The application of risk analysis to international trade in animals and animal products

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Summary: In an era when arduous land and sea journeys separated exporting and recipient nations, the duration and stress of transport dictated localised sourcing of stock and provided an implicit quarantine. Clinically latent infection, which remained undetected prior to embarkation, often surfaced and was eliminated before reaching the importing country. Many nations which would not accept the risk of importation, on clinical grounds, could effectively isolate themselves by prohibiting entry. Passive acceptance characterised much of the response of industry to the perceived wisdom behind such decisions.

Advances in transportation technology now permit the accumulation of an export consignment from across an entire country. The assembled shipment is a sentinel for the infection experience of the national herd. The journey to the final destination is measured in hours, rather than weeks. Parallel diagnostic and epidemiological advances face the challenge of compensating for the risks attendant in such widespread and rapid sourcing of stock. Nations which judge the risks as unacceptable face a concerted legal challenge on a series of levels, both domestic and international. Refusal of legal importation can be circumvented easily through the smuggling of germ plasm.

National Veterinary Services must respond to the economic, social and political realities of this new international trading environment. The means of facing this challenge through quantitative risk analysis are described. The theory of risk analysis, as well as the qualitative and quantitative evolution of the import applications of this analysis, is explained. Current challenges and potential solutions are discussed.


INTRODUCTION

Diseases are universally distributed, as are the livestock which they afflict; they are disseminated by many natural and other means which circumvent the best efforts to confine them (17). However, the effect of telluric conditions, the lack of susceptible indigenous species and human attempts to exclude various diseases from national territories, mean that distribution of animal diseases is not random (15, 32, 69); nor is distribution of the tremendous economic burden, which is borne by nations...
in which livestock are afflicted with those diseases categorised by the Office International des Epizooties (OIE) as belonging to List A or List B (6).

Livestock populations in many Third World nations make a significant contribution to the national gross domestic product (GDP). In many developed countries, the efficiency of animal production as a result of the absence of List A diseases guarantees that only a small percentage of the personal disposable income of consumers is spent on food (5). Given tremendous competition within the narrow bounds of the world marketplace for livestock and livestock products, an incursion of a List A disease in a trading nation can trigger a rapid diminution in worldwide market share and a parallel shrinkage within the national GDP (24, 69). Nations bear sufficient loss from indigenous diseases (39) without tolerating the introduction of disease from foreign sources.

An unwillingness to share in the economic losses attributable to disease has prompted national Veterinary Services to apply strict import regulations, pursuant to a tradition which is centuries old (17, 70). Through such means, those nations which have established a livestock population with an elevated health status seek to preserve this status (17). Those countries where the national herd is of a lesser health status aspire to improvement of the herd health status, if only on a zone basis. In another era, the application of import controls followed the dictum that there should be “zero risk” associated with the introduction of livestock and livestock products (69). This often implied that no importations could take place. While such an approach is now well recognised as both domestically and globally counterproductive (56), the intuitive appeal of a “zero risk” policy still holds sway with conservative sectors of the industry (16).

The OIE, pursuant to the mandate granted to the Organisation by the International Agreement of 25 January 1924 (14), seeks to ensure that import controls are formulated with full knowledge of the most recent disease prevalence information. The OIE keeps Member Countries fully informed with regard to the epidemiology of the diseases in question, and issues general guidelines which facilitate the development of bilateral agreements between trading partners. It was not unexpected, therefore, that the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), in a rekindled effort to reduce trade restrictions, should look to the OIE for assistance. Key principles established at the meeting included the tenet that import measures applied in the name of protecting animal and human health should be “based on sound science and ‘risk assessment’ principles and [should] not [form] disguised barriers to trade” (57).

While sound science has been a strong point in the work of the OIE since the inception of the organisation, the OIE International Animal Health Code (62) bears no chapter on “risk assessment”. In the absence of such a chapter, and in response to the GATT direction, the 10th Conference of the OIE Regional Commission for the Americas recommended that “the concept of ‘risk analysis’ be included in the OIE International Animal Health Code” and that “the OIE designate a technical group, to support the Code Commission, to be responsible for identifying the basic components of risk analysis” (60).

The 59th General Session of the OIE, witnessing a renewed international consciousness of the need for greater standardisation and transparency in import protocols (61), endorsed the recommendation (27) and commissioned this paper, in addition to initiating the introduction of a new chapter into the Code.

In 1991, in response to a call for comments on this subject, the Veterinary Services of the following nations made submissions which are discussed below (in the section “Comments contributed by OIE Member Countries”): Albania, Canada, Cuba, Egypt,
Ghana, India, Mexico, Mongolia, Myanmar, New Zealand, Norway, Portugal, South Africa, Switzerland, Turkey, the United Kingdom, the United States of America and the former Yugoslavia.

If the position statements of these countries are representative of the membership, there exists both an acceptance of the need for the objective approach to importation which risk analysis offers, and a genuine willingness to implement this approach. Within the current, demanding international marketplace (44), the application of such an approach would appear to be invaluable.

RISK ANALYSIS

The beginnings of veterinary medicine can be documented as early as circa 2500 BC (70); however, it was not until 1969 AD, in Science (73), that Starr proposed the formal, quantitative assessment of risk. This is not to say that the risks inherent in the natural environment had not hitherto been recognised, nor that there had been a lack of response to these risks. In fact, Veterinary Services have taken measures against perceived threats to their livestock populations, on a hit and miss basis, since the Middle Ages (69, 70). The difference between what Starr proposed in 1969 and the systems still operated by most Veterinary Services today is illustrated by the use of the terms "quantitative" and "perceived" above. Most national Veterinary Services still decide whether or not to allow foreign livestock and livestock products to enter the national territory on the basis of past experience and qualitative, not quantitative estimates (46).

The fact that the article by Starr appeared as recently as 1969 and was regarded as breaking new ground, is testimony to the "infancy" of quantitative risk analysis. While Starr singled out modern technology as a natural focus for the application of risk analysis, Lowrance (45) expanded to six the number of areas in which it could be used. While his list included subjects as diverse as the analysis of the risk of natural catastrophes and sociopolitical disruptions, number one on his list was infectious and degenerative diseases. While most risk analysis today focuses on the potential failure of large technological installations (e.g. the nuclear installation at Three Mile Island) and on low-level delayed-effect hazards (e.g. carcinogens) (80), the potential of such analysis for predicting and preventing the risk of infectious disease introductions is equally viable.

Since 1969, risk analysis has emerged as a formal discipline, with its namesake journal, Risk Analysis, having been introduced in 1981 (23). When epidemiology was similarly thrust upon veterinary medicine in the 1960s, it arrived with an associated vocabulary (49, 70), which has yet to fully permeate this science. Inevitably, the same learning curve will apply to risk analysis. Hathaway (34) and others (23, 26, 55, 59) have already defined the associated terminology both in a generic sense and in particular reference to livestock importations, and therefore this paper will not dwell upon this subject.

Suffice it to say that personal and business life is replete with hazards. Every day is a gamble in one sense or another. Will the alarm clock fail to awaken you for your flight? Will you bound from bed knowing that the odds of suffering cardiac arrest are $x$ times greater from 6 a.m. to 10 a.m.? Will you drink your morning coffee despite the association of caffeine with insomnolence and bladder cancer?

Consciously, or unconsciously, we identify these hazards daily. We make intuitive assessments of the seriousness of these hazards, not in a general sense, but rather in
direct relevance to our personal situations. We then decide whether or not to subject ourselves to these risks, depending on the other factors in play at the time. We weigh the benefit which we feel might be derived from the continued activity. If we do drink the coffee in spite of the associated risk, we may reduce our daily intake to mitigate the effect. We then explain to sceptical spouses how we have effectively dealt with this liquid challenge.

The above caffeine-based scenario encompasses the essential elements of risk analysis. A hazard, or source of danger, associated with a given activity was identified and the probability of harm resulting was assessed. Consideration was given to whether to proceed in spite of this risk, given local considerations and the estimated benefit to be derived from the activity. Appropriate steps were taken to mitigate the threat. The process and its anticipated outcome were explained to an audience which held a vested interest. While others employ much more defined and descriptive terminology (34), the above example conveys the sense of the process.

Protagonists define risk analysis as a decision-making tool which employs science but is not itself a pure science (23): in this sense, risk analysis plays a role not unlike that of epidemiology (49). Like epidemiology, risk analysis must deal with situations as they arise and tolerate the mathematical limitations of disease prevalence estimates or other such data on which findings are based.

Risk analysis can be divided into qualitative and quantitative components. The above caffeine-based example reflects the qualitative aspect, which relies on precedent, value judgements and subjective estimations. MacDiarmid describes this as a natural evolution from a situation in which hard facts are unobtainable (46). To have approached the risks involved in drinking coffee from a quantitative standpoint would have required quantifying our consumption, obtaining consumption-based attributable risk measurements and assessing the significance of consumption modification after x years of imbibing.

In this respect, Veterinary Services are not unlike the coffee drinker. They often lack the necessary information or the resources required for analysis, should the more demanding quantitative course of evaluation be considered. While the situation may be rationalised in this way, barriers to trade created by the lack of such quantitative evaluation are untenable in the current international marketplace (19, 22, 26, 34, 46, 55).

Quantitative risk analysis attaches numerical equivalents to the qualitative estimates which would otherwise be employed (37, 38). While the derivation of the associated figures is fraught with uncertainty (26, 29, 34, 46, 55), this yields finite values which can be exchanged, evaluated and discussed objectively by the trading partners involved. Import controls, as currently applied, represent a spectrum of qualitative and quantitative risk analysis approaches (2, 21, 44, 46, 52, 53, 57, 79). The evolution of these controls is described in the following section.

**EVOLUTION OF QUALITATIVE RISK ANALYSIS WITHIN IMPORT CONTROLS**

Schnurrenberger *et al.* (69) describe two basic systems which are employed by Veterinary Services to control importations. They describe the first as “interdiction”, in which everything is initially prohibited and a given importation must meet specific requirements established for that consignment alone. The second is based on general standards, and any qualifying shipment can enter the country. Schnurrenberger *et al.*
describe interdiction as being frequently employed for shipments arriving from what they qualitatively term as "high-risk areas".

It was following at least nine painful experiences with imported foot and mouth disease (FMD) that, in 1930, the United States of America (USA) adopted the interdiction approach based on prohibitory legislation "banning entry of domestic ruminants and swine" from any country determined as having the disease (69). This concept of "zero risk" represents the most conservative of import approaches. Cooper described a similar approach taken by Australia following the invasion of the Iberian peninsula by bluetongue in the 1950s (22). Canada applied interdiction to American swine in the same decade, following the discovery of vesicular exanthema in California (69). Given the high cost of introduced disease (21, 24, 39, 40, 41) and an import evaluation which still relied heavily upon clinical signs (58), the approach was understandable at the time.

However, in spite of dramatic subsequent improvements in diagnostic technique, many instances of interdiction are still encountered, as reported in the Interim Report of the Expert Consultation on FMD Risk Assessment and Updated Guidelines (59). It was stated that, given "the lack of quantitative information", governments have chosen risk avoidance over risk assessment, with an aim of achieving "zero risk".

The decision taken by Canada in the mid-1960s to import from France and other European countries – under stringent measures designed to "manage" any qualitatively determined FMD risk which might be associated with the process – marked a dramatic diversion from the previous North American stance (69). The approach was more akin to the qualitatively-based "risk management" approach which had been adopted over the same time interval for animal products (7, 18, 20, 25, 31) with great success, as described by Callis (18, 19). During the same interval, Australia progressed from absolute interdiction to qualitative assessments of commodity-related risk, to develop more than 120 import protocols with a risk management emphasis (22).

With the assistance of new diagnostic techniques and driven by "constant pressure to liberalise conditions for importation" (58), other nations have responded by replacing absolute interdictions with qualitatively-based risk identification and management requirements and a petition for changes in the OIE International Animal Health Code definitions in respect of the FMD status of exporting nations (79). At least one country has opened its doors to a candid third party assessment (16).

These changes acknowledge several realities. In an environment of intensive competition (2, 21, 26, 69), trading partners recognise the need for genetic enhancement of hitherto cloistered gene pools. Economic forces as mundane as the disparate costs of landfilling on the two sides of an international border evoke market demands (2). Consumer tastes have become more cosmopolitan (46) and importers are scrambling to meet the demand. Statistically-based diagnostic improvements now permit considerably higher confidence in the status of the imported commodity (43, 47, 48, 67, 76, 78).

Even insular nations recognise that zero risk is unattainable, given modern rapid transit possibilities and biological developments (44). From an altruistic viewpoint, trade restrictions applied to protect indigenous industry sectors can be seen as doing "more harm than good in the long term, because they discourage efficient use of world resources, which impinges on the imposing country in various ways" (55). From a more pragmatic viewpoint, GATT (59) has established a clear direction that the OIE should lead a process of developing more objective and transparent trading criteria.
In response to the GATT challenge, the OIE has initiated a thorough study of the three factors on which more objective and transparent trade practices must be based. The first is the enhanced application of epidemiology and surveillance in the country of origin. The second is the characterisation of the national Veterinary Service. The third, the subject of this paper, takes into consideration the findings of the first two factors (in addition to others) to determine quantitatively, not qualitatively, the risk associated with the importation of any given commodity from any given nation. The transition has already begun from intuitive judgements and bias-prone qualitative assessments to a system of import controls based on objective, quantitative information which can be easily critiqued, evaluated, discussed and negotiated.

EMERGENCE OF IMPORT BASED ON QUANTITATIVE RISK ANALYSIS

Cumming, in the lead editorial of the first issue of the journal Risk Analysis (23), characterised the relationship between qualitative and quantitative risk analysis. He stated that risk analyses will be made on the basis of whatever information is provided, adding: “If decisions, based in part upon these analyses, are to be optimised, it is important that they be as impartial and as accurate as it is possible to make them”. Impartiality and accuracy demand a quantitative approach.

Finkel, a decade later (29), in reference to environmental health risk assessment, extended the observation. He acknowledged that qualitative risk analysis at least accepted risk as something to be controlled as opposed to feared and run from (as in import interdiction). However, he emphasised 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”. He characterised qualitative approaches as tending to be “piecemeal” and as generating “laundry lists of uncertain assumptions”, with the results tending not to improve the decision-making process.

While qualitative assessment of risk still predominates, a growing list of countries have taken these words to heart. The latter would appear to agree with Finkel that while some programme managers “might be adept at implicitly incorporating probabilistic considerations into their decisions”, it is “wishful thinking” (29) to assume widespread distribution of such natural talent. These countries appear determined to provide national decision-makers with the objective information which can be derived only through quantitative risk analysis.

An implicitly simple quantitative approach was taken by the USA in assessing the risks associated with the dumping of Canadian garbage in landfill sites in the USA (2). The same clarity is evidenced in the quantitative assessment by the USA of the risk of emergence of bovine spongiform encephalopathy (BSE) on a national, state and even county level (10). The earlier generation by the BSE group of a parallel, qualitative analysis (9) provides an ideal demonstration of the limitations of qualitative analyses.

Hathaway (34) described the application by New Zealand of a quantitative model to assess the danger of introducing maedi-visna through a sheep embryo importation programme. The same approach was applied to estimate the probability of releasing imported scrapie in New Zealand, in spite of a rigorous four-and-a-half year quarantine provision.
Acree and Beal (1) derived a quantitative approach for establishing the degree of disease introduction risk which could be tolerated in association with embryo importations. MacDiarmid (46) reviewed the quantitative assessment by Australia of the risk of introducing porcine transmissible gastroenteritis (TGE) through importations of Canadian pork. Australia recently conducted a similar assessment of the potential for introducing porcine reproductive and respiratory syndrome (mystery swine disease) by the same route (42).

The preceding examples reflect evolving national positions which acknowledge the increasing necessity of facilitating trade (1, 21, 34, 44, 46, 53, 57, 79). Australia is a leader in the area, and this policy transition reflects the fact that 37% of the national export revenue is derived from agriculture (21). Without dwelling upon technical details which have been well presented elsewhere (53), the following section describes the theory behind a quantitative approach to risk assessment which has recently been developed by Canada in collaboration with Australia, New Zealand and the USA.

THE THEORY BEHIND THE QUANTITATIVE APPROACH TO IMPORT RISK ANALYSIS

The quantitative approach to risk analysis looks upon the transmission of infection through imports as the climactic conclusion to a complex series of events. This approach holds that the probability of each sequential event occurring is quantifiable. The product of all the individual probabilities represents the net risk of introducing infection (53). MacDiarmid listed an example of such a series of events (46) for imported meat and meat products. He derived examples of the related probabilities (34) during an evaluation of the risk of introducing disease through the importation of sheep into New Zealand.

The quantitative route first identifies the spectrum of diseases which might be transmitted by the species in question. For each ailment, the level of infection in the exporting nation is determined, in order to identify the probability that any animal, chosen at random, will be infected. The multiplication of these estimates by the number of animals involved in the shipment yields the respective probabilities that diseases “x”, “y” or “z” reside somewhere in the consignment (51).

When the shipment consists of live animals, it is assumed that the disease agents which the animals harbour at the point of embarkation are viable and capable of transmitting infection. If a commodity other than a live animal is being exported, secondary evaluations determine whether the disease in question can remain viable in spite of the processing (e.g. heat, salination) which the product characteristically undergoes.

By assessing the means by which the livestock of the recipient nation might become exposed to the imported commodity, the probability of transmission into the indigenous community is quantified.

However, this is not the end of the quantitative approach. In addition, this approach measures the degree to which the chain of transmission may be weakened, if not fractured, through a series of possible risk management measures. The first measure involves the selective aggregation of stock or product from geographical areas of lesser infection prevalence (21, 24, 57). A second measure assesses the degree to which diagnostic screening can weed out infected consignments (47, 48, 76, 78). A third measure acknowledges the time-honoured value of quarantine and transport (69) as a means of identifying, and hence eliminating, animals in an incubating phase of disease.
The same management approach quantifies the degree to which commodity manufacture (20, 46) impedes the viability of the infectious organisms in question. For both live animals and commodities, this approach determines the impact of post-entry protocols which are designed to preclude contact with the indigenous population (69).

By such means, the USA calculated as $1 \times 10^{-12}$ the risk of introducing a viable tropical fruit fly in a truckload of Canadian garbage (2). Australia calculated as $1.23 \times 10^{-5}$ the probability that TGE virus of Canadian origin would be fed to indigenous swine in any one year (46). New Zealand estimated as $6.02 \times 10^{-6}$ the likelihood that maedi-visna would enter the domestic sheep flock with each consignment under an embryo importation programme (34).

For a programme manager, such quantitative estimates of risk hold inherent advantages over qualitative terms such as "low risk" in conversations with domestic producers and entrepreneurs (42) and offer the transparency of analysis which the GATT process seeks (57). However, these estimates do make demands on the Veterinary Services which seek to derive them (46). Because the precision of quantitative risk assessments is "no greater than the accuracy of the many estimates entered into the equation" (1) there results an insatiable hunger for information which is often unavailable (46) in a desired depth or format. This and other challenges facing the quantitative approach are described in the following section.

**ADDRESSING THE CHALLENGES FACED BY QUANTITATIVE IMPORT RISK ANALYSIS**

The chain of disease transmission described in the preceding section, and the means of disrupting this chain, have long since been recognised by the regulatory veterinary community (69). The first challenge to quantitative analysis lies not in the identification of factors influencing disease transmission and the methods used to curtail such transmission, but rather in the need to accumulate objective facts (74). How can the percentage of animals in a given nation which are carrying TGE, for example, be established? How can the transition be made from reports of "exceptional", "low sporadic", "enzootic" and "high" disease prevalence (terms currently employed in annual OIE statistics) to mathematical equivalents? What is the mathematical probability that a diagnostic test applied during the importation process will identify a subclinically affected animal? What is the mathematical probability that one meat portion taken at random from the national livestock population will carry TGE despite ante-mortem and post-mortem examination? What mathematical equation describes the chance that the disease agent will gain access to the national swine herd of the recipient nation?

While such questions forced earlier generations to practise trade interdiction (17, 69, 70), analytical developments over the last twenty years (18, 20, 25, 46, 47, 48, 55, 76, 78) now justify a much more liberal approach. Although even the developed nations respect the difficulty of establishing the presence of extremely low prevalence diseases (3, 7, 58, 75) and identifying early epidemic situations (50), statistical and diagnostic developments now permit the accurate identification of infection levels (58) in wild (81) as well as domestic species (71, 77). As described above, the OIE has already launched an effort (59) to fill an historical need (56, 74) in national surveillance and epidemiology. The initiative parallels and complements the progress in risk analysis.
The seeds of this initiative are falling on fertile ground, as there is longstanding global recognition of the need to accumulate (4, 36, 64, 65) and share (63) such information. The possibilities have increased dramatically during the last decade alone (28, 54, 66).

On the basis of the available information and pragmatic derivations from it, Australia, the USA and New Zealand, among others, have already met the quantitative challenge in a number of situations (as described above). Canada, in collaboration with the above three countries, has progressed to the point of creating a generic model to guide the analytical process (52, 53). In addition to the model, data bases of detailed national disease prevalences will be established for distribution to all OIE Member Countries. Blajan and Chillaud have described the commitment of the OIE to facilitating the task of Member Countries in the future through improvements to the World Animal Disease Information System (14).

Callis, in personal reflections on the quantitative approach and the challenges to this approach, emphasised the area of international trust (19). He referred to the strong mutual trust which characterises trade in meat products between the USA and Argentina, as an example of the degree to which confidence can be instilled. Inherent in this achievement is faith in the Veterinary Services of the exporting nation.

The OIE also recognises the significance of this latter point. As described above, the OIE has established the assessment of Veterinary Services as the second prerequisite (the first being national disease surveillance) to facilitating the transition to quantitative import risk analysis (59). Building upon Resolution XIII of the 54th General Session of the International Committee of the OIE, an effort led by Dunn has already made considerable progress (27, 79).

The same uncertainty which led previous generations to ban importations will continue to challenge quantitative risk analysis (46) in the quest to facilitate trade. However, this problem is common to risk analysis in all fields (35) and need not paralyse the effort. Finkel addressed the subject by producing what he described as a Guide for decision-makers (29) which was intended, in his words, to provide "a systematic way to think about, quantify, and respond to uncertainty in risk assessment". He describes uncertainty as emanating from four sources.

The first source of uncertainty relates to the accumulation of the raw data on which estimates are based. As described above, efforts are already underway within the OIE to address this issue. The second source concerns the quantitative models built upon the data. The four-nation collaborative effort currently underway is cognisant of the challenge and incorporates sensitivity testing as a means of assessing the vulnerability of a given model to errors in prevalence estimation. The third source of uncertainty concerns the ambiguity and controversy which can surround the establishment of the acceptable level of risk: Acree and Beal (1) have already shown leadership in this area. The fourth and last source of possible uncertainty relates to the variability which is inherent in all natural systems. The latest sampling plans and statistical analyses of results specifically target such variability, providing confidence intervals to assist the model builder.

The guide produced by Finkel (29) proceeds to provide managers with guidance in how they might critically review (if not influence) the results of analysts by posing a series of basic questions. Finkel then introduces the last of the challenges to quantitative risk analysis which will be discussed in this paper. This final concern relates to how the information derived by quantitative analysis is to be communicated to the affected parties.

Hanson and Hanson (33), in a chapter on rural communication, write of the "need [for the public] to know" about the actions taken by the government on behalf of the
population. While recognising that all nations necessarily perform some activities in secrecy, these authors state that “today, government agencies in most free countries must keep the public informed about any actions they plan to take”. Auld describes risk communication as a priority in environmental and occupational health since the early 1980s (12). Using the Alar controversy in the USA as an example, she describes the ruinous results of a situation in which facts are not communicated in a timely manner by persons who retain credibility in the public eye (13).

Segal discusses the factors which invite outrage within an inadequately informed population (72) and describes two points which bear particular relevance to import risk analysis. The first relates to public concern that the community has some degree of control over decisions being taken which could affect it. The other point relates to fairness, and whether the community is being exposed to more risk than its neighbours, without access to greater benefits.

The conviction expressed by Acree that, in the short term at least, the benefits of import are shared by few while the risks are shared by many (1), is testimony to the need for dialogue.

Fisher describes a spectrum of approaches through which such dialogue has taken place in the past (30). At one extreme, the regulatory group does nothing but inform, and in so doing seeks to “put the best possible face on the risk message”, with the assumption that explaining the risk better will “make the recipients accept the message”. Scherer describes this approach as being founded on three assumptions (68):

- that “science alone can provide objective truths”
- that “scientific and technical experts are the only possible sources of correct risk information”
- that “the public is a passive receiver of risk information”.

The frailty of this method in the present informed society is borne out by reaction to the nuclear hazard at Three Mile Island and the bacterial hazard posed by Salmonella enteritidis in eggs.

At the other extreme of the spectrum of approaches described by Fisher, communication is used to empower the community to play a role in the outcome of the issue. In theory, a framework for dialogue is constructed which permits “a free flow and exchange of information among the experts and concerned publics about risk problems, policies and appropriate solutions”. She describes experts as often expressing concern, however, that such empowering could paralyse essential regulatory activity and allow concerns over small but dramatic risks to steal resources which should be used in addressing greater risks (30).

Hathaway describes the varied approaches taken by Veterinary Services in the USA, Japan, the United Kingdom, the Netherlands and some other European nations in such policy applications (34). He concludes that “a consensus approach, incorporating consultation and compromise, appears to be a better alternative” than either the adversarial or the authoritarian methods which he describes as characterising the route taken by some of the above countries.

Regardless of the approach used, Auld prescribes that information be provided to the affected group as early as possible (12). Auld advocates that the message be tailored to the needs and characteristics of the target audience, cautioning that the
attitudes, beliefs and perceptions of the audience with regard to the risk be assessed in advance. She suggests that the risk be compared with a common standard as a means of facilitating evaluation. Finally, Auld emphasises openness and truthfulness on the part of the regulatory agency.

Earlier sections introduced risk analysis, describing its qualitative and quantitative evolution in the regulatory control of imported animals and products; they described the theory behind the quantitative approach. This section discusses the solutions to the four major challenges facing the expansion of the quantitative method. While ostensibly directed to import controls on a national basis, these solutions are equally applicable to the evaluation of consignments derived from areas demarcated within a single nation or among adjacent nations. The following section discusses this corollary approach in greater detail.

IMPORT RISK ANALYSIS IN REFERENCE TO DISEASE-FREE ZONES

When Canadian cattle are exported to Australia, export certificate HA.1313 states *inter alia* that animals thus certified have never resided in the Okanagan Valley of British Columbia, the westernmost province of Canada. When importers introduce cattle from Australia into Canada, they do so on the basis of form CA-02, bearing related provisions which delineate an area of western Australia north of 28°S. The reciprocal provisions are related to the regional distribution of bluetongue vector species in the two nations (3).

The Uniform Methods and Rules of the American Brucellosis Programme recognise the variability in disease prevalence among states, and establish movement controls which respect the differing eradication achievements of contiguous jurisdictions (11).

When avian influenza afflicted Pennsylvanian flocks in the mid-1980s, Government of Canada memorandum T-86-307 did not prohibit the entry of all poultry and poultry products from the USA. Instead, the memorandum limited controls to the state of Pennsylvania.

A common thread runs through the preceding examples: the conviction that, within a nation, an area can be defined which bears a disease status different to that of the nation as a whole. Further, it recognises that the local jurisdiction is capable of maintaining and protecting the altered status.

Long regarded as a potential solution to continuing international restrictions against endemic FMD (21, 24), such “disease-free zones” are equally applicable to other disease issues and the subject of renewed evaluation (27, 59). From the standpoint of import risk analysis, these zones bear consideration equal to that which is given to nations, provided that the same criteria of surveillance, veterinary infrastructure and territorial integrity can be achieved. The promise held by such “disease-free zones” is the subject of a new chapter on “Zoning and regionalisation” (part of a section on import risk analysis) which has been approved by the International Committee (in May 1993) for inclusion in the OIE *International Animal Health Code* (8).

Many nations have commented on zoning and the other subject areas covered in the present paper. The positions of these countries are highlighted in the following section.
COMMENTS CONTRIBUTED BY OIE MEMBER COUNTRIES

The comments received cover a broad geographical and political spectrum and reflect a common theme – the need for a formal risk analysis approach. The comments of each country are addressed individually, as each conveys a pertinent message.

Albania

In the face of significant changes in the national infrastructure, Albania sees the need for considerable international collaboration in resolving the risks inherent in the importation of livestock and livestock products. The Balkan Veterinary Committee has already discussed this issue.

Canada

As an advocate of quantitative risk analysis, Canada has prepared a chapter on the subject for inclusion in the OIE *International Animal Health Code*. A review of the National Animal Health Program, conducted in 1987, identified the need for such a structured approach. On an informal basis, Canada has subsequently developed and applied the concept to such diverse domestic and international issues as BSE and the importation of captive ungulates. Canada is keenly aware of the need for the information which fuels the "analytic furnace": the country faces a dearth of factual data when confronted with requests to import llamas, elk and other captive ungulate species. Canada is committed to continued collaboration and leadership in quantitative risk analysis under the aegis of the OIE. The efforts undertaken by Canada incorporate considerable collaboration with and input from the USA.

Cuba

Cuba recognises that public and animal health precautions represent inevitable barriers to international trade. The country shares the concern of the OIE that international disease reporting among Member Countries should be strengthened to engender a mutual confidence which will reduce those barriers to a necessary minimum. Cuba calls attention to the relative safety in trade which has been achieved over the last thirty years through adherence to ever-improving OIE standards. As a nation which is free of OIE List A diseases and favourably positioned in the control of other diseases, Cuba supports zoning, provided that the nations in question are able to meet the strict criteria which must be applied in such an endeavour. Cuba advocates that other nations adopt the same willingness to meet the challenges of evolving international trade.

Egypt

As a nation which adheres to OIE recommendations in all its exports, Egypt has suffered due to the importation of animals and animal products from nations which have adhered less assiduously to OIE standards. The testimony of Egypt with regard to resultant economic losses within the Egyptian cattle herd explains, by illustration, the natural reluctance which grips nations as they consider importing. The Egyptian experience supports the need for the quantitative analytical approach.

Ghana

The introduction of disease into Ghana through illegal importations supports the position held by Callis (19) that, if economics so dictates, livestock movement will occur regardless of government efforts to control such movement. The experience of Ghana is representative of the challenge faced by all nations in the establishment of approaches which carefully control (without prohibiting) importation.
India

A nation of continental proportions, India firmly supports the role of zoning in recognising the achievements of smaller jurisdictions. India has achieved success in freeing large areas from rinderpest and in containing contagious bovine pleuropneumonia within several districts.

Mexico

Mexico has promoted the concepts of risk analysis and zoning for some time in domestic and international circles. Mexico has already established extensive areas which are free of classical swine fever through an eradication programme which has broad support from producers. Velogenic Newcastle disease is the subject of similar efforts.

Mongolia

The Mongolian situation is characteristic of the way in which telluric conditions influence the distribution of contagious diseases throughout the world, as described above. In Mongolia, the harsh extremes which distinguish summer and winter mediate against vector transmission. The relative isolation of settlements also facilitates effective disease control. In spite of these advantages, disease has been introduced into Mongolia through importations from developed nations. The country seeks assistance from the OIE in the development of means whereby these incidents might be prevented.

Myanmar

In support of OIE principles, a new Act concerning the control of contagious animal diseases is currently under review in Myanmar. If approved, this legislation will be enforced to OIE standards. Myanmar seeks to benefit from the concept of zoning through the creation of insular disease-free zones in the coastal region in accordance with the standards established by deliberations within the OIE.

New Zealand

As a nation which is dependent on international trade, New Zealand has applied considerable effort over a number of years to risk analysis within both domestic and imported commodities. The country does not operate a zero risk importation policy, in recognition of the frailties of that method which are described above. Instead, the more objective, analytical approach employed by New Zealand stands as a model for other nations. New Zealand has long since responded to the problem of uncertainty, described above as one of the challenges of quantitative risk analysis.

Through extrapolation, estimation and emphasis on the quantitative value of management techniques, New Zealand has come to grips with the issue of uncertainty. Excellent examples of managing the risk of introducing maedi-visna and scrapie were provided, as described above. New Zealand emphasises the necessity of striking a balance between the zeal of the entrepreneur and the concerns of established industry.

The desire of New Zealand to achieve such a balance within a framework of real and perceptible fairness relates directly to two of the items addressed above. These include communications skills and cost/benefit analysis, which are both valuable tools in such a situation. While recognising that import applications of risk analysis are still in the initial stages of development, New Zealand feels that the sharing of methodologies through the OIE will facilitate the growth of these applications and contribute to better bilateral understanding.
Norway

Relative geographical isolation has assisted Norway in maintaining high standards of animal health. Not surprisingly, Norway employs a very conservative approach to importation in order to protect this status. One goal of quantitative analysis is to provide such nations with the assurance that they can import on a more liberal basis without undue risk.

Portugal

As an importing nation, Portugal seeks the assurances which risk analysis can provide, particularly in reference to FMD. The country seeks to complement adherence to the relevant guidelines of the European Economic Community (EEC) with the additional safety measures which import risk analysis offers on an even broader basis. As in the case of Norway, Portugal plans to take advantage of its relatively isolated geographical position in this regard.

South Africa

South Africa is a firm advocate of quantitative risk assessment in trade in animals and animal products. This support stems from a recognition of the sense of fairness which is conveyed through the process to both the importer and the national Veterinary Service of the importing country. Dwelling heavily on information needs, South Africa has provided comments which support many of the areas addressed above, from cost/benefit analysis to zoning. South Africa defines information needs as often extending beyond OIE Lists A and B diseases, for reasons relevant to the particular nations involved, and pleads for flexibility, sensitivity and professional judgement to augment the hard facts which quantitative analysis provides. South Africa closes with a call for flexibility and sensitivity which echoes the position of advocates of risk analysis.

Switzerland

None could question Switzerland, were it to adopt a conservative attitude to importation. The history of animal health in the country records a litany of experiences with diseases which have accompanied legal and illegal consignments. The introduction of infectious bovine rhinotracheitis in the mid-1970s alone led to the slaughter of 52,000 cattle, with control and surveillance costing 130 million Swiss francs. The recent introduction of bovine spongiform encephalopathy has resulted in new restrictions on exports from Switzerland to fourteen nations. In addition, enzootic bovine leukosis, contagious equine metritis, Newcastle disease and avian infectious laryngotracheitis have all been introduced at various times.

Not entirely jaded by its misadventures, Switzerland does not question risk analysis but rather provides a list of factors which must be considered in the process.

Turkey

The Turkish submission emphasises the strict controls which are characteristic of international trade at present, based on identification, certification, diagnosis and movement restrictions. Turkey has gained experience in selectively identifying areas of higher risk based on the evolving indigenous disease situation in the country of origin.

United Kingdom

The position of the United Kingdom on risk analysis is reflected throughout this document. As an island nation, the United Kingdom itself represents a "zoning" situation, and has insight to offer regarding the successes and failures of such an
approach. The United Kingdom jealously safeguards the national health status through demanding import controls. The experience gained by the country during World War II enables the United Kingdom to relate to Third World situations, in which some level of import risk must be tolerated in order to ensure continued access of the human population to animal protein.

As a member of the EEC, the United Kingdom joins many other nations which share animal health accords with clusters of their peers. The multiple “layering” and division of disease control responsibilities which characterise such regional multilateral agreements could be looked upon as complicating risk analysis-based bilateral agreements with non-EEC members. On the other hand, these characteristics offer the inherent efficiency whereby entire blocs of countries may negotiate on a composite basis analogous to that which the USA employs in representation of all state jurisdictions within the USA.

Risk analysis, albeit qualitative, has characterised animal health decision-making in the United Kingdom for some time. The risk analysis conducted with regard to rabies and FMD has been described as some of the most extensive analysis of the kind ever undertaken in the country. The United Kingdom places considerable emphasis on the linkage between risk analysis and the corollary efforts being made by the OIE in the evaluation of Veterinary Services and surveillance, sharing the experience of the EEC. The country also admits to the considerable pressures which will continue to demand greater flexibility in assessing import demands. The United Kingdom is very supportive of the structured process which quantitative risk analysis offers in this regard.

United States of America

The USA joins Canada as an advocate and protagonist in the area of quantitative risk analysis. The views expressed in the Canadian comments and the model prepared for the OIE International Animal Health Code are a product of close collaboration between the USA and Canada.

Yugoslavia

The former Yugoslavia stood at a crossroads of many nations, with considerable numbers of consignments of animals and animal products crossing its national boundaries. Domestic legislation had traditionally sought harmony with the animal health provisions of the EEC and the OIE. Yugoslavia considered these actions as having successfully contributed to the management of the risks inherent in the tens of thousands of annual importations to the country. Yugoslavia looked to further developments to assist efforts which had limited to a handful the number of untoward disease entries documented in recent decades. In so doing, the former Yugoslavia supported the concept of disease-free zones.

CONCLUSIONS

In the preceding section, a host of nations representing disparate geographical, political and disease situations endorse the continued evolution of methods designed to harmonise and liberalise international trade in animals and animal products. A far cry from the attitudes of another era, these comments express a willingness to collaborate further within the OIE to achieve those ends. Several of these nations have already committed considerable resources to independent efforts which are now being shared with the international community.
Some countries seek access to markets which were previously denied to them. Some seek access to new species and products without the concomitant introduction of diseases considered significant to the OIE or only to the countries themselves. Personal motives notwithstanding, all of these nations recognise the universal advantage of liberalised trade.

The task of trading animals without transmitting disease is not easy, having foiled the efforts of earlier generations and led to trade interdiction as the only known "no-risk" option of the day. However, the relative isolation offered by that era is now lost, even to island nations. Irreversible social, political and economic pressures for freer trade, which have subsequently emerged, will not be denied. Fortunately, these pressures are accompanied by technological developments which were unheard of a generation ago, and which will facilitate the evaluation of the risks associated with animal trade and the management of these risks.

Computers and diagnostic aids notwithstanding, humankind has long since learned that technology is not the answer to all the problems in the world. Only the bilateral trust which is built upon credible experience can facilitate the greater understanding and openness on which freer trade is based. Through the establishment and sharing of approaches and information among Member Countries, the OIE now has the opportunity to build that trust, in response to clear direction from GATT.

Perhaps the most famous of all risk takers, Lloyd's of London has built a reputation of never refusing to accept a challenge. Instead, its actuaries build upon past experience and current knowledge to establish conditions and premiums which balance risk and the profit incentive. That even the most astute can sometimes be proven wrong is borne out by Lloyd's financial losses in the most recent year of record. However, during multiple generations of endeavour, the firm has not only profited but also facilitated endless commercial and development projects which otherwise might never have been conceived.

Given the current dynamics of the international marketplace in animals and animal products, the OIE and the Veterinary Services of Member Countries face an identical challenge. Where once they might have refused to respond, quantitative risk analysis can now provide them with the necessary tools. The world expects no less of them.

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Résumé: A une époque où les voyages difficiles par mer ou par terre séparaient les pays exportateurs des pays importateurs, la durée et les contraintes du transport imposaient un approvisionnement localisé en bétail et une quarantaine implicite à l'importation. Les infections cliniques latentes non décelées avant l'embarquement se révélaient souvent au cours du voyage et devaient être éliminées avant l'arrivée dans le pays importateur. De nombreux pays, ne voulant pas prendre de risques à l'importation, lorsque seul l'examen clinique prévalait, pouvaient effectivement s'isoler en interdisant les importations. L'industrie acceptait passivement de telles décisions, qu'elle considérerait comme sages.

Les Services vétérinaires nationaux sont confrontés aux réalités économiques, sociales et politiques de ce nouvel environnement commercial international. L’auteur décrit les moyens de répondre à ce défi, basés sur une analyse quantitative des risques. Il explique la théorie de l’analyse des risques, ainsi que l’évolution qualitative et quantitative de cette analyse appliquée aux importations. Il discute des problèmes actuels et des solutions à y apporter.


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Resumen: En tiempos en que arduos viajes por tierra y por mar separaban a los países exportadores de los países importadores, la duración y la fatiga del transporte imponían fuentes localizadas de suministro de ganado y un período implícito de cuarentena. Las infecciones clínicas latentes que no se detectaban antes del embarque se manifestaban a menudo durante el viaje y debían ser eliminadas antes de la llegada al país importador. Muchos países que no aceptaban los riesgos de la importación basada únicamente en antecedentes clínicos podían, efectivamente, aislar y prohibir las importaciones. El sector industrial admitía pasivamente esas decisiones por considerarlas prudentes.

Hoy día, el perfeccionamiento de las técnicas de transporte permite agrupar las exportaciones procedentes de distintas zonas de un país. Esta agrupación de las exportaciones es un indicador de la situación sanitaria que prevalece en un país. Son horas, y no ya semanas, lo que tardan ahora los envíos en llegar a su destino. Los progresos realizados en materia de diagnóstico y epidemiología deberían compensar los riesgos asociados a la variedad y rapidez de suministro de ganado. Los países que consideran inaceptables los riesgos se enfrentan a una voluntad de legislación concertada, tanto a nivel nacional como internacional. La prohibición de las importaciones es una medida que se esquiva fácilmente recurriendo al tráfico ilegal de semen y de embriones.

Los Servicios veterinarios nacionales deben reaccionar y adaptarse a las realidades económicas, sociales y políticas de la nueva situación del comercio internacional. El autor describe los medios de lograrlo, basados en el análisis cuantitativo de riesgos. Explica la teoría del análisis de riesgos, así como
su evolución cualitativa y cuantitativa aplicada a la importación y trata, por último, de los problemas actuales y de su solución.


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