

Standardization of nomenclature for animal health risk analysis

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Summary: The authors propose standard definitions for terms and concepts commonly used in agricultural risk analysis. The differences between risk analysis and risk assessment are explained, and the relationship of these two terms with the more familiar terms "epidemiology" and "biostatistics" is discussed. The authors stress the importance of differentiating words and phrases which share similar sounds but are subtly different, and the necessity of developing a common nomenclature in agricultural risk analysis. An opportunity is provided for readers to comment on the definitions presented.

KEYWORDS: Epidemiology - Nomenclature - Risk - Risk analysis - Risk assessment - Risk communication.

INTRODUCTION

The process of risk analysis and the act of conducting risk assessments are not new phenomena; these have been part of human activity since the dawn of the species. From the tribesman in an ancient forest making a decision which avoided attack by a wild predator to a modern citizen making good judgements before crossing a busy street, risk assessment and decisions regarding risk are part of everyday life. As the decisions in a modern technological society become more complex and the outcome of such decisions carry ever larger consequences, the search for ways to improve decision-making has become a driving force in many technical fields of operation. The science which addresses these issues is termed "risk analysis".

One of the most common queries of veterinarians with regard to risk analysis concerns the relationship of this discipline with epidemiology and statistics. Certainly, animal health risk analysis relies heavily on both epidemiology and statistics, as well as other sciences such as decision theory; however, these disciplines are not identical. An analogy with the science of meteorology will help in making distinctions and clarifying relationships. Meteorology studies past weather patterns and recent weather events, describing these in minute detail (just as epidemiology does for animal population health). These data are subjected to statistical analyses and placed into models, and thus provide the basis for weather prediction. Consider a prediction for a warm, sunny

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weekend with a 10% chance of thunderstorms. The prediction is based on the best data available; the model used to assist in making the prediction has had excellent success in the past. The uncertainty of the prediction is low (10%). A decision is made to have a picnic. However, on the day of the picnic, severe thunderstorms occur. In spite of a reasonable decision based on the best prediction available, there is an undesirable outcome. Predictive science is never perfect.

If decisions based on weather predictions may not be correct, one may ask: "Why bother at all?" However, weather predictions are far more accurate now than they were, for example, 25 years ago. When a prediction is not upheld, the data on which the judgement was based are examined, the model is reviewed and a careful evaluation of the prediction is made. Adjustments may be made in the model and in the handling of data and other items. The prediction process is documented, transparent, consistent, and open to evaluation and revision. This permits the science of meteorology to produce more precise predictions, approaching (but never reaching) 100% accuracy. Decisions based on these predictions (e.g. choosing to have a picnic) and actual outcomes are not causally related. Likewise, risk analysis involves a prediction or projection into the future based on the historical past and careful analysis of recent events. Epidemiology, statistics, economics, decision theory and other sciences contribute to risk analysis.

VALUE OF RISK ANALYSIS

A second common comment from public practice veterinarians is that decisions have been made for many years concerning the risk of transferring disease during importation. Many imports and exports have been successfully completed and the spread of disease has been minimal. With such success in the past, the question becomes: "Why place such particular emphasis on risk analysis now?"

There are numerous reasons for the present emphasis. The increased international importance of free trade has certainly been a driving force. Insistence on basing decisions on reasons and analysis is more common. Citing laws, rules or regulations is no longer accepted at face value. Demands for consistency in the treatment of different countries (on the basis of animal health concerns and not politics) have become stronger. Rapid changes in international boundaries and agricultural trading practices, in particular, suggest that traditional ideas of "country freedom" from disease may no longer protect animal agriculture. Demands for flexibility in defining country, region and area boundaries require the revision of traditional practices in import risk assessment. New methodological and technological developments also enable better access to information and model-building, and more sophisticated decision-making.

In the past, veterinary import decisions have not always been well-documented. Once a decision had been made and transformed into a regulation, retirement of the generation of public health veterinarians responsible for the decision meant that any documentation for the regulations might no longer be accessible. The reasoning and analysis behind a decision may not be clear. Indeed, the decision may have been the result of a committee process, leaving no clear indication of the precise underlying analyses. The lack of good documentation and transparency in import decisions means that consistency was unlikely. The emerging science of risk analysis, together with decision theory, technology for information management, and the more traditional subjects of epidemiology, statistics and economics, represent a powerful collection of

tools. These tools have the potential to help analysts and decision-makers to compile vast amounts of information in order to judge risk and make decisions in a manner which is transparent, consistent and documentable – these tools have become the promise of tomorrow.

As discussed above, expert knowledge and good deduction have been qualitative human tools for a long time. However, the formalized science and discipline of risk analysis and risk assessment are relatively new, with risk management and risk communication newer still. The fields of financial management and engineering have long been active in quantitative risk assessment, incorporating mathematical modelling and statistics in analyses (4, 6). Risk assessment for toxicology, human health and environmental assessment has been practised for many years (7, 2). The methodologies and technologies devised in these fields are now being adapted for use in the agricultural sciences.

NOMENCLATURE OF RISK ANALYSIS

Nomenclature in risk analysis is in a state of confusion. This is partly due to the newness and continuing rapid development of the field; however, it is also certainly due to the fusion of many scientific disciplines which may use the same words, phrases or acronyms in different ways. An example of this is the acronym "PRA": in agricultural circles, this is the acronym used for "pest risk assessment", while engineers use "PRA" to mean "probabilistic risk assessment". Where possible, it seems reasonable to preserve the agricultural usage and find substitutes for those terms imported from other disciplines.

In addition, there is not yet unanimity with regard to the meaning of terms in the general field of risk analysis. Common words with established dictionary meanings have been borrowed and given more specific definitions. For example, the Random House College Dictionary defines "risk" as "exposure to the chance of injury or loss". In the professional field of risk analysis, this has become the operating definition for "hazard", and the term "risk" has taken on a more specific quantitative meaning. Lowrance (8), in his classic work, defines risk as a "measure of the probability and severity of harm to human health". This definition has found wide usage in fields outside human health. For example, in engineering science, "risk" is used to signify the likelihood and magnitude of the occurrence of an adverse event (5).

Some experts define risk more restrictively. Scala (9), in a classic work in toxicology, defines risk as "the probability of a particular adverse effect" in human health. To confuse matters further, the Scala definition of risk is often employed in colloquial speech, even among risk analysts, to mean the quantitative estimate of the likelihood of an adverse event; magnitude is either ignored or assumed to be large and therefore important.

The Society for Risk Analysis publishes a journal, *Risk Analysis: an International Journal*. Approximately ten years ago, the Society undertook to standardize definitions in this field. The result was a compromise whereby each journal article would define key and pertinent terms in the context of each article (C. Travis, personal communication). This complicates the reading of articles in the literature, for the reader must constantly refer to the operating definitions in each article. Within the field, it makes for frequent and unnecessary arguments; individuals may actually agree in principle, but word usage may make it appear that they differ entirely.

Technical language – when agreement is finally reached among experts – becomes a precise tool for communication. However, these distinctions begin to blur as the ideas are translated for public consumption (a necessary and important social responsibility of scientists). The terms “risk analysis” and “risk assessment” provide an example. Experts make a clear distinction between these two terms. Risk analysis is the encompassing term used to describe the three major sub-fields of this discipline: risk assessment, risk management and risk communication. Figure 1 illustrates the relationship between the process of risk analysis and the component parts of this process (3). Risk assessment is further subdivided into hazard identification (qualitative) and risk evaluation (usually quantitative). However, individuals outside the field of risk analysis frequently use the terms risk analysis and risk assessment synonymously.

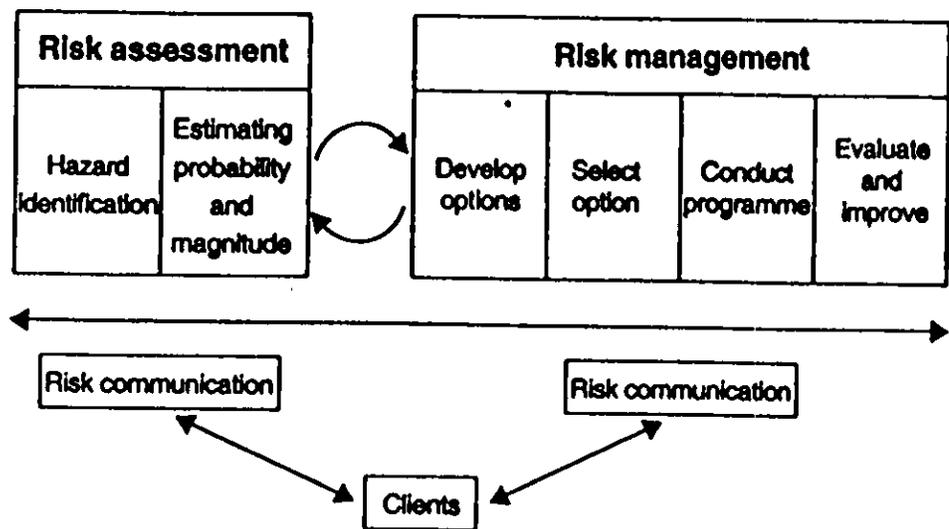


FIG. 1

Visual model showing the interrelationships of the process of risk analysis, risk assessment, risk management and risk communication (3)

Misunderstanding, whether among experts or between experts and others, often results in a lot of energy being used to argue about concepts and ideas when no fundamental disagreement actually exists. The obstacle is the use of language. Confusion and disarray caused by differences in the use of technical terminology are not uncommon (1).

While technical and scientific language bring about a fair degree of difficulty in communication, the vagaries of the English language itself are famous for causing trouble to new speakers of the language. Language as an obstacle to harmony in working together is an ancient phenomenon. Consider the Biblical story of the Tower of Babel – a classic case of failure due to language problems. The ambitious project of building a tower to heaven failed due to the breakdown of communication. The English word “babble” (meaningless or incoherent speech) is derived from this narrative.

AGRICULTURAL RISK ANALYSIS

In regulatory agriculture, more demands are placed on seemingly dwindling resources each year. If agreement can be reached on the terms used in risk analysis and arguments can be avoided where there is basic agreement, perhaps increased efficiencies will help to meet the new challenges. The goal, then, is to prevent babble (or Babel). This is a plea for unity of nomenclature.

To facilitate unity, the author - together with the Risk Analysis Systems staff of United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Policy and Program Development (PPD) unit - has collected some terms which are commonly used in risk studies. Terms with generally agreed definitions in other fields, such as epidemiology (e.g. "epidemic", "endemic"), have not been included. The definitions here are based on many sources, including both published and unpublished documents received from colleagues and following discussions. Specific sources for definitions are not cited, as it is impossible to trace the complete origin of each usage. This list should not be considered the definitive work on risk analysis nomenclature; rather, it provides an opportunity for those involved in agricultural risk studies to share ideas and understandings, with the eventual goal of developing a standardized nomenclature for risk analysis.

The following definitions are not listed alphabetically; they are arranged in functional groups. In some cases, there may be an additional text which attempts to explain the term more fully.

Comments and suggestions are sought from a wide spectrum of individuals and groups engaged in agricultural risk analysis. If you or your colleagues wish to respond to specific definitions, please label each term or concept as follows:

- a) satisfactory as it stands
- b) satisfactory with changes
- c) unsatisfactory.

For categories b) and c), please make changes or suggestions, or re-write the definition. If there is a term missing which you believe should be included, please indicate this and write a suggested definition. All comments and suggestions should be sent to the first author. Thank you for your interest in arresting babble/Babel.

SUGGESTED DEFINITIONS

Basics of risk analysis

Risk analysis: *the process which includes risk assessment, risk management and risk communication.*

Risk assessment: *the process of identifying a hazard and evaluating the risk of a specific hazard, either in absolute or relative terms. This process includes estimates of uncertainty and is objective, repeatable and scientific.*

Quantitative risk assessment characterizes the risk in numerical representations.

Hazard: *elements or events which represent potential harm; an adverse event or adverse outcome.*

In risk analysis, hazard is specified by describing what might go wrong and how this might happen.

Risk: *the likelihood and magnitude (of the consequences) of occurrence of an adverse event; a measure of the probability of harm and the severity of the adverse effects. Objective measurement and scientific repeatability are hallmarks of risk.*

In risk studies, it is common – especially in oral communication – to use “risk” synonymously with the likelihood (probability or frequency) of occurrence of a hazardous event.

In such instances, the magnitude of the event is assumed to be significant.

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

In the literature, this term is generally used when discussing safety for human health. What one individual views as safe, another may view as presenting unacceptable risk. In a regulatory context, managers make decisions about an importation, for example, based on an evaluation of the safety of the action for the health of the national herd.

Risk management: *the pragmatic decision-making process concerned with regulating the risk.*

As a decision process, risk management is involved in evaluating options to diminish or control present and predicted hazards to the biological and/or fiscal health of agricultural commodities. The decisions made may result in preventive or restorative actions. Risk managers make implicit judgements regarding the safety of particular courses of action.

Risk communication: *open, two-way exchange of information and opinion about risk, leading to better understanding and better risk management decisions.*

Risk communication is a tool to provide a forum for interchange among all those who are concerned about the nature of hazards, the risk assessment and how the risks should be managed, and to ensure unambiguous interchange of information among those affected by the outcome of risk assessment activities.

Risk description for management

Negligible risk (also known as “tolerable risk”, “no significant risk”, “de minimis risk”): *a mutually agreed measure of risk so low that all parties agree to accept risks at or below this level under most circumstances.*

For example, a risk of less than or equal to one in a million (with 95% confidence) that a hazard will cause damage is a common standard in human health and environmental risk studies.

Risk reduction options or mitigation measures: *any action (or actions) which reduces the risk of an agent causing harm (to domestic livestock); these actions may be applied to animals or animal commodities.*

Examples of such options/measures include quarantine, diagnostic testing, inspections, restricted use, processing, sentinel monitoring, etc.

Unrestricted risk estimate: *the measure of risk to agriculture if a commodity were to be imported in the usual commercial form with no risk reduction options or mitigation measures applied.*

Acceptable risk: *a management decision with regard to the permissibility of hazard; a decision made (in the risk management process) about the safety of a regulatory decision or the acceptability of a hazardous event.*

This is a subjective decision regarding issues over which there may be substantial disagreement. To say that a hazard is acceptable, admissible, allowable, or permissible appears to trivialize the concerns of a client community. For good risk communication to occur, it is preferable not to use the phrase "acceptable risk" or any of its variants.

Risk and geography

Area: *either a geographical area with natural boundaries or an administratively determined area with sufficient regulatory and quarantine enforcement to prevent both natural and artificial spread of the pest or disease; a parcel of land with defined geographical or legal boundaries.*

Region: *an area of relative homogeneity for a particular set of characteristics. A region may comprise a country, or may be a defined area within a country, an area comprising several neighbouring countries, or an area comprising portions of several neighbouring countries.*

Regionalization: *the application of standards (including those for risk analysis) developed by one country for a foreign region, with respect to a pest, organism or agent, for a given commodity to be imported into the country developing the standards.*

Pest- or disease-free: *used historically to refer to a country, area or region which met a given set of criteria; this implied that any animal or animal commodity originating in this area or region presented no hazard to an importing country with regard to a particular agent or organism.*

Scientifically, it is not possible to prove the absence of a disease agent. The term "disease-free" really means that the agent, if it was present, occurred at an extremely low prevalence. However, this is not the same as absence of disease. Thus, the importation of commodities from such an area would present negligible, tolerable, de minimis or "no significant" risk.

Risk and biology

Organism: *any active, infective, propagative or dormant stage or life-form of an entity characterized as living (including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, viruses and viroids) or as affecting living organisms. An organism is an entity in which reproduction is ultimately based on nucleic acids.*

Agent: *a vector, organism or chemical which causes a disease or other hazard to an agricultural commodity or resource.*

Vector: *an organism which can carry and transmit disease.*

Native: *grown, produced or originating in a particular area; inborn, natural or indigenous.*

Exotic or foreign: *situated outside an area; born in, belonging to or characteristic of some other area; that which is not known to occur in a given area or region.*

Pathway: *any means and/or route by which an agent can move or be moved from one place to another.*

Quarantine: *enforced isolation or restriction of the free movement of an animal or animal product, imposed to prevent an agent from spreading.*

Commodity: *an animal or animal product considered for import.*

Commodity factors: *parameters specific to an animal or animal product which affect the likelihood that the unit - if contaminated - will carry, maintain and transmit an agent after arrival in the country of destination.*

Origin factors (country factors): *parameters specific to a country which affect the likelihood that an agricultural commodity will be contaminated with a pest or agent.*

Parameters commonly used to estimate origin factors include prevalence, evaluation of veterinary infrastructure, inspection procedures, border controls, disease control practices, etc.

Destination or use factors: *parameters specific to the intended use of a commodity which affect the likelihood that the commodity, if contaminated, will expose appropriate host populations.*

Risk, data and information

Data: *facts or other information organized for analysis or used as the basis for a decision.*

Database: *a collection of data arranged for ease of use and speed of retrieval, as by a computer.*

Information: *knowledge derived from study, analysis or experience; in computer science usage, data which can be coded for processing by a computer or similar device.*

Information system: *a system for the gathering, manipulation, classification, storage and retrieval of data and information contained in databases.*

The computer is the organizing element.

Geographical Information system (GIS): *a computer-based system for storing, retrieving, manipulating, analyzing, displaying and mapping data. A GIS is used as a tool for planning, decision-making and risk analysis.*

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STANDARDISATION DE LA NOMENCLATURE POUR L'ANALYSE DES RISQUES EN SANTÉ ANIMALE. - A.S. Ahl, J.A. Acree, P.S. Gipson, R.M. McDowell, L. Miller et M.D. McElvaine.

Résumé : *Les auteurs proposent une liste de définitions pour les termes et concepts d'usage courant en analyse des risques dans le domaine agricole. Ils exposent notamment les différences existant entre l'analyse des risques et l'évaluation des risques, ainsi que la relation entre ces deux expressions et les termes «épidémiologie» et «biostatistique», plus courants. Il convient, pour les auteurs, de faire la distinction entre des termes et expressions qui, tout en paraissant proches, comportent certaines nuances, et de s'entendre sur une nomenclature commune à l'analyse des risques dans le domaine agricole. La possibilité est offerte aux lecteurs de commenter les définitions fournies.*

MOTS-CLÉS : *Analyse des risques - Divulgarion des résultats - Epidémiologie - Evaluation des risques - Nomenclature - Risques.*

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ESTANDARIZACIÓN DE LA NOMENCLATURA PARA EL ANÁLISIS DE RIESGOS EN SANIDAD ANIMAL. - A.S. Ahl, J.A. Acree, P.S. Gipson, R.M. McDowell, L. Miller y M.D. McElvaine.

Resumen: Los autores proponen definiciones estandarizadas de los términos y conceptos de uso corriente en análisis de riesgos en agricultura. Exponen las diferencias existentes entre análisis de riesgos y evaluación de riesgos, así como la relación entre estos dos términos y los términos «epidemiología» y «bioestadística», de uso más frecuente. Es importante, para los autores, distinguir entre palabras y expresiones que, aunque parecen próximas, incluyen matices de significación diferentes, y ponerse de acuerdo acerca de una nomenclatura común en el análisis de riesgos en agricultura. El texto ofrece a los lectores la posibilidad de comentar las definiciones propuestas.

PALABRAS CLAVE: Análisis de riesgos - Epidemiología - Evaluación de riesgos - Información sobre riesgos - Nomenclatura - Riesgos.

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