

Canadian Food Inspection Agency  
Agence canadienne d'inspection des  
aliments

Health Canada  
Santé Canada



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

## **Canada and United States Bilateral on Agricultural Biotechnology**

On July 15<sup>th</sup>, 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 attached report summarizes substantial areas of agreement and includes an appendix of essential elements considered by the participating agencies for the molecular genetic characterization of transgenic plants. 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 to their commercialization and during the recent bilateral discussions, the CFIA, Health Canada, and APHIS 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 mutual acceptance of assessments in the future. In the near term, the continued exchange of information between the CFIA, Health Canada, and USDA-APHIS further enhances the understanding of the three agencies' respective regulatory systems and requirements, and should expedite the review process.

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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 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).

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