



# CHEMICALS

## UPDATE

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

### Background on the Chemicals Management Plan: Challenge to Industry and an Update on the Progress

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#### Background

On December 8, 2006, the Canadian Government revealed Canada's Chemicals Management Plan (CMP). The CMP affects chemicals covered by a number of regulations including the Canadian Environmental Protection Act (CEPA), the Pest Control Products Act (PCPA) and the Food & Drugs Act. The CMP was put in place to proactively manage the risks to human health and the environment associated with the use of certain chemicals in Canada.

Since 2007, the industrial chemical industry has been particularly focussed on responding to the Challenge to Industry.

#### What is the Challenge to Industry?

A key element of the CMP is the collection of information on the properties, uses, and risk management measures currently in place for approximately 200 chemical substances identified as high priorities for action through the government's Categorizing and Screening of the Domestic Substances List (CSDSL) efforts\*.

Based on the outcomes of the CSDSL efforts, the government is predisposed to considering substances under the Challenge to be "toxic" (as defined under Section 64 of CEPA 1999) due to their potential hazards to environment and/or human health. Therefore, the challenge posed to industry is to contribute new information about the hazards and how these chemical substances are currently being managed. Armed with this new information, the government will make better informed risk-assessment and -management decisions.

*\*See Cantox's Fall 2002 Newsletter and our 2001 Year in Review for more information about the CSDSL.  
<http://www.cantox.com/PDFS/Chemicals/2002.pdf>  
<http://www.cantox.com/PDFS/Chemicals/2001-newsletter.pdf>*

#### What does this mean to you?

The substances have been divided into 12 "batches" and if you manufactured or imported a "batch" substance in excess of 100 kg or used a "batch" substance in excess of 1000 kg (Batch 2-9) 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.

If you do not meet the mandatory reporting thresholds above, you may wish to complete the voluntary survey in order to provide additional information about the substance or your use of it to the government. You may also simply choose to submit a "declaration of stakeholder interest" to ensure you are kept up-to-date during the risk assessment and management process.

The Notice response or voluntary survey submission for each substance is your opportunity to identify your specific use of a substance and controls you have in place to mitigate any hazards associated with the substance and if the government has not already considered it, any relevant hazard data.

Taking into account the responses provided along with other information available, the government will complete a screening-level risk assessment (SLRA) for each substance. The outcome of the SLRA may mean that a substance is:

1. Deemed to require no further action;
2. Added to the Priority Substances List for further evaluation; or
3. Deemed CEPA toxic (and added to Schedule 1 of CEPA).

Each SLRA will be published in the Canada Gazette and the public/industry will be given an opportunity to comment. It is important for industry to participate in the Challenge initiative and provide data or comments where appropriate, because if a  
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# Background on the Chemicals Management Plan: Challenge to Industry and an Update on the Progress ...cont'd

substance is deemed CEPA toxic, management measures will be put in place. Those management measures may range from recommending established codes of practice be instituted industry wide, all the way to virtual elimination (*i.e.*, essentially banning the substance). Therefore, in order to attempt to protect your interest in a substance, your current practices and uses should be shared with the authorities.

The Chemicals Management Plan and the Industry Challenge require a great deal of effort on the part of companies to review, respond and maintain awareness of activities related to many chemical substances. This is a rather onerous task for industries which have been hard hit in these economic times and are being forced to do more with less people and resources. Cantox's experts can help you to stay on top of these regulatory requirements by offering efficient and cost-effective services related to responses to the Notices under the Challenge, preparation of survey questionnaires, and knowledgeable advice on how SARs and proposed/final RM Scopes may impact your current or future business. Our staff have not only a wealth of experience in science and

regulatory affairs, but real practical knowledge gained through many years of work in industry.

Please contact Karen Levins (klevins@cantox.com) or Tracy McGinnis (tmcginnis@cantox.com) in the Chemicals Group to discuss how we can help you to comply and protect your company's interest in substances subject to the CMP.

## Updating Challenge Information and Dates

Batch Releases	Section 71 Data Submission		Publishing Date of Draft SARs/RM Scopes*		OUTCOMES		Publishing date of Final SARs/RM Approaches	
	(Number of substances)	Launch date	End date	If no new info is provided	If new info is provided	Number of substances deemed CEPA Toxic	Number of substances dropped from further consideration**	If no new info is provided
Batch 1 (15)	3-Feb-07	5-Jun-07	n/a	19-Jan-08	9	6	n/a	5-Jul-08
Batch 2 (17)	12-May-07	12-Sep-07	n/a	17-May-08	9	8	n/a	31-Jan-09
Batch 3 (19)	18-Aug-07	18-Dec-07	n/a	23-Aug-08	4	15 (3)	n/a	7-Mar-09
Batch 4 (18)	17-Nov-07	18-Mar-08	n/a	24-Jan-09	5	13 (5)	n/a	1-Aug-09
Batch 5 (19)	16-Feb-08	17-Jun-08	n/a	21-Feb-09	2	17 (1)	n/a	22-Aug-09
Batch 6 (18)	31-May-08	30-Sep-08	n/a	30-May-09	-	-	n/a	28-Nov-09
Batch 7 (14)	30-Aug-08	13-Jan-09	6-Jun-09	5-Sep-09	-	-	5-Dec-09	6-Mar-10
Batch 8 (14)	31-Jan-09	2-Jun-09	31-Oct-09	30-Jan-10	-	-	1-May-10	31-Jul-10
Batch 9 (17)	14-Mar-09	14-Jul-09	19-Dec-09	20-Mar-10	-	-	19-Jun-10	18-Sep-10

\* SARs=Screening Assessment Reports; RM Scopes=Risk Management Scope Documents.  
 \*\* The # in brackets is the # of substances included in this category, which are not currently anticipated to be entering the environment as a result of commercial activity; therefore, they will be subject to the Significant New Activity (SNAC)† provisions under CEPA. The SNAC provisions allow the government to gather additional data about these potentially CEPA-toxic substances if reintroduced to Canada in the future.

## European Union GHS Implementation

### What is the Globally Harmonized System (GHS) of Classification and Labelling?

The 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 *via* labelling and SDS. Many countries have agreed to implement GHS for some or all of the various sectors to which it applies. As one can imagine, countries with pre-existing hazard classification and labelling systems will have a different set of challenges to implementation from those countries where current systems do not exist.

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.*, industrial or commercial use, consumer

applications or pesticide purposes) and for transport, reducing barriers to international trade. Industry and governments also hope that by using internationally agreed-upon classification criteria and label elements, protection of humans and the environment from hazardous chemicals will be improved.

However, country-specific adaptation of the GHS criteria may make this impossible. 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.

### How is the EU Implementing GHS?

The EU has implemented some of the aspects of GHS under the REACH legislation (Registration, Evaluation, Authorisation and Restriction of Chemicals) which entered into force on June 1, 2007. In particular, the GHS recommendations for SDS format are provided in Annex II of the REACH Regulation (EC No. 1907/2006 as amended). (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF>)

# OECD Analysis of Polymer of Low Concern Characteristics

## Background

New chemical notification legislation in many countries provides for reductions in regulatory requirements when notifying a new polymer that is deemed to be of 'low concern'.

In 2007, the OECD Task Force on New Chemicals Notification and Assessment commissioned an Expert Group to study the various qualification criteria used to define 'polymers of low concern' (*i.e.*, PLCs). The objective of the OECD study was to identify correlations between polymer characteristics and the potential for human health or ecotoxicological concern. In January 2009, the OECD published the Expert Group's study results.

## The Analysis

With Australia acting as the lead country for this study, information on 205 polymers was collected from Australia, Canada, Japan, Korea, and the USA. Using information on physical-chemical properties, structural features and reactive functional groups, polymer class, health toxicity, ecotoxicity and biodegradability, the OECD Polymer Working Group identified and investigated various correlations to assess the validity of existing PLC classification criteria.

## OECD Conclusions

Overall, the Working Group concluded that the study results generally supported the assertion that polymers meeting PLC criteria have insignificant human health or environmental

impacts and, as such, the reduction in regulatory requirements for these polymers is scientifically justified. The Working Group offered that future work could be aimed at refining and widening the scope of evaluating the PLC criteria by establishing ways to remove the conservative assumptions that were used to address uncertainties in the understanding and analysis of some of the datasets.

For the full report, visit:  
[www.oecd.org/dataoecd/3/23/42081261.pdf](http://www.oecd.org/dataoecd/3/23/42081261.pdf).

## What Do PLC Criteria Mean to Notifiers in Canada and Australia?

As indicated above, many jurisdictions allow for reductions in the notification requirements for substances meeting their own definition of a PLC. Under Canada's New Substances Notification Regulations (NSNR), Polymers of Low Concern are referred to as Reduced Regulatory Requirement Polymers (RRRP). The NSNR's RRRP criteria are primarily based either on polymer class (*i.e.*, certain polyesters), or on the polymer's number-average molecular weight, percent residuals below 500 and 1000 Daltons, elemental constituency, degradability, cationicity, and presence of certain reactive functional groups of interest. Under Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the PLC criteria are very similar to the Canadian RRRP criteria, but the NICNAS PLC criteria have been extended to specifically deny PLC status to water-absorbing polymers and to polymers classified in Australia as a 'hazardous chemical'.

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The remaining aspects of GHS classification and labelling are being implemented in the recently-published Regulation on classification, labelling and packaging of substances and mixtures (CLP) (EC No. 1272/2008) which came into effect on January 20, 2009. (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>)

The CLP Regulation ultimately will repeal the pre-existing Dangerous Substances and Dangerous Preparations Directives (DSD 67/548/EEC and DPD 1999/45/EC) which previously provided classification and labelling requirements for chemical substances placed on the market in the EU.

The deadline for substance classification according to the CLP will be December 1, 2010 and for mixtures June 1, 2015. This transitional period gives suppliers the opportunity to learn the new rules and apply them to their products without having to immediately reclassify or relabel products already on the market.

Suppliers may choose to classify their products according to the CLP immediately; however, classification according to the

old DSD/DPD system must still be carried out until December 1, 2010 and June 1, 2015 respectively and this classification/labelling information must be provided in the SDS. In cases where classification according to CLP is undertaken before the deadlines given above, labelling of the product must be in accordance with the CLP requirements.

Understanding and classifying products according to this new legislation, may require experts in toxicology and chemistry to accurately classifying your products. Cantox is the leading toxicology and scientific consulting firm in North America. Coupled with our unparalleled scientific expertise, we have experts trained in the new CLP requirements to enable us to efficiently classify, label and prepare compliant SDS for your products. Our staff are available when you need them, so if you have 1 or 100 SDS you need prepared we can assist with dedicated, as needed staff, to fill your company's needs.

Contact Tracy McGinnis ([tmcginnis@cantox.com](mailto:tmcginnis@cantox.com)) in the Chemicals Group to discuss how we can help you update your current SDS or classify and label new products you wish to send to Europe.

# OECD Analysis of Polymer of Low Concern Characteristics ...cont'd

## Benefits Associated with Notifying a Polymer as a RRRP/PLC

Having a notifiable polymer classified as an RRRP/PLC will significantly reduce the cost and time associated with preparing and processing a new substance notification in Canada or Australia. RRRP/PLC notifications routinely require less test data and lower government filing fees. In Canada, RRRP notifications also qualify for reductions in the usual requirement for detailed exposure and use information. Following successful government assessment, RRRP/PLC notifications trigger eligibility for import or manufacture in unlimited quantities.

## Challenges Associated with Notifying a PLC

Classifying a polymer as a PLC (or RRRP) can be a complex process. Oftentimes, notifiers find themselves needing to provide robust technical reports that justify the PLC classification of their polymer. Failure to provide sufficient justification or to provide adequate test-report documentation has jeopardized PLC status and has been shown to significantly delay the approval process.

In Canada, a complete reaction scheme detailing the manufacturing process for a low-concern polymer must be provided as part of an RRRP notification, regardless of whether the polymer is domestically manufactured or imported. This requirement for a reaction scheme can be difficult to meet if the Notifier's foreign supplier is reluctant to share their confidential business information.

## Cantox Can Help You Overcome These Challenges

Cantox is an internationally-recognized, third-party consulting firm offering polymer expertise that has been well tested and proven invaluable. With more than 15 years experience in new substance notification, we have successfully prepared and shepherded more than 250 polymer notifications through the Canadian and Australian notification processes.

The vast majority of these notifications have contained Confidential Business Information that was entrusted to us under the protection of secrecy agreements between Cantox and the notifier's foreign supplier. Using this sensitive information, our experts have been able to prepare sufficiently robust PLC-justification reports that allowed for successful PLC/RRRP notification and advanced the business interests of both the notifier and their foreign supplier.

Given the number of complex PLC notifications that we have successfully cleared over the past 15 years, Cantox has developed a close working relationship with many government evaluators. Our ability to work with the evaluators in a trustworthy and transparent manner means that our clients benefit by having ready access to our expert knowledge on the latest policies and trends, thereby improving the accuracy of our predicted notification outcomes and allowing clients to plan accordingly.

For more information on the notification services that Cantox offers to companies who are interested in efficiently expanding their business in Canada and in Australia, please contact us at [chemicals@cantox.com](mailto:chemicals@cantox.com). We're here to help!

## TOX Tip...

Under the Canadian New Substance Notification (NSN) Regulations some higher-level notification Schedules require submission of an acute toxicity study as one of the toxicological endpoints. Acute toxicity can be tested by oral, dermal or inhalation routes of exposure, depending on the most significant route of potential human exposure. Testing conducted for the purposes of meeting NSN notification requirements must be done under conditions consistent with the appropriate Organisation for Economic Cooperation and Development (OECD) Testing Guideline. The OECD provides many different acute Test Guidelines including a number specifically for the oral route of exposure. OECD Test Guideline 401 (Acute Oral Toxicity) was deleted by the OECD in December 2002 in favour of some of their less animal-intensive testing guidelines for oral toxicity [*i.e.*, OECD 420 (Acute Oral Toxicity - Fixed Dose Procedure), 423 (Acute Oral Toxicity - Acute Toxic Class Method) and 425 (Acute Oral Toxicity - Up- and Down-Procedure)].

NSN guidance indicates that acute toxicity data generated after 2002, utilizing OECD test guideline 401, will not be considered acceptable to fulfill the regulatory requirements for this endpoint. Thus, submitting a notification to the Canadian authorities with such a study to fulfill the acute oral toxicity endpoint may result in the Notification package being rejected. Anyone conducting toxicity testing for NSN purposes should ensure that their chosen laboratory is aware of the nuances associated with the Canadian notification requirements.

Cantox's team of regulatory professionals and toxicology experts offer a long and successful history of placing and monitoring safety studies. For more than 25 years, Cantox has helped companies do the right thing, the right way, the first time. Need help?

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

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