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RISK ASSESSMENT PROVISIONS OF IMPORT AND EXPORT REGULATIONS

Alwynelle (Nell) S. Ahl
Director, USDA Office of Risk Assessment and Cost-Benefit Analysis

Risk Assessment for Biological Agents

Risk assessments for human health or environmental health have been carried out by the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) for a number of years. Historically, most of the hazards were chemicals or toxins; the risk assessment methods for these agents have been investigated for thirty years. However, many of the hazards of interest in agricultural imports are different: they are caused by biological agents which can replicate. Thus a commodity with no detectable level of a biological agent (bacterium, fungus, or virus) could enter an importing country, reproduce itself, establish and spread. In contrast, for chemicals and toxins, the "dose makes the poison." Risk assessment for these agents is focussed on understanding exposure and dose-response assessment for humans and the environment. For chemicals and toxins, the original amount of material deposited is known. However, once a reproducing hazard enters the importing country, it may be impossible to contain. Therefore the primary focus of import commodity risk assessment is to avoid bringing an unwanted agent into the importing country: prevention is foremost.

The development of the concept for the General Agreement on Tariff and Trade (GATT) in the 1980s provided the stimulus to use science-based risk assessment as one tool for evaluating the acceptability of an import. At that time, a specific sub-discipline for biological agent risk assessment did not exist. In the early 1990s work was begun in several countries to develop approaches and methods for biological agent risk assessment. USDA's Animal and Plant Health Inspection Service (APHIS) in 1989 began to evaluate concepts to support risk assessment for support of sanitary and phytosanitary (SPS) decision-making. Since that time, variety of methods, both qualitative and quantitative have been developed. The ways in which these methods may be most usefully employed in decision-making is a topic of current discussion in the fields of crop, livestock and human health (food safety).

Science and Risk Assessment

There is much confusion about the nature and uses of science and of risk assessment. Science proceeds by establishing an hypothesis and trying to discredit it. Following numerous tests of the hypothesis, if it cannot be disproved, it is accepted as part of the factual body of science. Basically science is a very conservative and time-consuming process which demands high level of proof to establish a fact. The goal is to advance our understanding about phenomena in nature.

Risk assessment is not science. Risk assessment structures the best available scientific and other

relevant information to make decisions about hazards. Hazards are things that can go wrong. For example, how likely is the dam to break? Or if I invest money in a particular stock, how likely will I achieve a net financial gain. As a formal discipline, risk assessment has been applied in fields such as engineering, finance, and insurance for many years. The General Agreement on Tariffs and Trade (GATT), now the World Trade Organization (WTO) and other treaties, from the late 1980s to early 1990s, require that science-based risk assessments be used to establish appropriate sanitary and phytosanitary protection (S.P.S.) for an importing country. World trade restrictions must be based on the findings of risk assessment, not the politics of the past.

Risk assessment as a formal academic discipline is young enough that the definition of terms in the field are not standardized. To complicate matters, risk studies took words from the vernacular and endowed them with special significance. The lack of unanimity about the meaning of the terms adds another layer of complexity in mutual understanding. In 1991, a basic set of terminologies were established for agricultural use to avoid unnecessary differences about items on which there is actual agreement. **Risk analysis** is the term used to encompass risk assessment, risk management and risk communication. **Risk assessment** is the term used to define the analytical approaches, processes, models, methods and calculations. Risk assessment answers three basic questions about hazard and risk. The question for **hazard identification** is what can go wrong. **Risk** is answered by two questions: (1) how likely is it that the hazard will occur and (2) what is the magnitude of the consequences if the hazard does occur. This latter question may be answered in biological or economic terms. **Risk management** is the decision making activity in which results of the risk assessment are incorporated. It is important, however, to understand that the results of the risk assessment is only one element which must enter the thinking of the risk manager. **Risk communication** is the open communication between and among all interested parties, especially the individuals and groups most affected by the decisions.

Risk Assessment and Decision-making

Risk assessment as a discipline formalizes some of the most successful strategies used in decision-making. For example, one performs an informal, intuitive risk assessment at each crossing of a busy street. In planning to arrive on time for a meeting in a distant location, the same informal and intuitive processes are at work. In fact, agricultural producers or farmers are among the most successful risk assessors. The market dictates that those who are not become “former farmers.”

Decision making in government for protection of human health, safety or the environment (including the protection of crop and livestock resources) in the past has been based on knowledge and science, but the risk assessment has largely been informal and intuitive. With the advent of WTO and NAFTA, these methods are no longer acceptable. Instead, risk assessments must be documented in writing, transparent to understanding, well-organized for clarity, flexible to take into account new information, and consistently applied.

International standard setting organizations (e.g., Codex Alimentarius, International Plant

Protection Commission, and Office of International Epizootics) are currently discussing standards, methods, procedures for evaluating biological risks associated with trade. This includes attempting to define what is an acceptable level of risk (ALR) and an appropriate level of protection (ALP). The WTO requires that the ALP be based on “...available scientific evidence, relevant processes and production methods, relevant inspection, sampling and testing, relevant ecological or environmental conditions...” If insufficient scientific information is available to make a decision, the importing country must “...seek additional information for more objective assessment of risk...in a reasonable period of time...” The ALP should minimize negative trade effects.

The ALP standard may include relevant economic factors. For example, the lost production and sales of a commodity in a country in the event of entry of the hazard (biological agent). The costs associated with containing the establishment and spread of the pest or disease agent may be considered, as well as costs of control and eradication should that be necessary. The cost-effectiveness of alternative mitigation measures is especially recommended because that assures that the risk is controlled in the least expensive way, an advantage to both the economy of exporting and importing countries.

Current Activities in Risk Assessment for Agricultural Trade

Current work in risk assessment focusses on methods for risk assessment (more research is needed in this area). There must be scientists trained to perform risk assessments. Decision-makers must continue working to understand the meaning and implications of risk assessments. And all must work toward the goal of international harmonization.

Risk assessment based on the best available science along with tools from economics and other disciplines offers the best opportunity for harmonizing world trade guidelines for reducing and preventing risks, and maximize benefits to all.