



## New Substances Program Advisory Note 2004-06

### Publication in the *Canada Gazette, Part 1*, of the proposed *New Substances Notification Regulations (Organisms)*.

This advisory note is intended to inform importers and manufacturers of animate products of biotechnology and other stakeholders about the proposed *New Substances Notification Regulations (Chemicals and Polymers)* and *the proposed New Substances Notification Regulations (Organisms)* that will replace the current *New Substances Notification Regulations (NSNR)*. The changes to the biotechnology portion of the regulations are not substantive but arise as a consequence of the significant amendments proposed to the chemicals and polymers portion of the regulations.

### Background

When the chemicals and polymers portion of the current NSNR came into force in 1994, Environment Canada and Health Canada committed to conduct a formal review of the regulations following the first three years of their implementation. A multistakeholder consultative process was initiated in 1999 to benefit from government, industry and public experience with the NSNR and New Substances Program for these substances. The outcome of these consultations was 76 consensus recommendations. The proposed NSNR (Chemicals and Polymers) therefore represent Environment Canada's and Health Canada's implementation of these recommendations. In addition, amendments to effect changes in program administration and ongoing international collaboration efforts are proposed.

One consequence to the process for implementing these recommendations is that the NSNR are being divided into two separate Regulations - NSNR (Chemicals and Polymers) and NSNR (Organisms). These will replace the current NSNR while continuing to ensure the same level of protection for the environment and human health. The new framework achieves two main goals:

- To reduce the complexity of the current NSNR by using plain language and flowcharts to provide manufacturers and importers a "roadmap" of the notification requirements under the proposed NSNR (Chemicals and Polymers);
- To separate the provisions governing chemicals and polymers (including biochemicals and biopolymers) and organisms (animate products of biotechnology as defined under Part 6 of the *Canadian Environmental Protection Act (CEPA 1999)*) into two stand-alone regulations, thus clarifying to manufacturers and importers the requirements pertinent to them.

As with the current NSNR, the proposed NSNR (Chemicals and Polymers) and NSNR (Organisms) intended to ensure that no new substance is introduced into the Canadian marketplace before an assessment of its potential effects on the environment and human health has been completed. Any substance not on the Domestic Substances List under the CEPA 1999<sup>1</sup> is considered to be a new substance to Canada and is subject to notification requirements under the NSNR.

Please note that the modifications made to the proposed NSNR (Organisms) are strictly administrative, for instance, the numbering of the schedules has changed, and will not create any changes to the provisions governing organisms.

The revised Regulations were published in the Canada Gazette, Part 1, on October 30, 2004. They are expected to come into force simultaneously in 2005. Environment Canada and Health Canada will publish an addendum to the existing Guidelines that will indicate the proposed changes to the NSNR (Organisms).

### **Contact Information**

New Substances Notification Information Line  
Telephone: 1-800-567-1999 (toll-free in Canada)  
1-819-953-7156 (outside Canada)  
Facsimile: 1-819-953-7155  
E-mail: [nsn-infoline@ec.gc.ca](mailto:nsn-infoline@ec.gc.ca)

For additional information or documentation regarding the NSNR, please visit the New Substances Web Site at [http://www.ec.gc.ca/substances/nsb/eng/index\\_e.htm](http://www.ec.gc.ca/substances/nsb/eng/index_e.htm).

***Original signed by Anne-Marie Pelletier on behalf of***

Bernard Madé  
Acting Director  
New Substances Branch  
Environment Canada

Signed on November 8, 2004

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<sup>1</sup> Unless the substance is regulated under an Act listed in Schedule 2 or 4 of CEPA 1999.