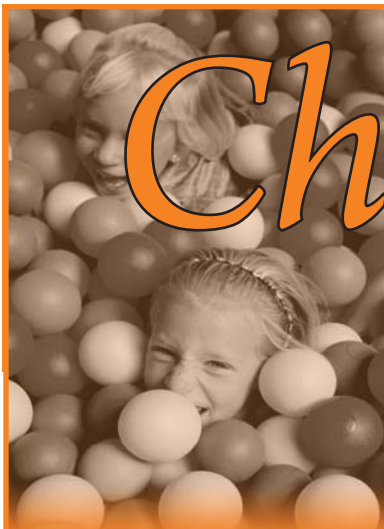


CHEMICALS

UPDATE

Spring 2011

...brought to you by
the
Chemicals Group
at Cantox Health
Sciences International
An Intertek Company



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If you have any questions regarding the contents of this newsletter, contact:
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Chemicals Management Plan Update

The Canadian Chemicals Management Plan (CMP) is a joint initiative between Environment and Health Canada (EC/HC) to assess and manage the risks associated with 4300 legacy substances identified through the categorization of the Domestic Substances List (DSL). The substances were prioritized for action into high (500), medium (3000), and low (750) categories. The CMP is science-based and designed to protect human health and the environment through activities in 4 major areas:

- Increasing industry stewardship role in actively managing the risks posed by the chemicals they produce and use;
- Taking action on chemical substances of high concern;
- Taking action with specific industry sectors; and
- Investing in research, monitoring and surveillance.

The data-gathering activities (*i.e.*, the Challenge and some sector-specific activities – see previous newsletters for more information) for the high-priority substances are now complete and final risk assessments have been published, with the exception of Batches 11 and 12 reports as drafts only. Risk-management tools are being developed for those substances that meet the Canadian Environmental Protection Act (CEPA) toxic criteria.

Of the high-priority substances handled under the Challenge, the government has concluded that approximately 39 are worthy of the designation “CEPA toxic” and an additional 5 have draft assessment conclusions declaring intent for the designation as “CEPA toxic”. The proposed risk-management actions on these substances range from limiting consumer exposure (*e.g.*, by applying Significant New Activity (SNAC) restrictions or adding the substance to the Cosmetic Ingredient Hotlist) through to the

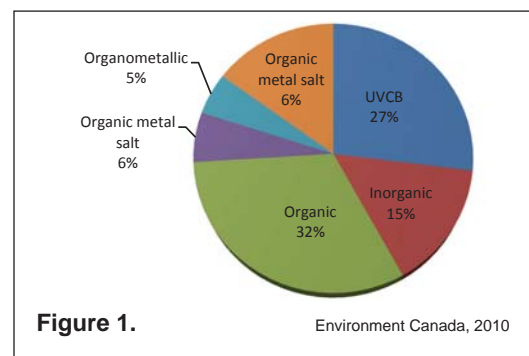
application of a “Virtual Elimination” requirement for at least 4 substances.

For many substances used in manufacturing processes in Canada, Risk Management actions have focused on the requirement for Pollution Prevention (P2) Plans.

Thus far under the CMP, SNACs have been used primarily when earlier survey results indicated that market activity for a substance was below the reportable threshold identified in the survey, but the hazardous properties of the material triggered concern that new activities for the substance could meet the criteria for designation of the substance as “CEPA Toxic”. The SNAC would have been applied to ensure that any new manufacture, import or use in quantities greater than the preset threshold of 100 kg/year is subject to Notification, which allows the government to perform a risk assessment prior to permitting use of the substance in Canada above that threshold.

It is important that companies and industry groups stay engaged and provide input into the CMP processes to ensure that industry’s product stewardship practices are taken into consideration in the government’s development of formal risk-management tools.

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Chemicals Management Plan Update ...cont'd

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Next Steps:

Moving into the next chapter of CMP activities (CMP-2), EC and HC are now beginning to actively address the remaining ~3800 substances that were categorized earlier into the medium- and low-priority groupings. Figure 1 (see page 1) provides a quick overview of the 3000 medium priority substances.

The authorities are working to group substances by chemical class, chemical structure, mode of action, industry sector, and/or use profile to enable efficient risk assessments. The accurate, appropriate grouping of these substances requires informed stakeholder input since assessment outcomes and any resulting risk-management actions may be applied across the entire group.

The action plan to assess the CMP-2 substances will be based on lessons learned from the first 3-years of the CMP. Government will continue to work with other jurisdictions to augment the knowledge-base for these substances and determine priorities, and authorities have committed to a transparent process. Stakeholders and the public have been told that they will know when to expect requests for information and decisions.

CMP-2 may not follow "challenge-like" timelines (e.g., 3-month data-gathering periods and 6-month review periods), and would be more likely tailored to the level of complexity and scope of the assessments for each substance grouping.

Priorities within CMP-2 could include:

- Low-volume substances with anticipated or predicted high-hazard endpoints of concern (e.g., carcinogenicity, mutagenicity, reproductive or development toxicity);
- Substances with exposure levels of potential concern for children or consumers;
- High-volume substances which are predicted to be persistent and inherently toxic;
- Substances predicted to result in cumulative exposure to organisms (e.g., multiple substances leading to environmental formation of a common moiety of concern); and
- Substances brought forward to replace "CEPA-toxic" substances.

Industry has played an important role in the success of the CMP. Stakeholders need to continue to ensure that science-based decisions are given due consideration in the assessment and management of priority substances. By working with the government to explore and assess opportunities for innovative risk-assessment approaches (e.g., substance groupings) and innovative risk-management approaches (e.g., sectoral approaches) industry can join hands with the government to ensure that effective policies for environmentally-sustainable economic growth are designed and implemented.

Cantox can assist you and your company to support the CMP process in a manner that addresses your market needs. More specifically, we can help you: respond to government surveys; provide additional technical input into the assessment process; and negotiate with regulators regarding proposed hazard-assessment outcomes and risk-management measures.

Contact Joyce Borkhoff, the Director of our Chemicals group for more details about how we can help at: chemicals@cantox.com.

Quick GHS Update

The United Nation's (UN) initial target date of 2008 for the implementation of the Globally Harmonized System for Classification and Labelling (GHS) has come and gone. While many countries such as Japan, China, and New Zealand achieved GHS implementation by the end of 2010, others continue to develop the regulatory instruments necessary to put this initiative into practice.

- **Australia** has finalized legislation to put the GHS requirements into practice.
 - Implementation of the new framework is expected to begin in 2012;

- Transitional arrangements are likely to continue for 5 years.
- **Mexico** is modifying their own chemical hazard communication laws to implement the GHS requirements.
 - No date has been announced for when these amendments will be published.
- **United States** issued a draft rule on September 30, 2009.
 - Draft rule was open for public comment until December 29, 2009;
 - Final rule is expected in August of 2011.
- **Canada** is planning to amend the Workplace Hazardous Materials Information System (WHMIS)

legislation to enact portions of the GHS.

- Implementation was originally targeted for 2008;
- Waiting for US rule in recognition of cross-border interests;
- Revised timeline has not yet been published.

Need assistance with GHS classification or SDS and label preparation? Contact our Hazard Communication specialists by email at: chemicals@cantox.com

To see the current text of the GHS (Revision 3) visit the following link: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

Environmental Assessment Regulations and In-Commerce List for Food & Drug Act Substances

Announcement and Intent of EAR Development

On September 13, 2001, the Minister of Health confirmed the government's intention to proceed with the development of new Environmental Assessment Regulations (EAR) for new substances present in products regulated under the Food and Drugs Act (F&DA). Until the new EAR come into effect, these F&DA-regulated, "new substances" would be subject to reporting requirements prescribed under the existing "New Substances Notification Regulations (NSNR)" under the Canadian Environmental Protection Act (CEPA).

How Do the NSN Regulations Work?

The CEPA is Canada's primary piece of environmental legislation. Under this act, the prescribed information requirements for notification of "new substances" are outlined in the New Substances Notification (NSN) regulations. A substance is considered "new" to Canada if it is not present on the Domestic Substances List (DSL), a registry of some 26,000 chemicals, polymers and products of biotechnology that are officially recognized as existing in commerce in Canada. A notifier wishing to manufacture and/or import a non-exempt new substance must submit the prescribed information to Environment Canada.

The NSN regulations operate on a volume-based tiered system wherein the amount of information required in a notification is directly related to the amount of unlisted ingredient to be introduced into Canada. The information requirements address topics such as physical-chemical properties; mammalian and aquatic toxicological properties; transport, storage, handling, use and disposal activities; environmental release potential; and human exposure information. Environment Canada and Health Canada then determine whether the substance poses an unreasonable risk to the environment and human health. The assessment must be completed within 5 to 120 days, depending on the notification type (*i.e.*, "notification Schedule") that was submitted. If the government requires more time to assess the substance, they are entitled to double the prescribed assessment period.

It is important to note that the notification process is a tiered system requiring subsequent notifications as the annual amount of the imported or manufactured substance increases. Once the maximum amount of information has been submitted to the government, the assessment period has expired, and the government receives a subsequent notice from the notifier indicating that the notifier has manufactured or imported the substance, the substance will be eligible for addition to the

Domestic Substances List provided that no notifier-specific conditions on the import or manufacture of the substance have been imposed as a result of the assessment process.

If all DSL-listing eligibility criteria have been met, Environment Canada is required to add the substance to the DSL within 120-days after eligibility.

How Will the New EAR Work When in Place?

When the Environmental Assessment Regulations are finally developed, they will replace the current NSN regulatory requirements for substances present in products regulated under the Food and Drugs Act. The Environmental Assessment Unit of Health Canada is expected to oversee the EAR notifications.

These new regulations are intended to reflect the government's prediction of the unique properties of these substances and, accordingly, the EAR are expected to trigger regulatory-reporting requirements at lower import and manufacture quantities as compared to the current reporting requirements under the existing NSNR.

Purpose and Creation of the In-Commerce List

In order to refine the definition of "new substances" for the EAR, action was taken by the government to form an administrative inventory of existing F&DA substances called the In-Commerce List (ICL). F&DA-regulated substances that were known by the government to be in Canadian commerce between January 1, 1987 and September 13, 2001 were eligible to be placed on the ICL.

With the creation of the administrative ICL, F&DA-regulated substances now fall into 1 of 3 categories:

- **Notification and Assessment under of the NSNR:** Substances manufactured, or imported into Canada for the first time after September 13, 2001 are subject to the notification and assessment requirements under the NSNR of CEPA until the EAR are developed. The NSNR assessments for F&DA-regulated substances are carried out by the Environmental Assessment Unit (EAU) within Health Canada;

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Environmental Assessment Regulations and In-Commerce List for Food & Drug Act Substances ...cont'd

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- **Grandfathering onto the DSL:** Substances that were manufactured, imported or introduced into Canadian commerce between 1984 and 1986 are eligible for addition to the DSL. Substances listed on the DSL are exempt from the notification requirements of the NSNR; and
- **Nomination to the ICL:** Substances that were known by the government to be manufactured, imported or introduced into Canadian commerce between January 1, 1987 and September 13, 2001 were placed, or are eligible to be placed, on the ICL. The ICL serves as a holding pen that will be taken into account when an assessment framework is developed to determine the potential environmental and indirect human health risks associated with these existing F&DA-regulated substances.

For the notification of "new substances" under the NSNR, the definition of "new" is defined by the absence of the substance from the DSL, a statutory inventory designated under CEPA. In contrast, the ICL is a policy-driven inventory that provides a guidepost to improve the understanding of "new" versus "existing" for F&DA-regulated substances. The ICL is not a statutory instrument; it is an administrative list designed to assist Health Canada officials in developing a framework that will direct the priorities and policies for protecting the health of Canadians and their environment until a full regulatory structure for F&DA-regulated substances is in place. The list is a way to recognize that these substances were placed into Canadian commerce in compliance with the regulations at that time but do not meet the timeline eligibility (*i.e.*, import/manufacture/sale between 1984 and 1986) to be grandfathered onto the statutory Domestic Substances List. It is anticipated that an assessment program will eventually be developed (either inside or apart from the EAR).

The ICL contains approximately 9000 substances found in pharmaceuticals, veterinary drugs, biologics and generic therapies, cosmetics, medical devices and food additives. The ICL consists of 4 sub-lists:

1. Substances in Human Pharmaceuticals, Veterinary Drugs and Similar Products In Commerce Between 1987 and 2001 - CAS Registry Number Known
2. Substances in Cosmetics and Personal Care Products In Commerce Between 1987 and 2001 - CAS Registry Number Known
3. Substances in Cosmetics and Personal Care Products In Commerce Between 1987 and 2001 - CAS Registry Number Not Found
4. Substances in Cosmetics and Personal Care Products In Commerce Between 1987 and 2001 - Ingredient or Mixture of Ingredients Unknown

In an effort to more accurately identify the substances listed on the ICL, Health Canada published a Notice of Intent, on September 4, 2010, to begin the formal nomination process to add eligible substances to the ICL. Up until this time, industry had been submitting requests for addition to the ICL on an informal and ad hoc basis. The purpose of this more formal initiative is to streamline industry's participation in the creation of the ICL and to ensure that substances listed on the "current" ICL are correctly identified and verified by Health Canada. This updated list will be referred to as the "revised" In-Commerce List. Health Canada is encouraging stakeholders to participate in a collaborative effort to revise the ICL by making nominations of substances believed to meet the eligibility criteria. Once the government receives and verifies the information of a nomination, the nominated substance will be added to the revised List.

The nomination process is divided into Phase I and Phase II. Phase I was from July 2010 to October 2010, for a group of pre-selected nominators. Phase II is anticipated to commence in March 2011 and conclude in August 2011. This phase will be open to all interested nominators.

**For more information
on the development of the EAR,
or how to nominate substances
to the DSL or the ICL,
contact the
Cantox Chemicals Group at:
chemicals@cantox.com
or by phone: 905-542-2900**

We're here to help!!

The OECD Parallel Process

Chemical companies wishing to notify new substances in multiple regulatory jurisdictions should consider the OECD's Parallel Process program (www.oecd.org). The pilot phase of this program, which began in 2006, allows notifiers to identify target jurisdictions, nominate Lead and Secondary Countries, and then submit a proposal for a Predetermined Set of Information (PSI) to a panel of those target jurisdictions for discussion in a Pre-Notice Consultation (PNC). Following the consensus-building PNC, the agreed-upon PSI is collected or generated by the notifier and then submitted to the Lead Country in their notification format. Following the assessment of the data, which proceeds per the Lead Country's standard regulatory process, a draft hazard assessment is prepared by the Lead Country, and shared with the Secondary Countries and the notifier. When the jurisdictions and the notifier reach consensus on the hazard assessment, the notifier submits the country-specific information to each of the Secondary Countries.

The objectives of the Parallel Process are to:

- i. enable countries to work cooperatively to increase understanding and acceptance of hazard assessments of new substances; and

- ii. provide industry with an opportunity for multi-jurisdictional consensus on the hazard assessment of the substance and a streamlined approach to new substance notification in key markets.

Cantox has experience with the Parallel Process program, and we can assist notifiers with many facets of the process. Our scientific expertise and direct access to government leaders, allows us to effectively suggest alternative methodologies which could potentially address regulatory endpoints where data is not readily available, saving our clients the time and money associated with running testing programs. Cantox can assist clients in preparing the regulatory documents required to notify substances in such international jurisdictions as Canada, Australia, the EU, the Philippines, Korea, Japan and China, and can also liaise with clients and government officials to respond to questions, receive and review draft hazard assessments on the client's behalf, and provide feedback based on our expertise. All of these services support our clients' interests to notify their substances through the Parallel Process program quickly and easily, so you can bring your products to international markets as soon as possible.

**For more information on this valuable program and the services we offer, please contact
Karen Levins at: klevins@cantox.com.**

EU Product-Safety Activities

Classification, Labelling and Packaging (CLP)

On 20 January 2009 the EU Regulation on classification, labelling and packaging of substances and mixtures entered into force. It aligns the previous EU legislation (Dangerous Substances Directive (DSD)/Dangerous Products Directive (DPD)) with the United Nations Globally Harmonised System (GHS). The new Regulation will complement the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation and will ultimately replace the current rules.

- Substance classification and labelling needed to be consistent with the new rules by 1 December 2010;
- Mixtures must follow suit by 1 June 2015; and
- Manufacturers and importers needed to formally notify the European Chemicals Agency (ECHA) by 3 January 2011 of the classification of substances placed on the market that are:
 - subject to REACH Registration (for substances registered by 30 November 2010, notification was part of the registration dossier); or
 - classified as hazardous [even for substances exempt from REACH registration (e.g., naturally occurring substances like crude oil)] regardless of volume.

Extended Safety Data Sheet (e-SDS)

Under REACH, the e-SDS will be the primary tool for the transfer of hazard information, exposure scenarios, and required risk management measures in the supply chain. The e-SDS is currently only required for substances that are sold in quantities of more than 10 tonnes per year, which are classified as hazardous. If a Registrant's Chemical Safety Assessment (CSA) has identified a substance as hazardous, the Exposure Scenarios (ES) from the subsequent Chemical Safety Report (CSR) need to be annexed to the SDS. The SDS combined with the ES is referred to as the e-SDS.

When an EU customer receives an e-SDS, they are expected to identify the relevant ES(s) for their particular uses and then apply the appropriate risk management measures.

**If you require technical support
for understanding and complying with REACH,
CLP and e-SDS requirements,
contact Tracy McGinnis at:
chemicals@cantox.com.**

Protecting Your Secret Substance Identity under REACH

Notwithstanding REACH's right-to-know mandates, registrants are able to claim substance identity confidential under certain circumstances. In order for ECHA to accept the confidentiality request, registrants must provide a public name in their dossier, and these public names must be created in accordance with the recently-published guidance manual from the European Chemicals Agency (ECHA).

The rules presented in the manual describe the masking of various structural elements in the IUPAC name in order to derive a public name with a single level of masking. Valid justifications are required for each additional level of masking and up to 3 levels may be permitted. If the confidentiality claim is rejected, the IUPAC name will be published.

Existing registrants who requested confidentiality, and did not provide an adequate public name had the opportunity to update their registration by 1 March 2011. In those cases where ECHA finds deficiencies in the public name, the registrant will be informed and will have one opportunity to correct the name.

The masked-name system adopted by ECHA draws heavily on experience from Canada's treatment of masking substance identities. Cantox's senior chemist, Neil Bullock, has been preparing Canadian-compliant masked names for over 13 years.

For more information on how we can help you apply this experience to support your CBI (Confidential Business Information) interests under REACH, contact Neil Bullock at: 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 and masked names. 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/SDS 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 or by phone: 905-542-2900.**

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