



CHEMICALS UPDATE

Fall 2009

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by the
Chemicals
Group at Cantox

Chemicals Management Plan: Industry Challenge Update

Inside this Issue:

- Chemicals Management Plan: Industry Challenge Update
- What is the DSL Inventory Update (DSL IU)?
- Changes to the CCCR 2001
- Ontario Section 34 Notifications
- Tox Tip...Klimisch Ratings: What are They?
- Helping Companies Do the Right Thing, the Right way, the First Time!

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On December 8, 2006, the Canadian Government revealed Canada's Chemicals Management Plan (CMP). The CMP affects products covered by multiple Acts of parliament (CEPA*, PCPA*, F&DA*). The purpose of the CMP is to proactively manage the risks to both human health and the environment which arise from the use of certain chemicals in Canada.

Information obtained from the government's Categorization and Screening of the DSL (CSDSL) is being used to prioritize some of the activities under the CMP. The CSDSL efforts focussed on rapidly screening the ~23,000 substances grandfathered onto the DSL. As a result, all ~23,000 substances were categorized to determine priorities for further action. The vast majority of substances were set aside as not requiring any further efforts, while 4300 substances were deemed to require additional review. These 4300 substances were further subdivided into high, medium, and low priorities for action.

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

The ~500 substances in the high-priority group have been the subject of current efforts under the Industry Challenge** and various sector-specific approaches.

What Now?

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.

The outcome of the risk assessment will determine what the next steps may be for a substance.

	If the substance is deemed to be:	Then the likely course of action will be:
OPTION 1	Not CEPA Toxic with no concern that new uses might result in the substance meeting the criteria for CEPA Toxic.	No risk management measures required.
OPTION 2	Not CEPA Toxic - However, based on the properties of the substance, the government believes that a new activity may result in it meeting the criteria for CEPA Toxic.	A Significant New Activity (SNAc) Notice will be published, requiring notification of new activities as defined.
OPTION 3	CEPA Toxic	Addition to Schedule 1 of CEPA and development of risk-management measures (RMM).
OPTION 4	Of indeterminate toxicity	Add the substance to the Priority Substances List for further evaluation.

Option 4 has not been used for any of the Challenge substances to date, because the government is predisposed to considering all of the high-priority substances as CEPA Toxic. Therefore, in the face of no additional information or insufficient information to choose Options 1 or 2, the authorities have, thus far, been proposing Option 3.

If a substance is deemed to be CEPA Toxic and placed on Schedule 1, the government has a number of possible options for RMMs including, but not limited to:

- recommending established codes of practice be instituted industry wide;
- preparing new voluntary codes of practice;
- creating regulations;
- using existing legislation;

continued on page 2...



What is the DSL Inventory Update (DSL IU)?

As part of the Chemicals Management Plan (CMP), the government needs to gather updated information on the substances that were “categorized-in” as requiring further action under the CSDSL (~4300 substances). The means of gathering this information will be the DSL IU. Additionally, ~1200 substances which were not initially categorized-in, due to uncertainties in the reliability of categorization input information, will also be subject to the IU. Collection of information under the IU will be dependant on import or manufacture volumes. At present, it is believed that the government will be seeking company information and volume and use information about the substance, including whether the substance is found in consumer products and products intended for use by children. Starting with the proposed launch in 2010 (collecting 2009 information), the IU is expected to be repeated every five years.

Chemicals Management Plan: Industry Challenge Update

...continued from page 1

- recommending the substance for Virtual Elimination (*i.e.*, reduction of the quantity or concentration released to below detectable limits – essentially banning all releases of the substance); and
- prohibiting import, manufacture, use, sale or offering for sale of the substance.

Why Care?

Companies should carefully review the content of the draft SARs in order to ensure that the information they provided was accurately captured and assessed. Reviewing the proposed RMSD will also be crucial to ensure your company's uses of the substance will be allowed to continue. Missing the opportunity to provide input into the draft RMSD could put your company's supply chain in jeopardy.

Stay Tuned!

As the assessment of the high-priority substances continues, and the need for risk management is identified, the government plans to begin assessing the CSDSL's medium priorities (~2600 substances). To prioritize the assessment of these substances, the government intends to launch additional surveys that will poll industry for, primarily, updated quantity and use information. The government currently plans to have the survey efforts and screening assessments completed for all 2600 medium-priority substances by 2020.

* CEPA = Canadian Environmental Protection Act, PCPA = Pest Control Products Act, F&DA = Food & Drugs Act

** See Cantox's Spring 2009 Newsletter for more details about the Industry Challenge. http://www.cantox.com/news_chem.html

Changes to the CCCR 2001

If your company sells chemical products intended for use by consumers in Canada, then the packaging and labelling of those products must be in compliance with the Consumer Chemicals and Containers Regulations (CCCR 2001). Products must be classified in accordance with the hazard criteria and if the consumer chemical product or container falls into a hazard category, then specific labelling elements and packaging requirements may apply.

A recent amendment to the CCCR 2001 was published in the Canada Gazette on June 24, 2009 and some noteworthy changes include:

- The units of inhalation toxicity used for the classification of gases and vapours have been changed to mL/m3 instead of mg/m3;
- The fuel container exemption has been amended to include all fuel containers, not just those designed to store “toxic”, “harmful”, or “very flammable” fuels;
- Ethanol and propane have been removed as examples of “very flammable” substances in Section 53 since they are both “flammable”;
- The “Do not induce vomiting” is no longer a mandatory first-aid warning for toxic products; and

- The mixing hazard warning is no longer mandatory for corrosive products.

To review all of the changes being made to the Regulations, see the Canada Gazette notice: www.gazette.gc.ca/rp-pr/p2/2009/2009-06-24/html/sor-dors165-eng.html.

Summer CCCR News:

With summer coming to a close you may be looking for bargains at your local garden centre and might notice something different. Proper labelling of refillable decorative garden torches, such as “tiki torches”, is an area that currently has the attention of Health Canada (HC). Though usually sold empty, these containers are designed to hold a hazardous liquid fuel and according to recent HC guidance, the containers are thus subject to the CCCR requirements. This means CCCR-compliant labelling (specific to the intended fuel to be used) must be displayed on the container in a location visible to the consumer. Additionally, the container may require a child-resistant closure if the hazards associated with the intended fuel warrant it. For more information see www.hc-sc.gc.ca/cps-spc/advisories-avis/aw-am/torches-eng.php

Ontario Section 34 Notifications

Companies experienced in importing and manufacturing chemicals in Canada will likely have heard of the federal New Substances Notification Regulations (NSNR). What many companies may not be aware of is a requirement to provide a notification prior to manufacture, import or introduction of a “new” substance into a workplace in Ontario. This notification program falls under Section 34 of the Ontario Occupational Health and Safety Act (OHSA) and is often referred to as the Ontario Section 34 (S.34) notification requirements.

S.34 notification requirements are not superceded by the federal NSNR, but rather they complement each other. The focus of S.34 is to protect the health and safety of workers by assessing new substances (referred to as agents). The focus of the NSNR is the safety of the general public and the environment.

Unlike with the NSNR, there are no *de minimus* volume triggers under S.34; therefore, importing, manufacturing or introducing any quantity of a “new” agent to an Ontario workplace would trigger the need for notification. Under S.34, however, there is no need to await the results of the government’s assessment to begin activities with the agent.

An inventory of substances considered to be NOT “new” to Ontario does exist but unfortunately, it is not entirely publicly available. To determine if an agent is “new” under S.34, you can search the original TSCA inventory of 1979. If the agent is on this inventory, then it is deemed not “new”. If not found on the inventory, you can send a formal letter of intent to the Ministry of Labour (MOL) advising them of your intent to manufacture, import or introduce the substance into a workplace in Ontario. The MOL will then advise if the substance is “new”.

Exemptions from notification under S.34 do exist; however, the exemptions are sometimes slightly different than those under the NSNR. For example, the substances in the ink in a pen imported into Canada are currently exempt from the NSNR notification requirements. However, under S.34 the agents in the ink in a pen imported into an Ontario workplace are not exempt.

Many years ago, the Ontario government declared their intent to repeal S.34 of OHSA, but the program continues to be in full force and some companies continue to comply. There have been discussions between the federal and provincial governments to develop an information-exchange program, but insufficient progress has been made to suggest that the repealing of S.34 will occur anytime in the near future.

Tox Tip... Klimisch Ratings: What are They?

Assessing the validity and reliability of toxicological data is necessary to ensure that risk assessments of chemical substances are based on unbiased and accurate data. The GDCH (German Chemical Society) Advisory Committee on Existing Chemicals of Environmental Relevance developed a study-report rating system in order to provide a standardized approach for scoring studies based on their perceived reliability. This system was described on behalf of the GDCH by H.J. Klimisch et al. (1997) and is referred to as the Klimisch rating system.

Experts in the field of toxicology and ecotoxicology use the Klimisch rating system to characterize the reliability of study reports by considering a number of criteria including: the study’s adherence to internationally accepted testing methodologies (e.g., OECD or EU guidelines); whether the procedures and results are clearly described; and if the results seem plausible. Once the Klimisch criteria have been assessed for a particular study report, a reliability rating is assigned. According to Klimisch 1997, there are four possible reliability ratings:

1. “Reliable without Restriction” - study conducted or appears to have been conducted according to Good Laboratory Practices (GLP) and accepted guidelines with insignificant or no deviations from the guideline, and there is no apparent reason to distrust the study results.

2. “Reliable with Restrictions” – study conducted or appears to have been conducted according to GLP and accepted guidelines but deviations from the guidelines or errors in the study may have compromised the results of the study; however, the study is still scientifically acceptable.
3. “Not Reliable” – study report reveals major deviations from acceptable guidelines and results should not be relied upon to form a conclusion.
4. “Not assignable” – insufficient detail provided to determine the quality of the report. (Abstracts and summaries are often assigned a rating of 4.)

The Klimisch rating system plays a crucial role in the EU’s program for the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH). Study reports summarized in the Registration phase of REACH must be Klimisch rated to ensure reports are of acceptable quality to fill required endpoints. Klimisch ratings can also be used as a standardized approach for grading and ranking the reliability of multiple reports for the same endpoint, thereby helping the owners of data recuperate some of the money they invested in testing when their quality test reports need to be shared with others who have a common interest in a REACH-controlled substance.

continued on page 4...

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

Cantox can assist your company in the following technical and regulatory areas:

Consumer Chemicals and Containers Regulations (CCCR), 2001

Our experience in classifying products in accordance with the CCCR requirements can alleviate the need for product testing. We can conduct literature searches to locate existing information on the components of a product and determine the classification of the product. This can help you avoid costly and time-consuming testing. In addition, we can assist you in completing the CCCR checklist and provide a label mock-up and instruction sheet for your product.

Klimisch Ratings for REACH

Our seasoned toxicologists, chemists and regulatory professionals are available on-demand to assist individual companies, consortia or SIEFs. Our scientific and regulatory experience includes the effective review and Klimisch evaluation of more than 1000 study reports currently being considered for REACH Registrations.

Ontario Section 34

With our understanding of this provincial notification program, we can help you determine whether notification is required and what information is demanded. We can prepare a notification that is sufficiently detailed to ensure prompt acceptance and assessment by the Ministry of Labour. As we work with the government regulators on a daily basis, we can offer pre- and post-notification consultation with the authorities on matters relating to the notification and assessment of a new agent.

Chemicals Management Plan

Cantox's experts can help you to stay on top of program developments by offering the following efficient and cost-effective services:

- Updating you on the status of current and future Batches;
- Determining your obligations to respond to S.71 Notice(s);
- Preparing responses to survey questionnaires;
- Informing you of any relevant Screening Level Risk Assessment notices; and
- Providing strategic advice on how screening assessment reports and risk management scope documents may impact your current or future business.

Cantox also offers new substance notification services and workplace hazard-communication assistance for many jurisdictions worldwide.

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:

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or by phone: 905-542-2900

We're here to help!

Tox Tip... Klimisch Ratings: What are They?

...continued from page 3

Under REACH, registrants are typically placed into groups (called SIEFs) with other registrants of the same substance. Each SIEF must assemble a common dataset to be used for Registration and Classification purposes. As part of this effort, all available study reports are rated according to the Klimisch criteria and, depending on study reliability and other factors, a "key study" is identified for each regulatory endpoint. The owner of the key report may be compensated by other registrants in the SIEF, for costs incurred in conducting the study.

Given the EU REACH requirement for Klimisch ratings and given the bartering power that these ratings carry, it behooves companies to ensure that they understand the Klimisch-rating criteria and can defend their rating decisions.

Ref: *Klimisch HJ, Andrae M, Tillmann U (2007). A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regul Toxicol Pharmacol 25(1):1-5.*

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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