Canadian Food Inspection Agency

Health Canada

U.S. Department of Agriculture
Marketing and Regulatory Programs
and Plant Health Inspection
Services
Plant Protection and Quarantine

U.S. Environmental Protection
Agency
BioPesticides and Pollution
Prevention Division
Office of Pesticide Programs

On July 15 and 16, 1998, regulatory officials of the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), and the Canadian Food Inspection Agency (CFIA) and Health Canada met to compare and harmonize where possible, the molecular genetic characterization components of the regulatory review process for transgenic plants. In addition, this meeting provided the participating agencies an opportunity to discuss and prioritize future areas of cooperation and information exchange that will facilitate the safe incorporation of transgenic plants into agricultural production and commerce. The meeting led to substantial areas of agreement, and a meeting report, that includes an appendix of essential elements considered by the participating agencies for the molecular genetic characterization of transgenic plants.

On September 20 and 21, 2000, regulatory officials of APHIS's Biotechnology Assessment Branch, the United States Environmental Protection Agency's (USEPA) Office of Pesticides Program, and the CFIA's Plant Biosafety Office began the next phase in the Bilateral on Agricultural Biotechnology, when they met to compare and harmonize, where possible, the environmental characterization components of the regulatory review process for transgenic plants and to review and update, if necessary, the molecular genetic characterization components described in Appendix I to the July 15-16, 1998 Bilateral on Agricultural Biotechnology. Representatives from Argentina and Mexico were present as observers and provided useful input to the discussion and drafting of documents. Amendments to clarify the text of Appendix I and a draft version of a document describing the elements of an environmental assessment were discussed. Health Canada's participation in this bilateral pertained only to drafting the molecular characterization component in 1998 and providing input on amendments in 2001.

The text of the proposed amendments to Appendix I and the draft document were further discussed at a subsequent meeting on May 8-9, 2001 and finalized December 31, 2001. Attached is Appendix II which describes the essential elements considered by the participating agencies for the environmental characterization of transgenic plants. Also attached is the revised Appendix I (now Appendix Ia) which replaces the version from July 15-16, 1998.

The agencies believe that these unprecedented agreements will be instrumental in facilitating the safe commercialization of transgenic plants. Canada and the United States have enjoyed a long history of cooperation in the area of agricultural biotechnology, both in bilateral and in international fora. In simultaneous reviews of transgenic plants prior totheir commercialization and during the recent bilateral discussions, the CFIA, Health Canada, APHIS and the USEPA have discussed the types of data that each office reviews before making a regulatory decision. Regulators in both countries reaffirmed that reviews continue to be conducted on a case-by-case basis to allow for the assessment of additional or fewer data sets, depending upon the individual case, and the regulatory authority of each agency.

The results of this meeting, and other activities, may lead to considering mutual acceptance of assessments in the future. In the near term, the continued exchange of information between the CFIA, Health Canada, USDA-APHIS and the USEPA further enhances the understanding of the respective regulatory systems and requirements, and should expedite the review process.

The CFIA is responsible for the regulation of importation, environmental release and feed use of plants with novel traits which include, but is not limited to, transgenic plants. Health Canada has jurisdiction over authorizing the sale of novel foods, including food products derived from transgenic plants. In the U.S., APHIS is responsible for the regulation of importation, interstate movement, and environmental release of transgenic plants that contain plant pest components, but regulatory authority for food and feed use of plants lies with the Food and Drug Administration (FDA). In the USEPA, the mission of the Office of Pesticides Program is "to protect public health and the environment from the risks posed by pesticides and to promote safer means of pest control".

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