



New Substances Program Advisory Note 2006-04

Administrative Change for New Substances Used in Products Regulated by the *Food & Drugs Act*

This advisory note is to inform manufacturers and importers of new substances and any other stakeholders of an administrative change made to the New Substances Notification (NSN) process for substances used in products regulated by the *Food and Drugs Act* (F&DA).

Background

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) includes a provision whereby substances regulated by other Acts and Regulations that meet the criteria for providing appropriate notification and assessment are not subject to the *New Substances Notification Regulations (chemicals and polymers)* [NSNR (chemicals and Polymers)] and the *New Substances Notification Regulations (organisms)* [NSNR (organisms)]. Acts and Regulations that meet the criteria are listed in Schedules 2 and 4 of CEPA 1999. Schedule 2 lists the Acts and Regulations relating to chemicals and polymers and Schedule 4 lists those relating to animate products of biotechnology.

The F&DA is not listed in Schedule 2 or 4 of CEPA 1999, therefore, new substances used in products regulated by the F&DA are subject to the new substances provisions of CEPA 1999. Please note that the F&DA pre-market approval process remains unchanged, therefore these substances may be subject to regulations under both Acts.

Previously, Notifiers submitted NSN packages for substances used in products regulated by the F&DA to Health Canada, while all other NSN packages were submitted to Environment Canada. An Industry association proposed that a single administrative window approach to notification be adopted for all notifications under the NSNR (chemicals and polymers) and the NSNR (organisms). Stakeholders were consulted on this proposal in spring 2006. The New Substances Program has now made a final decision on this proposal.

Single Administrative Window Approach To Substance Management

Effective January 1, 2007, all NSN packages, including those for substances used in products regulated by the F&DA, must be submitted to the New Substances Division at Environment Canada:

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Mailing Address:

Director, New Substances Division
Department of the Environment
Ottawa ON K1A 0H3

Courier Deliveries:

Director, New Substances Division
Department of the Environment
14th Floor, Place Vincent Massey
351 St. Joseph Blvd.
Gatineau QC J8Y 3Y5

Environment Canada will forward all NSN packages for substances used in products regulated by the F&DA to the Environmental Assessment Unit at Health Canada for review and assessment. NSN packages for substances used solely for F&DA purposes must be identified by checking off the appropriate box in the NSN reporting form.

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-info@ec.gc.ca

If you have any questions or comments, please contact the NSN Information Line or visit the NSN Website at www.ec.gc.ca/substances.

Original Signed by

Bernard Madé
Director
New Substances Division
Science and Risk Assessment Directorate

Signed on November 17, 2006