Chemicals Update

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Vision and Value of the OECD's Clearing House on New Chemicals (CHNC)

The OECD CHNC gathers together representatives from interested governments and from the chemical industry to explore and develop opportunities that reduce overall burdens associated with new chemical notification reviews, without compromising the high quality of health and safety decisions. These opportunities focus on streamlining the New Chemicals notification and assessment processes by: (i) enhancing information-exchange and work-sharing; (ii) facilitating greater mutual recognition of assessments (MRA), and (iii) progressing towards mutual acceptance of notifications (MAN).

The CHNC vision is for a sustainable world where:

- "Countries can see, understand and accept each others' decisions aimed at protecting human health and the environment;
- Companies can submit one notification and then market globally;
- Countries and companies are more efficient and effective in their activities related to new chemicals;
- This world will be achieved within an equivalence framework, if applicable."

The CHNC's activities are generally distributed across themes.

- Work Item A: Parallel Process
- Work Item B: Exemptions and Exclusions (including polymers)
- Work Item C: Electronic Notification Software
- Work Item D: Outreach and Communications

Work Item A activities bring together notification experts from industry and government to develop operating protocols and explore possible standards for the development of templates and expectations for a pre-determined set of information (PSI) that support the direction of Mutual Acceptance of Notification. The results of industry and government pilot-testing have enabled the development of OECD Standard Operating Procedures that now deliver clear guidance on: industry and government communication protocols (including CBI protection), Pre-Notification Consultation Phase; and the Notification and Assessment Phase for new chemicals. The CHNC strongly encourages industry to step forward with more new chemical notification candidates for this Parallel Process.

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Work Item B activities currently focus on opportunities to expand the "polyester approved reactant list" (the List) that delineates those polyesters qualifying as "polymers of low concern" under US TSCA, Canada CEPA and Australia NICNAS jurisdictions. The two-pronged approach included the nomination of:

1. Reactants accepted as being "Equivalent" to reactants already present on the List
2. New reactants for which dossiers of information will need to be submitted

The nomination stages have been completed, and an announcement is expected soon regarding which reactants have been accepted as "Equivalent", and how to proceed with the preparation of information dossiers for nominated new reactants.

Work Item C activities currently focus on bringing together industry and government representatives to explore requirements and possible software solutions for generating forms to support the notification of a new chemical in multiple jurisdictions.

Work Item D activities are focussing on updating websites and developing promotional material that widens the awareness of the CHNC vision and the value of its activities. Efforts are also focussed on strengthening the linkages with the Asia-Pacific Economic Cooperation (APEC), especially as countries in the APEC region develop or refine their new chemical notification and assessment processes.

For more information on the vision and value of the OECD CHNC, contact Karen.Levins@Intertek.com

VOC Regulations in Canada are Changing

Environment Canada recently announced that the Canadian regulations regarding Volatile Organic Compounds (VOCs) will be amended. The proposed VOC Concentration Limits for Certain Products Regulations, initially published on April 26, 2008, have been revised to include the requirements of the VOC regulations currently in place for architectural coatings and automotive refinishing products. The revised proposed regulations would reflect the current VOC legislation repealed and the requirements for VOC limits in architectural coatings and automotive refinishing products included in the VOC Concentration Limits for Certain Products Regulations.

The revised proposed regulation will set concentration limits for VOCs in 98 categories of certain products, including personal care products, household maintenance products, adhesives, sealants and caulking, just to name a few. The proposed VOC limits are intended to align as closely as possible with those set by California Air Resources Board (CARB) to help manufacturers and importers meet the requirements in both Canada and the United States.

The government has published a consultation document that provides background information and outlines the proposed path forward regarding the revision of these proposed Regulations. The intent is to publish proposed regulations for certain products in the Canada Gazette, Part I, in the summer of 2014. The consultation document is available on-line at: www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=3851F293-1

The public consultation period expired March 22, 2013.

Do you have a question about the VOC Regulations or related topic?

Share your comments or questions on our blog (http://www.intertek.com/blog/2013-03-13-canada-voc-regulations/) or contact us at: chemicals.cantox@intertek.com and our experts will get back to you.

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Mixing, Blending and Formulating: Salt does happen!

A note of caution to all you formulators out there - when cold-mixing, blending or formulating (or whatever other name the activity goes by in your plant) your performance products for sale into Canada, 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 to see if you should expect them to form a salt, and if so, whether that salt is listed on the Domestic Substances List. If it isn't, then, by definition, it's a new substance, and is, therefore, notifiable.

The same consideration also should 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 at all, make sure that the CAS name and number you use to describe it adequately captures the counterions present, and are listed on the DSL.

Do you have questions about Canadian New Substances Notifications or other related topics?

Share your comments or questions on our blog (http://www.intertek.com/blog/2013-05-13-salt-happens/) or contact us at: chemicals.cantox@intertek.com and our experts will get back to you.

Government Releases Revised In-Commerce List

On May 3, 2013, the results of the nomination process were published on the Government of Canada's website http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/list/index-eng.php.

The Revised In-Commerce List (ICL) is an administrative list of Food & Drug Act (F&DA) substances that were identified as having been in Canadian commerce between January 1, 1987 – September 13, 2001; therefore, these substances were not eligible to be grandfathered onto the Canadian Domestic Substances List (DSL).

The Revised ICL is a policy-driven inventory that provides a guidepost to improve the understanding of "new" *versus* "existing" for F&DA-regulated substances in Canada. 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 to be grandfathered onto the statutory DSL. Substances listed on the Revised ICL should not experience market interruption in order to comply with the New Substances Notification Regulations (NSNR) of CEPA or the pending Environmental Assessment Regulations (EAR) developed to specifically address F&DA substances. It is anticipated, however, that a priority assessment program may eventually be developed (either inside or apart from the EAR) to manage any risk that may be associated with substances on this list.
The original ICL contained approximately 9,000 substances found in pharmaceuticals, veterinary drugs, biologics and generic therapies, cosmetics, medical devices and food additives, divided across four sub-lists:

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

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Government Releases Revised In-Commerce List...*cont'd*

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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 nomination process to the ICL. The purpose of this initiative was to ensure that substances listed on the ICL were correctly identified and verified by Health Canada. The updated list is referred to as the "Revised" ICL.

How does this affect Industry? Substances that are not present on the DSL or the Revised In-Commerce List are now considered to be "new" substances and may be subject to notification under the Canadian NSNR.

Do you need to nominate substances to the Revised In-Commerce List post formal nomination period? Do you have questions about the Revised In-Commerce List or the Canadian NSNRs or another related topic?
Share your comments or questions on our blog (http://www.intertek.com/blog/2013-05-06-publication-of-the-icl-update/) or contact us at: chemicals.cantox@intertek.com and our experts will get back to you.

Time is Ticking on Mandatory DSL Survey to Industry for 2700 Substances

The Domestic Substances List Inventory Update (DSL IU) is an initiative put forward by Environment Canada to gather and update the information on all the medium priority DSL-listed substances which were not captured under the Substance Groupings Initiative. The information requested by Environment Canada under the DSL IU will benefit risk assessment and risk management activities, inform priority setting and contribute to monitoring trends. The key objectives of the DSL IU will be to update the "commercial status" of substances, assist in planning for the next phase of the Chemicals Management Plan (CMP), inform the Rapid Screening Approach for lower-risk substances, and inform the Polymer Approach. Phase 1 of the DSL IU was initiated in 2009 and targeted ~500 chemicals and ~50 microorganisms. The deadline for data submission under Phase 1 of the DSL IU was March 30, 2010.

Phase 2 of the DSL IU, targeting ~2700 chemicals and polymers which were not captured in Phase 1, was published in the Canada Gazette on December 1, 2012 in the form of a Section 71 mandatory survey. Manufacturers and importers of these substances will be required to submit information pertaining to their specific use to Environment Canada using either the online Single Window Information Manager (SWIM) program or mail. The DSL IU involves a targeted approach with respect to reporting thresholds, the identification of which groups are required to report, as well as the categorization of manufactured items.

So, what do you need to do? To comply with the mandatory Section 71 survey, you'll need to collect, organize and report specific use and quantity information for any substances you manufacture or import at volumes that exceed the reporting thresholds. You will have to determine whether your substances meet those reporting thresholds based on raw sales data, and then compile that raw data and categorize your substances in order to prepare your response to the survey. If you do not have a SWIM account, you may wish to set one up with Environment Canada, since preparing and submitting the information by mail can be extremely laborious and time consuming. Make sure you submit the information before the September 4, 2013 deadline to ensure your company's compliance with this government program.

Do you have questions about the DSL Survey or related topic?

Share your comments or questions on our blog (http://www.intertek.com/blog/2012-12-10-canada-dsl-survey/) or contact us at: chemicals.cantox@intertek.com and our experts will get back to you.

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GHS in North America – How is it different from Europe?

After much anticipation, the Globally Harmonized System of Classification and Labelling (GHS) has hit North America!

On May 26, 2012, the amendment to the United States Hazard Communication Standard to adopt GHS came into effect. The final rule is commonly referred to as OSHA HCS-2012. The new rule requires that companies train their employees in the new safety data sheet (SDS) and label requirements by December 1, 2013. Chemical producers have until June 1, 2015 to ensure their labels and SDS comply with the new rule. Distributors do not need to comply until December 1, 2015. In the meantime, chemical producers and users can choose to comply with the old standard, the new standard or both.

OSHA HCS-2012 is based on the UN GHS "building block approach" and does not include all of the UN GHS hazard categories but does include some hazard categories not contained within the UN GHS. Similarly European Classification, Labelling, and Packaging (CLP) Regulation (EC) No. 1272/2008 is based on the UN GHS "building block approach". As such, while U.S. and European classification and labelling are similar, they are not identical. The following are examples where there are differences in which "building block" was adopted, differences in the definitions regarding classification, and/or differences in the cut-offs regarding mixture toxicity:

- Flammable Liquids
- Self-Heating Substances and Mixtures
- Acute Toxicity by Inhalation
- Serious Eye Damage / Eye Irritation
- Respiratory or Skin Sensitization
- Carcinogenicity
- Reproductive Toxicity
- Specific Target Organ Toxicity – Single Exposure
- Specific Target Organ Toxicity – Repeated Exposure
- Combustible Dusts
- Simple Asphyxiants
- Pyrophoic Gases
- Physical and Health Hazards Not Otherwise Classified

Canada is continuing to work towards amending the Controlled Products Regulations under the Hazardous Products Act and it is anticipated that these changes will be largely in-line with the new U.S. standard to facilitate more seamless cross-border trade. However, similar to the unique customizations demonstrated in jurisdictions that have already moved forward, there will likely be a few strictly Canadian requirements in the "new WHMIS".

If you have any questions about GHS implementation, or if you need assistance with GHS classification or SDS and label preparation, we can help! Contact our Hazard Communication specialists by email at: chemicals.cantox@intertek.com

South Korea Launches K-REACH

Did you know?
The South Korean Act on the Registration and Evaluation of Chemicals (K-REACH) was adopted by the National Assembly on April 30, 2013 and published in the official Gazette on May 22, 2013. K-REACH is scheduled to be implemented on January 1, 2015 and will require the mandatory registration and notification of manufactured and imported chemical substances, substances with potential to be hazardous to human health or the environment, and products containing hazardous substances. K-REACH will allow the Ministry of the Environment (MoE) to perform hazard and risk assessments and, based on the results of those assessments, identify substances as being subject to authorization by the MoE (with possible restrictions imposed by the MoE pending further information from notifiers) if the substance is deemed to be carcinogenic, mutagenic, a reproductive toxin, an endocrine disruptor, both bioaccumulative in humans, plants or animals as well as environmentally persistent, or possessing any similar or worse risks than those mentioned above. Products containing hazardous substances will be issued appropriate safety statements and labelling requirements by the MoE following risk assessment.

Are you prepared?
Manufacturers, importers and sellers of new or existing chemical substances into South Korea should be aware that, depending on volume information and whether the substance is deemed to be of concern to human health or

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the environment, volume and use reporting as well as registration and notification of the substance to the MoE may be required before manufacture or importation of the substance will be permitted. Exemption opportunities are available in certain circumstances. There are also obligations for suppliers of registered substances to provide information on those substances to downstream users and distributors.

What are your obligations?
The regulatory requirements for notification of new or existing chemical substances under K-REACH include use information, classification and labeling, physical-chemical data, and handling instructions (including control measures for substances with volume thresholds >10 tpa). Test plans may be submitted in lieu of test information, and there are opportunities for joint registrations if multiple users have interest in the same substance. The deadlines for registration of substances under K-REACH are based on tonnage bands and classification of substances, with greatest tonnage (>100 tpa) and most hazardous substances taking top priority. The deadline for registration of this first wave of substances is January 1, 2015, with subsequent deadlines in 2017, 2018, 2019 and 2020 for lower volume thresholds. There is still an obligation for manufacturers and importers to provide updated information to the MoE, following registration, if there are any changes to volumes, uses, hazards or risks.

How can we help?
Intertek Cantox has experience with the EU REACH program and access to a global network of scientific and regulatory staff. In our Mississauga office, we have a Scientific and Regulatory Associate fluent in the Korean language who further contributes to the effective and efficient management of these K-REACH projects. Our knowledge of the regulations and our ability to offer a "one-stop shop" for both testing and on-the-ground regulatory support can help you save time and money with preparing your registrations and notifications under K-REACH.

Come Visit Our New Blog!

Do you want to be kept up-to-date on regulatory issues that may affect your business? Check out what our expert, Joyce Borkhoff, is blogging about at www.intertek.com/blog/joyce-borkhoff to get the latest regulatory news, information and answers to your questions.

We're here to help!

As part of Intertek's Health, Environmental & Regulatory Services (HERS) Team, the Intertek Cantox Chemicals Group focuses on delivering scientific and regulatory consulting services including the following:

- Global New Chemical Notification
- CMP/Other Prioritization & Assessment Schemes Support
- Hazard Communication Training & Support
- (M)SDS Authoring
- Workplace & Consumer Label Advice
- Hazard Classification & Product Safety Evaluation
- Supply Chain Mediation & Government Relations
- Regulatory & Technical Support
- Food Contact Notification Support

…and more

Our clients save time and money and expand their business opportunities when we help them...
… streamline new product development programs and eliminate unnecessary steps;
… efficiently address scientific & regulatory issues prior to and during government review;
… negotiate workable solutions with governments when risk management actions are proposed;
... resolve issues of non-compliance in a timely and sensitive manner; and
… address the need to assign limited internal human resources to other critical priorities.

For more information on the scientific and regulatory services available from Intertek Cantox, contact:

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Chemicals Update is a periodic newsletter published by the Chemicals Group of Intertek 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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