sub-models are qualitative or quantitative (as described above) although, in general, will comprise the following six broad categories:

- Descriptive information regarding analyses or models
- The name and description of the stages in the model
- Question response statements
- Decisions and data
- Citations
- Risk assessment results

An example of the comprehensive report produced by HandiRISK is given in the screen captures in Figures 65-70. This report was generated for an hypothetical analysis investigating the risks associated with importation of live pigs from the United States of America into New Zealand.

Figure 65: Comprehensive report (I) - Title page showing analysis description

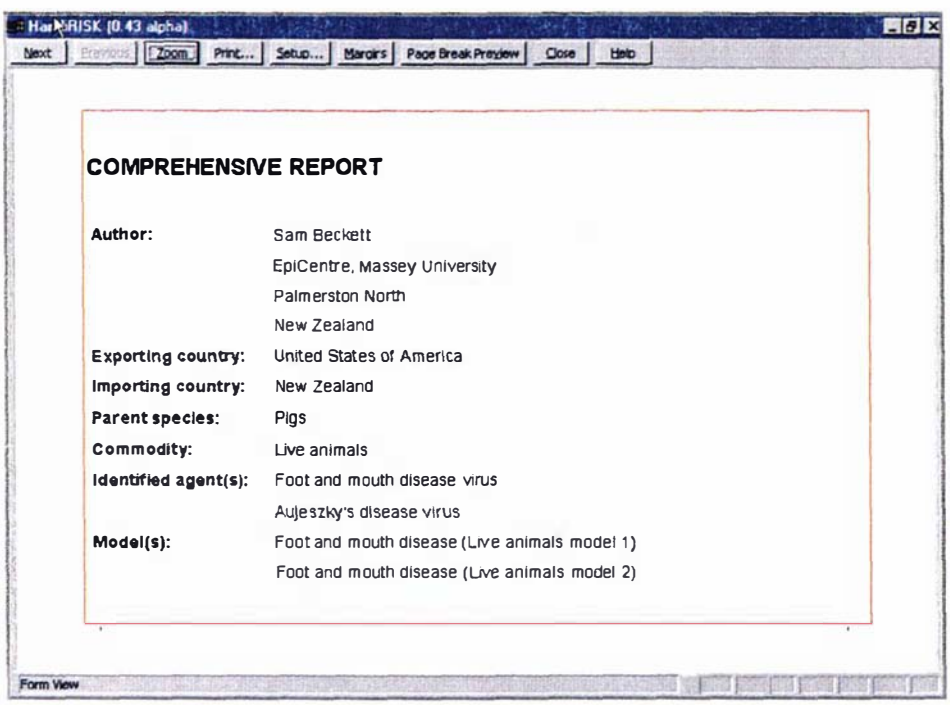


Figure 66: Comprehensive report (II) - Consequence assessment

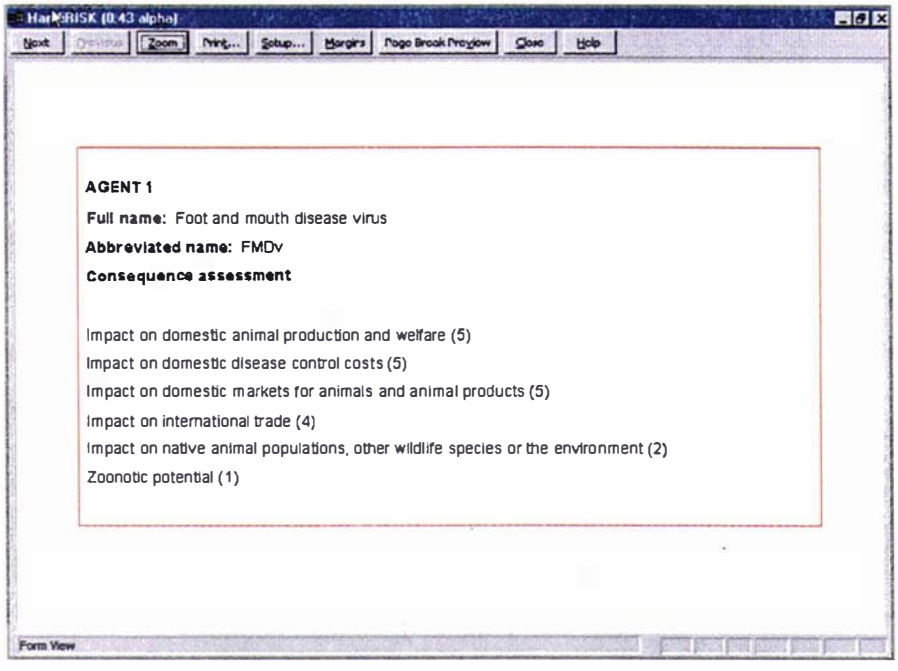


Figure 67: Comprehensive report (III) - Description of Model 1

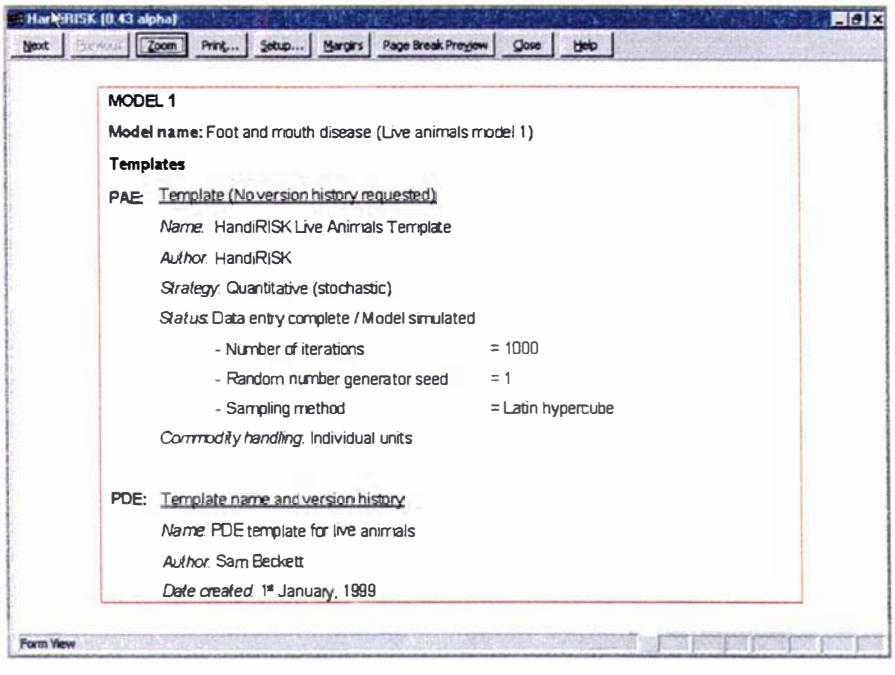


Figure 68: Comprehensive report (IV) - Excerpt from the data entry and calculations for Live Animals Model 1

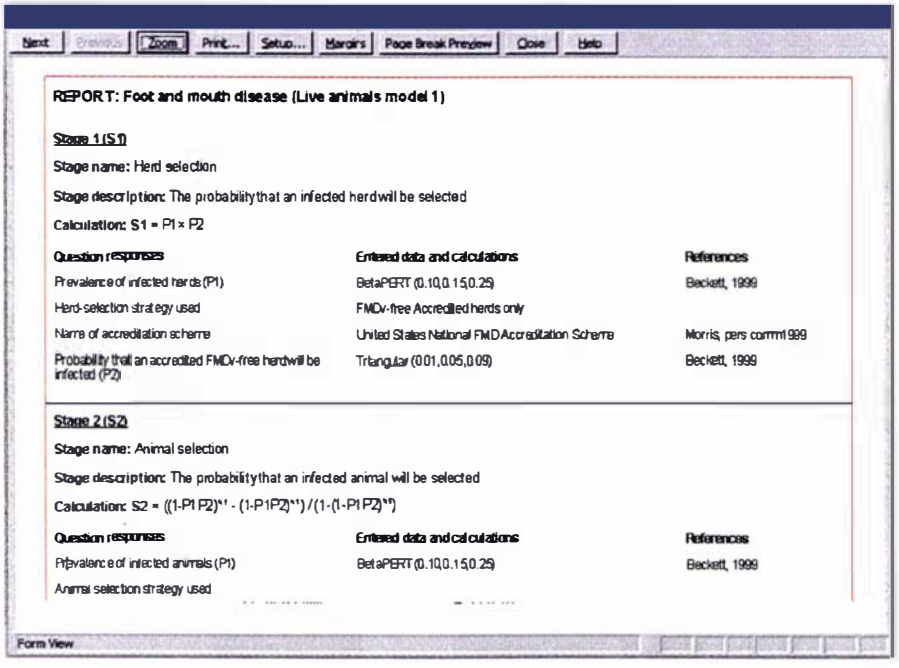


Figure 69: Comprehensive report (V) - Excerpt from the results generated for Live Animal Model 1

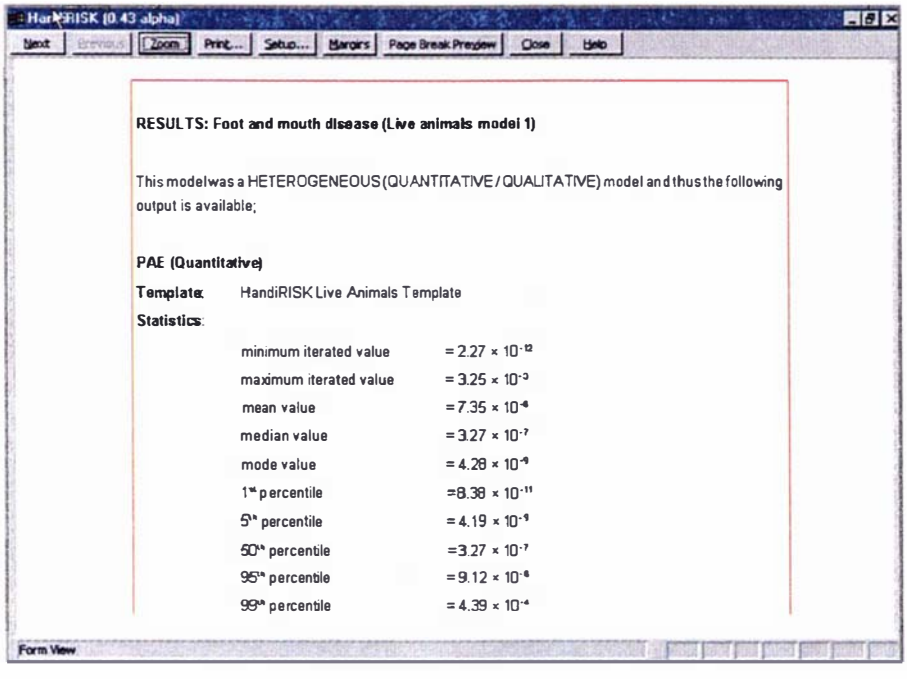
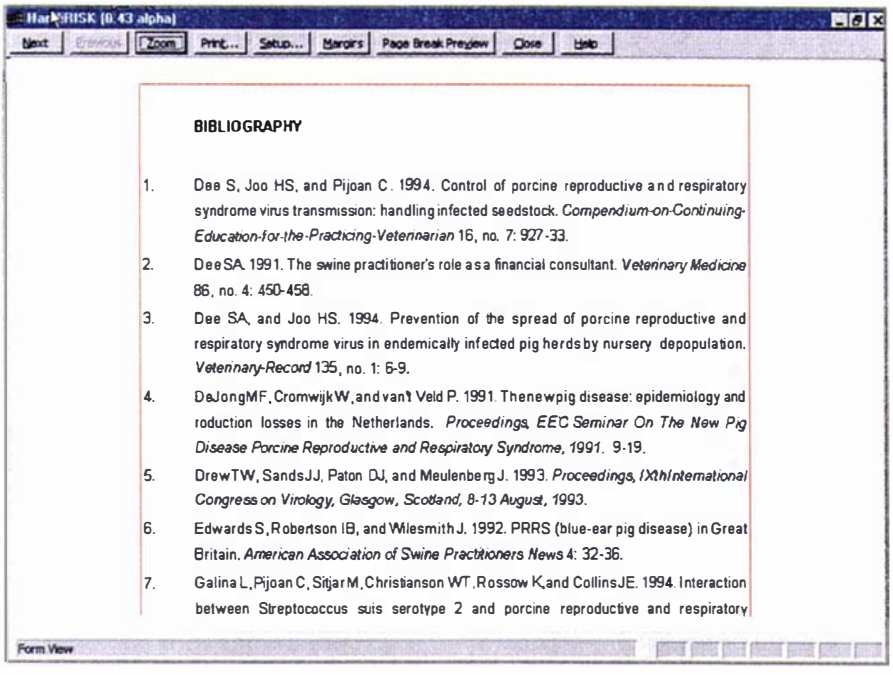


Figure 70: Comprehensive report (VI) - Excerpt from the bibliography



Descriptive information

Several levels of descriptive information are provided in the comprehensive report.

Description of analysis

All comprehensive reports, whether generated for an analysis, agent(s) or model(s) open with a summary of the parent analysis:

- The name and personal details of the analyst (if more than one has contributed, the remaining report is sorted alphabetically by analyst)
- The imported commodity, parent species and exporting country
- A list of identified disease agents
- A list of models created for each identified disease agent

It can be seen from Figure 65 that where a comprehensive report is generated for a model or group of models, the information above will be pertinent and will therefore be provided as the report header.

Description of disease agent(s)

The remaining contents of the report are displayed on an agent-by-agent basis, and the summary that appears for each agent will be identical to that given if a report is generated for a single agent:

- The full name of agent
- The abbreviated name of agent
- A consequence assessment

Description of model(s)

As shown in Figure 67, the complete description of each model is preceded by a summary of the templates from which it was created and, where at least one component is stochastic, a summary of the pertinent simulation parameters. Template summaries include the following categories of information:

- Template name and author with or without version history as requested
- Modelling approach - that is, qualitative or quantitative
- Stochastic models - simulation parameters
- Deterministic models - no further information
- Commodity-management strategy - batched consignments or independent units

In some cases the template used will simply be the generic template provided with the system. However, since HandiRISK templates may be copied and altered, new templates derived from first principles or new templates created by editing existing user-built templates, it may be useful to know the history and original author of the template version used in a particular model. Template version histories will not be generated automatically, but will be available as an option when a comprehensive report is generated.

The following information is given for a template version history:

Date created	Name of creator
Date modified	Name of modifier
Date modified	Name of modifier ... etc

Additional model-specific information provided in the comprehensive report includes:

- Model stages
- Question response statements
- Decisions and data
- Citations
- Risk assessment results

Summary report

The purpose of the summary report is to provide users with a condensed account of the results of a group of similar quantitative models. Such models may then be compared simply and objectively, with respect to expected values or percentiles of their final risk estimates and decisions made regarding the particular groups of risk-management strategies that lead to acceptable estimates. To facilitate this, the summary report is provided in a 'sortable' format such that the records or models for any given disease agent may be arranged in ascending or descending order by the relative magnitude of percentiles, means or medians.

An example of a summary report generated for an hypothetical analysis investigating the risks associated with the importation of live pigs from the United States of America into New Zealand is provided in Figures 71-73. Although this example was hypothetical, it serves to illustrate the features of the summary report. In particular, it can be seen that seven models have been constructed for the disease agent, foot-and-mouth-disease virus, and that summary statistics have been generated for each of these seven models. In this instance, the models have simply been sorted by model number (Model 1 to Model 7) although they could equally have been sorted by any of the chosen statistics.

Figure 71: Summary report (I) - Description of analysis

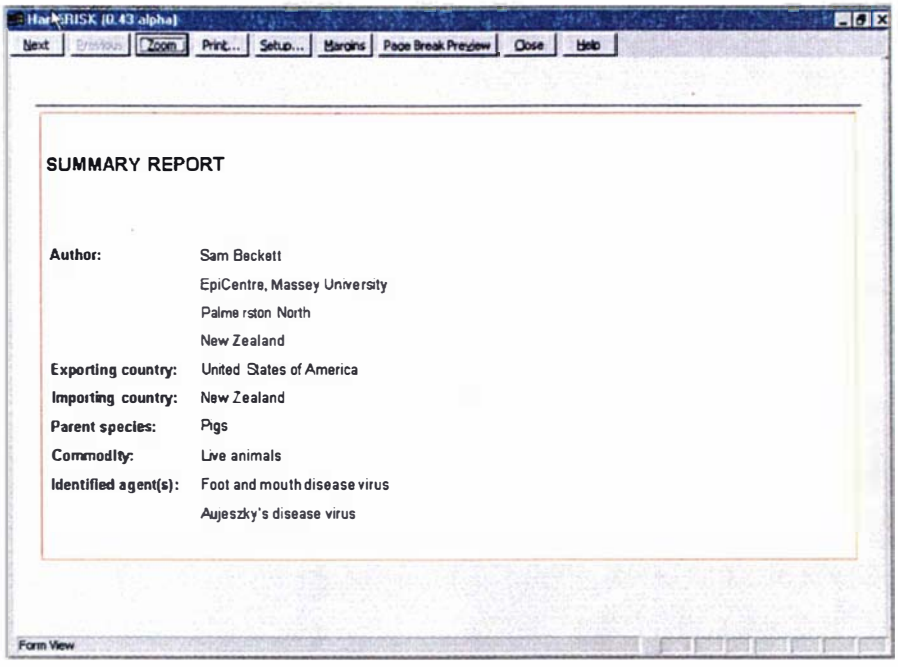


Figure 72: Summary report (II) - List of models to be reported

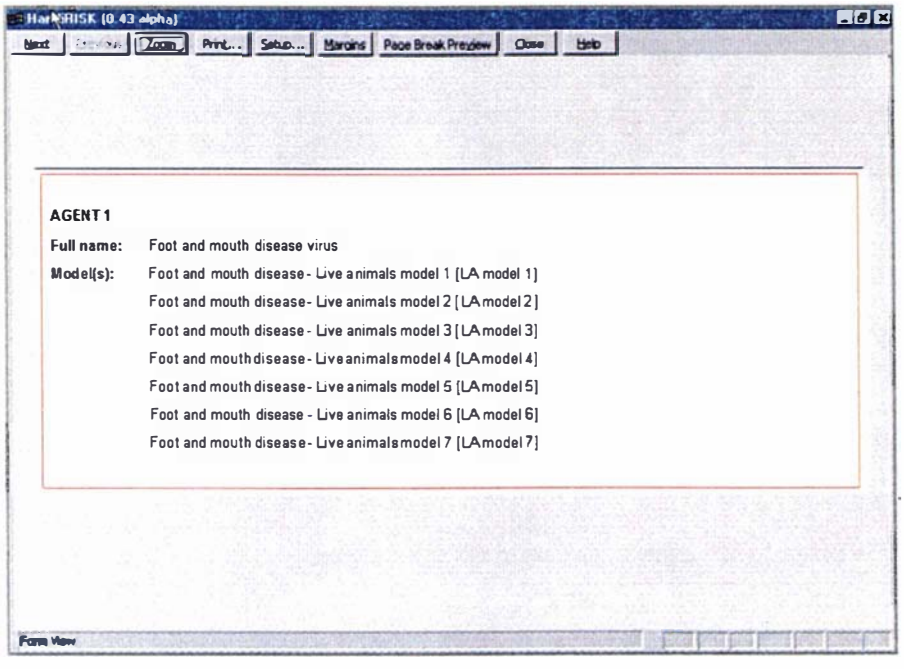
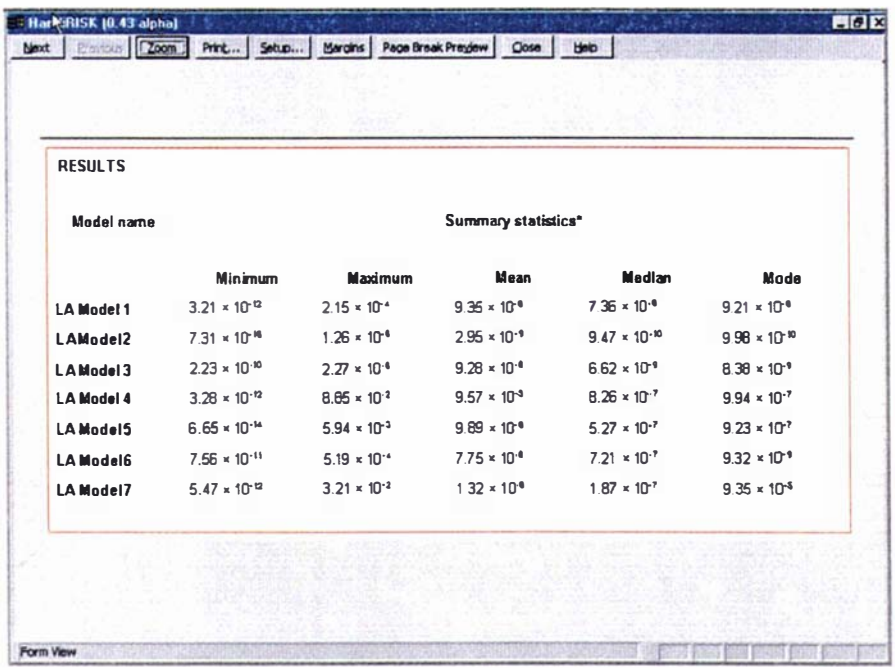


Figure 73: Summary report (III) - Summarised results for the seven models



The summary report may be generated in the MMS by selecting an analysis, a single agent or a model (see, Section 2.2). The only prerequisite is that at least one component of at least one of the models selected or implied is quantitative. Figure 71 shows that the summary report is headed and punctuated by descriptive summaries identical to those described for the comprehensive report discussed above. The summary report, however, contains a single line or 'record' for each completed quantitative model and, as such, is substantially more concise and manageable than the comprehensive report and therefore more appropriate if a precis of the results of a large number of quantitative models is required.

The user will be required to select those fields on which a comparison between models is to be based. Where more than five fields have been selected, the user will be advised that concurrent visibility of all fields will not be possible, and that the number should be reduced if the report is to be printed. Reports with more than five fields may be viewed on-screen with the use of horizontal scroll bars.

Aside from statistical information, details regarding the parent disease agent and analysis for each group of models are also provided in the summary report. Indeed, the report is automatically sorted in this way so that hierarchical structure portrayed in the MMS is replicated for direct

comparison.

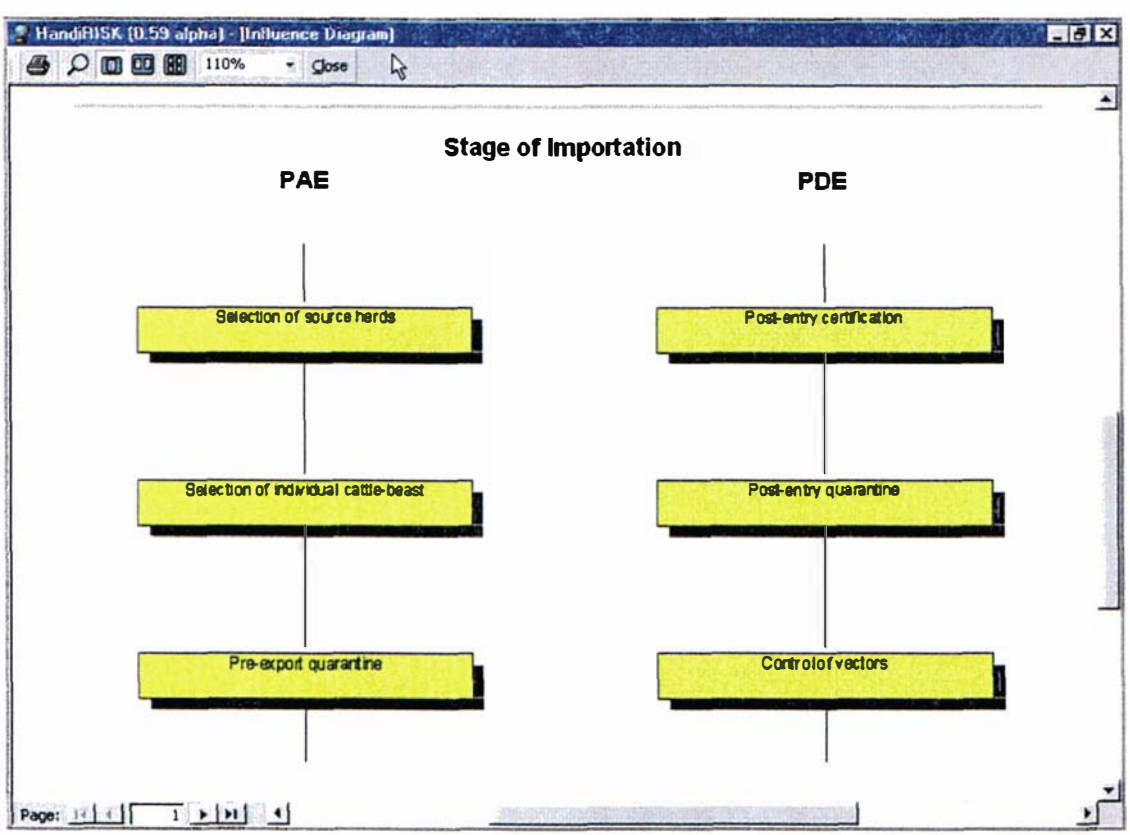
4.6.2 Path diagrams

All path diagrams have the central objective of describing the structure or flow of events, or steps, in importation and/or exposure pathways.

Influence diagram

From the screen capture (Figure 74) it can be seen that the influence diagram in HandiRISK graphically represents each the two model templates used to create a model instance. The nodes represent the discrete steps within each model template, starting with the first stage in the release assessment and moving through to the calculation of the exposure assessment.

Figure 74: Influence diagram (excerpt) for a model based on the importation of porcine semen



The main purpose of the influence diagram is to provide analysts with a simple and easily

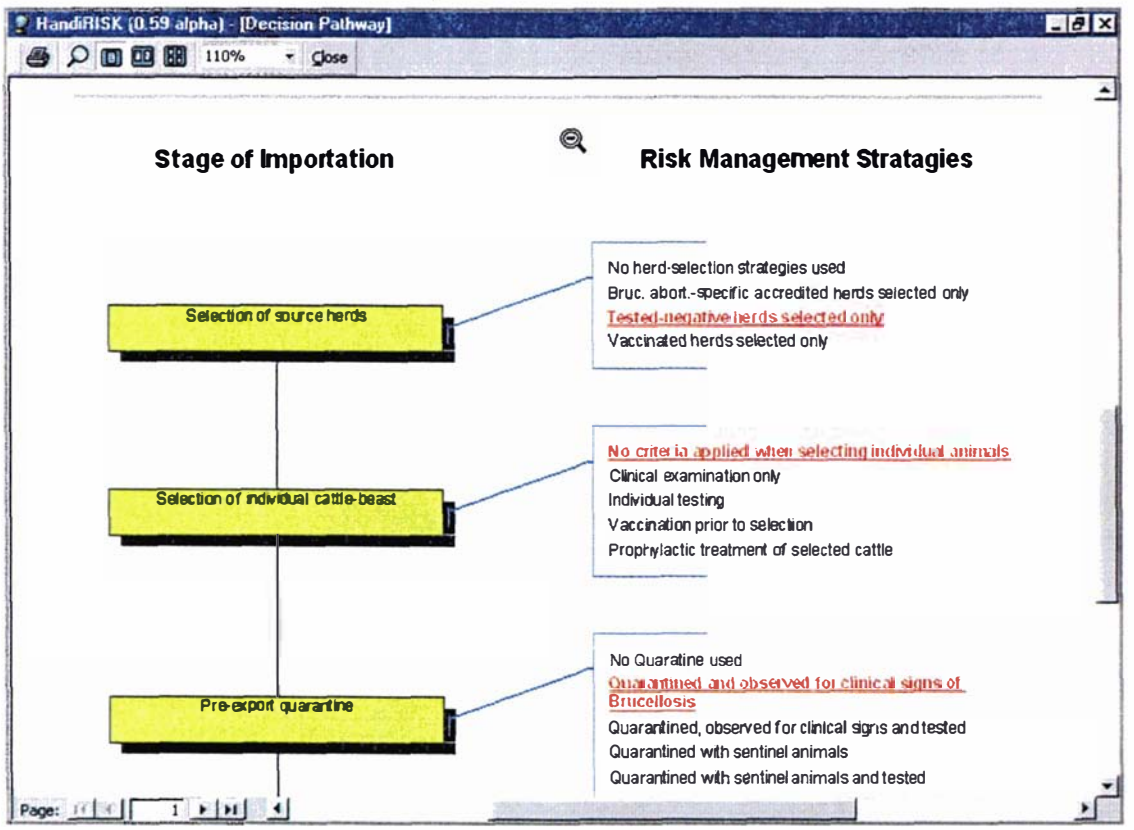
understood pictorial schema, which can be used to communicate the structure or flow of events in an import scenario. It is envisaged that this form of pathway diagram will be of most value in discussions between analysts, or the risk analysis team, and members of the relevant industry groups who have requested or opposed the proposed importation. That is, the influence diagram will provide analysts with the first stage toward communicating their understanding of the given scenario and will enable persons without technical experience in this field to understand and critique the approach that has been taken.

Influence diagrams are generated from the MMS, by highlighting a model and using either the right mouse-click menu option or the pull-down menus at the top of the home screen (see, Section 2.2). Since influence diagrams are derived solely from information regarding the model template, they may be generated for any model instance, regardless of its structure or state of completion.

Decision pathway diagram

The decision pathway diagram (Figure 75) is a logical extension to the influence diagram. Where the influence diagram is used to describe the framework of an importation scenario, the decision pathway diagram is a means of illustrating both the range of alternative strategies available at each step, and specific combination of these that models an individual importation scenario. It is envisaged that both the decision pathway and influence diagrams will be used as pictorial additions to tabulated outputs and written analysis reports. These diagrams will allow non-technical persons to rapidly determine the approach taken in an analysis and the range of individual import protocols that might be considered for any given importation scenario.

Figure 75: Decision pathway diagram (excerpt) for a model based on the importation of porcine semen



The decision pathway diagram may be generated for any model stored and displayed in the MMS. In contrast to the influence diagram, however, the decision pathway diagram is based on a specific model instance and not simply on the model template. Decision pathway diagrams may thus be generated for models that are qualitative or quantitative, based on batched-consignments or individually handled units, and even for models that are incomplete. Where the latter is the case, the resulting diagram will display decisions made at each completed stage and will simply give the range of alternative strategies for stages of the scenario that the analyst has not yet described.

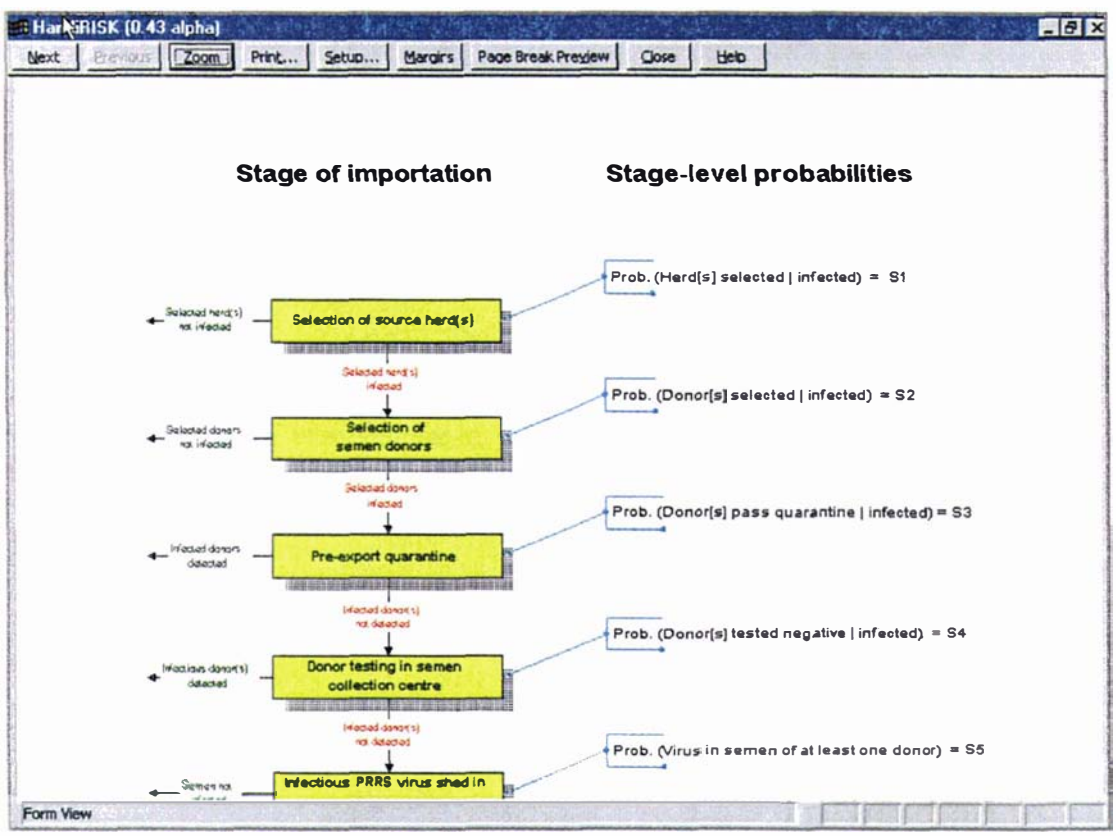
Scenario pathway diagram

Scenario pathway diagrams (also called scenario trees or event trees) show the flow of events and probabilities in an importation and/or exposure pathway. Scenario pathway diagrams start with an 'initiating failure event' (such as the selection of a diseased herd or animal) and progress through a series of 'branch points' denoting stages within the model template, to conclude with an 'end

state'. Scenario trees created in HandiRISK (Figure 76) combine the two model templates required for a complete model instance and, where both are quantitative, include the calculation of the final risk estimate.

As stated above, scenario trees illustrate the probabilities attributed to each branch point. Where branch points or stages represent *simple events*, the probability should be expressed as either the probability that the commodity will remain infected after this stage (p), or one minus this probability (1-p). Where branch points represent *interventions*, *p* should represent the probability that infection will be detected and the animal or commodity removed (the 'sensitivity' of the stage) or one minus this probability. Alternatively, qualitative scenario trees will show the semi-quantitative likelihoods (l) for each of these events. This convention is illustrated in Figure 76.

Figure 76: Scenario pathway diagram (excerpt) for a model based on the importation of porcine semen



4.6.3 Distribution plots

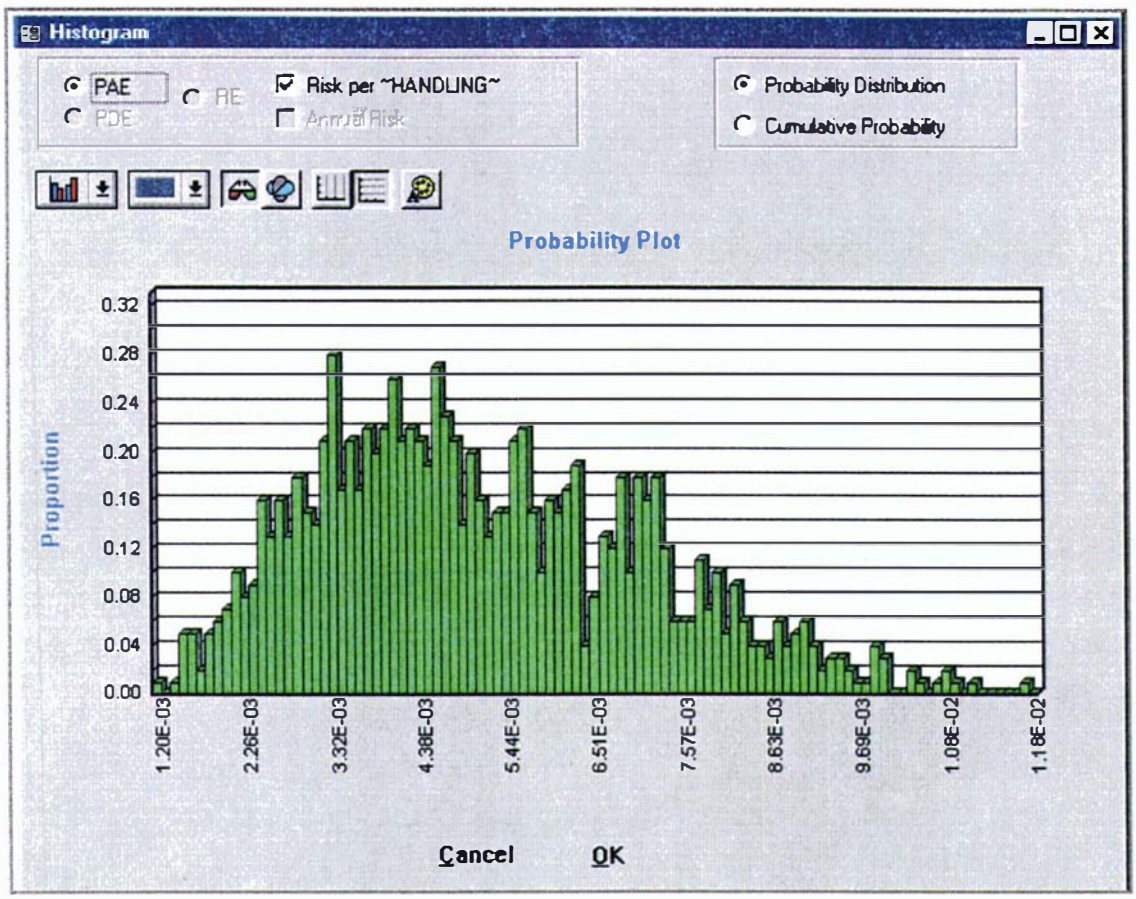
Distribution plots are the categorised and graphed results of stochastic quantitative models. HandiRISK collects the distribution samples obtained for a model's output, returns them to a table within the database and subsequently manipulates them to create either or both of the probability densities:

- Histogram
- Cumulative probability plot (CPP)

Histogram

A histogram (Figure 77) refers to the distribution or graph created when the set of values obtained from a simulation are ranked and categorised, then graphed against the proportion of each category observed in the sample. HandiRISK contains an algorithm that divides the number of iterations in each simulation by 10, and uses this result as the appropriate number of categories. Category boundaries are subsequently determined by dividing the range by the number of categories and applying the usual histogram convention - that is, a value falls in a category if it is greater than the lower boundary and less than or equal to the upper boundary.

Figure 77: Histogram



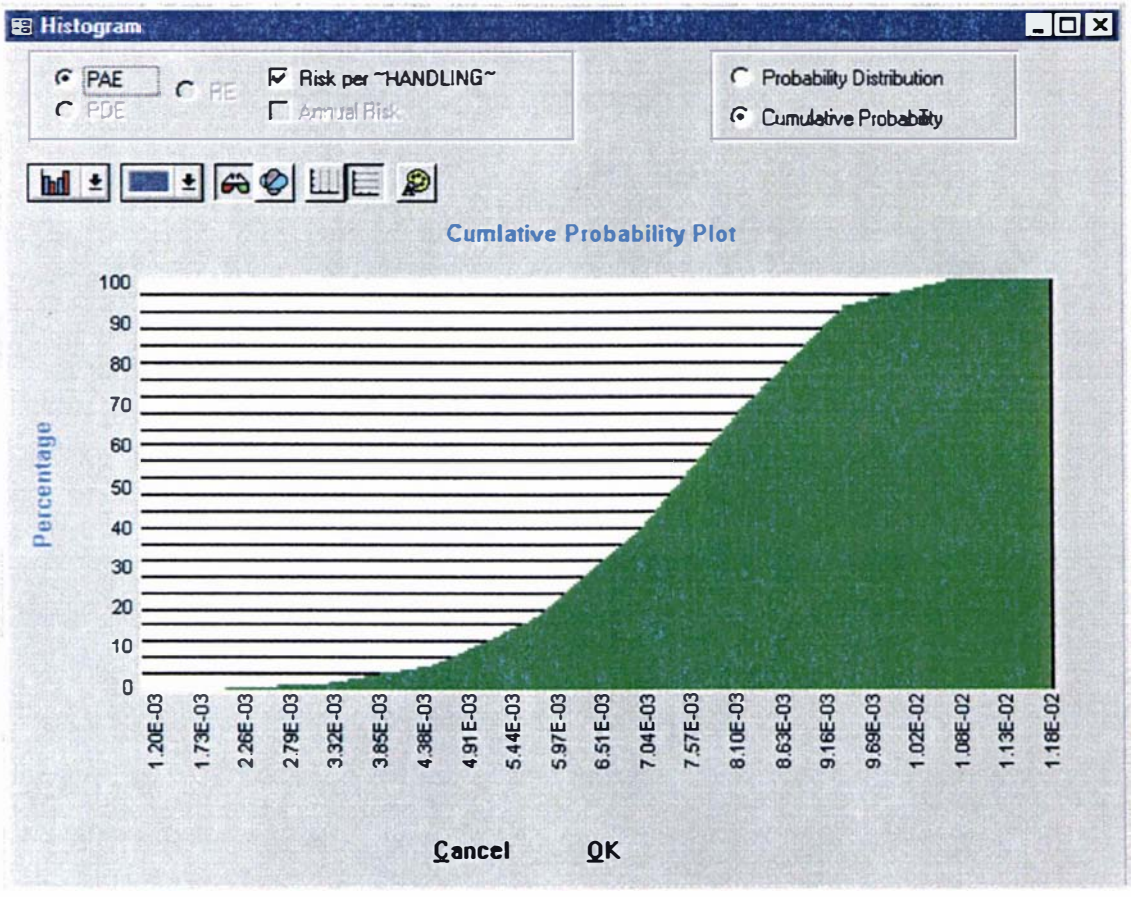
It can be seen from Figure 77 that the histogram for an output probability density displays both the spectrum of iterated values, and the likelihood of any given value. Histograms obtained from the simulation of an import risk analysis model will typically be in the form of left-skewed bell-shaped curves with a clear maximum and minimum, and a range of likely values. Since some output distributions will have a range spanning many orders of magnitude, HandiRISK allows the user to manipulate both the range of the X-axis and the number of 'tick marks', such that an output distribution may be 'clipped' or focussed on the region in which most iterated values lie. This facility means that a highly skewed distribution with a large range of iterated values may be centred and displayed in a form that best characterises its shape.

Cumulative probability plot

The cumulative probability plot (CPP) (Figure 78) is also derived from the results of a stochastic simulation. The CPP is obtained by ranking the iterated values and plotting these against the

probability of observing a value of the magnitude or less - that is the 'cumulative probability'. For ease of interpretation, cumulative probabilities are displayed as percentages, such that the Y-axis ranges from zero to one hundred percent while the X-axis illustrates the range of iterated values. Similarly, HandiRISK provides guidelines on all cumulative probability plots which mark the 5th, 50th (median) and 95th percentiles of the outcome risk.

Figure 78: Cumulative probability plot (CPP)



The CPP is generally a sigmoidal, or 'S-shaped', curve. It can be seen from Figure 78 that by selecting a value on the X-axis and reading off the corresponding cumulative probability, the observer may determine the likelihood of observing a risk of at least the chosen magnitude. Thus it can be seen that the principal purpose of the CPP is to enable analysts to illustrate the 'percentiles' of the likelihood estimate - that is, those values below which 1, 5, 10, 90, 95, etc percent of iterated results lie. This in turn is useful, since many analysts choose to report the likelihood estimate in terms of both expected value and the more conservative 90th or 95th percentiles, and the difference between the these clearly reflects the degree of variation in the

simulated risk estimate. Cumulative probabilities are thus little different to histograms but are a useful means of supplementing the latter as graphical aids to illustrating the behaviour of an outcome risk estimate.

5 System Development life cycle

5.1 Principles of cyclic development

While many models for software development and engineering have been proposed, the three listed below are amongst the more commonly cited:

- The classic life-cycle or waterfall model
- Prototyping
- Fourth generation techniques (4GTs) (Stevens, 1991; Pressman, 1992)

A thorough and systematic discussion of approaches to software engineering is beyond the scope of this thesis. Given this, each of these three models was applied during the development of HandiRISK and thus will be briefly outlined.

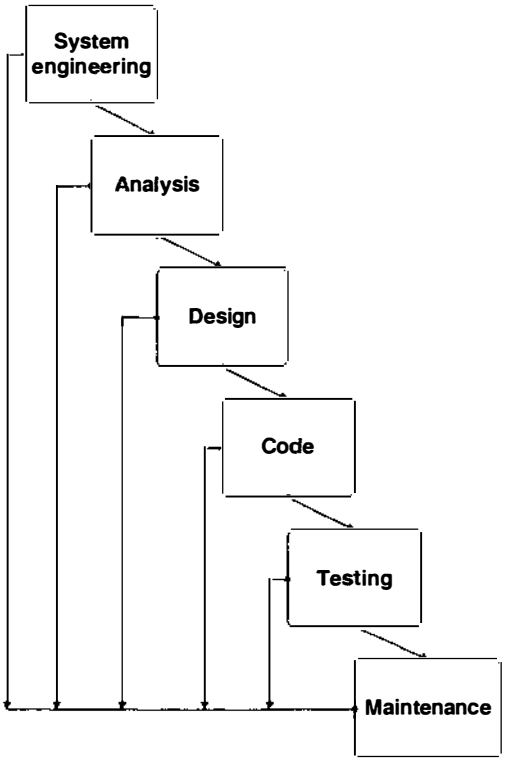
5.1.1 The classic life-cycle or waterfall model

This is one of the earliest models for software development and, with the increasing use of predesigned 'tools', 'developer's kits', 'shells' and high level programming languages is becoming difficult to adhere to in its original form (Pressman, 1992). Nevertheless, the principles of the waterfall model remain useful as a conceptual framework and, at an early stage of the process, may be employed as a means by which to illustrate the stages and various elements of design that will be required. The model is also useful from a philosophical standpoint since it emphasises the fact that coding is only one of six fundamental steps in the development procedure - an issue that many software users do not find intuitive (Stevens, 1991).

A simplified diagram of the life-cycle waterfall model, as adapted from one of its original representations (Pressman, 1992), is shown in Figure 79. Aside from containing a logical series of components, the procedure is not described as iterative and, thus, may prove difficult to adhere to in a practical engineering environment. In particular, it would be uncommon for a 'requirements analysis' to be completed adequately with a single iteration, and likewise for the coding to be

finalised without revision (Simmons, pers comm 1998)[3]. Iterative programming and requirements specification were in fact prominent features in the development of HandiRISK and it was noted early in the conceptualisation and planning of the project that this model was unlikely to provide an adequate approach if adopted in a literal manner.

Figure 79: The "waterfall" model for software engineering, adapted from Pressman (1992)



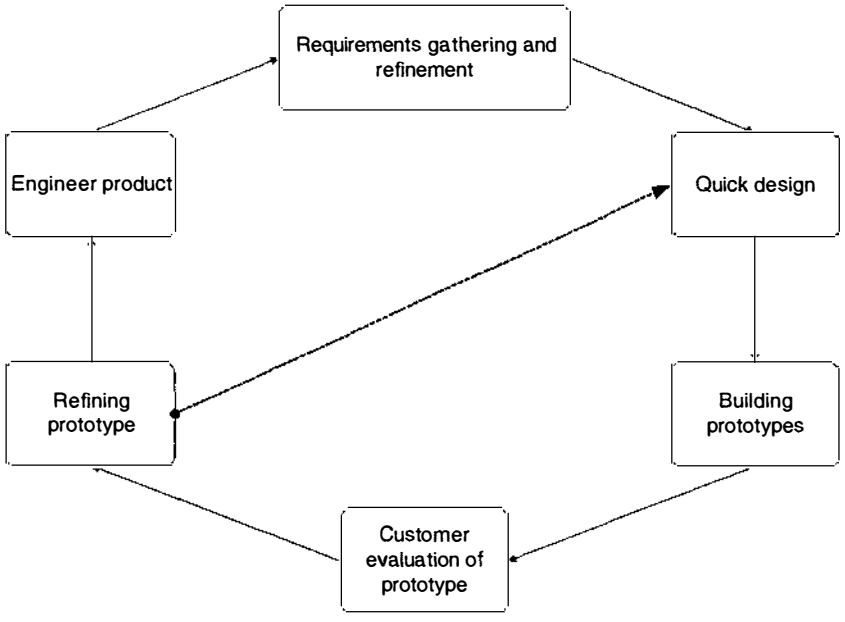
5.1.2 Prototyping

Prototyping requires the developer to create a model of the system - that is, a representation of the system components that contains some of the system's elements, or a full program that provides some or all of the functions required but has other features that necessitate development (Pressman, 1992; Sallis et al, 1993). Prototyping is not generally described as an iterative process and while this approach was adopted during the development of HandiRISK, the paradigm itself was modified so as to allow this extra flexibility. A typical representation of software engineering

[3] Simmons, K: EpiCentre, Institute of Veterinary Animal and Biomedical Sciences, Massey University, Palmerston North, New Zealand

by prototyping is given in Figure 80.

Figure 80: The "prototyping" model for software development, as adapted from Pressman (1992)



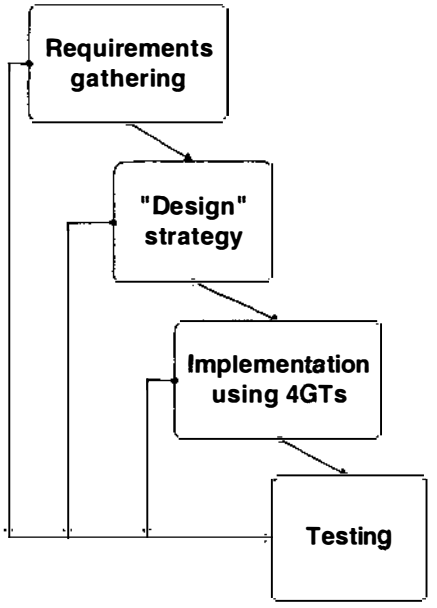
5.1.3 Fourth generation techniques

The term 'fourth generation techniques' (4GTs) describes development in which one or more of the broad array of software development tools, developer's kits, 'shells' and high-level languages are used. Each of these elements enables the programmer to specify a particular component's functionality at a high level and, ultimately, to build the software application with a minimal amount of 'new' coding. The advantage of 4GTs is thus the relative speed with which sophisticated applications can be developed and the fact that each encapsulated component should be virtually free from programming errors. These features, when combined, will mean that projects may potentially be completed in less time and with a less resource-intensive error-checking procedure. The 4GTs paradigm also means that the prototyping approach can proceed more rapidly, since prototypes themselves can potentially be little more than loosely integrated pre-developed components.

A representation of software development using the 4GTs approach is provided in Figure 81 although, as mentioned, this approach is also useful when combined with aspects of the waterfall

or prototyping strategies. Many examples of 4GTs were used in the development of HandiRISK. Pre-formed components such as the @Risk Developer's Kit (RDK), the active-X tree-view control (Microsoft Corporation, Redmond WA, USA) and many of the tools within the Microsoft Access Developer's Kit, were included in the system to achieve specific functionality without the additional coding that would otherwise have been required.

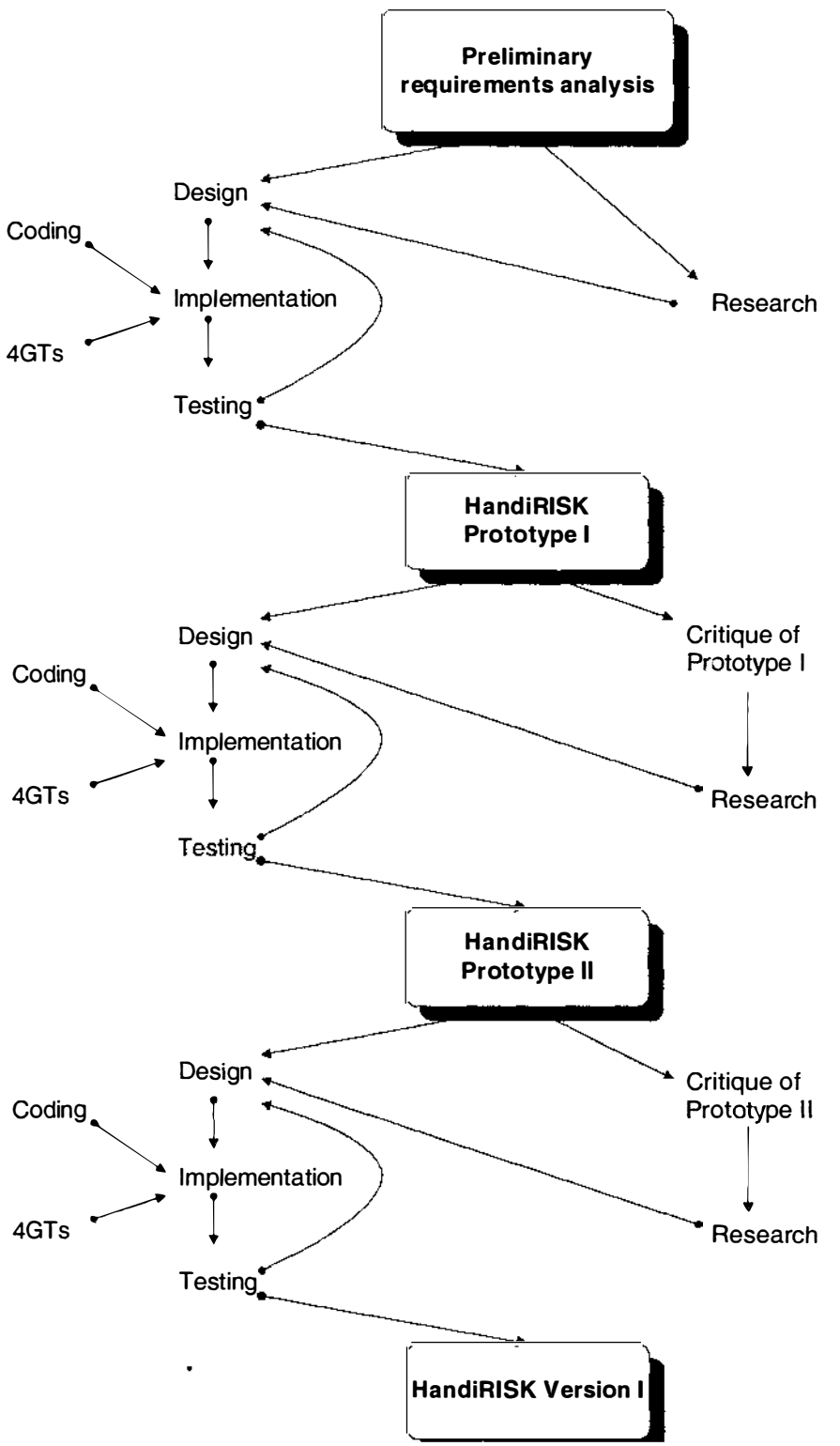
Figure 81: The "fourth generation techniques" approach to software engineering, adapted from Pressman (1992)



5.2 Approach to the development of HandiRISK

One of the key characteristics of the development of HandiRISK was the fact that while the system's fundamental requirements could be identified at an early stage, the specification of individual components was carried out in tandem with the research and evaluation described in Chapters 1 and 2 of this thesis. In addition to this, it was considered essential to the success of the overall project to create discrete prototypes so as to be able to demonstrate specific phases of the system's development and for the purpose of comment and critique. The combination of a need to accommodate ongoing research and to simultaneously demonstrate existing techniques dictated an intensely iterative or cyclical development strategy (Figure 82).

Figure 82: HandiRISK's development life-cycle



The project was thus initiated with a preliminary requirements analysis, and following an interim system design period, implementation of HandiRISK Prototype I proceeded as an amalgamation

of contributions from ongoing research, from coding and implementation of the data base design and from the inclusion of various 4GTs. Testing followed each phase of implementation and, inevitably, lead to a period of design revision. This procedure continued iteratively until testing revealed a satisfactory product, which was subsequently 'released' as HandiRISK Prototype I. A similar iterative or cyclical process occurred with the development of Prototype II and Version I although, in both cases, continued research followed a series of critiques of the existing 'demonstration prototype'.

The development approach adopted for the HandiRISK project thus involved a pragmatic combination of the traditional waterfall or life-cycle strategy, two interim prototypes and the use of various 4GTs. This approach was quite unusual (Stevens, 1991; Pressman, 1992) although it was concluded toward the end of the development period that the combination of strategies appeared to provide a workable solution to the inherently complex scenario of ongoing research and concurrent system development (Stern, pers comm 1999).

5.2.1 HandiRISK Prototype I

Development objectives

The dominant objective in the design and implementation of HandiRISK Prototype I was to create an inexpensive preliminary model for the computerised system. It was hoped that this model might serve to demonstrate key elements of the envisaged interface and a subset of the system's outputs, and thus familiarise supervisors, advisors and potential end-users of the software with the system's concept and potential.

A more technical objective was to explore the suitability of Microsoft Access Version 2 as a programming environment for the system. Specific requirements included a high degree of flexibility with regard to the design of the relational HandiRISK database, and the ability create or import interface elements and code modules (Simmons, pers comm 1997).

Scope and limitations

As a demonstration model for the system, this prototype was almost completely devoid of interactive functionality, and simply allowed the user/demonstrator to 'walk' through a 'slide show' presentation formed from a series of Microsoft Access forms and macros. Despite this, the interface was created so as to appear as realistic as possible, with active buttons that enabled the

continuation of the slide show and yet gave the appearance of functionality.

HandiRISK Prototype I contained and illustrated a single quantitative import risk analysis model which was, in effect, a replica of an existing assessment of the risk of introducing porcine reproductive and respiratory syndrome (PRRS) into New Zealand with the importation of frozen porcine semen from the United States (PRRS2 NZ, 1998). While the forms that made up this prototype's interface contained data entry text boxes and check boxes, and thus appeared to be registering data and references, all entered information was discarded with the closure of each form. Likewise, 'outputs' that were 'generated' were simply hard-coded pictures based on a manual assessment of the said import scenario. This approach, while obviously limiting the flexibility of the prototype, allowed the interface and question sequence to be demonstrated and gave a valuable first impression of the manner in which further functional prototypes would operate.

The only significant drawback to the simplistic design of HandiRISK Prototype I was that several key elements of the interface could not be demonstrated. These included the MMS, the option of creating model templates from first principles using the template-building engine and the ability to model importation scenarios qualitatively. Each of these facilities was considered a key element and a significant design challenge, and it was thus unfortunate that the incorporation of further forms and macros to demonstrate their functionality would have escalated the scale of HandiRISK Prototype I beyond practical bounds.

Conclusions

HandiRISK Prototype I successfully achieved each of the objectives outlined above. The process of documenting system requirements and design provided an invaluable means of clarifying and solidifying early impressions and ideas for the software. Likewise, the successful demonstration of this prototype meant that future versions could be presented to audiences that were familiar with the general interface, and that embellishments or enhancements could be discussed without dwelling unnecessarily on the more fundamental aspects of the system.

5.2.2 HandiRISK Prototype II

Development objectives

The principal objective of HandiRISK Prototype II was to explore a range of database design and

implementation issues associated with the construction of the functional expert system. This involved the design and construction of a small number of prototyped generic model templates and generic questions (see, Section 3.2.2). These generic templates and questions, while simplified and limited to importations of genetic material (semen and ova), could be used to generate quantitative model instances for these commodities and were thus considered to be functional. Although ostensibly simple, the conceptual base for these fundamental system elements was one of the first key database design and implementation issues to be tackled and solved.

HandiRISK Prototype II also provided continued opportunity to assess the suitability of Microsoft Access as a development environment although, by this stage, the code had been migrated from the Windows™ 3 based Access 2, to Access 7, the first of the 32-bit versions of Microsoft Access. It was postulated that difficulties regarding the relative inflexibility of a high-level development environment such as Microsoft Access might arise as the complexity of the project, and the demand for more specific interface and output elements, increased.

This prototype was scheduled for demonstration at a major international conference (the International Symposium for Veterinary Epidemiology and Economics, ISVEE, Paris, 1997) and it was hoped that constructive comment and critique might arise from this.

Scope and limitations

As described above, HandiRISK Prototype II was designed and implemented as an exploratory and demonstration exercise and, as such, there was no requirement for a knowledge base more comprehensive than that required to demonstrate the decision-making and model-generating process. Given this, the model templates and generic questions for the importation of genetic material (semen and ova) used in Prototype I were once again implemented. While these allowed model instances to be created, risk-management decisions to be made and data to be stored, the resultant data-tables were not accessed and used to generate real output from the models.

Despite this limitation, hard-coded sample templates for a wide range of outputs were designed and included in HandiRISK Prototype II so as to gain feedback from the conference audience regarding their completeness and legibility. Specifically, sample templates for the comprehensive and summary reports, for the influence diagram, the scenario pathway diagram and the decision pathway diagram, for the histogram and cumulative probability plots, and for the tabulated and graphical results of sensitivity analyses were included. Descriptions and examples of these

outputs are given elsewhere in the document (see, Section 4.6). Finally, as was the case for Prototype I, several key elements of the interface were not implemented. In particular, the MMS, the option of creating model templates from first principles using the template-building engine, and the ability to model import scenarios qualitatively were not included in the design specifications.

Conclusions

HandiRISK Prototype II proved to be a successful means by which design and implementation issues associated with the generation of 'generic models' from a 'generic model template' and 'generic questions' could be explored and validated. As mentioned, this was a key database design issue and, while the knowledge base of HandiRISK Prototype II was limited, the success and simplicity of the final solution was considered a significant development (see, Section 3.2).

The second key objective of HandiRISK Prototype II was to demonstrate the functioning expert system to an audience of potential users and to generate constructive comment and criticism. In this regard, the exercise was not so successful as minor operational bugs in the prototype prevented demonstration on all but the final day of the conference. Regardless, a discussion paper regarding the software's development objectives was delivered and well received and, since this conference, international interest in the project has continued to flourish.

The final key objective for HandiRISK Prototype II was to continue to evaluate the suitability of Microsoft Access as a development environment and, from this point of view, the added complexity proved a useful test. Development was moved from the 16-bit Version 2 to the 32-bit Version 7, as this similar but significantly enhanced product became available and, at the completion of this phase of development, Access was still considered to be the most suitable prototyping environment for this application.

5.2.3 HandiRISK Version I

Development objectives

HandiRISK Version I was the final prototype of HandiRISK to be produced as a component of this doctoral project. The global objective of Version I was thus the global project objective - that is, to implement an expert system for import risk analysis which might aid analysts to produce efficiently, structured and transparent risk analyses. Accepting this as the overriding mission

statement, the specific development objective of HandiRISK Version I was to create a system that contained the interface elements, outputs and other features specified in this chapter, and that was sufficiently robust to be distributed to regulatory risk analysts for their comments and critique. It was envisaged that enthusiasm for the system might lead to its further development and embellishment and eventual acceptance as an international standard for risk analysis methodology.

Features of HandiRISK Version I

Complete details regarding the interface, operation and outputs of HandiRISK Version I have been supplied in the preceding sections of this chapter and suffice it to say that the following features were implemented:

- Generic model templates for:
  - Live animals
  - Genetic material
  - Meats and meat products
- Wizard-based model template building interface
- A sophisticated user interface incorporating:
  - The model management system (MMS), a graphical system for organising model templates and analyses and for generating most of the functions performed by HandiRISK
  - Intuitive pull-down menus
  - The flexible 'question window interface' within which the various function wizards operate
- Wizard-based hazard identification and refinement, including the use of HandiSTATUS logic and the ability to search the OIE's animal health database
- Wizard- based risk estimation for models built from qualitative or quantitative templates or a mixture of the two
- Wizard-based simulation of stochastic models
- Risk communication through the use of tabulated reports, pathway diagrams, distribution functions and the results of sensitivity analyses

Further development

During the planning and development of HandiRISK, various additional features were designed

or simply documented. These were generally elements that were not thought to be essential to the functionality or performance of the system within its given objectives, but which should be considered in the event of its further development.

The following issues have been considered:

- Context-sensitive help and explanations for all operational features
- Extension of the template-building interface into an interactive graphical system based on the construction of 'intelligent' influence diagrams
- Standardisation of bibliographic reporting, such that citations might be output as a ProCite (ProCite for Windows, Research Information Systems, USA) compatible data-file
- Extension of the knowledge base of generic questions and generic templates to cover a broader range of importation scenarios
- Implementation of the rank order correlation facility for modelling dependencies between the input variables of stochastic quantitative models
- Derivation of a series of generic model templates based on the standardised export protocols for animals or animal-derived commodities described in the OIE Code
- Extension of the knowledge base so as to enable the system to carry out risk assessments for pests, plants and food safety issues
- Conversion to other major languages

In addition to these embellishments, it was noted that the procedure for qualitative likelihood evaluation and modules for consequence assessment and risk estimation have been simplified, or left out of this version of HandiRISK. The reasons for this were outlined in the Introduction, and will not be reiterated. Suffice it to say that with the peer review of methods for qualitative likelihood evaluation, consequence assessment and risk estimation proposed in Chapter 2, or with the development of alternative approaches, the relevant components of HandiRISK will be modified and existing procedures and modules either replaced or enhanced.

6 System Validation

6.1 Introduction

In a traditional sense the validation of a model, whether a computer simulation model or any other artificial representation of a system, involves determining how closely its output resembles

the observed behaviour of that system (Averill andKelton, 1992). This perception immediately raises two issues with regard to the validation of HandiRISK.

Firstly, HandiRISK is not itself a model but, rather, an integrated system of model templates and discrete data gathering components - the generic questions and model templates. Thus the validation of HandiRISK *per se* is quite a different issue to the validation of HandiRISK model instances, and should be based upon the determination of whether the expert system components behave in the expected logical manner and generate, run and analyse model instances exactly as an analyst would if following the guidelines in the revised generic standard.

The second level validation of HandiRISK involves an assessment of the model instances themselves. Traditionally, this level of validation would involve creating a series of model instances and comparing their outputs to historical data regarding the system under study, or the results of other accepted models (Averill andKelton, 1992). Unfortunately, since A) import risk analyses provide predictive information for events that occur rarely, if ever, and, B) existing models are not directly comparable, this approach could not be carried out.

In view of these difficulties, the validation of HandiRISK was divided into two separate groups of investigations:

- Rule-based components
- Model instances

6.2 Validation of rule-based components

Two broad groups of rule-based components were incorporated in HandiRISK:

- Context-sensitive menu items
- Rule-based procedures within the operational phases (hazard identification and consequence assessment)

6.2.1 Context-sensitive menu items

The context-sensitive right-mouse-click and pull-down menus have been outlined and discussed elsewhere in this document (see, Section 2.2). Given this, validation of the menu items was undertaken both by systematic manual experimentation, and by using SQA Suite (Rational

Software Corporation, USA), an automated software testing program, or 'robot'. This testing program required the user to 'walk' through each of the menus available from the different levels of the MMS so as to enable both the instructions given to the system, and the system's responses, to be recorded as a series of scripts. Scripts recorded for the menu system were stored, and subsequently replayed as a form of macro at each point where significant changes had taken place in the database design or coding. As the scripts were replayed, the SQA software monitored the system's response and reported any changes in the system's functionality. This approach proved to be an invaluable means by which the impact of ongoing development or modification on operation of the central menu system could be determined and documented.

6.2.2 Rule-based procedures within operational phases

Aside from the context-sensitive menu system, the following operational phases included rule-based components:

- Hazard identification
- Consequence assessment

Hazard identification

Hazard identification was implemented in HandiRISK as a composite phase derived from preliminary hazard identification and hazard refinement. Each of these contain rule-based procedures.

Preliminary hazard identification

Preliminary hazard identification was based on three separate queries of the OIE's animal health database, each of which isolated disease agents at an increasing level of specificity. At the top, or least specific level, a complete list of the disease agents recorded in the OIE data tables and their occurrence in the importing and exporting countries may be generated. At the next level, the database may be sorted by animal species so as to view a subset of the disease agents relevant to the species to be imported. Finally, the OIE data tables may be sorted by the species and commodity to be imported, such that a minimal list of agents and their occurrence information is generated.

Given the above, it can be seen that the list of disease agents produced by each of these three

queries required validation. This was achieved by systematically generating lists of disease agents using the HandiRISK interface, and comparing the results to those obtained from simple select queries of the OIE's data tables performed within an independent Microsoft Access data base. Comparing both sets of results with those obtained directly from HandiSTATUS, the OIE's database management system, further augmented the procedure. This led to the detection of a number of errors both in the original OIE data and in the HandiRISK queries, each of which were rectified by cross-referencing the query results with printed lists of disease information supplied by the OIE.

Hazard refinement

Hazard refinement is carried out in accordance with the rule-based procedure described in Chapter 2. Simply stated, this procedure uses standardised criteria to determine, A) the endemic disease agents that should be retained for a formal risk assessment, B) the exotic disease agents that may conceivably be transmitted in the importing country, and, C) the exotic disease agents which, if introduced, would produce a measurable impact on various economic, sociological, environmental and other parameters.

It was important to establish that the rules described in the generic standard and reiterated in the discussion of the implementation hazard identification were faithfully transformed into code. This procedure was relatively easy to undertake manually and each combination of responses for the various groups of criteria were assessed in this way. The procedure isolated several instances of mis-coding and ambiguously written specifications, each of which were easily rectified.

Consequence assessment

Consequence assessment, as implemented in HandiRISK, consists of a semi-quantitative record of the impact of a given disease agent on various environmental, sociological and other parameters. Validation of the consequence assessment routine therefore involved ensuring that the semi-quantitative scores entered into the data entry form were faithfully recorded in the data tables. This could be achieved by running consequence assessments and subsequently exposing the tables for inspection. No errors in the consequence assessment routine were uncovered.

6.3 Validation of model instances

As stated, the events that the HandiRISK models are largely hypothetical. Given this, validation

of model instances was based on a structured confirmation that entered data (whether quantitative or qualitative) was faithfully recorded in data tables, and that the results were based on the specified routines for assimilating and manipulating the data. Validation of model instances was significantly more complex than the validation of rule-based components and, as such, required the formal description of process Methods and Results.

6.3.1 Methods

In order to assess the manner in which entered data was assimilated and manipulated in HandiRISK, qualitative, quantitative and heterogeneous models generated using the generic 'Live Animals' template were assessed. This involved determining the integrity of stages, the integrity of within-stage questions and the integrity of data entry, and the correctness of any results produced by the system.

The integrity of stages and within-stage questions was determined by manually examining the various risk-management alternatives that may be generated from the Live Animals template (and the generic questions it interacts with) and ensuring that:

- The questions posed complied with those described in the system's specifications
- The correct text was posed to the user
- The on-screen elements were functionality correctly

Here it should be reiterated that the implementation of each prototype of HandiRISK was based on a separate and exhaustive documentation of both design and operational specifications. These documents described all aspects of the prototypes, including the design of the database and evolution of systems for knowledge representation, the on-screen appearance of various modules and a complete reference of generic questions and model templates. The design document for HandiRISK Version I was used as the definitive guideline for the intended operation of the system. Each of the three bulleted issues above were subsequently investigated by comparing the on-screen progression through a model instance with that which was predicted by following the documented logic and functional characteristics.

The integrity of data entry was verified by manually recording the data entered during the process of building a model, and comparing this with the comprehensive report. Where a disparity between the two appeared, the data tables were examined so as to ensure that the error was not in the reporting engine (see, Section 3.1).

The correctness of quantitative results was determined by running the model or sub-model in HandiRISK and comparing the output to that obtained when the equivalent model was implemented manually in a spreadsheet. This was a comparatively simple task, since the comprehensive report generated a record of every data entry and decision in a particular model or sub-model, as well as any mathematical logic used by the system. The comprehensive report also displayed simulation parameters (the number of iterations, the random number generator seed and the sampling method) and thus a stochastic model could be recreated and re-simulated by running @Risk in a spreadsheet environment. It follows that since HandiRISK uses the @Risk simulation engine, this procedure should produce an identical result if the system is functioning correctly.

The correctness of qualitative results was also determined from the comprehensive report although, in this case, simply involved ensuring that the algorithm used to derive either the release or exposure assessment, or the overall likelihood of entry and exposure, was functioning correctly. This could be achieved by manually inspecting the report.

The validation of model instances was undertaken as an iterative process. That is, as each aspect of a qualitative, quantitative or homogeneous model was examined, the inevitable errors and malfunctions were observed and corrected. In order to keep track of the process, the objectives were plotted in a table similar to Table 30, and each cell 'ticked' as the particular issue it represented appeared to be robust.

Finally, having achieved a clean state, the SQA robot described in the previous section was used to monitor the effect of changes to the database or code on each of the four columns in Table 30. This was carried out by recording an electronic script during the final run of manual data entry and testing. Having established that the system was functioning adequately, and that the output was correct, this script could then be replayed using the SQA software each time that HandiRISK was significantly altered or installed in a different environment (for example, Windows™ NT). For each instruction given to HandiRISK, the SQA software compares the response with that recorded from the previous 'correct' run, and stores the result in a log file. The system is very powerful in this respect, since 'responses' may be specific actions, such as the instantiation of a procedure, or may be screen captures that display the exact on-screen appearance of a generated data entry form. The latter is particularly useful since it is a rapid means by which complex text substitutions may be assessed without specifying a particular 'response' per se. Disparities between the correct and current runs are determined by paging through the log and noting the

entries highlighted as errors.

As an aside, the development of the SQA system was considered a very significant progressive step for software engineering and development *per se* since, historically, ongoing system validation could only be achieved by iteratively repeating the exhaustive process of manual testing each time significant alterations were implemented. This process was not only labourious and costly, but since it relied on human observation, was inevitably prone to occasional errors.

6.3.2 Results

The results of the iterative process described above are shown in Table 30. It can be seen that each of the cells has now been completed, and that the system therefore appears to be functioning adequately. Given this, the SQA robot continues to be used to examine each aspect of the 'validity' of a model instance and any disparities are investigated and rectified. It is interesting to note that occasionally the disparities recorded are in fact improvements over the original specifications and, where this is the case, the more recent script and results are adopted as 'correct' and the system thus updated.

Table 30: The results of the systematic validation of model instances generated from the generic Live Animals model template

Model	Integrity of stages and within-stage questions			Integrity of data entry	Correctness of output
	Question sequence	Question text	On-screen elements		
Qualitative	✔	✔	✔	✔	✔
Quantitative	✔	✔	✔	✔	✔
Heterogeneous I1	✔	✔	✔	✔	✔
Heterogeneous II2	✔	✔	✔	✔	✔

Legend

1 Heterogeneous I - quantitative pre-export template (PAE) and qualitative post-entry template (PDE)

2 Heterogeneous II - qualitative pre-export template (PAE) and quantitative post-entry template (PDE)

ANNEX TO CHAPTER 3

Contents

1 Generic questions

Four groups of generic questions were encoded in the HandiRISK knowledge base;

- Simple questions
- Intervention questions

- Composite questions
- Utility questions

A complete list of the generic questions encoded in the HandiRISK knowledge base was provided in Section 3.2.1. One example of each has been selected from the implementation document titled 'System Design and Specifications of HandiRISK Version I', and is shown below;

1.1 Simple question: MEAT_PROC

1.1.1 Name

Meat processing.

1.1.2 Description

Meat model specific question for the processing of meats or meat products.

Note 1: The objective of the MEAT_PROC question is to obtain the information necessary to estimate the probability that AGENT within meat or meat products will not be inactivated by processing (MP1).

1.1.3 Question text

Global flag = QUANTITATIVE

Will this meat/meat product undergo any form of processing prior to export (MEAT_PROC.1)

Yes

Describe the procedure (MEAT_PROC.2)

Ask VALUE

Send text {What is the PROBABILITY that this procedure will inactivate all infectious AGENT (MEAT_PROC.3)}

No

Global flag = QUALITATIVE

Ask MEAT_PROC.1

Yes

Ask MEAT_PROC.2

Ask VALUE

Send text {What is the likelihood that this procedure will inactivate all infectious AGENT (MEAT_PROC.4)}

No

1.1.4 Calculations

Global flag = QUANTITATIVE

IF MEAT_PROC.1	=	'Yes'
THEN MP1	=	(1-MEAT_PROC.3)
IF MEAT_PROC.1	=	'No'
THEN MP1	=	1

Global flag = QUALITATIVE

THEN MP1	=	(1 - MEAT_PROC.4)

1.2 Intervention question: CLINIC3

1.2.1 Name

Clinical examination.

1.2.2 Description

Generic group-level clinical examination question for commodities handled as independent units.

Note 1: The global objective of this question is to obtain the information necessary to determine the PROBABILITY that a group of independently selected and handled ANIMALS, in which at least one is infected with DISEASE, will not be identified as infected following clinical examination (C3).

Note 2: The keyword GROUP2 appears repeatedly to designate the specific term (eg 'quarantine group', 'collection centre group', etc) to be substituted. These key words will be sent by the generic templates but, where the latter are not being used, Version I simply substitutes the (lowercase) word 'group'.

Note 3: While the specificity of clinical examination is asked, this information will not be used in Version 1.

1.2.3 Question text

Global flag = QUANTITATIVE

Ask CLINIC1

Ask VALUE
    Send text {How many ANIMALS are there in this GROUP2 (CLINIC3.1)}

Ask VALUE
    Send text {What is the PREVALENCE of infected animals within this GROUP 2 (CLINIC3.2)}

Do you wish to specify or determine the number of ANIMALS from this GROUP2 to be examined GROUP2 (CLINIC3.3)
    Specify
        Ask VALUE
            Send text {How many ANIMALS from this GROUP2 will be examined (CLINIC3.4)}
    Calculate
        Ask VALUE
            Send text {What PROPORTION of the GROUP2 will be examined (CLINIC3.5)}

Global flag = QUALITATIVE

Ask VALUE

Send text {How likely is it that at least one infected ANIMAL in the group will be detected by clinical examination (CLINIC3.6}

1.2.4 Calculation

Global flag = QUANTITATIVE

C3 = $((1-Ps)^n - (1-P)) / (1-(1-P)^n)$

Where,

IF there are no top-level probabilities in the existing model,

THEN P = CLINIC3.2

ELSE P = Product of all preceding top-level probabilities (P1, P2, ...)

s = CLINIC1.1

IF CLINIC1.3 = 'Specify'

THEN n = CLINIC3.4

IF CLINIC1.3 = 'Calculate'

THEN n = CLINIC3.5 × CLINIC3.1

Global flag = QUALITATIVE

C3 = (6 - CLINIC3.6)

1.3 Composite question: EMB_CONT1

1.3.1 Name

Embryo management.

Description

Global embryo management question for individually selected DONORS.

Note 1: The objective of the EMB_CONT1 question is to obtain the data necessary to determine the probability that at least one embryo from an individually selected DONOR will be contaminated.

Note 2: In this question, 'contaminated' implies that infectious agent is either 'attached' to an embryo, or has penetrated its zona pellucida and has thus 'infected' that embryo.

1.3.2 Question text

Global flag = QUANTITATIVE

Ask VALUE

Send text {How many embryos will be harvested from each DONOR (EMB_CONT1.1)}

Ask VALUE

Send text {What is the probability that infectious AGENT will be present in the reproductive tract of a DONOR and subsequently in the collection fluid (EMB}_CONT1.2)}

Will embryos be washed prior to storage (EMB_CONT1.3)

Yes

Ask VALUE

Send text {What is the probability that AGENT will attach to an embryo (EMB_CONT1.4)}

Ask VALUE

Send text {What is the PROBABILITY that washing embryos will remove infectious AGENT attached to an embryo (EMB_CONT1.5)}

No

Ask EMB_CONT1.4

Will embryos be examined microscopically so as to detect a damaged zona pellucida (EMB_CONT1.6)

Yes

Ask VALUE

Send text {What PROPORTION of embryos are likely to have a damaged zona pellucida and therefore be considered non-exportable

(EMB_CONT1.7)}

Ask VALUE

Send text {What is the PROBABILITY that a non-exportable (damaged) embryo will be detected during microscopic examination (EMB_CONT1.8)}

Ask VALUE

Send text {What is the PROBABILITY that AGENT will penetrate the undamaged zona pellucida of an exportable embryo and infect that embryo (EMB_CONT1.9)}

Ask VALUE

Send text {What is the PROBABILITY that AGENT will penetrate the damaged zona pellucida of a non-exportable embryo and thereby infect the embryo (EMB_CONT1.10)}

No

Ask EMB_CONT1.7

Ask EMB_CONT1.9

Ask EMB_CONT1.10

Global flag = QUALITATIVE

Ask VALUE

Send text {How likely is it that infectious AGENT will be present in the reproductive tract of a DONOR and subsequently in the collection fluid (EMB}_CONT1.11)}

Ask EMB_CONT1.3

Yes

Ask VALUE

Send text {How likely is it that AGENT will attach to at least one embryo (EMB_CONT1.12)}

Ask VALUE

Send text {How likely is it that washing embryos will remove infectious AGENT attached to an embryo (EMB_CONT1.13)}

No

Ask EMB_CONT1.12

Ask EMB_CONT1.6

Yes

Ask VALUE

Send text {How likely is it that AGENT will have penetrated and infected at least one embryo whose zona pellucida has been evaluated microscopically (EMB_CONT1.14)}

No

Ask VALUE

Send text {How likely is it that AGENT will penetrate and infect at least one embryo (EMB_CONT1.15)}

1.3.3 Calculations

Global flag = QUANTITATIVE

IF EMB_CONT1.3 = 'Yes'
AND EMB_CONT1.6 = 'Yes'
THEN EC1 = EMB_CONT1.2 × {EMB_CONT1.4 × (1-EMB_CONT1.5)} × {EMB_CONT1.7 × (1-EMB_CONT1.8) × EMB_CONT1.10 + (1-EMB_CONT1.7) × EMB_CONT1.9}

IF EMB_CONT1.3 = 'Yes'
AND EMB_CONT1.6 = 'No'
THEN EC1 = EMB_CONT1.2 × {(1-EMB_CONT1.5) × EMB_CONT1.4} × {EMB_CONT1.7 × (1-EMB_CONT1.8) × EMB_CONT1.10 + (1-EMB_CONT1.7) × EMB_CONT1.9}

IF EMB_CONT1.3 = 'No'
AND EMB_CONT1.6 = 'Yes'
THEN EC1 = EMB_CONT1.2 × EMB_CONT1.4 × {EMB_CONT1.7 × (1-EMB_CONT1.8) × EMB_CONT1.10 + (1-EMB_CONT1.7) × EMB_CONT1.9}

IF EMB_CONT1.3	=	'No'
AND EMB_CONT1.6	=	'No'
THEN EC1	=	EMB_CONT1.2 × EMB_CONT1.4 × {EMB_CONT1.7 × EMB_CONT1.10 + EMB_CONT1.9 × (1-EMB_CONT1.7)}

Global flag = QUALITATIVE

IF EMB_CONT1.3	=	'Yes'
AND EMB_CONT1.6	=	'Yes'
THEN EC1	=	The lowest of {EMB_CONT1.11, EMB_CONT1.12, (6-EMB_CONT1.13), EMB_CONT1.14}

IF EMB_CONT1.3	=	'Yes'
AND EMB_CONT1.6	=	'No'
THEN EC1	=	The lowest of {EMB_CONT1.11, EMB_CONT1.12, (6-EMB_CONT1.13), EMB_CONT1.15}

IF EMB_CONT1.3	=	'No'
AND EMB_CONT1.6	=	'Yes'
THEN EC1	=	The lowest of {EMB_CONT1.11, EMB_CONT1.12, EMB_CONT1.14}

IF EMB_CONT1.3	=	'No'
AND EMB_CONT1.6	=	'No'
THEN EC1	=	The lowest of {EMB_CONT1.11, EMB_CONT1.12, EMB_CONT1.15}

1.4 Utility question: REF

1.4.1 Name

Reference.

1.4.2 Description

Generic reference question.

Note 1: The global objective of the REF question is to obtain information necessary for generating references in the comprehensive report.

1.4.3 Question text

Has this information been published (REF.1)

If the answer to this question is "Yes", a series of publication-specific questions are posed to the user who completes the required information for each of the published references indicated above.

Yes

- Type of publication (REF.2)
- Refereed journal
  - Full name of journal (REF.3)
  - Volume number (REF.4)
  - Serial number (REF.5)*
- Un-refereed journal
  - Full name of journal (REF.6)
  - Volume number (REF.7)
  - Serial number (REF.8)*
- Governmental publication
  - Full name of department (eg Regulatory Authority) (REF.9)
  - Abbreviated name of department (eg Reg) (REF.1o)
  - Name of organisation (eg Ministry of Agriculture) (REF.11)
  - Abbreviated name of organisation (eg MAF) (REF.12)
  - Country of organisation (New Zealand) (REF.13)
  - Publication identification (REF.14)*
- Conference proceedings
  - Full name of conference (REF.15)
  - Country where held (REF.16)

City/town where held (REF.17)*

Date of conference (REF.18)

Name of the author(s) (REF.19)

1st Author's surname

1st Author's initial(s)

2nd Author's surname*

2nd Author's initial(s)*

...

...

nth Author's surname*

nth Author's initial(s)*

Full title of article (REF.20)

Year of publication (REF.21)

Start page number (REF.22)*

End page number (REF.23)*

If the answer to REF.1 is "No", the following questions are posed to the user:

No

Source of this information (REF.24)

OIE statistics

Source (REF.25)

Date obtained (REF.26)

Official national statistics

Organisation full name (REF.27)

Organisation abbreviation (REF.28)

Date of issue (REF.29)

Personal communication

Surname of communicant (REF.30)

Initials of communicant (REF.31)

Position (REF.32)

Date of obtained (REF.33)

Analyst's personal opinion

1.G.1.1

1.G.1.2

1.G.1.3

1.G.2

Do you wish to cite any further references (REF.29)

If the answer to this question is "Yes", the analyst is taken back through the question sequence. If the answer is "No", the analyst is returned to the instantiating question.

1.4.4 Calculations

None required

2 Model templates

In this annex, examples of a quantitative and qualitative model templates are provided. The first, a quantitative template (Generic template 3.1), describes pre-exportation stages for importation of embryos from domestic production animal species. The second, a qualitative template (Generic template 3.6), describes the post-entry events for the same importation scenario. Both templates were based on importation scenarios in which commodities were handled as individual units (cf. batched consignments).

These example templates were extracted from the implementation document titled 'System Design and Specifications of HandiRISK Version I'. In this document, various conventions were adopted so as to simplify the description of the template's logic - these included the following;

- Questions to be instantiated at each point in a model template are written;

  Ask QUESTION

- Top-level probabilities to be stored at each point in the model are written;

  Quantitative template: Store P1, 2, ... = QUESTION
  Qualitative template: Store L1, 2, ... = QUESTION

- Question answers to be entered automatically by Version 1 at any given stage of a model template are represented using the convention;

  QUESTION 1 = QUESTION 2

2.1 Example model templates

2.1.1 Template 3.1

Description

- Embryos (cattle, sheep, pigs, goats, deer and horses)
- Quantitative

- Individual units
- Release assessment

Opening screen

The first screen presented to the analyst summarises the pre-importation stages in the embryo import model for independently-selected and managed DONORS. The purpose of this screen is to orientate the user before he/she begins to work through risk management options and data entry. This screen is generated by Version 1 with the instantiation of Template 3.1. Key fields are substituted automatically.

These are the pre-importation events identified by Version 1 as relevant to importations of HANDLING embryos from COUNTRY. In order to complete this model, you will be prompted to give information regarding the use of risk-management practices, and to enter data relevant to the epidemiology of DISEASE or to the importation process.

Probability of agent entry (RELEASE ASSESSMENT)

- Selection of source GROUP
- Selection of individual DONOR
- Pre-export quarantine and testing of DONOR
- Testing of DONOR at the time of collection
- Contamination and infection of harvested embryos
- Prophylactic treatment of harvested embryos
- Testing of harvested embryos and collection fluid
- Survival of AGENT during pre-export storage of harvested embryos

Template

Stage 1

Name:	Selection of source GROUP		
Description:	This stage models the probability (P1) that the GROUP from which a DONOR is drawn will be infected		
Methods:	Ask GROUP_PRELIM1		
	Store P1	=	G1 or SH1

Stage 2

Name: Selection of individual DONOR

Description: This stage models the probability (P2) that a selected DONOR will be infected

Methods: Ask INDIV1

Store P2 = I1

Stage 3

Name: Pre-export quarantine

Description: This stage models the probability (P3) that an infected DONOR will not be detected during quarantine

Methods: Ask QUAR

QUAR.1 = 'Yes'

QUAR.3 = P1 × P2

Store P3 = Q1

Stage 4

Name: Testing of DONOR at the time of embryo collection

Description: This stage models the probability (P4) that an infected DONOR will not be detected as a result of testing in the embryo-collection facility

Methods: Ask COLL_CENT2

COLL_CENT2.1 = 'Yes'

COLL_CENT2.3 = P1 × P2 × P3

COLL_CENT2.4 = 'Yes'

COLL_CENT2.5 = 'Yes'

Store P4 = CC1

Stage 5

Name: Contamination and infection of harvested embryos

Description: This stage models the probability (P5) that at least one embryo from an individually selected DONOR will be contaminated

Methods: Ask EMB_CONT1

Store P5 = EC1

Stage 6

Name: Prophylactic treatment of embryos

Description: This stage models the probability (P6) that infectious AGENT will not be inactivated as a result of the prophylactic treatment of processed embryos

Methods: Ask PROPH_TREAT

Store P6 = PT1

Stage 7

Name: Pre-export testing of processed embryos

Description: This stage models the probability (P7) that pre-export testing of embryos will fail to detect infection

Methods: Ask

TEST4.1 = EMB_CONT1.1

TEST4.2 = 'Yes'

TEST4.3 = EC1 × PT1

Store P7 = T4

Stage 8

Name: Survival of AGENT during pre-export storage of embryos

Description: This stage models the probability (P8) that AGENT will remain viable and infectious following pre-export storage

Methods: Ask STORE

Store P8 = ST1

2.1.2 Template 3.6

Description

- Embryos (cattle, sheep, pigs, goats, deer and horses)
- Qualitative
- Individual units
- Exposure assessment

Opening screen

The first screen presented to the analyst summarises the post-importation stages in the embryo import model for independently selected and managed DONORS. The purpose of this screen is to orientate the user before he/she begins to work through risk management options and data entry. This screen is generated by Version 1 with the instantiation of Template 3.2. Key fields are substituted automatically.

These are the post-entry events identified by Version 1 as relevant to importations of HANDLING embryos from COUNTRY. In order to complete this model, you will be prompted to give information regarding the use of risk-management practices, and to enter data relevant to the epidemiology of DISEASE or to the importation process.

Probability of domestic exposure (Exposure assessment)

- Post-entry certification of imported embryos
- Infection of recipient RECIPIENTS
- Quarantine of recipient RECIPIENTS
- Control of any vectors necessary for the transmission of AGENT
- Post-entry monitoring of recipient GROUP
- Surveillance of national GROUP

Template

Stage 1

Name:	Post-entry testing of imported embryos
Description:	This stage models the likelihood (L1) that certification or testing will fail to detect infection in imported embryos from a selected DONOR
Methods:	Ask POST_ENTRY3
	Store L1 = PE1

Stage 2

Name:	Infection of recipients
Description:	This stage models the likelihood (L2) that at least one recipient of embryos from an infected DONOR will be infected with AGENT and develop DISEASE

Methods: Ask INF_RECIP1

Store L2 = IR1

Stage 3

Name: Quarantine of recipients

Description: This stage models the likelihood (L3) that quarantine of recipients will fail to detect at least one infected RECIPIENT

Methods: Ask QUAR

QUAR.1 = 'Yes'

Store L3 = Q1

Stage 4

Name: Control of vectors

Description: This stage models the likelihood (L4) that limiting the season during which embryos are imported or directly controlling any necessary vectors will fail to limit the successful transmission of AGENT

Methods: Ask VECT

Store L4 = V1

Stage 5

Name: Post-entry monitoring of destination GROUPS

Description: This stage models the likelihood (L5) that monitoring recipient GROUPS will not detect early cases of DISEASE and therefore prevent a national epidemic

Methods: Ask MONIT2

Store L5 = M2

Stage 6

Name: Surveillance of national GROUP

Description: This stage models the likelihood (L6) that surveillance of the national GROUP will not detect early cases of DISEASE and therefore prevent a national epidemic

Methods: Ask SURV

Store L6 = S1

Discussion

Contents

1 The emerging field of import risk analysis

1.1 Introduction

Throughout Chapters 1 and 2, the rapid evolution of import risk analysis and its emergence as a discrete sub-discipline of veterinary epidemiology was observed and discussed. The accelerated evolutionary process has been characterised by a single precipitating event - the formation of the WTO - but describes a number of phases during which the focus of the discipline and its methodologies have changed markedly. It was interesting to compare this situation with an analogy first suggested by Goffman and Newill (1964), and subsequently developed by Garfield (1981b), in which the dissemination of scientific ideas was likened to the transmission of disease. Goffman and Newill (1964) identified the fundamental elements of disease epidemics, and thus characterised the development of a particular field of scientific research.

The first of these elements was considered to be the infectious material and the means by which it is transmitted or communicated. According to the analogy, scientific 'ideas' may be considered infectious material, communicated directly through personal communications and conferences, or indirectly through scientific journals and other vectors. The second fundamental element of an epidemic was said to be the population through which the contagion is disseminated, and here

individuals were categorised as infectives, susceptibles or removals. Where a scientific idea is the contagion, infectives were considered to be those individuals who harbour or support that idea, while suceptibles were those who may experience adequate contact with this idea and have the potential to become infected. Finally, removals were those individuals in the population who resist the idea, or who are no longer in a position to respond and thus contribute to its dissemination.

Goffman (1966) applied the analogy in a further paper by carrying out a retrospective analysis of mast cell research and fitting each of the fundamental elements to a conventional mathematical model for disease epidemics. As a result of this, the author was able to demonstrate rates of change over time in the number of active authors, the number of publications and the number of active ideas within a discipline. In addition, by considering the balance of susceptibles, infectives and removals within the population and the rate of infection, he was able to characterise periods during the development of mast cell research when this scientific discipline was considered to be in a stable (endemic) or unstable (epidemic) state. Likewise, where an epidemic was considered to be occurring, the same principles were used to determine the point source - that is the primordial author or group of authors - and to measure the lag period and other temporal characteristics of the propagation of that epidemic through the population. Finally, Goffman (1966) was able to identify periods where the distribution of susceptibles, infectives and removals favoured a stable endemic state, but where an extraneous factor had precipitated an epidemic. From these observations, the author proposed a mapping system for the development of emerging disciplines, a concept that was extended by Garfield (Garfield, 1974; Garfield, 1981; Garfield, 1983) through a series of analyses based on the international scientific citation index, Current Contents.

The discovery of these early works from the field of scientific historiography provided a means by which patterns observed in the emerging discipline of import risk analysis could be further explored. In this context, the contagion may be a general philosophical issue such as the use of quantitative methodologies or the integration of likelihood and consequence assessments, or a specific technique such as Monte Carlo simulation. Continuing the analogy, the establishment of the WTO can be viewed as the precipitating factor that transformed the discipline of import risk analysis from a stable state into an epidemic of research activity. Trends in the direction of the discipline were thus associated with changes in the distribution of infectives and susceptibles, as new ideas were trialed and evaluated.

One of the principal objectives of a scientific review is to provide an objective synthesis of ideas, such that further research and development can become more focussed. If the synthesis of ideas generates a substantial discovery, then this may be viewed as a new contagion. The mission of this project was thus to evaluate systematically trends in the methods and approaches for various aspects of import risk analysis, and to identify areas in which further research is most necessary. It was envisaged that the results of this evaluation might be viewed as a significant contribution to the discipline and, thus, a contagion. In order to facilitate the transmission of this contagion, the expert system HandiRISK was designed and implemented. The success of HandiRISK as a vector for the results of the evaluations will be determined by its flexibility and adaptability, and by its ability to meet the practical requirements of individual analysts.

1.2 Stages in the evolution of import risk analysis

As stated, the evolution of import risk analysis has been characterised by discrete phases. Between these phases, the focus of the discipline has shifted markedly. As the international trade environment evolved during the late 1980s and early 1990s, regulatory authorities worldwide, and particularly those in Canada, New Zealand, Australia and the United States, began developing techniques that might enable import risks to be estimated more objectively and transparently. The quantitative approach was viewed as one means by which a greater level of objectivity and transparency could be obtained, and much research was concentrated on the application of quantitative models to common importation scenarios, such as live animals or genetic material. At this time, Monte Carlo simulation became accessible through the development of commercial spreadsheet add-in programs, notably @Risk®. Monte Carlo simulation was seen as a convenient means by which uncertainties and natural variation could be included in a quantitative model. In particular, Monte Carlo simulation appeared to offer a practical solution to the dearth of concrete data that had hindered the application of traditional quantitative models.

This period of activity coincided with an international consensus on the need to take stock and standardise import risk analysis methodology and terminology. Important conventions and 'training courses' were held, first in Ottawa and then in Zurich, and the first OIE Code chapter on import risk analysis was prepared. At around this time, OIE Scientific and Technical Review 12(4), an important collection of technical discussions and sample import risk analyses was published. It was also at this time that the concept of an expert system for import risk analysis was first considered, although the system envisaged was to have been principally a means by

which to enable popular but technically demanding quantitative analyses to be more accessible to regulatory analysts.

As the number of published quantitative analyses grew it became clear that this approach had important limitations. Simple quantitative models were criticised and 'adequate' models became increasingly difficult to produce. In addition, technical issues such as the use of Monte Carlo simulation to model natural variation, and the effect of model structure and choice of distributions on the percentiles of the resulting likelihood, arose as potential points of contention between quantitative analysts. The value of the structured quantitative approach has never been denied, but the degree of objectivity and transparency afforded by the approach were also questioned. Above all, however, the volume of analyses demanded by stakeholders and trading partners as a result of the new trade regulations meant that the extremely intensive quantitative analyses could only be undertaken for unusual or controversial scenarios. These factors led to a general return to qualitative methods, and what appeared to be a move away from an internationally standardised approach to import risk analysis.

It is my opinion that this period continues to the time of writing, although an important international event may lead to its closure. That is, recent activity in the dispute settlement forum of the WTO has bought home the need for countries to adhere precisely to the requirements of the SPS Agreement. It has also reiterated the importance of the OIE Code as the international standard for import risk analysis methodology. The OIE Code chapter on import risk analysis has been revised, and the current document likewise addresses the requirements of the SPS Agreement more closely, and provides analysts with more substantial guidelines for import risk analysis. In particular, the following issues are described:

- The need to include a rule-based classification step in hazard identification
- The need to consider importation and exposure pathways an ordered sequence of stages
- The need to consider the direct and indirect consequences of each identified hazard
- The need to consider the likelihood attributed to direct and indirect consequences
- The need to combine likelihood and consequence assessment so as to generate a single integrated risk estimate

The first issue is perhaps the least technical or controversial, but was nevertheless considered an important phase in the evolution of the risk analysis procedure. In the revised OIE Code chapter, hazard identification was described as a preliminary step, separate to risk assessment *per se*, in

which analysts should document each potential hazard and subsequently provide a transparent summary of why it should be included in the ensuing assessment. The process was described in Chapter 2 as 'hazard refinement'. It was concluded that criteria used to screen a list of potential hazards should be dichotomous and should not require a 'mini risk assessment' in order to justify the inclusion or exclusion of particular disease agents. The criteria proposed in the OIE Code did not include the significance of the possible consequences, beyond requiring that each included disease be notifiable in the importing country. It was concluded in Chapter 2 that a dichotomous preliminary consequence assessment was a useful enhancement. It was also concluded that a preliminary assessment of the potential for exposure in the importing country should not be included in hazard identification. This criterion appeared in internal guidelines produced by both New Zealand and Australia, but was considered a potential source of contention and best left for discussion in the risk assessment.

One of the legacies of the period of enthusiasm for quantitative methods is a widespread recognition of the need to consider the importation and distribution of a commodity as a sequential series of stages. In the revised OIE Code chapter on import risk analysis, this principle is termed a 'biological pathway'. A hazard must persist through each stage in the biological pathway if it is to realise an effect in the importing country. Of importance however is the fact that the OIE Code does not delineate between qualitative and quantitative approaches when describing the need to consider biological importation and exposure pathways.

Qualitative analyses obtained for review generally documented importation and exposure pathways, but did not subsequently utilise the pathway framework as the basis for an epidemiological approach to assessing the likelihood of entry or exposure. Early criticism of the qualitative approach focussed on an apparent lack of structure and repeatability, generally interpreted as a lack of objectivity. By qualitatively assessing the likelihood associated with each step in a biological importation and/or exposure pathway(s), and subsequently combining these to give an overall likelihood of entry and/or exposure, the structure and 'objectivity' generally attributed to the quantitative approach can be extended to qualitative analyses. Moreover, the approach encourages the analyst to view each step-level likelihood in the context of its position in the pathway and thus to consider the epidemiology of the overall process rather than simply focus on the likelihood of disease transmission through the given commodity.

This principle was extended in Chapter 2 with the derivation of a semi-quantitative method for likelihood evaluation that was based on clearly defined probability ranges. It was shown that by

adopting this approach, entry and exposure scenarios could be modelled with the practical advantages of the qualitative approach, but with a degree of structure and transparency formerly reserved for quantitative assessments. In addition, it was shown that the semi-quantitative method could be used in a systematic evaluation of multiple exposure scenarios and, for each, enabled a 'partial probability of exposure' to be calculated.

A further group of issues raised in the revised OIE Code chapter is concerned with the importance of consequence assessment, and the need to integrate this with a likelihood assessment so as to report a single overall estimate of quarantine 'risk'. Consequence assessment was described in the earlier OIE Code as an essential component of import risk analysis, although guidelines were not provided and the final risk estimate was described only in terms of likelihood of entry and exposure. Similar sentiments were evident amongst the sample analyses, where it was noted that only 16 of the 55 included a consequence assessment in any form. Of these, three reported an integrated risk estimate. Consequence assessment was treated more seriously however in the revised OIE Code chapter, where the need to consider both the direct and indirect consequences of each identified hazard was identified. The complication with this approach arises from the parallel need to consider the likelihood that consequences will occur at a given magnitude. Neither the OIE Code nor any of the identified import risk analyses provided a systematic approach to assessing the likelihood and magnitude of disease consequences. For this reason, the novel semi-quantitative approach to likelihood evaluation was extended experimentally to consequence assessment and, subsequently, to risk estimation and management.

According to this approach, 'outbreak scenarios' are generated for each of the identified exposure pathways (as described above). For each outbreak scenario, the impact of a disease agent on a predefined range of direct and indirect criteria, and an estimate of the likelihood that each scenario will occur, are obtained. These estimates are then inserted into a scenario tree that depicts each stage in the incursion of a disease agent (Figure 9). By combining the probability of entry, the partial probability of exposure and the probability that a given outbreak scenario will occur, with an estimate of the consequences associated with that outbreak scenario, a series of partial risk estimates can be obtained. These are then combined so as to give an overall estimate of the risk associated with the proposed importation. This approach may be implemented using the semi-quantitative method of probability ranges, or may be adapted to include a more traditional quantitative release assessment, exposure assessment or consequence assessment.

If the approach is continued, risk estimation is performed using dichotomous rules described in a risk estimation matrix. The cells in this matrix can be shaded so as to illustrate the importing country's appropriate level of protection, or ALOP. By confining the level of ALOP to a band of cells, the matrix can be used to demonstrate that risk management is not overly protective. As will be discussed below, the matrix also serves to deflect the quandary WTO Member Countries face with regard to defining their ALOP, since a consistent risk attitude both within and between analyses can easily be demonstrated. Overall, this experimental approach to risk analysis was thought to represent an exciting possibility for risk analysts seeking to comply with the requirements of the SPS Agreement and, by extension, the OIE Code, in a manner that is technically practical and efficient.

1.3 Issues for continued development

Arising from the evaluation of risk analysis methodologies was a group of important issues for which continued research and development was considered to be critical. Each of these is pertinent to the SPS Agreement. It is my impression that recent activity in the WTO dispute settlement forum will prompt regulatory authorities to consider these issues, and that analyses produced in the near future will contain a range of new approaches:

- The role and conduct of 'generic' risk assessments
- Risk estimation
- Assessment of a country's appropriate level of protection (ALOP)
- Interpretation of integrated risk estimates in the light of ALOP
- The role of quantitative methodologies

One observation to arise from the discussion of qualitative likelihood evaluation was that 18 of the identified analyses were not carried out for a single specific country. These analyses were termed 'generic'. Four of the 18 generic analyses categorised countries with regard to particular country-specific factors (for example, disease prevalence or the adequacy of veterinary services), and thus included these factors in the release assessment. Of the remaining analyses, some appeared to be evaluating an existing import protocol while others were simply deriving a series of unrestricted release assessments for a group of identified hazards. The difficulty with truly generic release assessments, as undertaken in the last of these groups, is that they do not consider the effect of country factors and, therefore, are not based on the complete biological importation pathway. The application of risk management when importing from a given country must be

based on a demonstrably unacceptable unrestricted risk estimate. Unless the unrestricted risk is based on the complete importation pathway, it will not be possible to justify the application of risk management if a proposed import protocol is called to question by the exporting country.

The issue is particularly serious, since the concept of a generic import risk analysis offers an attractive means by which importing countries can reduce the overall number of studies that need to be carried out to meet trade obligations. There are currently two approaches to generic import risk analysis that will be acceptable to the WTO. The first is the categorisation of countries with respect to the relevant country factor(s). This method will reduce the number of individual analyses to the number of categories, and may be particularly useful for unusual commodities or diseases, where information is limited and the release assessment is unlikely to be compromised by treating country factors in a more cursory manner. One notable example of the successful application of this approach was an analysis of the risks associated with importing live crocodiles into Australia. Very little is known about the distribution and/or characteristics of many diseases of crocodiles, and thus it was quite acceptable to dichotomously categorise exporting countries with regard to disease prevalence, and carry out two separate analyses.

The second and more complex approach to generic import risk analysis is to demonstrate that country factors are not likely to have a measurable effect on the release assessment. Once this has been achieved, country factors can be ignored and a truly generic analysis carried out. This is an area in which quantitative techniques can be successfully employed. That is, sensitivity analysis and sensitivity simulation can be used to demonstrate that the critical stages in an importation scenario are not country-specific. This process will not necessarily require data to be as precise as would be needed if the purpose of simulation were to derive an accurate output. Rather, it is the mathematical structure of a model that determines the extent to which variables of an approximate magnitude and variance will affect its output. If the magnitude and variance of input variables can be approximated (for example, a 'very low prevalence' or a 'very high test sensitivity'), then sensitivity analysis can be used to determine which stages in the importation pathway have an important effect on the release assessment. It stands to reason that country factors will generally be less relevant to highly processed commodities, unless the processing itself is not equivalent between countries. For example, it is likely that the risk of introducing foot and mouth disease with the importation of ham prepared according to the *Proscuitto de Parma* (Parma ham) process, will not differ greatly between countries - regardless of differences in the prevalence of FMDv or the adequacy of veterinary services.

The problems associated with generic import risk analyses were not discussed in the sample analyses or technical papers. Given this, the WTO requires that risk management measures over and above those recommended in the OIE Code be based on a demonstrably unacceptable unrestricted risk, and this cannot be formulated without considering in some way the effect of country factors. I envisage that the issue will be raised with a test case, and that any subsequent generic analyses will be carried out using one of the approaches discussed above, or new and experimental approaches.

Another important issue concerns the ongoing development of methods for risk estimation. It was stated previously that only three of the identified analyses integrated likelihood and consequence to give an overall estimate of quarantine risk. It was also stated that these analyses used a simple 'risk assessment matrix' to display the dichotomous rules upon which risk estimation was based. Given this, the issue is central to the risk assessment process, as described in both the SPS Agreement and the OIE Code, and it is envisaged that more technical or sophisticated approaches might appear in the near future. The semi-quantitative system for risk assessment and management developed in Chapter 2 was outlined briefly above. This system would appear to address many of the problems facing the practical implementation of the principles for risk analysis outline in the SPS Agreement and OIE Code, and should now be applied to 'real' import risk analyses in order to assess its practical applicability. While not directly relevant to this thesis, it should also be mentioned that the system was intended to be applicable to the 'pest risk analyses' carried out for the importation of plants and plant products. The derivation of a system that can be used for both animal- and plant-based imports is appealing, since it further supports the WTO requirement for consistency in quarantine decision making.

Directly linked to risk estimation is the issue of ALOP. Appropriate level of protection has been defined in an Australian import policy statement[1] as a societal value judgement, based on a trade-off between maximal sanitary and phytosanitary protection and the need to comply with international trade regulations. Appropriate level of protection is essentially the WTO answer to the 'zero-risk' philosophy that was advocated historically by many countries with a favourable disease status. While the principle behind ALOP is sound and in keeping with the concept of free trade, it is nevertheless difficult to understand how this somewhat nebulous value can best be defined and utilised. The issue is critical to import risk analysis and yet one of the observations

[1] Animal Quarantine Policy Memorandum 1999/26: Australia's appropriate level of protection and AQIS' import risk analysis process. Available at http://www.aqis.gov.au/sitemap.htm

made in Chapter 2 was that there are neither guidelines nor templates for assessing or interpreting ALOP. Indeed, while ALOP was mentioned in a small number of recent reports, neither these nor any of the remaining analyses actually described, A) what their ALOP was, B) how it was determined, or, C) how ALOP was used to determine the acceptability of unrestricted risks.

This is one of the most important and yet least developed aspects of the modern import risk analysis process. As the pivotal point in the justification of risk management, it is also open to be challenged in the situation where trade restrictions are called to question. In the Australian import policy statement mentioned above, it is stated that "*there may be difficulties in describing the ALOP in practical terms*" and that "a *guide to the ALOP may be found in community and industry acceptance of quarantine policy and practice over the years*". It can be seen that the only security that can be drawn from such obscure statements is the fact they may be as difficult to challenge as they would be to defend. This is not a criticism, since neither the WTO nor the OIE has developed precise methods for determining and stating ALOP. It is, however, an issue that national regulatory authorities and international organisations should continue to address, particularly in reference to the WTO requirement for consistency and the potential for a perceived lack of consistency to be the focus of trade disputes.

The final area identified as a focus for further development is the refinement of the role of quantitative techniques. It is my opinion that the principal benefit of quantitative likelihood evaluation is the need to create a structured model of the importation and/or exposure pathway(s), and to carefully consider the effect of each stage in the model on the outcome. It was mentioned above that this approach has been described in the revised OIE Code chapter as equally applicable to qualitative and quantitative evaluations. One of the challenges at this stage in the evolution of risk analysis is to ensure that the international body of experience with structural importation and exposure models is utilised. Quantitative analysts have explored a large range of issues, including the implication of batched versus individually handled commodities, the relevance of the volume of trade, the advantages and limitations of conditional likelihoods and the use of sensitivity analysis to identify critical points in importation or exposure pathways. Each of these issues can be adapted for use with structured qualitative models, or models based on a mixture of qualitative and quantitative approaches.

Sensitivity analysis in particular is a powerful tool. Sensitivity analysis can be used to identify important stages in an importation or exposure pathway. These stages can be targeted for risk management, so as to maximise the efficiency of any potentially trade restrictive measures. As

discussed above, sensitivity analysis can also be used to determine the role of county factors. Where country factors are not important to the final risk, risk management can be justifiably based on generic release assessments. Finally, sensitivity analysis can be used to identify data of particular importance to the risk analysis. Where the quality of data is inadequate, the results of the sensitivity analysis may be used to validate conservative trade measures, or a research proposal.

The challenge at this point in the development of sensitivity analysis will be to investigate the feasibility of extending the graphical or descriptive account of importation and exposure scenarios that generally precedes qualitative release and exposure assessments, so as to include a quantitative structural model. This model could theoretically be used for sensitivity analysis, since this procedure does not require particularly precise data. Knowledge of critical stages could then be used for each of the purposes described above, while the release and exposure assessments remain qualitative. Thus, the role of a quantitative model would be to establish and enforce the structure of biological pathways, and to focus the qualitative discussion of likelihood evaluation and risk management.

An adaptation of this approach would be the combination of quantitative and qualitative release and exposure assessments. Stages in the importation pathway(s) are generally well defined. If this is not the case, regulatory authorities will generally be unwilling to endorse the importation of the commodity. Exposure pathways however are often less well defined, particularly where the hazard may affect multiple species and/or wildlife, or where aquatic animals are involved. Given this, it follows that release assessments will generally be more amenable to quantification, if only for the purpose of sensitivity analysis. This may be a useful exercise, since a quantified importation pathway will often provide analysts with a more concrete understanding of the likelihood of agent entry and a clearer basis for offshore risk management. Combination of qualitative and quantitative assessments to give an overall estimate of the likelihood of entry and exposure should not be complicated or controversial, since quantitative figures can quite easily be converted to qualitative scores or probability ranges (as described previously). In fact, given the difficulty inherent in interpreting quantitative results in the light of less precise estimates of consequence of ALOP, there may be benefit in converting all quantitative outputs to qualitative scores. This would help to reiterate the fact that quantitative assessments are generally carried out using imperfect or incomplete data, and that percentiles reflect the highly complex process of combining probability distributions. Alternatively, and as stated previously, if the novel approach to risk assessment and management developed in Chapter 2 were implemented, quantitative

estimates for the probability of entry, partial probabilities of exposure and the probability of observing each identified outbreak scenario could be used in the place of semi-quantitative estimates.

2 HandiRISK: an expert system for import risk analysis

2.1 Representation of expert knowledge

The most significant difficulty in designing an expert system for import risk analysis stemmed from the need for analysts to be able to model an extremely diverse range of importation scenarios at least as accurately as could be achieved manually. This difficulty equated to a requirement for a maximally efficient and flexible system for representing expert knowledge.

The HandiRISK knowledge base was designed by following the principles of the object-orientated paradigm, a conceptual model for knowledge representation that rests on the notion of discrete encapsulated and interactive objects. The object-orientated paradigm gains its power from properties assigned to these objects. That is, their attributes, methods and class hierarchies. The paradigm results in a system in which, A) objects may be modified, or new objects added, without greatly disturbing the functionality of the system, B) objects may be generated quickly and efficiently from a parent object of the same class, and, C) class hierarchies may be created in which each progressively more specialised object automatically assumes the characteristics of those at a higher level.

The object-orientated paradigm was employed in the design of the HandiRISK knowledge base by conceptualising the latter as two pools of discrete but interactive elements, or objects - the generic questions and model templates. By following the abstract rules described above, each pool was subsequently divided into classes of objects and the characteristics of each class formally specified. If the generic questions are taken as an example, those in the class of 'simple questions' have, as attributes, a form that is necessary for visual display and data entry, and an attached data table. Likewise, this class of generic question has as methods, coded modules that control both their internal logical processes and their interaction with a model template or with other questions. Extending the principle it can be seen that according to the object-orientated convention of inheritance, these characteristics may be derived automatically from a parent simple question, or question shell, and that alterations to this parent question will be reiterated through any subsequent simple questions. A similar representation was followed for the model

template objects, which were grouped in eight discrete classes according to particular combinations of characteristics and, like the simple questions, could be generated from a parent template shell.

The result of this process was the translation of a large number of abstract entities into an efficiently represented knowledge base containing two groups of interactive elements. Each of these objects may be arranged and rearranged to form a huge number of alternative combinations. From a practical perspective, the system gave a relatively small number of model templates access to the larger pool of generic questions, such that two or more model templates could use the same questions but in a different sequence or to provide a different level of information. For example, one model template may represent pre-exportation stages in the process of quantitatively modelling the importing of live animals from a certain country. Here, the generic quarantine question may be used to enable analysts to specify and describe any quarantine procedures. The generic quarantine question will recognise the need for quantitative data and will coordinate the instantiation of further questions to collect and store this data and record the necessary references. Alternatively, another template may represent post-entry stages in the process of qualitatively modelling the distribution of imported semen in the importing country. The same quarantine question may be invoked, but this time will recognise that the template is a post-entry one that requires qualitative data, and will instantiate a different set of secondary questions.

The critical point is that the quarantine question was specified a single time and exists in the pool of generic questions as a type of intelligent 'tool'. This tool may be called and asked to generate information relevant to the requirements of the active model template. Other generic questions have exactly the same functionality and thus enable a very large number of different model instances to be constructed from the limited pool of generic templates.

HandiRISK also has a template-building engine that enables analysts to generate their own model templates and to edit those already created. Creating a model template involves selecting the pre- or post exportation phase in an importation scenario, making a decision to model these stages qualitatively or quantitatively, specifying the stages that will be undertaken and determining which generic question will provide the information required for each stage. The template-building engine generates a wizard that walks the user through the process of providing this information, and exposes the pool of generic questions as a pool of modelling 'tools'. Some of these, the quarantine question for example, are quite sophisticated and specific while others are

more general, and designed to be used in the situation where an analyst wishes to model a particularly unusual stage. I envisage that as the system evolves, the number of more sophisticated and commodity-specific questions will increase. It follows that the system can be extended relatively easily both within the domain of import risk analysis, and to related fields such as food safety risk analysis or plant and pest risk analysis. In fact, having designed the generic architecture, the system could also be extended beyond the agricultural focus to actuarial, project or industrial risk analysis.

2.2 User interface and operational characteristics

The second significant challenge was to design a clear and unambiguous user interface that would convey the phases of a risk analysis in a structured fashion. HandiRISK was implemented in the Windows™ environment and thus the user interface was characterised by interactive graphical screens. HandiRISK was designed to be operated from a central home screen based on three principal elements - the model management system (MMS), the question-window-interface, and the context-sensitive menu system. The MMS consists of an interactive expanding tree of selectable elements and in this sense is similar to the Windows™ 95/98 'Explorer'. The MMS is, however, extremely powerful as it not only provides a categorised library of model instances and model templates, but also acts as the platform from which each of the systems functions are generated. By selecting an element in the MMS and using either the right-mouse-click menu or the pull down menus, the user is able to view the operations that may be performed on that element and subsequently activate the desired option. The design and specification of this system was considered a significant milestone in the design of HandiRISK's interface as it enabled the entire expert system to be focussed on a single intuitive and interactive screen.

The central HandiRISK home screen also contains a question-window-interface. This interface represents a separate system which operates within a form created in the home screen, and provides the generic questions and the template-building tool with the elements required for the visual display of question statements or the recording of responses and instructions. The question-window-interface arose from an early prototype of HandiRISK in which these functions were performed not from a home screen, but by using the more commonly applied technique of sequential full-screen windows. It was noted during the trialing of this early prototype that users would tend to feel disorientated by the process of following an extended series of full-screen windows, and would quickly lose the perspective of the particular process they were performing. Given this, the current interface allows users to be led through interactive screens by the logic of

a wizard or a model template, but also ensures that they retain perspective by simultaneously viewing the MMS and the selected element from which the particular process was requested. This system, while simple in appearance, was considered another significant milestone in the quest for an intuitive and unambiguous user interface.

2.3 Implementation of an automated approach to import risk analysis

In general, the philosophy adopted during the design and implementation of HandiRISK was that the software should be based on principles familiar to the community of risk analysts. More specifically, the system was designed to be compatible with the approach to import risk analysis advocated by New Zealand's regulatory authority. It was shown above that HandiRISK was designed on a modular format, so that each individual component could be modified without disturbing the system's logic. This meant that new or experimental approaches could be included in later versions of HandiRISK without requiring that the database design concepts or system architecture be revised. New or experimental methodologies were described in the first section of this discussion as 'issues for further development'.

HandiRISK was based on the framework for import risk analysis outlined in the revised OIE Code chapter. Hazard identification incorporates a two-step procedure such that analysts can specify a preliminary list of hazards (with or without the assistance of HandiSTATUS) and subsequently refine that list according to a classification procedure. The classification criteria included in HandiRISK are precisely those used by NZ MAF. The criteria can however be customised to be compatible with criteria used by individual countries.

Likelihood evaluation accounts for the bulk of HandiRISK's coded modules and procedures, and is characterised by the following features:

- Release and exposure assessments are modelled independently
- The release and exposure assessment need not both be qualitative or quantitative
- Both qualitative and quantitative models are based on structured importation or exposure pathways composed of discrete steps or stages
- Quantitative models may be deterministic or stochastic
- Sensitivity analyses can be generated from quantitative models to identify important stages in importation or exposure pathways

When combined with the facility for generating model templates, these features enable technical likelihood evaluations to be carried out efficiently. The system of model templates and generic questions also ensures that likelihood evaluations are completely repeatable, and that the biological importation or exposure pathways are constantly reinforced.

HandiRISK's facility for consequence assessment was based loosely on the qualitative categorical approach adopted by NZ MAF. This was considerably less technical than the experimental approach proposed in Chapter 2. It was noted, however, that for this and all other modules, modifications could be made without significant disturbance to either the database design or code. It is envisaged that as that with the peer review of the experimental approach, or the development of alternative approaches, the existing module for consequence assessment will either be replaced, or will be extended to allow analysts to choose between approaches.

For similar reasons, this version of HandiRISK does not contain a separate module for risk estimation. The quandary of risk estimation has been discussed previously. Suffice it to say that with either the accreditation of the experimental approach proposed in Chapter 2, or the development of viable alternatives, a module for risk estimation will be designed and implemented.

As a discrete process within risk analysis, risk management can be divided into two phases. The first is the need to classify unrestricted risk estimates as acceptable or otherwise. The second entails the identification and evaluation of alternative risk management strategies for risks considered unacceptable in their unrestricted form. The procedure of classifying unrestricted risks is closely linked to risk estimation (as described above), and was not represented in this version of HandiRISK. In contrast, the procedure for evaluating alternative risk management strategies was considered one of the most comprehensive features of HandiRISK.

The evaluation of alternative risk management strategies was implemented in HandiRISK as an iterative model-editing procedure. This facility enabled analysts to construct a large number of similar models, and thus investigate and document the relative efficacy of alternative risk management strategies. The specification of risk management may follow a sensitivity analysis, or may result from the need to investigate existing import protocols. Alternatively, it may be important to demonstrate the additional security provided by risk management procedures over and above those recommended in the OIE Code.

HandiRISK provides three separate facilities for risk communication - tabulated reports, pathway diagrams and distribution plots. The comprehensive report is the most sophisticated of these and was designed as a means by which the entire risk analysis can be made transparent. The comprehensive report enables users to recreate an analysis and thus validate technical issues. The comprehensive report may also be used as the framework for expanded discussions of each identified stage, since many analysts will wish to format the risk analysis report as a test document. The summary report enables results generated from similar quantitative models to be sorted, and displayed in a format that highlights the efficacies of different risk management strategies. Flow diagrams provide a means by which the structure of models can be communicated, while the distribution plots enable the results of stochastic simulations to be displayed.

3 Conclusions

In the Preface to this document, 3 principal project objectives were described:

1. To review and summarise pertinent aspects of the regulation of international trade in animals and animal products

2. To evaluate alternative approaches to, and methodologies for, import risk analysis

3. To implement the results of the evaluations in a computerised expert system for import risk analysis

It can be seen from the discussions above that these objectives have been addressed systematically. It can also be seen that the identification of phases in the evolution of this discipline has emerged as a critical element in understanding the value of a systematic review. Equally critical is the need to provide a vehicle by which the results of the review can be disseminated for comment and critique. Design and implementation of an expert system for import risk analysis proved to be extremely challenging. Given this, HandiRISK has emerged as a sophisticated application with a modular object-orientated design that will enable it to be customised to particular users, or updated as methodologies continue to evolve. By the same token, the system can be extended to related fields such as plant, pest or food safety risk analysis, or to non-biological disciplines of actuarial, project or engineering risk analysis.

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