Regulatory Essentials – October 17, 2018

Cosmetics Alliance Updates

Cosmetics 101 – Introduction to Cosmetics in Canada

Designed for New Employees and New Cosmetics Alliance Members

Objectives

- Learn the language of cosmetics in Canada
- Understand the set-up of Canadian Law
- Overview of the Cosmetic Regulations
- Enable attendees to access the Canadian market

Training will include exercises, a quiz and a training certificate for your training file.

Register

Health Updates

Introducing the New Health Product Inspections and Licensing Blog

The new blog is a convenient place to find current and past editions of Drug Establishment Licensing (DEL) Bulletins issued by the Health Product Inspection and Licensing Division. The blog also includes some recent notices to stakeholders.

GC Collab is a professional collaboration platform, connecting public servants from across Canada with external stakeholders such as DEL holders. GCcollab offers an innovative, open, and collaborative platform.

Join now & get the GCcollab app on iOS and Android

- Create an account on the GCCollab platform in order to access to our blog by visiting https://gccollab.ca
- Once your account is created, request access to the HPIL group page via https://gccollab.ca/groups/profile/804947/health-product-inspections-and-licensing-blog-blogue-des-inspections-des-produits-de-sante-et-octroit-des-permis
- use the “request membership” button

Should you have any questions regarding this Bulletin, please contact the DEL Unit at: hc.del.questions-leppp.sc@canada.ca

The blog will be updated every time a new DEL Bulletin is issued. At this time, we will continue to send the Bulletins by email.

New from Health Canada’s Consumer Product Safety Program

Health Canada has posted two new Consumer Product Enforcement Summary Reports that is relevant to Personal Care Products.

The Consumer Product Safety Program (CPSP) released the Cyclical Enforcement Project 2016 -2017 for Cosmetic Regulations on October 5, 2018. The purpose of this Cyclical

Enforcement (CE) project was to verify industry's compliance of cosmetics with specific requirements of the Food and Drugs Act and the Cosmetic Regulations. Specifically, Methylcholorisothiazolinone (MCI) and Methylisothiazolinone (MI) and MI/MCI combined were tested in cosmetic products. Prior to initiating this CE project, CPSP carried out a market survey to determine the presence of cosmetic companies in Canada. This effort resulted in CPSP sending out a notice advising companies of the risks posed by MCI and MI, and MCI/MI in combination, and of the new hotlist restrictions. Targets were then selected from that list of companies. Over the course of the 2016-2017 fiscal year, inspections at 40 establishments for 90 different products were carried out. Of these 90 products, chemical testing of 14 different products was carried out. The inspections and chemical testing resulted in 1 voluntary recall and 15 stop sales to address non-compliance. There were 74 instances where no corrective action was required.

In conjunction with the release of this report, the summary report for the Cyclical Enforcement Project 2017-2018: Cosmetic Regulations (Fragrances) was released. Certain substances on the Cosmetic Ingredient Hotlist indicated as being prohibited or restricted for use in cosmetics were tested, specifically those associated with fragrance ingredients and possibly hidden under the umbrella term "fragrance/parfum". Over the course of the 2017-2018 fiscal year, chemical testing of 206 different products was carried out. The chemical testing resulted in 2 stop sales to address non-compliance. There were 204 instances where no corrective action was required.

Please take the time to review the report and if you have questions or want to discuss the details of the report please do not hesitate to contact your CA Regulatory Team.

2018 Canada-U.S. Regulatory Cooperation Council Stakeholder Forum

The Canada-U.S. Regulatory Cooperation Council's (RCC) 2018 RCC Stakeholder Forum will be held December 4-5, 2018 at the Walter E. Washington Convention Center in Washington, D.C. This event will bring together senior regulatory officials, industry, and other members of the public on both sides of the border to provide progress reports on existing RCC work plans and to discuss new opportunities for regulatory cooperation. In the coming weeks you will receive an invitation including details on how to register. A report highlighting what we heard from stakeholders, as well as the submissions received can be found at: What We Heard Report on Regulatory Cooperation stakeholder consultations. The U.S. is currently conducting its own consultation process on the RCC to which you may consider making a submission. Further information on how to comment can be found here.

Good Clinical Practice (GCP) and Multi-Regional Clinical Trials (MRCT) Training: ICH E6(R2) and ICH E17

When: February 26-28, 2019

Where: John G. Diefenbaker Building (Old City Hall) – 111 Sussex Drive, Ottawa, Ontario

What: Didactic and Case-based learning, presentations, and open discussion

Who: Regulators from Health Canada (reviewers and inspectors), and individuals from industry, academia, and non-profit organizations

Registration: No cost

Learning Objectives:

- Describe the standards of Good Clinical Practice (GCP) and key considerations in Multi-Regional Clinical Trials (MRCTs) design as set out in ICH E6(R2) and ICH E17 guidance, respectively
- Use case studies to apply the changes of ICH E6(R2) addendum and ICH E17 to increase the acceptability of MRCT data by multiple regulatory authorities
- Demonstrate practical approaches to fulfilling the requirements of ICH E6(R2) and ICH E17

For Regulators:

- Describe and demonstrate best practices to assess clinical trial regulatory submissions, including study design, data packages, essential documents, reports, and filings for alignment with ICH GCP and MRCT
- Describe inspection methodologies to assess clinical trial conduct for alignment with ICH GCP and MRCT standards, including review of corrective actions.

For other Stakeholders:

- Gain better understanding and knowledge of Health Canada expectations with regards to compliance with the Canadian clinical trial regulations and GCP inspection processes

CA will provide further information on registration when it is available.

For any questions please contact HPFB_ICH_DGPSA@hc-sc.gc.ca.

Notice of Intent to Amend the Prohibition of Certain Toxic Substances Regulations, 2012

The *Prohibition of Certain Toxic Substances Regulations, 2012* are a multi-substance risk management instrument used to prohibit the manufacture, use, sale, offer for sale or import of the toxic substances listed in Schedule 1 and 2 of these Regulations, as well as products containing these substances with a limited number of exemptions.

The amendments to the Regulations would further restrict the manufacture, use, sale, offer for sale and import of two flame retardants (hexabromocyclododecane (HBCD) and polybrominated diphenyl ethers (PBDEs)) and three oil and water repellents (perfluorooctane sulfonate, its salts and its precursors (PFOS), perflurooctanoic acid, its salts and its precursors (PFOA) and long-chain perfluorocarboxylic acids, their salts and their precursors (LC-PFCA)). It would also prohibit two additional flame retardants (Dechlorane Plus (DP) and decabromodiphenyl ethane (DBDPE)) should their final screening assessment reports conclude that they are toxic under the Canadian Environmental Protection Act, 1999.

A 30-day comment period, closing on November 12, 2018, will follow the publication of the Notice. We encourage you to provide your written comments on the proposed scope of the amendments outlined in the Notice, indicating "Oct 2018 – PCTSR NOI Comments" in the subject line, to:

Chemicals Management Division
Environment and Climate Change Canada
351 St-Joseph Blvd., 10th floor
Gatineau QC K1A 0H3
Email: ec.interdiction-prohibition.ec@canada.ca

A consultation document outlining the proposed regulatory approach to amending the Regulations will be published for public comment in Fall 2018. Comments received during the comment period for this Notice and for the consultation document will be considered in the development of proposed regulations to amend the *Prohibition of Certain Toxic Substances Regulations, 2012*.

Environmental Updates

Canadians Share Their Views on Eliminating Plastic Waste as the Government of Canada Looks to Next Steps

From April 22 to September 21, 2018, the Government of Canada asked Canadians to share their views on the topic "Moving Canada Toward Zero Plastic Waste."

Canadians submitted over 1,900 comments and emails and 12,000 campaign letters. Summaries of what we heard have now been published. Initial feedback made it clear that Canadians recognize the need for prompt action to reduce plastic waste and marine litter and acknowledge that everyone—government, industry, and consumers alike—shares responsibility for managing plastics throughout their lifecycle.

Canada is taking action. They are working with provinces and territories and gathering input from Indigenous Peoples, industry, municipalities, not-for-profit organizations, and research institutions to develop an approach by the end of 2018. Environment ministers will meet in November at the annual meeting of the Canadian Council of Ministers of the Environment to discuss a Canada-wide framework for eliminating plastic waste and reducing marine litter. Discussions will continue into 2019 through the Canadian Council of Ministers of the Environment and with other levels of government, Indigenous communities, industry, and others to identify specific actions to reduce plastic waste and its pollution.

Throughout its G7 presidency, Canada has been a champion on international efforts to reduce plastic pollution, including spearheading the launch of the Ocean Plastics Charter at the G7 leaders summit last June. This leadership role continued at the G7 Environment, Energy and Oceans Ministers meeting in Halifax, last month, where plastic pollution remained a priority for discussion and collaboration with international partners.

Canada is committed to protecting our environment and preserving our waterways so that all Canadians can continue to enjoy the beauty, health, and economic benefits that oceans, lakes, and rivers provide.

Transparency in Chemicals Management Plan Risk Assessment Activities

Transparency is important to build and maintain public confidence, and the Government of Canada also has an obligation to protect confidential business information. Under section 313 of the Canadian Environment Protection Act, 1999 (CEPA 1999), any person who provides information to the Minister of the Environment and Climate Change may request that this information be treated as confidential. This protects commercial interests by ensuring that confidential information is protected from public disclosure. The degree of protection given to

such information is subject to sections 314-321 of CEPA 1999 and some provisions of the Access to Information Act (ATIA).

In 2017, the Government of Canada published the Proposed Approach to Promote Transparency in Chemicals Management Risk Assessment Activities. This approach seeks to balance transparency to support decisions in risk assessments with the right of stakeholders to protect confidential information. Of relevance is the aim to publish a robust rationale for supporting decisions in risk assessments while protecting confidential information. An updated version of this approach is now available.

Post-Consumer Waste Updates

Recycle BC Program Plan Submitted to BC Ministry of Environment and Climate Change Strategy

Following consultations on the updated Recycle BC Program Plan, Recycle BC made several important revisions to the Plan. Having now received approval from the Recycle BC Board of Directors, the Plan has been submitted to the BC Ministry of Environment and Climate Change Strategy (MoECCS). The Plan requires approval by the MoECCS prior to implementation and may be subject to change if requested by the government. The entire Stakeholder Consultation Report addressing these and more stakeholder feedback is available here.