



ChemICALS

UPDATE

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The Chemicals Management Plan

What is the Industry Challenge?

On December 8, 2006, the Canadian Government revealed Canada's new Chemicals Management Plan (CMP). A key element in the CMP is the collection of information on the properties, uses, and risk management measures currently in place for the approximately 200 chemical substances identified as high priorities for action. This initiative is known as "The Industry Challenge".

The Challenge to industry and other stakeholders is to contribute new information about how industry is managing these chemical substances. The substances have been divided into 12 "batches" for ease of information processing.

What does this mean to you?

If you manufactured or imported a "batch" substance in excess of 100 kg or used a "batch" substance in excess of 1000 kg (Batch 2-7) in 2006, you are legally obligated to respond to the s.71 Notice(s). This applies whether you manufactured, imported or used the substance alone, in a mixture, in a product or in a manufactured item. *(cont'd on page 2...)*

"Not All SNACs are Bad for You"

A SNAC (Significant New Activity condition) is an information-gathering tool that is used by the government and generally assigns one of the following two types of boundaries on the use and handling of a substance:

- a boundary specifically describing acceptable activities and requiring importers, manufacturers, and/or users, wishing to use or handle the substance outside these boundaries, to submit defined information before the new activity commences.
- a boundary describing potentially unacceptable activities and requiring importers, manufacturers, and/or users, with interest in the described activity, to submit specific information for assessment before the activity commences.

The new activity information is submitted as a Significant New Activity notification (SNAN), which is evaluated during the prescribed assessment period (usually 90 days). The assessment outcome may either widen the acceptable boundaries for the substance, or trigger risk management controls.

Unlike a "CEPA s.84(1)(a) condition" (aka 'Ministerial Condition'), which is imposed on a specific notifier and prevents a new substance from being added to the Domestic Substances List (DSL), SNACs are applied more generally to all importers, manufacturers and/or users and do not interfere with DSL eligibility.

For new substances, notifiers are informed, before the assessment period expires, of the government's intention to impose a SNAC. Thereafter, the SNAC must be finalized and published in the Canada Gazette within 90 days after the assessment period has expired. Under the appropriate circumstances, notifiers can participate in the SNAC-drafting process in order to ensure that the SNAC does not unnecessarily hamper business opportunities.

For existing substances, a notice of intent to apply a SNAC is published in the Canada Gazette Part I with a 60-day public comment period allowing stakeholders to provide input. All stakeholder comments are reviewed by the government and the SNAC may be amended. The final SNAC notice is published in the Canada Gazette Part II. (A consolidated list of these substances is unavailable at this time.)

For more information, visit: www.ec.gc.ca/substances/nsb/eng/cp_snac_e.shtml

The Chemicals Management Plan cont'd

If you do not meet the mandatory response thresholds, you may wish to complete a voluntary survey to provide additional information about the substance, or your use of it, or you may simply choose to submit a "declaration of stakeholder interest" to ensure you are kept up-to-date during the entire process.

The initial Notice response or voluntary survey for each "batch" is your first opportunity to identify your specific use of a substance and controls you have in place to mitigate any risk. The information you provide in this first step will be considered by the government when they assess the potential risks associated with these substances.

Once the government has completed the screening level risk assessment (SLRA), there are three possible outcomes:

1. No further action required;
2. Substance is deemed CEPA toxic (and added to Sch 1 of CEPA) and risk management strategies will be developed. Management strategies may include, but are not limited to, specific use restrictions, virtual elimination or prohibition; and
3. Substance is added to the Priority Substances List for further evaluation.

Outcomes of the SLRA are published in the Canada Gazette and are open for a 60-day public comment period. This is your second opportunity to offer information that may influence future management strategy decisions.

Other opportunities for your input occur at several intervals during the decision making process. If you have a stake in the disposition of a "batch" substance, it is important you raise your concerns during the legislative process. Once a management strategy has been enacted, you may be required to comply.

Failure to participate in this initiative may result in your application of a substance being omitted from a risk management strategy or even

the use of the substance being banned altogether. Either of which may significantly impact your business.

What's New?

New information was provided by stakeholders for all Batch 1 and 2 substances. Six substances in Batch 1 were determined not to meet the definition of CEPA toxic. The remaining nine are expected to be added to Schedule 1 (Toxic Substances List) in the Fall of 2008. The draft screening assessments for all Batch 2 substances have been published in the Canada Gazette. SNACs are proposed for two Batch 2 substances (see our article on "SNACs" pg 1).

On August 23, 2008, notices relating to the release of draft screening assessments for the 19 substances in Batch 3 of the Challenge were published in the Canada Gazette. SNACs are proposed for three Batch 3 substances. The draft screening assessments and risk management scope documents are available for review on the government website. The public comment period will remain open until October 22, 2008.

Important Dates:

Batch Releases (Number of Substances)	Section 71 Data Submission		Publishing Date of Draft SARs ¹ /RM ² Scopes		Publishing Date of Final SARs ¹ /RM ² Scopes	
	Launch date	End date	With no info	With new info	With no info	With new info
Batch 1 (15)	2007-02-03	2007-06-05	n/a	2008-01-19	n/a	2008-07-05
Batch 2 (17)	2007-05-12	2007-09-12	n/a	2008-05-17	n/a	2008-09-12
Batch 3 (19)	2007-08-18	2007-12-18	n/a	2008-08-23	n/a	2009-02-21
Batch 4 (18)	2007-11-17	2008-03-18	2008-08-16	2008-11-15	2009-02-14	2009-05-16
Batch 5 (19)	2008-02-16	2008-06-17	2008-11-15	2009-02-14	2009-05-16	2009-08-15
Batch 6 (18)	2008-05-31	2008-09-30	2009-02-28	2009-05-30	2009-08-29	2009-11-28
Batch 7 (14)	2008-08-30	2009-01-13	2009-06-06	2009-09-05	2009-12-05	2010-03-06

¹SAR=Screening Assessment Report; ²RM=Risk Management

To keep abreast of this ever-changing landscape, visit the Government of Canada's Chemical Substances portal: www.chemicalsubstanceschimiques.gc.ca/en/index.html

Harmonization is the Key for Industry

By now you've likely heard something about the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals. But what is it?

What is GHS?

GHS is a framework created by the United Nations (UN) to enhance the protection of human health and the environment by providing a globally recognized system for hazard classification and communication.

The expectation of industry has been that eventually one Safety Data Sheet (SDS) and label (translated into local languages) will be sufficient for worldwide use of their materials in multiple applications (e.g. workplace, consumer or pesticides) as well as transport.

However, local adaptation of the GHS criteria may not make this true. While classification efforts will, for the most part, be harmonized, the "building block" approach to implementation and country-specific SDS and labelling requirements may make complete harmonization difficult.

Country-Specific Implementation May Make Complete Harmonization Difficult

One of the tenets of the GHS is the "building block" approach of implementation, allowing countries to implement selected parts of the system of key interest. For example, countries can decide whether to assign GHS requirements to consumer products and whether to use all 5 acute toxicity categories or apply only categories 1-3.

Individual countries may also implement country-specific requirements for labelling (e.g., special borders or ingredient disclosure requirements) and for trade-secreting ingredients. In most cases, it is expected that companies will be allowed to 'over label'

Small Particles, Mean Big Changes

Nanotech Substances in Canada

The increased use of nanotechnology in the consumer and industrial sectors is expected to significantly influence the global economy. Nanotechnology research is making headlines, and hundreds of consumer products using nanotechnology are already on the market. In general, nanotechnology is defined as the ability to create and use materials, devices and systems with unique properties at the nano-scale (approximately 1 to 100 nm). Concern has been expressed that the very same properties of nanomaterials that render them unique (e.g., size, relative surface area, chemistry and functionality) may also be associated with unanticipated biological effects and toxicity in humans and the environment.

Nanomaterials that are manufactured in, or imported into, Canada, and are not listed on the DSL, are subject to the New Substances Notification (NSN) requirements of the Canadian Environmental Protection Act, 1999 (CEPA 1999). Additionally, the nanoscale form of a substance present on the DSL is, likewise, considered a new substance if its unique structures or molecular arrangements were not addressed during the notification process and is subject to notification.

Nanomaterials present challenges to the current regulatory framework under CEPA 1999 due to their novel properties; hence, current requirements for traditional chemicals and polymers may not be appropriate to permit adequate risk assessments of these materials. On Sept 10th, 2007 Environment Canada proposed the following two-phased regulatory framework for nanomaterials under CEPA 1999.

Phase I (Began in 2006)

- Work with international partners (OECD, ISO) to develop scientific and research capacities;
- Initiate communication with potential notifiers to inform them of their regulatory responsibilities under the current framework;
- Develop initiatives to gather information from industry on the uses, physico-chemical properties, and effects of nanomaterials; and
- Consider legislative amendments to CEPA 1999 or the NSNR that would be needed to improve the risk assessment and management of nanomaterials.

Phase II (2008-2010)

- Develop standard terminology/nomenclature system;
- Consider establishing data requirements under the NSNR specific to nanomaterials; and
- Consider the use of the Significant New Activity (SNAC) provision of CEPA 1999 to require notification of nanoscale forms of substances already on the DSL.

Information learned about new and existing nanomaterials will direct the development of regulatory frameworks and the undertaking of preliminary risk assessments. In order to gather this information, mandatory surveys issued under Section 46 or 71 of CEPA 1999 are forthcoming and will require companies responsible for manufacturing, importing or engineering nanomaterials to provide certain prescribed information, if available. Response to such notices is mandatory, and companies must make efforts to answer the questions by providing information "to which they have reasonable access".

For more information visit:

www.ec.gc.ca/substances/nsb/eng/nano_e.shtml

products in jurisdictions that have implemented only some of the building blocks, giving companies the option to be harmonized for worldwide sales. However, this might create a competitive disadvantage in some situations where competitors' products are only labelled for one country's specific requirements, and thus, 'over-labelling' could make a product, by comparison, seem more hazardous, when, in fact, the true hazards of both products are identical.

Status of GHS Implementation

For many companies it would be ideal if all countries implemented GHS simultaneously, but this is not realistic given the different political climates and regulatory change requirements in different countries. For example, the Canadian legislative process requires that, for the workplace application of GHS, the interests of government, industry and labour stakeholders be considered and addressed as part of the regulatory amendment process.

As this newsletter goes to press, the following countries have offered the following implementation updates:

- Canada: Regulatory changes to include GHS criteria are expected in 2008, although the recent call for a federal election is certain to delay the regulatory amendment process
- China: GHS legislation is expected to come into effect in January 2009
- Japan: GHS labels are already required for certain chemicals. SDS and labels are expected to be required for all chemicals in 2010
- Korea: Have postponed adoption of GHS until 2010, but will currently accept GHS-format SDS and hazard classification
- Mauritius: GHS legislation has been implemented
- New Zealand: GHS legislation has been implemented (but other labelling is permitted until 2010)
- Taiwan: GHS legislation is expected come into effect in January 2009

For the full text of the current GHS, visit the following link:

www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html

Surprised By Salt?

A note of caution to all you formulators out there. When cold-mixing, blending or formulating your performance products, remember to keep an eye out for ingredient interactions that might produce a new substance right there in the vat. For example, if your ingredient list includes both acidic and basic materials, check reaction conditions to see if you should expect them to form a salt, and if so, confirm whether that salt is listed on the DSL. If it isn't listed or otherwise exempt, then, by definition, it's a new substance, and is, therefore, notifiable.

The same consideration should also be given to polymers – during manufacture as well as formulation. Remember that Canada has no equivalent to the USEPA's TSCA "(h) (7)" exemption, so if you've neutralized your polymer make sure that the CAS name and number you use to describe it adequately captures the counterions present, and that your domestically manufactured or imported polymer is accurately listed on the DSL.

If you need help identifying potential ingredient interactions, or finding DSL entries that might adequately describe the products of such interactions, contact us at chemicals@cantox.com.

Canada's Answer to the TRI (Toxic Release Inventory)

Did you know that CEPA 1999 requires that industry report releases of pollutants identified on the National Pollutant Release Inventory (NPRI) each year?

Cantox has experience using the calculation and estimation tools to prepare NPRI reports, and we can easily help clients prepare comprehensive data packages for the NPRI. So if you have no time or personnel available to run the necessary calculations, and process detailed spreadsheets, give us a call – we're here to help!

Helping Companies Do the Right Thing, the Right Way, the First Time

Here are just some of the areas we can assist with:

The Challenge under the Chemicals Management Plan:

- Propose response strategies for current and future Batches;
- Determine if you are obligated to respond and prepare the s.71 Notice response(s); and
- Keep you informed of any Screening Level Risk Assessment notices so you can voice your concerns and advocate for your uses at the appropriate time.

Nanotechnology submissions:

- Collect and compile relevant information pertaining to the design, manufacture and testing of nanomaterials;
- Design and coordinate nanoparticle toxicology studies;
- Understand and apply the evolving regulatory guidelines for nanotechnology-based materials and products; and
- Address potential health and environmental effects of nanomaterials.

The SNAC process:

- Assist during the SNAC assessment and/or consultation period to ensure that your business interests are considered;
- Keep you informed of possible business implications when a SNAC is published in the Canada Gazette; and
- Prepare and submit SNAC notifications (SNACs) on your behalf.

GHS Compliance:

- Classification;
- Safety Data Sheet (SDS) and label preparation; and
- Strategies for implementing GHS in your company.

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