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HARMONIZATION OF RISK ASSESSMENT BETWEEN DISCIPLINES OF ANIMAL HEALTH, FOOD SAFETY AND PLANT HEALTH

McNab W.B.[1]

L'analyse des risques est de plus en plus utilisée dans le développement des règles sanitaires d'échange de produits agricoles et alimentaires pouvant présenter des risques pour la santé humaine, animale et végétale. Un effort considérable a été fourni pour harmoniser les approches de base de l'analyse de risque, au sein et entre les disciplines, entre les juridictions nationales, afin d'améliorer et de faciliter le commerce international. Les organismes réglementaires, au sein des gouvernements, seraient amenés à prendre des décisions concernant l'attribution de ressources pour la gestion des risques à travers différents programmes. Il existe des avantages certains à harmoniser l'approche d'analyse de risque entre les disciplines.
Au Canada, Agriculture and Agri-Food Canada, au niveau fédéral ainsi que le ministère des produits agricoles et des affaires rurales de l'Ontario, ont coopéré afin de développer une approche commune à l'analyse de risque à travers les disciplines de la santé humaine et végétale, et de la sécurité alimentaire. Ce système commun s'aligne, généralement, sur les approches d'analyse de risque utilisées au niveau international et peut être appliqué à un large éventail de scénarios à travers les diverses disciplines. On définit, ainsi, des scénarios de séquences d'événements biologiques rentrant dans un modèle mathématique de calcul du risque considéré. Ceci inclut la représentation des facteurs influençant la probabilité, l'impact et l'incertitude des composantes du risque. Les fonctions de ce système, quel que soit le niveau à développer, vont des simples appréciations qualitatives aux appréciations quantitatives détaillées, en utilisant la méthode de simulation de Monté Carlo.

RISK and TRADE

We all face risks to our quality of life, on a daily basis. For example a dairy farmer might face risks of injury, infection, poisoning, disease or death; to himself, his family, his employees, his cattle, or his crops. All of these have certain probabilities of occurring and certain direct or indirect impacts on his quality of life. Risk is a function of the probability of something undesirable happening and the impact if that undesirable outcome occurs. It cannot be assessed by considering probability alone. Both components must be studied. Risk may be managed by reducing either probability or impact, or both. The uncertainty surrounding factors that influence probability and impact must be studied to understand the overall uncertainty of risk. Risk management and risk communication can be improved by understanding uncertainty. Risk communication can also be improved by avoiding ambiguous use of the term "risk". This can be achieved by using terms such as probability, odds or likelihood, when describing the probability component of risk, and terms such as impact or consequences, when describing the impact component of risk.

There are risks associated with trade of agri-food products. These risks have changing probabilities, impacts and uncertainties. They can affect our quality of life through direct or indirect influences on the health of people, animals or plants.

The World Trade Organization (WTO) recognized the importance of risk assessment in trade. The Sanitary and Phyto-Sanitary (SPS) sections of WTO agreements specifically identify the Office International des Epizooties (OIE), the Codex Alimentarious Commission (CAC), and the International Plant Protection Convention (IPPC), as organizations providing guidelines for the assessment of trade risks to animal health, food safety and plant health respectively. Much good work has been done by these organizations to promote systematic and transparent methods of risk assessment, that are equivalent across regulatory jurisdictions. This helps facilitate trade across jurisdictions, within each respective discipline. However, some elements are common among risks across disciplines. Furthermore, managers within regulatory organizations may be required to make decisions concerning the allocation of resources for the management of risks, across disciplines (e.g. moving some resources from the management of risks to animal health, to the management of risks to plant health). These decisions are more difficult if the approach to risk assessment and the terminology used, differs significantly between disciplines. There are benefits to aligning risk assessment methods between disciplines. This has been attempted in Canada at the federal level within Agriculture and Agri-Food Canada (AAFC), and at the provincial level within the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA).

A COMMON APPROACH TO RISK ANALYSIS and RISK ASSESSMENT, ACROSS DISCIPLINES

Unfortunately, terminology is still evolving within the field of risk analysis and risk assessment. For example, it is not unusual to see documents in which the term "risk" was defined as including components of probability

[1] Ontario Ministry of Agriculture Food and Rural Affairs, ERLD 4 NW, 1 Stone Rd. W., Guelph, ON., N1G-4Y2, Canada.

and impact, but the term was subsequently used to imply only the probability component of risk. Similarly it is not unusual to see the term "hazard" officially defined as being the cause of a negative impact, but subsequently used to imply impact.

In this document, risk analysis is defined as a process that includes risk assessment, risk management and risk communication. Risk assessment is a process within risk analysis that involves identifying a hazard that can cause a negative impact, and characterizing the risk presented by that hazard. The risk may be characterized in qualitative or quantitative terms. This includes assessment of: 1) the probability of the negative outcome occurring because of the identified hazard, 2) the magnitude of the impact of the negative outcome, and 3) consideration of the uncertainty of the data used to assess the probability and impact components of the risk. Risk management is a process within risk analysis that includes identifying, evaluating, selecting, implementing and monitoring alternatives for mitigating risk. Risk communication is a process within risk analysis that includes an open exchange of information and opinion leading to a better understanding of risks and risk related decisions. It involves elements of information acquisition and information distribution.

Much of the current thinking in risk assessment has evolved from work on the assessment of risks to human health from potentially carcinogenic chemicals. This classical model of risk assessment consists of four steps: 1) hazard identification, 2) hazard characterization (also called response characterization), 3) exposure assessment, and 4) risk characterization. The latter step 4, is often defined as an integration of steps 1 through 3. Notwithstanding the logic of the above classical system, risk assessment may also be applied to non-human species (including animals and plants), for hazards other than chemicals (e.g. bacterial, viral or physical hazards), for outcomes other than cancer (including the whole range of negative impacts on health).

Table I summarizes a transition from the classical model, to a more general model that: 1) follows better the sequence of events that must occur biologically for a risk to be realized (i.e. exposure, then response or the consequence of exposure), 2) follows better the sequential order in which steps must be modeled mathematically to represent and quantify risk in a quantitative risk assessment, 3) more clearly represents "risk" as function of probability and impact, plus uncertainty, 4) better facilitates refinement of a given risk assessment (or the comparison of two assessments), evolving from a subjective qualitative assessment, to an objective quantitative risk assessment, complete with Monte-Carlo simulation of uncertainty, and 5) promotes use of a common framework in risk assessment across disciplines.

Table I
Transition from classical to a general model for risk assessment

Classical Steps	Modified Classical	General Model
1) hazard identification	1) hazard identification	1) hazard identification
2) response characterization	2) risk characterization	2) risk characterization
3) exposure characterization	2a) exposure characterization	2a) probability
4) risk characterization	2b) response characterization	2b) impact
i.e. roll-up of 1 through 3, plus uncertainty	2c) uncertainty	2c) uncertainty

Within an organization, the task of risk assessment should not be limited to a few specialists. Effectiveness will increase if many employees understand and apply the basic principles of risk assessment, on a daily basis, to the risks they face in their personal lives and to the problems and decisions they make at work. When required, they will then be better able to: 1) seek out and contribute information to a formal risk assessment, 2) interpret reports from formal assessments, and 3) listen to and communicate with clients when discussing formal assessments. In some situations, it may be appropriate to conduct and formally document very detailed quantitative assessments requiring input of technical data from several sources, with sophisticated mathematical modeling including quantitative simulations of uncertainty. However in many situations, it may be appropriate for less technical staff to apply the basic principles, to conduct and briefly document less formal assessments

Table II provides an outline of headings and questions that one can use to guide and document a basic risk assessment. The detail appropriate for different assessments may range from: a one-page document that consists of one or two lines of information under each heading; to a multi-page report consisting of a few paragraphs under each heading and subjective ratings of key headings; to a lengthy detailed report of a quantitative assessment including mathematical modeling and Monte-Carlo simulation. In all cases, the basic headings remain the same. The difference lies in the amount of detail. Note that the headings follow the chronology of events that must occur biologically for a harm to be experienced. That is, the hazard must first enter the area, farm or food chain of concern; then contact susceptible hosts (humans, animals or plants). It may then spread and cause biological harm that leads to direct and indirect economic harm. If mathematical modeling is appropriate, it must model this same sequence of events

Table II
The basic components of a risk assessment

The Question (process initiation):
- exactly what situation is to be assessed ?
- what is being requested, by whom, what product or commodity, processed how, to come from where, how much, how often, to go where, to be used for what, why ?

Concerns (hazard identification):
- what hazards (disease agents, pests, etc.) could enter the scenario ? (what can go wrong?)
- what is the outcome of concern (e.g. injury, infection, clinical disease, death, lost sales) ?
- how strong (or uncertain) is the causal link between the hazard(s) and the outcome(s) of concern ?

Likelihood of Going Wrong (probability component of risk):
Probability of Entry / Contamination:
- describe or model what commodity or product, from where, process controls, testing employed etc.
- what is the likelihood of the hazard(s) entering the food chain or host's area of concern

Probability of Exposure / Transmission:
- describe or model intended use, risk controls in use, and likelihood of exposure / transmission to susceptible hosts of concern (human, animal or plant)

Probability of Impact and Spread:
- describe or model probability of infection or impact outcome of concern given assessment of exposure
- describe or model distribution of the hazard and the biology / epidemiology of the hazard / host relationship to assess the likelihood of the spread / distribution of the hazard and subsequent impact, or secondary spread from initial outbreak and the likelihood of outbreak control / eradication

Consequences of Going Wrong (impact component of risk):
Biological Impact:
- describe or model biological impact (dose / response, sub-clinical, clinical, permanent disability, death) on human, animal or plant health, including the range of potential hosts expected to be affected.

Economic Impact:
- describe or model direct economic impact as result of biological impact (e.g. treatment, lost production)
- describe or model indirect economic impact beyond the immediate biological impact (e.g. lost trade)

Environmental Impact:
- describe or model environmental impacts beyond the immediate host(s) of concern (e.g. effect on wildlife)

Uncertainty and Summary of Risk Assessment:
- describe or model the uncertainty of the data used
- summarize the overall risk in terms of probability, impact and uncertainty

Recommendations:
- risk assessor's suggestions for actions, for consideration by risk managers

The tool of risk assessment does not provide a magic solution. It can however document and clarify the components of risk, leading to a more effective and efficient utilization of resources and better decisions, within and between disciplines. Retaining a consistent sequence of headings across disciplines encourages risk assessors, risk managers and risk communicators to think, assess, model, report, interpret and communicate in a consistent and logical framework regardless of the detail appropriate for a given situation. This approach can be applied across disciplines to assess risks as varied as: importing cattle from another country, moving seed potatoes between regions within a country, purchasing ingredients for an established food product, or designing a new processed food product.