



New Substances Program Advisory Note 2004-04

Amendments to the Domestic Substances List – Addition of 623 substances found in products regulated under the *Food and Drugs Act*

This advisory note describes the addition to the Domestic Substances List (DSL) of 623 substances found in products regulated under the *Food and Drugs Act* (FDA), and next steps for substances that cannot at this time be added to the DSL due to lack of information.

Current Status

Environment Canada is responsible for administering the *New Substances Notification Regulations* (NSNR) under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), as well as the Domestic Substances List (DSL). The DSL is the sole basis for determining whether a substance is new to Canada and lists substances that:

- were used commercially in Canada between January 1, 1984 and December 31, 1986; and,
- were introduced to Canada since that time and have undergone notification and risk assessment under CEPA 1999 as new substances.

The NSNR currently apply to substances in products regulated under the *Food and Drugs Act* (FDA). FDA substances in commerce between 1984 and 1986 are eligible to be added to the DSL provided they meet the legislative requirements as per s.66 of CEPA 1999, which specify that the Minister must be satisfied (based on information provided by Canadian notifiers) that these substances, between 1984 and 1986,

- were manufactured in or imported into Canada by a person in a quantity of not less than 100 kg in any one calendar year; or
- in Canadian commerce or used for commercial manufacturing purposes in Canada.

Nominations for 1226 FDA substances on the Canadian market between 1984 and 1986 as candidates for addition to the DSL have been received by Environment Canada. Two of these 1226 substances are already on the DSL. Environment Canada proceeded with the addition of 623 of these substances to the DSL based on evidence provided by Health Canada indicating that the listing criteria are met. A notice adding these 623 substances was published in *Canada Gazette*, Part II (Vol. 138, No. 3), on February 11th, 2004. You may view the list of substances on the New Substances Web site at www.ec.gc.ca/substances/

Due to lack of information, 601 substances have been returned to Health Canada for further investigation.

Path Forward

Substances added to the DSL pursuant to section 66 will be subject to the DSL categorization by September 2006. Those that meet the criteria will proceed to the next phase, screening assessments.

Efforts will be made to obtain missing information for those substances described earlier that cannot be added to the DSL at this time. Cooperation from industry stakeholders may be solicited in order to address the information gaps. The remaining eligible substances will be added to the DSL once the missing information has been obtained and the listing criteria are met.

Please send inquiries to:

- New Substances Branch, Environment Canada, Gatineau, Quebec, K1A 0H3, (819) 953-7155 (Facsimile), or by electronic mail to the New Substances Notification Webmaster, nsn-infoline@ec.gc.ca

Or to:

- Office of Regulatory and International Affairs, Health Canada, 2936 Baseline Rd., 3rd floor, A.L. 3303A, Ottawa, Ontario, K1A 0K9, or by electronic mail to the Environmental Assessment Unit Webmaster, ear-ree@hc-sc.gc.ca, or call 1-888-492-1104 (attn: Judith Lockett, Director General, Office of Regulatory and International Affairs, Health Canada)

Sincerely,

Original signed by

David McBain
Director
New Substances Branch
Environment Canada

April 23, 2004