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CAPACITY BUILDING IN THE REGULATION AND SAFETY ASSESSMENT OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY - A CANADIAN PERSPECTIVE

(Prepared by Canada)

Introduction

1. Modern biotechnology involves the application of techniques that overcome the natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (e.g. recombinant DNA technology, direct injection of nucleic acids, cell fusion). Using these techniques, researchers can take a single gene from a microorganism, plant or animal cell and insert it into another microorganism, plant or animal cell to give it a desired characteristic, such as a plant that is resistant to a specific pest or disease[1].

2. Genetic modifications that can change the agronomic, production, processing or nutritional characteristics of microorganisms, plants and animals are now routinely achieved using the techniques of modern biotechnology. However, the wide variety of manipulations possible through genetic modification, and the potential for the introduction of toxic compounds, unexpected secondary effects and changes in the nutritional and toxic characteristics of the food product requires that a thorough pre-market safety assessment be undertaken.

3. Several countries have put in place requirements and procedure for the pre-market assessment of genetically modified organisms and foods derived from them. In the context of food safety, such requirements are based upon scientific principles developed through expert international consultation with agencies such as the, Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), the Organization for Economic Co-operation and Development (OECD) and, more recently, the Joint FAO/WHO Codex Alimentarius Commission, which elaborates international food standards and guidelines.

4. In July 2003, the Codex Alimentarius Commission adopted three documents, developed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, that relate to foods derived from biotechnology. The *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*[2] lays out a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from biotechnology and is supported by two guidelines that describe a detailed approach to conducting the safety assessments of these foods: 1) *Guideline for the Conduct of Food Safety Assessment of Foods*

[1] Cartagena Protocol on Biosafety. Available at http://bch.biodiv.org/about/default.shtml.

[2] Codex Alimentarius. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. 2003. Available at ftp://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf

Derived from Recombinant-DNA Plants [3] and 2) *Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms*[4]. These internationally agreed upon documents reflect the expertise and experience of those countries, including Canada, with a history of regulating products of biotechnology. Non-governmental organizations such as Greenpeace and Consumers International participated in the development of these international standards and endorsed their adoption.

5. With regard to capacity building, it is important to note that the *Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* states that "efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess, manage and communicate risks, including enforcement, associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognized expert bodies, including access to analytical technology. In addition, capacity building for developing countries either through bilateral arrangements or with assistance of international organizations should be directed toward effective application of these principles."

6. Over the past several years, Canada has led and participated in a number of capacity building initiatives aimed at sharing our regulatory and safety assessment experience with countries that have requested guidance in this area. Training workshops were conducted to provide regulators in these countries with information on the most recent advances in the evaluation of foods derived from biotechnology based on the experiences of countries that have conducted safety assessments of these products. The present document will focus on how these capacity building initiatives have been successful in promoting a harmonized international regulatory approach for foods derived from biotechnology and describe future work being planned in order to further our outreach efforts to different regions around the world.

A Canadian Experience in Capacity Building

7. Recent technological advances in the field of foods derived from biotechnology have been especially challenging for developing countries in assessing the potential impact on their populations. Some developing countries have shown significant interest in acquiring the technical knowledge and skills to better manage the evaluation and regulatory control of these foods. Due to the complex nature of these assessments it was felt that hands-on training workshops using actual case studies would be highly beneficial in demonstrating how the concepts and principles developed internationally can be practically applied to assessing the safety of foods derived from modern biotechnology.

8. This led to Canada developing a number of training modules on the safety assessment of foods derived from modern biotechnology. Since 1999, Canadian officials have delivered capacity building workshops to over twenty countries, providing regulators with hands-on experience in the food safety assessment of foods derived from genetically modified organisms. While the original modules were based on Health Canada's *Guidelines for the Safety Assessment of Novel Foods*[5], more recent case studies reflect the risk analysis principles and safety assessment guidelines recently endorsed by the Codex Alimentarius Commission.

9. Basing these workshops on the internationally agreed-upon Codex principles and guidelines has given Canada the opportunity to co-deliver capacity building workshops in collaboration with other national food

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[3] Codex Alimentarius. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. Available at ftp://ftp.fao.org/es/esn/food/guide_plants_en.pdf

[4] Codex Alimentarius. Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms. Available at ftp://ftp.fao.org/es/esn/food/guide_mos_en.pdf.

[5] Health Canada. Guidelines for the Safety Assessment of Novel Foods. Available at http://www.hc-sc.gc.ca/fn-an/gmf-agm/pol/index_e.html

safety authorities, such as the Food Standards Australia New Zealand (FSANZ), the US Food and Drug Administration (USFDA), and the Health Council of the Netherlands. In addition, close collaboration with multilateral organizations such as the Association of Southeast Asian Nations, the Asia-Pacific Economic Cooperation, the International Life Sciences Institute, and the OECD, has allowed these capacity building efforts to have a regional focus by facilitating the participation of officials from several neighbouring countries in any given workshop.

10. More recently, FAO, in collaboration with WHO, has invited Canada and the OECD to work on a capacity building project. The objective of the project is to develop a standardized training package to assist countries in implementing the internationally accepted risk analysis principles and safety assessment approach for foods derived from modern biotechnology. This project will involve training regional experts (i.e., train-the-trainer) to deliver workshops in their home countries.

Conclusions and Lessons Learned

11. The approach to the safety assessment of genetically modified (GM) foods taken by Canada is currently applied by regulatory agencies around the world in countries such as the European Union member states, Australia/New Zealand, Japan and the United States. This safety assessment process is consistent with the international standard for the safety assessment of GM foods adopted by the Codex Alimentarius Commission.

12. The safety assessment principles and criteria used by workshop participants are based on the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. This promotes a harmonized internationally accepted approach to the safety assessment of GM foods.

13. Greater success was achieved when training workshops were facilitated in collaboration with different regulatory organizations. Workshops co-delivered with FSANZ, USFDA and European Union regulatory authorities promoted a more consistent and predictable international assessment approach.

14. Capacity building workshops provide participants with information on the most recent advances in the evaluation of foods derived from modern biotechnology based on the experiences of countries that have conducted safety assessments of these products. Properly trained regulators can enhance the safety of foods thereby improving the health of its consumers and ensuring the safety of foods entering international trade.

15. It is apparent from these workshops that some developing countries would benefit from further assistance to establish the technical capacity to conduct safety assessments of GM food products. The development of a standardized training package by the FAO will ensure consistency and uniformity in the application of international standards and will meet a vital need for delivery of regional training programmes.