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Director
Existing Substances Division
Environment Canada
Gatineau, Québec
K1A 0H3

(fax) 819-953-4936
(email) ESB.DSE@ec.gc.ca

Sent via email and regular mail

Re: *Canada Gazette*, Part 1, Vol. 140, No. 49, December 9, 2006
Notice of intent to amend the *Domestic Substances List* to apply the Significant New Activity provisions under subsection 81(3) of the *Canadian Environmental Protection Act, 1999* to 148 substances

Environment Canada's Use of SNAcs

On December 9, 2006, Environment Canada posted a notice in the *Canada Gazette* indicating its intention to amend the Domestic Substances List (DSL) by applying the Significant New Activity (SNAc) provisions under subsection 81(3) to 148 substances. The proposal to limit the use of these substances through restrictive SNAcs is pragmatic in light of the fact that the government does not currently have the ability to delete these substances from the DSL. However, since the review of the *Canadian Environmental Protection Act, 1999* (CEPA '99) is now underway, the government should seek an amendment which would allow substances to be deleted from the DSL in these and other appropriate circumstances.

Following categorization, an industry survey under section 71, and a draft screening assessment under section 74, these substances are believed to be:

- Persistent, Bioaccumulative, and inherently Toxic (PBiT), and
- *Not* presently imported or manufactured in Canada in quantities above 100 kg per year, and therefore not considered to be CEPA-toxic under section 64 due to the lack of Canadian exposure.

The conclusion that these substances are not being imported or manufactured in quantities above 100 kg / year derives primarily from the results of an industry survey which was published in the *Canada Gazette* on March 4, 2006. In that survey, industry stakeholders were asked to indicate whether they manufactured or imported the substances in quantities more than 100 kg during the 2005 calendar year. While the intention of the survey was to identify those substances which are no longer in Canadian commerce (i.e. the 148 substances now subject to the SNAc notice), the survey had a

number of limitations.[1] These limitations create the possibility that substances manufactured or imported in some year other than 2005, or in amounts smaller than 100 kg, continue to pose a hazard in Canada.

The SNAc proposal would require industry to reassess these substances under the New Substances Notification Regulations (NSNR) before undertaking any significant new use. The NSNR process is only triggered once the quantity of the substance reaches 100 kg / year, and the SNAc notice defines "significant new activity" as any activity involving more than 100 kg of the substance in a calendar year. This is problematic for two reasons. First, as noted above, such activities could already be occurring, and government would not be aware of them based on its 2006 survey results. It is unclear whether existing / ongoing uses not captured by the survey would be considered significant "new" uses and subject to the NSNR. Second, the threshold of 100 kg could still allow for damage to be done by these hazardous substances. The reasons for this could include their persistence in the environment, synergistic effects with other DSL substances, or potential for long range transport, to name a few.

There are other problematic aspects of the NSNR approach which should be modified with respect to these 148 substances. For instance, there is a lack of adequate and effective public transparency in the NSNR assessment process. Under that process, the Minister is required to post a notice in the *Canada Gazette* upon adding a substance to the DSL or the NDSL, granting a waiver, or imposing a condition, prohibition, or SNAc restriction. However, the public is not informed of new notifications, nor is the public typically given the opportunity to comment on draft risk assessment reports before final decisions are made.

Given the hazardous properties of these 148 substances, we urge the government to improve upon the NSNR process by imposing stricter transparency requirements through the Chemicals Management Plan. The public is entitled to be informed of, and comment upon, any proposed commercial use of these substances.

The SNAc notice goes on to indicate that, prior to the commencement of the proposed new activity, notifiers should submit the NSNR information requirements contained in:

- Schedule 4,
- Item 8 of Schedule 5, and
- Item 11 of Schedule 6.

Schedule 4 is the basic, minimal data set which is required of new substances which are being notified at the lowest volume trigger. The Schedule includes primarily identification information, and does not require the production of any test data (beyond

[1] Note: early in 2006, NGOs voiced a number of concerns regarding the structure of the survey. Most notably, the survey failed to capture companies that used the substances in 2004 or previously, or planned to use the substances in 2006 or subsequently, or used the substances in amounts under 100kg. See J. Ginsburg and F. de Leon, "Letter to Environment Canada regarding a Domestic Substances List (DSL) categorization survey" (16 March 2006), online: <cela.ca/uploads/f8e04c51a8e04041f6f7faa046b03a7c/537EC_surveys.pdf>.

that which is already in the possession of the manufacturer or importer). Item 8 of Schedule 5 and Item 11 of Schedule 6 relate only to exposure information. Accordingly, should industry seek to (re)introduce the substances onto the market at quantities above 100 kg, they could be allowed to do so without submitting any test data whatsoever.

Government has indicated that "[c]onsidering the hazardous profile of these substances, there is limited possibility that they would be reintroduced."[2] However, given the fact that 1) government conducted its categorization and screening assessment without requiring any new test data, and 2) these substances are already believed to be highly hazardous, there should be no opportunity for continued use without industry demonstrating through scientific testing that the substances are safe. This would require proponents to provide, at a minimum, substantive testing data equivalent to the most rigorous data schedule provided under the NSNR, including:

- Data from one repeated-dose mammalian toxicity test, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure;
- Mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and
- For chemicals having a water solubility of greater than or equal to 200 µg/L, adsorption-desorption screening test data, the hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.

Further, we would augment the NSNR test schedules by requiring companies notifying these substances under the NSNR to also submit data on chronic toxicity, endocrine toxicity, neurodevelopmental toxicity, as well as information regarding safer alternatives. Additionally, the government should provide explicit guidance on how the precautionary principle will be applied to regulatory decisions affecting these substances, in light of their hazardous characteristics identified through the categorization process.

Recommendation: The Government of Canada should seek an amendment to CEPA '99 which would allow substances that are no longer in Canadian commerce to be deleted from the DSL.

Recommendation: Any existing or ongoing uses of the 148 substances which were not captured by the 2006 survey should be considered "new" and subject to the NSNR requirements. Before and until such time as they have received approval under the NSNR, government should impose mandatory risk management measures to eliminate these uses from the Canadian market.

Recommendation: The Government of Canada should establish a process to enhance public transparency and participation in any notification to the NSNR involving these 148 substances. The public should be informed of any notifications

[2] Government of Canada, "Provisions for Significant New Activities and Outcome from DSL Categorization" (Presentation at the Chemicals Management Plan: Technical Briefing, Ottawa, 15 December 2006).

and have the opportunity to comment on draft assessments before final decisions are made regarding the use of these substances at any quantity.

Recommendation: Given the hazardous properties of these substances, the SNAc notice should define *any* activity involving these substances to be new, not merely those activities in excess of 100 kg / year.

Recommendation: These 148 substances should not be approved for import, manufacture, or use unless industry can demonstrate their safety through scientific testing. At a minimum, industry should be required to submit testing data equivalent to the highest schedule for non-NDSL substances under the NSNR. Additionally, notifiers should be required to submit data on chronic toxicity, endocrine toxicity, neurodevelopmental toxicity, as well as information regarding safer alternatives.

Health Canada's Use of SNAcs

The Government of Canada has indicated that in early 2007, Health Canada will apply the SNAc provisions to certain substances that have inherently hazardous properties for humans. We have yet to see the details of this proposal, however, the comments provided above may also be relevant to Health Canada's process. We look forward to providing additional comments once further information becomes publicly available.

For further information, please contact:

Jessica Ginsburg
Special Projects Counsel
Canadian Environmental Law Association
(416)960-2284 ext. 226
jginsburg@cela.ca

Fe de Leon
Researcher
Canadian Environmental Law Association
(416)960-2284 ext. 223
deleonf@lao.on.ca

PREPARED FOR:

Canadian Environmental Network Toxics Caucus

ENDORSED BY:

Canadian Environmental Law Association - ***CELA Publication #561***
Centre for Long-term Environmental Action in Nf/Ld (Inc.) (CLEANf/Ld)
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