



# CHEMICALS UPDATE

Spring 2010

...brought to you  
by the  
Chemicals  
Group at Cantox

## The Challenge and the Chemicals Management Plan – What's Next?

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On December 8, 2006, the Canadian Government revealed Canada's Chemicals Management Plan (CMP). The CMP was created to help the government ensure that the risks associated with the use of certain chemicals in Canada are managed proactively. In order to determine which substances had the highest potential to cause harm and prioritize their efforts accordingly, the government first looked at results from the Categorization and Screening of the Domestic Substances List (CSDSL) efforts.\*

\*See our 2002 Year-in-Review Newsletter for more information about the CSDSL. ([http://www.cantox.com/news\\_chem.html](http://www.cantox.com/news_chem.html))

About 500 substances from the high-priority group from the CSDSL have been the subject of current efforts under the Challenge to Industry (the Challenge)\*\* and various sector-specific approaches. The Challenge focussed on 195 of the high-priority substances which were split into 12 batches and published as Notices in the Canada Gazette.

\*\*See Cantox's Spring 2009 Newsletter for more details about the Challenge to Industry.

[http://www.cantox.com/news\\_chem.html](http://www.cantox.com/news_chem.html)

### Final Batch Released:

**The Final batch was released in the Canada Gazette on December 26, 2009 and responses to the Notice are required by no later than 3:00 p.m. EDT, April 27, 2010.** *(In certain cases, an extension to this deadline may be granted, for a maximum of two months; however, an extension must be requested in writing and approved by the authorities in order to be valid. Remember to leave sufficient time before the deadline for processing of your extension request.)*

Batch 12 includes 16 substances which have been subdivided into 5 different groups. The substances were subdivided in order to facilitate gathering of different types of information

for different substances and to enable the application of different exemption criteria for certain substances. The reporting quantity criteria are the same for all substances in Batch 12: if a person or company manufactured or imported any of these substances in a quantity exceeding 100 kg in 2006 (in all cases quantities of the substance in pure products, mixtures, or manufactured items must be considered) or used these substances in a quantity exceeding 1000 kg in 2006, then reporting is required. However, the Notice further specifies that for substances in Part 4 (i.e., quartz and cristobalite) and Part 5 (i.e., carbon black) the person or company need only report if they meet the general quantity requirements above AND if the substances are intended for use of any kind in a residence.

Additionally, if the substances do not contain at least 5% of respirable crystalline silica (for quartz or cristobalite) or if carbon black is not available for inhalation (in a solid form or suspended in a liquid), then reporting is not required.

Batch 12 Information can be found at: <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-12-26/html/notice-avis-eng.html#d104>

### What Now?

If you're just hearing about the Challenge or Batch 12 now, call Cantox! We can help you review your chemistry, manufacture, import and use information to determine if you are required to respond. If you do need to respond, Cantox can assist you to prepare a plan of action to obtain the information you require and complete the survey and/or voluntary questionnaire.

### What Next?

If you've complied with everything under the Challenge, are you done? Unfortunately, no.

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# The Challenge and the Chemicals Management Plan– What's Next? ...cont'd

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Although the initial data-gathering phase of the Challenge is coming to a close, industry's work is not complete. On the contrary, the most important phase of the Challenge is now underway. Industry must now review the outcomes of the screening assessment reports (SAR) and provide input into the proposed risk-management scope documents (RMSD) for their substances of interest. Industry should continue to monitor the Gazette and the CMP website for updated information about the outcomes of the government risk assessments and any risk management measures that they are proposing to implement for various substances. Additionally, the first CMP efforts focussed only on about 500 of the high-priority substances. The government also recently began efforts to collect information on some of the medium-priority substances. The DSL Inventory Update (IU) "Quickstart" Notices for chemicals and biotechnology (*i.e.*, micro-organisms) were published in October 2009 and the

deadline for reporting on these nearly 500 substances was March 30, 2010.\*\*\*

\*\*\*The chemicals DSL IU Notice is available at: <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-10-03/html/notice-avis-eng.html#d101>

The biotechnology Notice is available at: <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-10-03/html/notice-avis-eng.html#d108>

The government will be providing more information about their next steps for the medium-priority substances at the ICG CEPA Update Conference to be held in Toronto in May. For more information about this conference, please visit Cantox's website: [http://www.cantox.com/whats\\_new.html#ICG](http://www.cantox.com/whats_new.html#ICG)

Please see the back panel for information about how Cantox can assist you with your CMP compliance efforts.

## Current Observations on the New Substance Notification Regulations

### Background:

Except where specifically exempted from new substance notification under CEPA, the import or domestic manufacture of substances not present on the Domestic Substances List (DSL) is subject to pre-import/pre-manufacture notification and assessment under the New Substances Notification Regulations (NSNR).

The NSNR is a quantity-based, tiered-submission system that requires subsequent notifications as the annual amount of the imported or manufactured new substance increases.

Under this complex set of regulations, several notification options exist and the amount of toxicological, physical-chemical, and exposure-based information to be submitted in the notification dossier depends on many factors including, but not limited to, the following:

- annual quantities of the substance to be imported/manufactured;
- whether the substance is present on the Non-Domestic Substances List (NDSL);
- whether the substance meets

the regulatory definition of a chemical, polymer or product of biotechnology;

- whether the new polymer meets the Reduced Regulatory Requirement Polymer (RRRP) criteria defined in the Regulations;
- whether the reactants used to manufacture the polymer are on the DSL or NDSL;
- whether the new substance's intended use pattern falls within the definition of special-use categories including research and development, contained export only, or contained site-limited intermediate; and
- whether a new micro-organism will be introduced to a geographical area (*i.e.*, ecozone) where it is indigenous.

Based on a review of the notification dossier, and any other information that may be requested by the federal government, representatives of Environment Canada and Health Canada will attempt to determine whether or not the substance is suspected of being toxic as defined by Section 64 of CEPA. If the government fails to indicate otherwise during the

assessment period, then the Notifier may, when the assessment period expires, commence the import or domestic manufacture of the substance in quantities allowed by the type of notification that was submitted.

### Current Observations:

Based on our involvement in successfully clearing more than 400 Canadian NSNR notifications over the past 16 years, the following observations have become evident:

- Low-level notifications are reasonably easy to clear.
- Higher-level notifications require much more effort.
- Detailed test reports are required for higher-level notifications.
- Low-Concern Polymers require careful justification to achieve the RRRP designation.
- Waivers of some NSN requirements are possible but must be thoroughly justified.
- Government assessment of known and possible uses has become more rigorous.

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## Computerized REACH Tools

If you are in the chemical business in Europe, you've undoubtedly heard of REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) and if you need to file registrations for your substances you may have also heard about the IUCLID (the International Uniform Chemical Information Database) software.

IUCLID is an important tool, which allows users to input and manage data related to their chemical substances of interest. IUCLID version 5 or greater is required for preparation of REACH registration dossiers, although data can be migrated from old to new versions of the software (current version: IUCLID 5.2). IUCLID structures the information that REACH requires in each registration dossier into relevant sections:

- Section 1 General information (including registrant information and substance identity information);
- Section 2 Classification and labelling;
- Section 3 Manufacture, use and exposure;
- Section 4 Physical and chemical properties;
- Section 5 Environmental fate and pathways;
- Section 6 Ecotoxicological information;
- Section 7 Toxicological information;
- Section 8 Analytical methods;
- Section 9 Residues in foods and feeding stuffs;
- Section 10 Effectiveness against target organisms;
- Section 11 Guidance on safe use;
- Section 12 Literature search; and
- Section 13 Assessment reports

REACH registration requirements are quite complex and although a computerized tool like IUCLID offers a great deal of functionality to make things easier on registrants, the European Chemicals Agency (ECHA) has reported that only about 35% of registrations received between Jun 1, 2008 and August 4, 2009 passed their completeness check.

**Thus, about 65% of registrations were rejected.**

ECHA has therefore, developed the Technical Completeness Check tool (TCC tool) to assist registrants to prepare acceptable registration dossiers. The TCC tool (released in December 2009 and updated in March 2010) is a plug-in designed to work with IUCLID to help users identify gaps and errors in their registrations. The TCC tool is quite helpful but users should exercise caution because a computerized tool cannot be considered a complete replacement for knowledge from the guidance documents and up-to-date information about application of the legislation and guidance by ECHA. Cantox has noted a few peculiarities with the TCC tool, which users will need to be aware of to avoid doing unnecessary testing and to avoid rejection of their registration dossier by ECHA. For example, the TCC tool would mark a dossier as incomplete if a repeated-dose study is not entered in IUCLID for all routes of exposure; however, only one study is actually required. Additionally, the TCC tool would not mark an Annex VIII registration dossier as incomplete if only one *in vitro* mutagenicity study was provided; however, two are actually needed for this tonnage band and a dossier containing only 1 study would be rejected by ECHA. Finally, the TCC tool would accept handbook data as a key study; however, ECHA has recently rejected a registration where a handbook reference was used as a key study, because no other supporting information was provided (e.g., QSAR or an additional handbook reference).

Cantox has a great deal of experience assisting our clients with their technical REACH needs. We can: provide Klimisch ratings; prepare Derived No Effect Levels (DNELs); classify according to the Classification, Labelling and Packaging (CLP) requirements; prepare robust endpoint summaries; and fill gaps of information with alternatives to testing.



If you are registering your substances under REACH and you need help, Cantox is well-positioned to assist you with your technical REACH needs. We have dedicated and experienced toxicologists and chemists on staff who are ready to assist you.

Contact us at [chemicals@cantox.com](mailto:chemicals@cantox.com) for more information.

## Current Observations on the New Substance Notification Regulations...cont'd

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- Government evaluators use web searches to collect info beyond the Notifier's submission.
- The merging of government evaluators from the new and existing substances divisions has triggered a more onerous assessment process and more questions during the NSN assessment period.
- Notifiers have seen a significant increase in the number of controls and restrictions accompanying their NSN approvals.

The NSNR are complex. Government policy and evaluator expectations are ever-evolving. So whether you file only one notification per year or you file many on a regular basis, you need the experience of Cantox's team of experts who know the NSNR Program requirements inside-and-out and can help you seize all possible money- and time-saving opportunities. Don't take risks with copycats; go with the proven success that the Cantox team has been delivering for the past 16 years:

- Cantox knows the rules and we understand and respect the government's expectations;
- Cantox offers 16 years experience in filing successful and timely NSNR notifications;
- Cantox is the industry leader in the cost-effective use of waivers and surrogate data; and
- Cantox is the industry favourite for delivering practical advice and reliable solutions to chemical companies and their legal counsel.

Cantox lives and breathes in the NSN world on a daily basis and we are well positioned to help you respond and adapt to evolving policies in this area.

Contact us for more information about how we can help you with our full suite of timely and cost-effective NSN services ([chemicals@cantox.com](mailto:chemicals@cantox.com)).

## We're Here to Help!

### Chemicals Management Plan

Cantox's experts can help by: keeping you apprised of program developments including risk assessment and management outcomes; determining your obligations to respond to government Notices; assisting your company to prepare sufficiently-detailed responses; and working with your company and regulators to ensure risk management measures are realistic and appropriate.

### New Substance Notifications

Cantox offers new substance notification services for many jurisdictions worldwide. We can help you prepare your notification packages, fill in any gaps of information with methods other than testing whenever possible, place and monitor studies when necessary, and negotiate with authorities to obtain the best-possible outcome for your substance in the shortest time possible.

### REACH Technical Assistance

Our seasoned toxicologists and chemists are available on-demand to assist individual companies, consortia or SIEFs. Cantox is often consulted by other firms who have the regulatory expertise for REACH but do not have the technical background necessary to handle all of the scientific work required to prepare registration dossiers. Our scientific experience includes the review, Klimisch rating, and IUCLID entry of more than 1000 study reports and the preparation of countless DNELs currently being considered for REACH Registrations.

### Hazard Communication

Our hazard communication experts can provide assistance to companies who require single or multiple MSDS and labels for workplace or consumer applications. We can also provide or set up an entire hazard-communication program for our clients with longer-term, hazard-communication needs. Cantox is well positioned to offer expert assistance to our clients by applying professional judgement to adequately classify and warn users of applicable hazards, without falsely over-classifying and triggering market disadvantages.

If you would like to discuss our services and learn how we can help you and your company - do the right thing, the right way, the first time,

**contact the Cantox Chemicals Group at:  
[chemicals@cantox.com](mailto:chemicals@cantox.com) or by phone: 905-542-2900.**

*Chemicals Update is a periodic newsletter published by the Chemicals Group of Cantox Health Sciences International (Cantox) for the purpose of keeping our clients and other interested parties informed of scientific and regulatory items of interest affecting the chemical industry.*

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