

## DEPARTMENT OF HEALTH

### FOOD AND DRUGS ACT

#### **NOTICE TO INTERESTED PARTIES: Intent to Develop Environmental Assessment Regulations for products regulated under the *Food and Drugs Act***

This notice is to advise the public of Health Canada's intention to undertake the development of environmental assessment regulations for products regulated under the *Food and Drugs Act* (novel food, food additives, pharmaceuticals, human biologics and genetic therapies, medical devices, veterinary drugs and cosmetics), pursuant to Subsection 30(1) of the *Food and Drugs Act* and/or pursuant to Sections 89 and 114 of the *Canadian Environmental Protection Act*. Draft regulations are expected to be pre-published in the *Canada Gazette* Part I in the fall of 2003.

The Minister of Health has responsibilities for the safety, efficacy and quality review of products under the *Food and Drugs Act*, and for environmental assessments, under the *Canadian Environmental Protection Act*. Health Canada is undertaking this regulatory initiative for products regulated under the *Food and Drugs Act*, as part of its mandate to improve and protect the health and safety of Canadians and its shared federal responsibility for the protection of the environment. Health Canada is committed to ensuring that Canadians have access to safe and effective products while protecting the environment.

Health Canada's intention is to develop, in consultation with Environment Canada and all stakeholders, efficient and effective regulatory requirements that would permit adequate and diligent assessment of products regulated under the *Food and Drugs Act* with respect to their potential effect on the environment or human life and health resulting from the release of these products into the environment. These proposed environmental assessment regulations would define the information and reporting steps required by the Department to perform adequate and diligent review of products. This regulatory initiative would build on and broaden the proposed regulatory framework pre-published in the *Canada Gazette*, Part I, on July 3, 1999 for products of biotechnology.

As part of Health Canada's commitment to establish an open and transparent process for the development of regulatory frameworks for environmental assessments of products regulated under the *Food and Drugs Act*, interested parties will be invited to participate actively in the discussions that will lead to the drafting of regulatory proposals. Throughout the process, interested parties will be able to provide input using a variety of means, including electronic dialogue and the presentation of written briefs and comments.

As a first step in the consultative process, Health Canada is seeking input from interested parties on the development of environmental assessment regulations for *Food and Drug Act* products. Through this Notice of Intent, government is soliciting comments on: the scope and applicability of this regulatory initiative, the issues which the regulations should address, and how interested parties would like to be involved and informed during the development of regulations. Additional

information on this initiative and links to other related sites can be found on the following web site:  
[www.hc-sc.gc.ca/ear-ree](http://www.hc-sc.gc.ca/ear-ree)

Interested persons are invited to submit comments with respect to this proposed regulatory initiative within 60 days of the date of publication of this notice. All submissions should cite the *Canada Gazette*, Part I, the date of publication of this notice and be addressed to Karen Proud, Manager, Environmental Assessment Regulations Project, Office of Regulatory and International Affairs, Health Products and Food Branch, Room 0353, Health Protection Building, Address Locator 0700B4, Tunney's Pasture, Ottawa, Ontario, Canada K1A 0L2. Comments can also be provided by facsimile at (613) 954-4627 or by E-mail at [EAR-REE@HC-SC.GC.CA](mailto:EAR-REE@HC-SC.GC.CA)

Persons submitting comments should clearly indicate on their submission any and all restrictions regarding disclosure under the *Access to Information Act*. Persons are required to provide the reasons why disclosure should be refused and the period during which the comments should not be disclosed. Restrictions may apply to the submission as whole or to specific sections therein.

A summary of comments received by the Government will be made available within thirty days following the closure of the comment period.

September 1, 2001

Diane Gorman  
Assistant Deputy Minister  
Health Products and Food Branch  
Health Canada