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## **FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

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### **SUMMARY**

#### *Shared responsibilities in the Canadian regulation of food safety*

Food safety policy in Canada is based on the risk analysis process using risk assessment, risk management and risk communication as its basic tenets. This responsibility is shared by Health Canada and the Canadian Food Inspection Agency (CFIA) and, depending on the issue, other levels of government may be involved. Health Canada's risk analysis process, referred to as a Decision-Making Framework (DMF), provides the basis for a systematic, comprehensive and coordinated approach in the policy development process. Similarly, the CFIA has developed a Risk Analysis Framework to guide its enforcement, compliance and control processes. Both frameworks call for the establishment of separate risk assessment and a risk management teams. It is critical, however, for each team to have a leader who provides direction while maintaining a linkage with the other team. Canada has found that a team approach is necessary for the successful management of risks. In addition, there needs to be an overall risk manager responsible for guiding and integrating the work of the two teams, moving the process forward, and dealing with the various process-related issues. Along with the establishment of the teams, the assignment of roles, responsibilities and accountabilities is critically important.

Canada has used the decision making process across a number of food safety files. Health Canada undertook a review of its DMF through a pilot study on prion diseases. The study concluded that the DMF significantly enhanced Health Canada's ability to deal with prion diseases and other potentially hazardous threats to the health of Canadians. Some lessons learned confirmed that the commitment, leadership and involvement of senior management is critical to implementing a systematic approach; that all decisions must be evidenced-based and pulled together in an issue identification document; that barriers must be overcome to ensure that the different teams effectively share information; and that all participants must work through teams. Access to the best available science and the right people for building consensus; developing horizontal relationships through collaboration, partnerships and team work; and documenting all aspects of the decision-making process are some of the key challenges in achieving effective communication and interaction.

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## **Shared responsibilities in the Canadian regulation of food safety**

Canada's food safety system involving federal, provincial/territorial and municipal authorities establishes food safety policies based on the risk analysis process. The success of the system depends on close working partnerships, collaboration and communication amongst the various levels of governments, as well as with industry and consumers.

It is important to understand the complexity of the Canadian situation in regards to how the shared responsibilities and interactions impact on risk assessment and risk management decisions. At the federal level, the responsibility for food safety is shared by Health Canada and the Canadian Food Inspection Agency (CFIA) and, depending on the issue, other levels of government may be involved in the establishment of food safety policy.

Health Canada sets standards and policies governing the safety and nutritional quality of food sold in Canada and engages in research, risk assessment, pre-market review and evaluation of issues related to food safety and nutrition, including the regulation and registration of pest control products and veterinary drugs. It is also responsible for surveillance of food-borne, water-borne and enteric human illnesses and provides comprehensive expertise and support for the epidemiological investigations.

The CFIA is responsible for enforcing all federally mandated standards and policies on food safety and inspection, compliance and quarantine services. It designs, develops and manages inspection, enforcement, compliance and control programs and service standards. In establishing inspection and compliance programs, CFIA consults with non-government organizations, industry and trading partners and consults and establishes partnerships with other levels of government. The CFIA also provides laboratory support for inspection, compliance and quarantine activities.

## **Canada's Risk Analysis Process**

Canada has established a multi-faceted decision making process for food safety that distinguishes between the role of scientists and policy advisors working within two distinct teams. The science/risk assessment team assesses the risk and develops options that deal with the risk and incorporates any public health benefit. The policy/risk management team, considers the science within the broad range of national, international and socio-economic factors and develops a strategy that is relevant to the Canadian context. Members of both teams, which may include Health Canada and CFIA staff, use a rigorous and objective assessment of all available information, including reproducible scientific research, the identification and fair weighting of scientific uncertainty and recent advances in knowledge when rendering decisions related to food safety standards and policy setting.

Health Canada's risk analysis process is referred to as a Decision-Making Framework (DMF). The DMF is a modernised approach to risk assessment and risk management established through the application of a common decision-making process that can be applied across a broad range of health protection issues, including food safety. It provides the basis for a systematic, comprehensive and coordinated approach. The purpose of the DMF is as follows:

- to provide guidance in the policy development process; and
- to articulate the underlying principles embedded within the policy development.

The underlying principles recognize that health maintenance and improvement is the primary objective and further include integrity of science, stakeholder involvement, transparency and openness, a broad risk perspective, the use of precaution, effective communication, and consideration of acceptable risk levels. These principles embody the key role of good risk communication in the decision making process. The DMF will also take into account emerging challenges.

Similarly, the CFIA has developed a Risk Analysis Framework (RAF) for the development and implementation of “risk-based inspection systems” to address CFIA’s broad mandate which includes food safety and the protection of plants and the health of animals. The RAF is used to guide CFIA’s enforcement, compliance and control processes.

While there may be some differences in terminology used in the Health Canada and CFIA frameworks, reflecting the diversity of activities of the parent organizations, the activities and the principles are compatible and consistent with the approaches taken at the international level by the Codex Alimentarius Commission. Both frameworks comprise the three components of risk analysis - risk assessment, risk management and risk communication.

### **Optimizing interactions between Risk Assessment and Risk Management Teams**

A key consideration in the Health Canada and CFIA risk analysis process is the clear identification of the issue and its context so that appropriate risk management goals may be established. Information obtained through this task may be used to identify key issues during the risk assessment and risk management processes. It will also lead to the development of an action plan describing how and when the various steps in the process will be taken. This is an important process which requires efficient communication and interaction between food safety risk assessors and risk managers.

While both the risk assessment and the risk management teams play a role in issue identification and need to exchange information throughout the entire decision making process, their roles are distinct. The role of the risk assessment team is to assess risk based on science and to identify potential risk management options that are related to the level of risks. The role of the risk management team is to consider the results of the risk assessment, together with a broad range of other factors, and to use this information to make risk management decisions.

It is critical for each team to have a leader who provides direction while maintaining a linkage with the other team. Canada has found that a team approach is necessary for the successful management of risks. In addition, there needs to be an overall risk manager responsible for guiding and integrating the work of the two, moving the process forward, and dealing with the various process-related issues. While risk assessment must be conducted separately from risk management, in order to maintain scientific integrity, the two processes must be linked through team work and interactive communication.

Along with the establishment of the teams goes the assignment of roles, responsibilities and accountabilities. It is critical that both teams and other interested and affected parties know what is expected and required. This should be documented in the action plan, one of the most important documents produced in the decision making process. The action plan provides the documented basis for obtaining the “up-front” understanding and agreement from the risk assessment and risk management teams, and helps to ensure that the process is not only clear but that effective communication and interaction occurs between the two teams.

## **A case study of Health Canada's Decision-Making Framework**

Canada has used the decision making process across a number of food safety files. The process is under continuous scrutiny and refined where necessary to maximize the interaction and communication between the two teams. Recent food safety issues subject to the rigour of the decision making framework by Health Canada include the development of a policy on unpasteurized juices, contamination of imported product by dioxin and the management of the human health risks associated with prion diseases. It is with respect to the latter issue that Health Canada undertook a review process for implementing the DMF. The prion pilot case study took 18 months to complete. The actual risk assessment study took 14 months to carry out. Results of this study concluded that:

- the DMF process significantly enhanced Health Canada's ability to deal with prion diseases and other potentially hazardous threats to the health of Canadian;
- modification of some of the elements of the DMF were required to adapt to the issue under consideration;
- the issue identification paper is a dynamic knowledge management tool that captures at any given time the level of consensus between two teams.

### **Some lessons learned**

Some lessons were learned during the intense period of the case study:

- the commitment, leadership and involvement of senior management is critical to implementing a systematic approach;
- all decisions must be evidenced-based and pulled together in an issue identification document;
- barriers must be overcome to ensure that the different teams effectively share information and the latest up-to-date facts;
- all participants must work through teams and that individual team members must be prevented from operating outside of the team. The team approach offers a unique opportunity for checking and verifying the validity of science-based information and encourages a consensus approach.

### **Challenges**

In making risk management decisions it is important that effective communication and interaction between risk assessors and risk managers be achieved during the risk analysis process. Some of the key challenges in achieving this include:

- access to the best available science and the right people for building consensus;
- documenting and maintaining control on the roles, responsibilities and accountabilities during the process;
- achieving a high degree of transparency;
- building capacity within the organization to maintain and sustain the process;
- developing horizontal relationships through collaboration, partnerships and team work; and
- documenting all aspects of the decision-making process.