

July 2003, Health Canada Public Consultation

Revision of Health Canada's Guidelines for the Safety Assessment of Novel Foods

Preface and Request for Comments

The present consultation is intended to solicit comments on the revised *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms* and on several issues related to the regulation of novel foods in Canada. This consultation continues the dialogue initiated during the *Joint Consultation on the Revision of the Regulatory Directives and Guidelines for the Assessment of Novel Foods, Plants with Novel Traits and Livestock Feeds derived from Plants with Novel Traits*¹ hosted by Health Canada and the Canadian Food Inspection Agency (CFIA) in Gatineau, Quebec, on May 29-31, 2002.

Part I: The first part of this consultation specifically concerns *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms (June 2003 revised version)*. The Part I Consultation Document provides background information on various sections of the *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganism (June 2003 revised version)*, and highlights the areas where we are most interested in feedback to facilitate the submission of comments on these revised guidelines.

Part II: The second part of the consultation covers issues related to the general context under which novel foods are regulated in Canada. Examples of such issues include the coordination of regulatory decisions between Health Canada and the CFIA, proposals to increase transparency and create more opportunities for providing input into decisions related to novel foods as well as technical issues such as the use of antibiotic resistance marker genes.

Part III: The last part of the consultation provides background information and seeks your input on the issue of the use for food production of animals reproduced by cloning using somatic cell nuclear transfer.

We invite you to provide comments on the proposed revised guidelines and the other topics covered in this document. Your detailed comments can be forwarded to us in several ways:

- By mail to: Novel Foods Section
Food Directorate, Health Products and Food Branch, Health Canada
4th Floor West, Sir Frederick G. Banting Research Centre

¹ The proceedings of the consultation and a summary of comments received from the web-based forum are available at: www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_novel_foods_and_ingredient.html.

Tunney's Pasture, Postal Locator 2204A1
Ottawa, Ontario K1A 0L2

- By email to: nf_consultation_an@hc-sc.gc.ca
- By fax to: (613) 941-8849

Comments received by **September 30, 2003** will be considered in finalizing the revised guidelines and refining policies related to the regulation of novel foods in Canada. **Please note that in keeping with our commitments to an open and transparent process, comments submitted in response to this document will not be considered confidential.** However, the names of the individuals sending comments that have identified themselves and who are not representatives of groups/organizations will be protected pursuant to the *Access to Information Act*.

For a paper copy of this publication and proposed revised guidelines, please contact:

Novel Foods Section
Food Directorate, Health Products and Food Branch, Health Canada
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NOTE: The Canadian Food Inspection Agency (CFIA) is currently conducting a parallel consultation. It is on draft revisions to the existing regulatory directive 95-03, Guidelines for the Safety Assessment of Livestock Feed from Plants with Novel Traits, and to the existing Dir 94-08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. If you are interested in this consultation, please go to the following web page:
<http://www.inspection.gc.ca/english/plaveg/pbo/dir/dir9408comme.shtml>