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Developing a quantitative risk assessment process

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Summary: The international animal health community is advocating a more widespread use of quantitative risk assessment in making international trade decisions. In this article, the authors explain why quantitative risk assessment is a valuable tool, outline a process with key steps for developing a quantitative risk assessment, and describe a method for quantifying the uncertainty associated with the results of a risk assessment.

KEYWORDS: Likelihood estimates – Probability – Quantitative risk assessment.

INTRODUCTION

Animal health regulatory officials are increasingly interested in applying risk assessment techniques to international trade issues. Risk assessment is an evaluation of the likelihood of an adverse event occurring and the magnitude of impact should it occur. Essentially, a risk assessment tries to answer the following three questions (5):

- What can go wrong?
- How likely is that to happen?
- What would the consequences be if things went wrong?

A formal risk assessment documents the process and information used. The process should be scientifically-based, well-documented, flexible, consistent, and open to review. Applied to international trade, specifically importing animals and animal products, risk assessment estimates the likelihood of importing an undesired animal disease agent or vector along with the imported animal or animal product in a specified set of circumstances. Regulatory officials may then use this risk estimate to establish risk management guidelines and procedures, and to determine if and how the proposed importation should proceed.

The concepts of risk assessment as applied to international trade decisions are fairly basic and straightforward. They include the following:

- a) evaluating evidence of the likely presence of specific animal disease agents or vectors in an animal or product of animal origin presented for importation;

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b) evaluating evidence with regard to the likelihood that the disease agent or vector would survive transit and commercial processing;

c) evaluating the expected impacts of regulatory protocols and risk mitigation procedures on the ability of the disease agent or vector to survive in the specific commodity to be imported; and

d) evaluating the level of risk associated with each importation which can be tolerated by the importing country when weighed against the expected benefits of the importation.

The application of risk assessment to biology and infectious diseases is still relatively new, and the practice is more complex than the concepts outlined above. As yet, there is no formal international agreement on the application of risk assessment methods to international trade issues. This paper discusses reasons for conducting risk assessments, and presents a process for quantitative risk assessment. The process includes a method to quantify the uncertainty which results from the inherent limitations of information and biological variability when conducting a quantitative risk assessment.

WHY CONDUCT RISK ASSESSMENTS?

Regulatory officials are required to make decisions in the face of uncertainty using incomplete or equivocal data. The outcomes of these decisions can affect tremendous numbers of people as well as the international balance of trade. Risk assessment has proved to be an effective method of providing decision-makers with more complete information, in order to help them to make more informed decisions and to better assess the impact of these decisions.

A second reason for conducting risk assessments is the growing support for using these methods, as seen in the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA). As tariff barriers to international trade diminish, the biggest potential barriers to trade are plant and animal health restrictions. In order to ensure that these restrictions do not become arbitrary non-tariff trade barriers, the international community is seeking a way to determine which sanitary restrictions, if any, are necessary. The application of arbitrary sanitary restrictions could result in international trade sanctions under proposed GATT rules.

Regionalization provides a third reason for using risk assessment in international trade decision-making. Regionalization identifies an area based on characteristics which could affect the presence and spread of animal disease agents or vectors, independent of national boundaries. Evaluating these characteristics is synonymous with evaluating risks for the presence of specific agents associated with a given region. In effect, a full application of the concept of regionalization requires the use of risk assessment. Regionalization is one domain which highlights the vital importance of information. Those areas with the necessary infrastructure to gather and analyze data, and the ability to provide this data to the international community, will be in a better position to expand export markets than those countries which fail to provide information regarding risk characteristics for animal diseases.

QUANTITATIVE RISK ASSESSMENT METHODS

A variety of scientific fields and applications have developed methods to evaluate the likelihood and consequences of an unwanted event occurring. The Planning and Risk Analysis Systems Staff of the Animal and Plant Health Inspection Service, United States Department of Agriculture, is developing a process which meets the demands for a scientifically-based, well-documented, flexible, consistent and open system. The process focuses on quantitatively evaluating the likelihood of importing an exotic animal disease agent, and the uncertainty associated with this likelihood estimate. The process used to evaluate likelihood has nine components, as follows:

- a) State the question
- b) Identify the hazard of interest
- c) Develop a scenario tree which outlines the pathway of expected events and all the failures which could occur, culminating in the occurrence of the identified hazard
- d) Label the scenario tree and assign units
- e) Gather and document evidence
- f) Assign values to the branches of the scenario tree
- g) Perform the calculations to summarize the likelihood of the hazard occurring
- h) Consider risk management options
- i) Prepare a written report.

The impact of the resulting disease introduction is qualitatively evaluated on the basis of the designation of the disease as an Office International des Epizooties (OIE) List A or List B disease.

The evaluation of likelihood begins with a statement of the question to be addressed by the risk assessment. The question should be as specific as is necessary to provide useful information to decision-makers. A question usually specifies the disease(s) of concern, the animal or animal product to be imported and the time-frame of interest. A sample question, which will be followed through this paper, might be "What are the risks of importing any exotic animal diseases or vectors with a shipment of cattle from country X?" The question may be reformulated as new information is learned.

The original question may be so broadly phrased that additional research is necessary to identify specific hazards. A hazard is defined as any event which has the potential to produce harm. Using the sample question above, the process of hazard identification includes determining which exotic diseases are present in the country of origin. If the hazard is broad, the question might be divided into a series of questions; for example, "What is the likelihood of introducing foot and mouth disease with a shipment of cattle from country X? Rinderpest? Rift Valley fever? Bluetongue?"

Once the hazard of interest is identified, the assessor lists all the events which are expected to occur during importation. This is called the "as planned" scenario because it represents the expected flow of events which prevent the unwanted event from occurring (Fig. 1) (5). A scenario tree is developed by constructing a diagram of each

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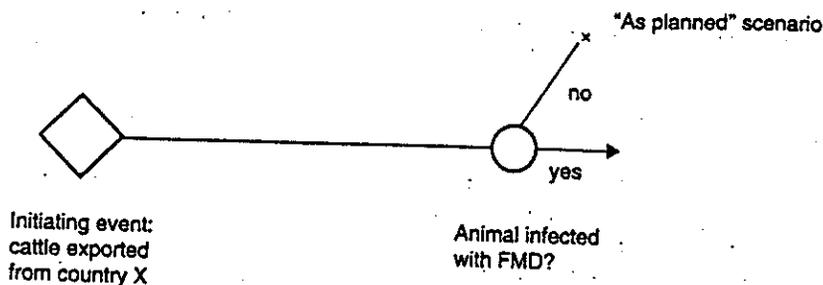


FIG. 1

Diagram of the "as planned" scenario
Hazard of interest: introducing foot and mouth disease (FMD)
with a shipment of cattle from country X

step in which an unplanned event could occur (Fig. 2) (7). These deviations are presented in the form of diagrams until they reach one of three end-points: the deviation results in the same outcome as the "as planned" scenario (i.e. it does not pose an actual hazard); the deviation ends at a point which is neither the hazard of interest nor the outcome of the "as planned" scenario; or the deviation culminates in the occurrence of the hazard of interest (Fig. 3). If an outcome which is neither the "as planned" outcome nor the hazard of interest appears in the scenario tree, it may indicate another facet of the risk situation which deserves investigation and the development of another risk assessment. For example, if animals infected with an OIE List A disease are detected while in quarantine in the importing country (Fig. 4), this is neither the "as planned" scenario of "no infected animals are selected for export from

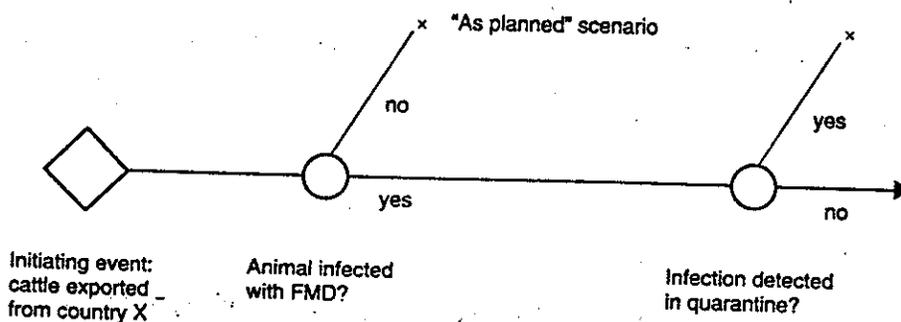


FIG. 2

Scenario tree developed by the preparation of a diagram showing deviations
from the "as planned" scenario

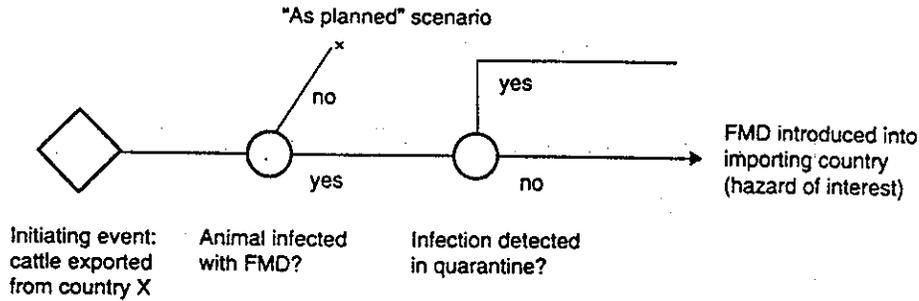


FIG. 3

Hazard of interest represents end-point of scenario tree

country X", nor does it correspond to the hazard of interest "FMD introduced through a shipment of cattle from country X". Detection of infected animals in quarantine in the importing country entails certain costs which might then become the focus of an assessment to answer the question, "What is the probability (i.e. both likelihood and consequences) that a quarantine station must be closed for cleaning and disinfection because of the detection of a List A disease in a shipment of imported animals within the next calendar year?"

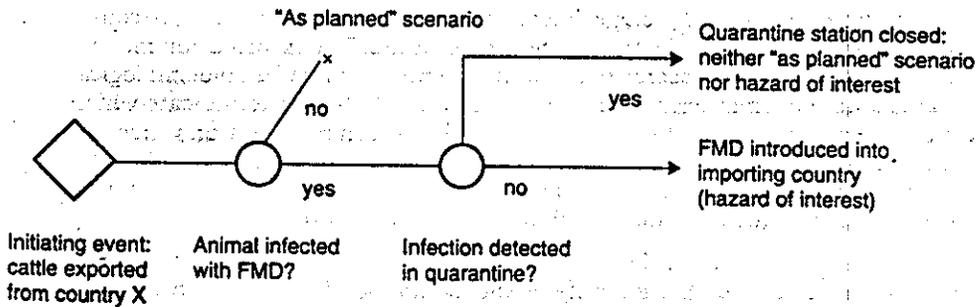


FIG. 4

End-points to scenario tree may indicate hazards different from hazard of interest

As the scenario tree is developed, each branch is named for the event which it represents. For ease of use, each branch is also assigned an algebraic label, which decreases confusion and diminishes requirements for writing long descriptive phrases. Assigning units and carrying these units through the tree also checks that the algebraic model is correct (although it does not necessarily validate the conceptual model). In developing a tree, it is important that all possible outcomes are included and that these outcomes are mutually exclusive. If all outcomes are mutually exclusive, then the sum of their probabilities (i.e. the likelihood that one of the outcomes will occur) totals 1. When two branches emanate from one node, they each represent some portion, or some fraction, of the total possible outcome. Therefore, if one branch were labelled A, the other branch (by definition) can be labelled 1 - A (Fig. 5). Units are assigned to each of the branches to ensure that they are consistent with the events which the branch represents and that the end-point of the assessment will be expressed in usable, comprehensible units.

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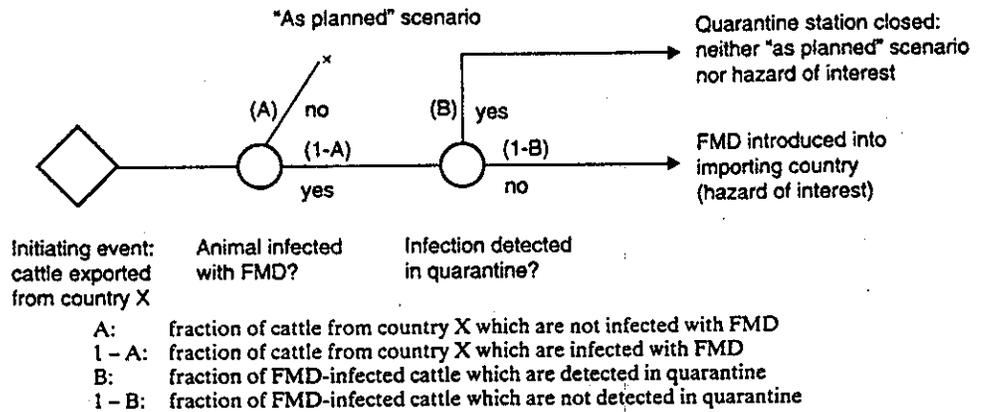


FIG. 5

Completed, labelled scenario tree for the risk of introducing foot and mouth disease (FMD) in a shipment of cattle from country X

Once the scenario tree has been developed, it is necessary to gather and document the evidence which will allow the assessor to assign numerical values to the likelihood of the described events occurring. Although information is continually gathered throughout the earlier components of the risk assessment, it is formally included at this stage because it is most efficient to search for only that information which directly applies to the branches of the developed scenario tree. This information then becomes the evidence on which quantification of the tree is based. The information may be obtained from experimental research or actual experience, or it may be epidemiological data or anecdotal information; this can then be arranged in order to indicate which sources are deemed most credible by the assessor. In the sample question which has been followed from Figures 1 to 5, the research may begin by determining the prevalence of each disease of interest in country X, the specificity and sensitivity of current testing procedures, and other details of the quarantine process.

On the basis of the evidence collected, the assessor assigns numerical values to each branch of the scenario tree, thus quantifying the likelihood of each event occurring. These values are based on the evidence, which includes some degree of uncertainty. A discussion of how to address uncertainty is presented in the next section of this paper.

When values have been assigned to the branches of the scenario tree, the actual quantitative risk assessment is performed. All independent, sequential events which lead to a specific end-point are multiplied, to arrive at the likelihood of a particular event occurring via a specific pathway, as shown:

$$(1 - A) \times (1 - B) = \text{probability of introducing FMD.}$$

If more than one pathway leads to the same end-point, the likelihood values for each pathway are added to obtain the overall probability of the end-point occurring via any pathway. Multiplying the value of the initiating event by the value of the sequence of events which lead to the hazard of interest, results in the expected frequency (expressed in number of cattle) with which FMD-infected cattle are not detected in quarantine and are released into the importing country, as shown below:

$$(\text{number of cattle in shipment}) \times (1 - A) \times (1 - B) = \text{expected number of FMD-infected cattle released from quarantine.}$$

When values are assigned to the branches of the scenario tree and summary values calculated, it is particularly easy to identify specific branches of the tree with the largest impact. These branches highlight areas of particular interest in risk management decisions, where a single intervention would have a more significant impact on the overall likelihood of adverse events occurring. A scenario tree allows the assessor to present the impact of a variety of risk management options to decision-makers in a concise, uniform format, increasing the ability of management to make an informed decision. It is also easy to pinpoint those branches in which uncertainty plays the largest role, allowing the assessor to recommend areas for additional research before more precise likelihood estimates can be made.

The final step is to write a formal report presenting all methods, models, evidence, statistical or quantification methods used, with a text summary which clearly explains the assessment. The development of this report starts with the identification of the hazard, the initial background research and the (re)statement of the question, and continues through the consideration of risk management options. Evidence used to assign values to each branch of the scenario tree is documented by citing reference articles, expert opinion, or results of laboratory and/or field studies. The use of the scenario tree ensures that all evidence is both evaluated and documented, and provides a logical format which provides an explicit diagram of the model and the underlying assumptions.

LIKELIHOOD, UNCERTAINTY, AND RISK ASSESSMENT

Performing a risk assessment and estimating the likelihood of an adverse outcome (such as the introduction of an unwanted animal disease agent or vector), essentially involve trying to predict the future. Risk assessment requires an estimation of the probability that one of many potential future events will actually transpire. This process necessarily involves uncertainty. A risk assessment method must include some estimation of the degree and source of uncertainty associated with predicting the likelihood of introducing an animal disease (1).

Decision-makers are faced with uncertainty in every decision they make. Familiarity with the uncertainty surrounding decision-making often leads decision-makers to accept uncertainty as inevitable, leaving the sources and magnitude of this uncertainty undefined, unquantified and unevaluated (6). A "point estimate" is often used to represent the results of a risk assessment because a single value is clear, precise, and easy to understand. Unfortunately, the very precision of a point estimate gives the misleading impression that the value presented is the answer. The statement of a single value as the result of risk assessment encourages decision-makers to focus on one single possible outcome. This ignores the fact that the single value was derived from evaluating many possible outcomes, and represents only an estimate of one potential outcome among many. In addition, a point estimate may be based on the mean, median or mode of the distribution of all possible outcomes. Therefore, point estimates which represent very different data distributions can have the same numerical value. For example, Figure 6 illustrates two different probability distributions which have the same mean. Obviously, the risk represented by these distributions is very different, a difference which is not apparent if only the mean (typically selected as the point estimate) is presented. Decision criteria used by managers are often based on knowing the likelihood of the worst case scenario. Presenting only a point estimate does not provide managers with the information required for informed decision-making.

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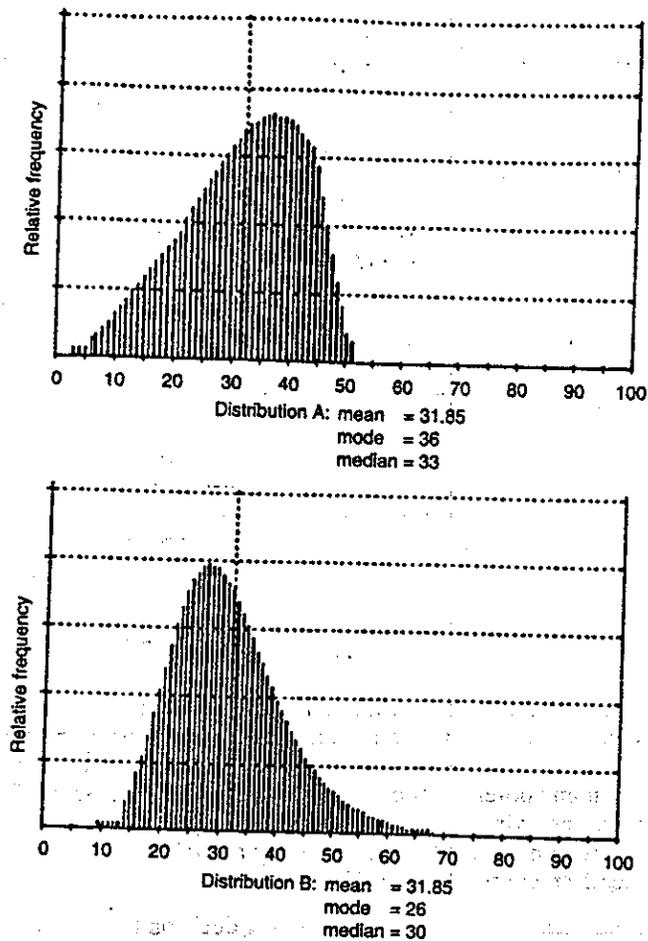


FIG. 6

Summary statistics and probability density functions for two random variables

It is common to address the deficiencies of point estimates by presenting a point estimate associated with the range of expected likelihood values (8). This serves to recognize the uncertainty associated with the point estimate and to give expected upper and lower boundaries. However, a range does not convey the changes in probability for all possible outcomes, resulting in an incomplete and potentially misleading representation. One very effective way of representing uncertain data is to present all the data in the form of a probability density function (PDF) (3, 4). A PDF graphically represents the complete distribution of possible outcomes, weighted by the likelihood of their occurrence. In a PDF, the horizontal (x) axis displays the values of the outcome of interest. Figure 7 portrays a PDF where the x axis represents the weight of prohibited material entering Alaskan landfills annually. The vertical axis (y) represents the probability density. As the y axis represents density, the probability of a specific value on the x axis is determined by calculating the area under the curve at that point, and not by simply reading the corresponding y coordinate. The total area under the curve is

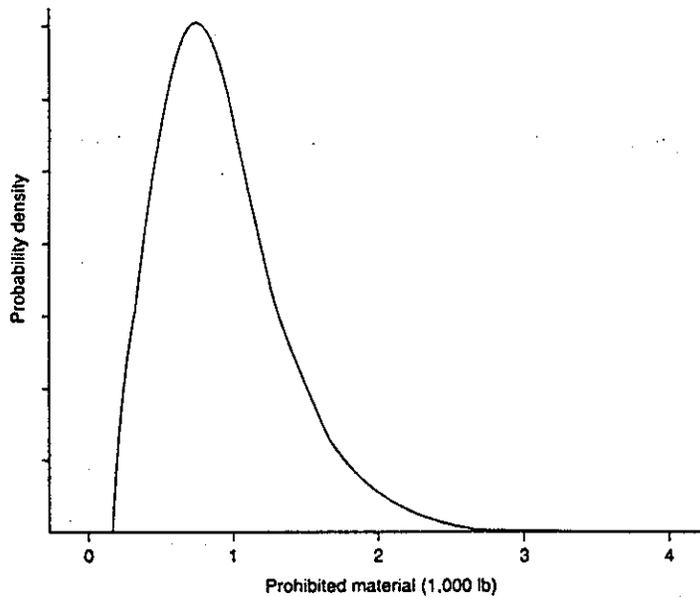


FIG. 7

**Probability density function of prohibited material
entering Alaskan landfills annually**

equal to 1 because it represents the sum of probabilities associated with the full range of possible values for the outcome of interest. The amount of dispersion in the curve gives an excellent indication of the amount of uncertainty associated with the estimates. If the curve is a sharp peak over a narrow base, most of the area under the curve is concentrated over a narrow range of potential outcomes, indicating a limited amount of uncertainty. With a wide, shallow curve, the area of the curve is spread out over more potential outcomes, with less likelihood that any one value is the "true" value, and thus indicating more uncertainty. Because PDFs can be difficult to interpret without extensive experience, the information presented in a PDF is often converted to a cumulative distribution function (CDF). A CDF (Fig. 8) also represents the probability associated with a full range of possible outcomes, but is easier to interpret at a first glance. The x axis still represents the possible values of the outcome of interest, but now the y axis represents the cumulative probability. Using a CDF, the x,y intercept can be read directly from the axes, without calculating the area under the curve as required when using PDFs. Using either the PDF or CDF accomplishes the desired goal of representing the uncertainty associated with the results of quantitative risk assessment.

There are many potential sources of uncertainty in conducting a risk assessment. For example, disease prevalence is often expressed as a point estimate, creating uncertainty with regard to the range and distribution of prevalence estimates. Biological variation in disease susceptibility or reaction to diagnostic tests produces another source of uncertainty. Human errors in measurement, and both systematic and random errors in sampling contribute to overall uncertainty. The development of a conceptual model and the selection of variables lead to yet another source of uncertainty. Displaying this uncertainty, and examining the source as well as the magnitude of uncertainty, allows decision-makers to evaluate various management options in the face of uncertainty.

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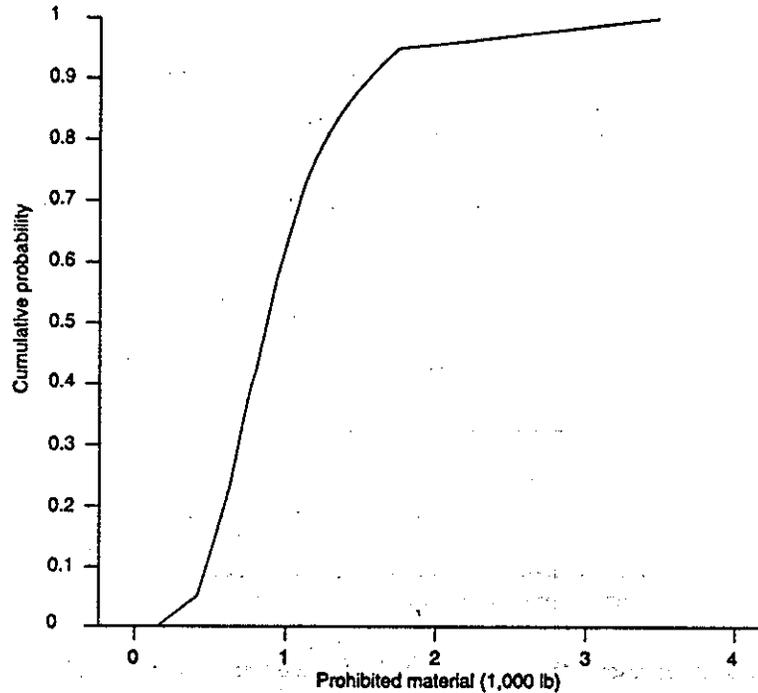


FIG. 8

Cumulative distribution function of prohibited material entering Alaskan landfills annually

CONCLUSION

Animal health regulatory officials have always made decisions in the face of uncertainty, while attempting to prevent the introduction of exotic animal diseases. Decision-makers have rightly "erred on the side of caution", particularly when the degree and sources of uncertainty were not explicitly stated. More recently, decision-makers, producers and the international animal health community have recognized the high costs – such as diminished genetic diversity and loss of markets – associated with this evolution of an arbitrary set of sanitary regulations. In order to reap the benefits of more open trade, while maintaining control over exotic disease exclusion programmes, animal health officials are turning to risk assessment.

In an article describing ways to evaluate the risks associated with capital investment, Hertz states (2):

"Risk analysis has become one with public policy. Without it, any important choice that leads to uncertain outcomes is uninformed; with it, properly applied and understood, the decision-maker – business executive, government administrator, scientist, legislator – is better able to decide why one course of action might be more desirable than another."

Developing a quantitative risk assessment process provides better information to decision-makers so that the most beneficial courses of action can be taken.

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MISE AU POINT D'UNE PROCÉDURE D'ÉVALUATION QUANTITATIVE DES RISQUES. – L. Miller, M.D. McElvaine, R.M. McDowell et A.S. Ahl

Résumé : Les responsables de la santé animale mondiale souhaitent une plus large utilisation de l'évaluation quantitative des risques dans les décisions concernant les échanges internationaux. Dans cet article, les auteurs expliquent l'intérêt de l'évaluation quantitative des risques, indiquent les principales étapes de mise au point d'une telle procédure et décrivent une méthode permettant de quantifier les incertitudes que comportent les résultats d'une évaluation des risques.

MOTS-CLÉS : Estimations de probabilités – Evaluation quantitative des risques – Probabilités.

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ESTABLECIMIENTO DE UN PROCEDIMIENTO DE EVALUACIÓN CUANTITATIVA DE RIESGOS. – L. Miller, M.D. McElvaine, R.M. McDowell y A.S. Ahl

Resumen: Los responsables de la sanidad animal mundial desearían una mayor difusión de la evaluación cuantitativa de riesgos como etapa previa a las decisiones que se toman sobre intercambios internacionales. En este artículo, los autores explican por qué la evaluación cuantitativa de riesgos resulta una herramienta útil, proponen un proceso con distintas etapas para desarrollarla y describen un método capaz de cuantificar las incertidumbres que resultan de una evaluación de riesgos.

PALABRAS CLAVE: Estimación de probabilidades – Evaluación cuantitativa de riesgos – Probabilidades.

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VETERINARY RISK ANALYSIS GLOSSARY

Risk Analysis: the process that includes risk assessment, risk management, risk communication, and risk characterization.

Risk Assessment: the process of identifying a hazard and evaluating the risk of a specific hazard, whether in absolute or relative terms. It includes estimates of uncertainty and is based on the best reasonably obtainable and sound scientific knowledge available.

There are three questions which define risk assessment:

- (1) What can go wrong?
- (2) How likely is it to occur?
- (3) What is the magnitude of the outcome should the unwanted event occur?

Question 1 is **Hazard Identification**. Questions 2 and 3 comprise a definition of **Risk** (see below for further discussion).

Hazard: elements or events that pose potential harm; an act or phenomenon that has potential to produce harm or other adverse consequence to humans or what they value. Hazard is specified by describing what might go wrong and how that might happen.

Risk: the likelihood and magnitude of the outcome of the unwanted event; a measure of the probability of harm and the severity of the adverse effects. **Risk** is the likelihood of harm or loss, in terms of spread of disease.

Risk Mitigation: the alternatives developed from the **risk assessment** in order to reduce the effects of the hazards being evaluated. **Risk mitigation** may be a single activity, or a group of activities, identified as ways to diminish the hazard or its effects. The most effective way(s) to reduce the hazard should be identified

Cost-Benefit Analysis: an economic process for evaluating the costs and benefits of an event or an activity. **Cost-benefit analysis** should be applied to each **risk mitigation** measure. Such analysis can help select the most efficient means of reducing the hazard. In some cases, a combination of **risk mitigation** measures might be selected as the most cost-effective way to regulate the risk.

Risk Management: the pragmatic decision making process concerned with regulating risk. As a decision making process, it involves consideration of mitigation measures which might make an unacceptably high-risk activity safe. The decisions made may result in preventive or restorative actions based on the best scientific and/or economic evidence available.

Risk management is also a term used to refer to risk policy management which encompasses the broader concerns of politics, diplomacy, and international relations. It is important to recognize the context of discussion when the term risk management is used.

Risk Characterization: a synthesis and summary of information about a potentially hazardous situation that addresses the needs of decision makers and interested and affected parties. It describes the larger context in which the hazard occurs. For example, are other hazards incurred by the mitigation proposed? What is the magnitude of the new hazards? Are there social or economic effects not reflected in the risk assessment or cost-benefit analysis? Who is affected by the hazard(s), by the mitigation(s)? How do these risks compare with others managed by the agency? In other words, **risk characterization** should include information from the risk assessment, risk mitigation, and cost-benefit analysis as well as all other information that may be pertinent and relevant to the decision maker.

Safety: the degree to which risks are judged acceptable; a subjective decision about the acceptability of a risk.

In an individual situation, one makes one's own decision about the safety of an action. For example an individual decides to eat salt or not when faced with health problems related to high blood pressure. In some cases, the state feels it has an interest strong enough to intervene and require, by law, certain safety devices; an example is the state laws requiring the use of seatbelts in motor vehicles. What one individual views as safe, another may view as presenting unacceptable risk. In a regulatory context, managers are empowered to make decisions about, for example, an activity based on their evaluation of the safety of the action for the health of the environment or a group of individuals.

Risk Communication: the open, two-way exchange of information and opinion about risk leading to better understanding and better risk management decisions. It provides a forum for the interchange of information with all concerned about the nature of hazards, the risks, the risk assessment, and how they should be managed. It helps assure the unambiguous interchange of information among those affected by the outcome of risk assessment activities.

THE USE OF THE @RISK PROGRAM FOR THE ESTIMATION OF RISK: AN EXAMPLE

The following very simplified hypothetical example illustrates the use of the @RISK/Excel software for the estimation of financial risks a farmer is trying to envision when planning for next years growing season. This year his production was 3,000 kg/ha, selling for 25 dollars/100 kg. His production costs per ha were 600 dollars, including labor, fertilizers etc. Thus, he made a profit of 150 dollars/ha.

Production (100 kg) / ha	30
Price/ 100 kg	25
Production cost / ha	600
Total profit / ha	150

He considers several factors that may influence his profits next year: this year his profit per ha was rather mediocre because of the drought. In normal years with sufficient rains the production would have been 3,500 kg/ha, but there have been years with top productions as high a 4,500 kg/ha. However, under extreme poor weather conditions the production could be as low as 2,000 kg/ha. Price fluctuation based on the past 10 years could range from 20-40 dollars/100 kg, but during a normal harvest year can be expected to be slightly lower that this year (22.50 dollars/100 kg). The production cost per ha is likely the same for next year, but historically the range has been from 550 dollars to 800 dollars per ha.

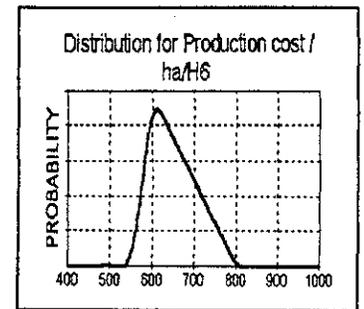
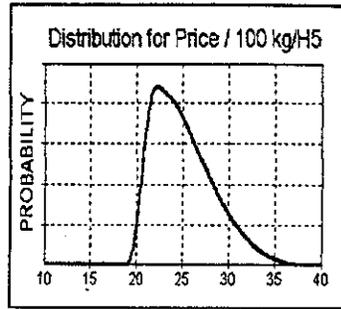
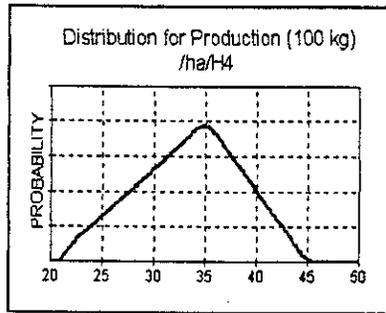
Based on these considerations our farmer constructs a following table:

	<i>Lowest</i>	<i>Probability Most likely</i>	<i>Highest</i>
<i>Production (100 kg) / ha</i>	20	35	45
<i>Price / 100 kg</i>	20	22.50	40
<i>Production cost / ha</i>	550	600	800
<i>Total profit / ha</i>	-150	187.50	1000

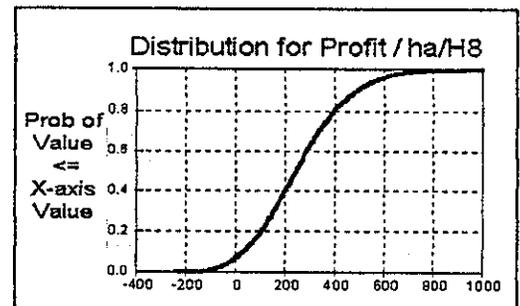
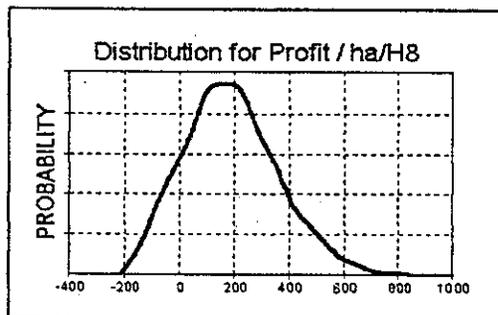
Our farmer figures that, if things are "normal", the most likely profit he will make is about 187 dollars / ha. He also observes that he may loose 150 dollars / ha if all values are low, but that he can make 1000 dollars / ha if all values are high. However, what if high production costs would coincide with a low production or low prices? What would be the result for any other combinations of those values? Our farmer would be able to look at a few, but certainly not too many of them. He also would not know what the probability would be of any of those combinations to occur.

Here is where the @RISK program comes in. It can calculate thousands or 10 thousands of these combinations in a short time, using the range and the most likely value as

parameters. The results of those calculations are presented as a so-called probability density function (PDF). An example is the PDF as shown in the following figures for the production per ha and the price of the product per 100 kg according to the parameters as defined by the farmer.



The @RISK program can combine all PDFs generated for the above individual factors to produce a final PDF for the profit/ha as shown in the next figures.



The left figure shows what the farmer can expect: he can make a profit of say 600 dollars / ha, but the chances are slim that this occurs. On the other hand there is some possibility that he may lose money. The risk that he is running is more easily to read from the right-hand graph where the probability of risk is plotted as an ascending cumulative curve. It can be observed that there is about 8% or less of a probability that he will break even or lose money. It is most likely he will make a profit of 150-300 dollars / ha, but it is unlikely that he will make more than 500 dollars per ha.

Thus, as a result of this "risk assessment" the farmer now has a clearer picture of the financial risk he is taking when planning his next year's crop. He now will have to use his professional judgment on what risks to take. Should he consider to plant another product next year? He could try, for instance, to narrow the range of his production costs by stocking up on fertilizer (risk management). Finally he should talk to his wife and show her the results of his simulations in order to obtain her consent for the next year's crop (risk communication!).