Regulatory Essentials – November 28, 2018

Cosmetics Alliance Update

Introduction to Natural Health Products

Date: Tuesday, December 11, 2018

Time: 1:00 p.m. – 2:30 p.m.

Cost: Member - $225 Non-Member - $395

Objectives:

- Overview of the Natural Health Product Regulations
- Understand what a Natural Health Product is
- Understand the basic requirements for:
  - Product Licensing
  - Site Licensing
  - GMPs
  - Labelling
  - Clinical Trials
  - Reaction Reporting
- Enable attendees to access the Canadian Market

Register

Health Updates

Release of the new Web-based Natural Health Product License Application Form (Web PLA Form)

The Natural and Non-prescription Health Products Directorate (NNHPD) has announced the release of the new Web-based Natural Health Product Licence Application Form (web PLA form). The new form was made possible thanks to the innovative and collaborative efforts from committed staff and interested stakeholders including Cosmetics Alliance. Thank you to those members who participated in the July 2017 development session and those who provided feedback from the ePLA Testing session in September this year.

Health Canada will be holding two webinar sessions on the web PLA form:

- The English session will take place on Tuesday December 4th from 1:00 pm to 3:00 pm EST and
- The French session on Wednesday December 5th from 1:00 pm to 3:00 pm EST.

If you would like to participate in one of these sessions, please email HC.nnhpd.consultation-dpsnso.SC@canada.ca. Please provide your name, title, and association. The registration for the webinar will be available until November 30th.

The new web PLA form:

- is accessed and completed online
- saves to your local workstation as a readable HTML file

- accesses data from the Natural Health Product Ingredient Database (NHPID) and the Compendium of monographs to auto populate fields with ingredient information and monograph statements
- supports monograph attestation, thereby eliminating the need to submit a Monograph Attestation Form (MAF),
- includes help links for quick access to guidance
- replaces all previous versions of the PLA form

Applicants may now begin using the web PLA form for all new product licence applications.

As of today, the NNHPD will only accept the new web PLA and the latest version of the ePLA PDF form (version 2.3.1).

Other versions of the PDF form will be refused, including scanned/printed copies.

The NNHPD will continue to accept applications using the current version of the PDF (version 2.3.1) until November 23, 2019.

It should be noted that the web PLA form does not support kit products. Applicants submitting these types of applications should continue to submit the latest version of the ePLA form (version 2.3.1).

Please note that to use the web PLA form, applicants must have a valid company code issued to them by the NNHPD. Applicants can access their company code on previous correspondence from NNHPD (i.e., Issuance Letters and Refusals). New applicants can obtain a company code by:

- becoming a registered Trading Partner which will allow applicants to communicate electronically with NNHPD through epost Connect; or
- contacting NNHPD to create their company and obtain a company code. Please provide the company name, primary address, senior official information (name, email, phone number) and information for additional contacts on company letterhead with the senior official's signature.

Please refer to the Guidance Document on How to Interact with the Natural and Non-Prescription Health Products Directorate Electronically for information on how to become a Trading Partner.

Please continue to provide feedback and suggestions as Health Canada works towards the next phase of modernization efforts: the integration of electronic validation against the applicable Health Canada monograph(s) into the product licence applications process.

Drug and Natural Health Products Recall Guide

Health Canada has developed the draft document Drug and Natural Health Products Recall Guide to help companies comply with the requirements applicable to the recall of drugs and natural health products. Health Canada is seeking comments from all affected stakeholders. The consultation on this guidance document is open for comments from November 15, 2018 until January 14, 2019. Cosmetics Alliance encourages stakeholders to review the draft consultations and if you have any questions or concerns please reach out to your CA

Regulatory Team. We will also be commenting on this consultation and request interested stakeholders to send in comments to regulatoy@cosmeticsalliance.ca by January 7, 2018.

Recall Guide – EN

Recall Guide – FR

Recall Report – EN

Recall Report – FR

Comments Table

Release of Cleaning Validation Guide (GUI-0028) and Guide to Validating Drug Dosage Forms (GUI-0029)

Health Canada released the Cleaning Validation Guide (GUI-0028) and Guide to Validating Drug Dosage Forms (GUI-0029) on November 20, 2018. The consultation is open till February 20, 2018. Please email your comments to regulatory@cosmeticsalliance.ca as we will be submitting comments or directly to hc.hpil.consultation-ipsop.sc@canada.ca using one comment form for each guidance document. All comments will be considered in the finalization of the documents.

Comments can also be mailed to:

Health Product Inspection and Licensing Division
Health Product Compliance Directorate
13th Floor, Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture
Address Locator # 1913D
Ottawa Ontario K1A 0K9

Overview of Key Changes:

The Health Canada guidance documents have been rewritten and formatted using plain language principles to make the documents easier to read and understand. This is in conformance with requirements for migration of documents to the Canada.ca website.

GUI-0028 Cleaning Validation Guide for drug products is applicable to all pharmaceutical, biological and radiopharmaceutical manufacturing in Canada, including: fabricators, packagers/labelers, testers, importers, distributors and wholesalers including Inspectors and evaluators and regulated industry. External and internal consultation comments were considered and addressed as appropriate. It was recognized that the content needed additional revisions since the 2012 consultation, therefore, this consultation will provide stakeholders with the opportunity to provide further input to the document.

Changes include:

- Updates to principles and analytical methods.
- New sections on Quality Risk Management (QRM), cleaning validation master plan and cleaning validation lifecycle approach, microbial controls, and general equipment cleaning,

- Considerations for cleaning of active pharmaceutical ingredient (API) production processes and cleaning validation of Biotechnology processes.

GUI-0029 Guide to validating drug dosage forms is applicable to all pharmaceutical, biological and radiopharmaceutical manufacturing in Canada, including: fabricators, packagers/labelers, testers, importers, and distributors.

Changes include:

- Updates to general format of the guide.
- New sections on life cycle approach to validation programs, guidance related to analytical method validation and equipment/facility qualification.

GUI – 0028 – EN

GUI - 0028 – FR

GUI – 0029 – EN

GUI – 0029 – FR

Annex F Consultation Form GUI-0028&0029 - EN

Annex F Consultation Form GUI-0028&0029 - FR

Notifying Health Canada of Foreign Actions – Guidance Document for Industry

The final version of the Notifying Health Canada of Foreign Actions – Guidance Document for Industry has been posted along with an electronic on-line reporting form and list of foreign regulatory authorities.

The purpose of these documents is to provide manufacturers, importers and other holders of instruments of market authorization (Drug Identification Numbers and Notices of Compliance) under the Food and Drug Regulations, with information that may be useful in achieving compliance with the regulatory requirements of notification to Health Canada (HC) of foreign regulatory actions as outlined in sections C.01.050 (2)(a), (b) and (c) and C.01.050 (3) of the Food and Drug Regulations.

Drug Submission Performance Quarterly Reports (July – September 2018)

On November 15, 2018 Therapeutic Product Directorate (TPD), Biologics and Genetic Therapies Directorate (BGTD), Natural and Non-prescription Health Products Directorate (NNHPD) released the quarterly drug submission performance reports from July to September 2018. The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from July – September 2017 to July – September 2018. The reports are broken down by operational areas. The Therapeutic Product Directorate (TPD) report summarises performance metrics for pharmaceuticals. The Biologics and Genetic Therapies Directorate (BGTD) report summarises performance metrics for

biologics. The Natural and Non-prescription Health Products Directorate (NNHPD) report summarises performance metrics for non-prescription (over-the-counter) and disinfectant drugs. Within each report, statistics are provided by submission type and show the number received, the number in workload, the number of decisions and the number of approvals.

BGTD

NNHPD

TPD

The Canada – U.S. Regulatory Cooperation Council (RCC) Stakeholder Forum

The Regulatory Cooperation Council (RCC) Stakeholder Forum brings together senior regulatory officials, industry, and other members of the public from both sides of the U.S. - Canada border. Canadian and U.S. regulators will provide progress reports on existing regulatory cooperation efforts and solicit public input on new opportunities for regulatory cooperation. The RCC promotes economic growth, innovation, competitiveness, and job creation through the elimination of unnecessary regulatory differences between our two countries. To join the RCC Stakeholder Forum please RVSP (first-come-first-served basis). Additional information and an agenda are available here. If you have any questions please contact rcd-dcmr@tbs-sct.gc.ca or international-OIRA@omg.eop.gov.

Changes in Natural and Non-prescription Health Products Directorate Management

Recently, there have been changes to the NNHPD management. Carly Wood, Manager of Stakeholder Engagement Division in Bureau of Policy, Risk Management and Stakeholder Engagement in NNHPD has accepted an assignment with Treasury Board Secretariat until summer 2019. In her absence, Dr. Bio Aikawa who has recently joined Health Products and Food Branch has taken her role. Bio comes with a wealth of experience in stakeholder engagement in her previous roles within Health Canada including Chemicals Management Plan and pesticide re-evaluation program.

ICMAD – China National Medical Products Administration

On November 9, 2018, the China National Medical Products Administration announced that registration of first-imported non-specials cosmetics will be entirely replaced by filing management nationwide from November 10, 2018. Under this new regulatory scheme, foreign manufacturers shall designate a domestic responsible person (RP) and authorize this person to file a record via online filing system (at the administration website of NMPA prior to import). Only after obtaining a filing certification on the system will the product be permitted to be imported and distributed.

Domestic responsible person located in the pilot zones capable of filing management including Tianjin, Liaoning, Shanghai, Zhejiang, Fujian, Henan, Hubei, Guangdong, Chongqing, Sichuan, and Shanxi must complete filing to provincial administration for market regulation only after online filing application and dossiers submission. Domestic responsible person located outside pilot zones in China shall complete filing to NMPA only after online dossiers submission. Currently, the filing certification has no limit of validity provided the authorization of RP is valid, in comparison to a registration certificate, with a 4-year term.

Manufacturers of imported cosmetics are responsible for authorization of the domestic responsible person, user registration of online system, submission of filing dossiers, in accordance with the previous CFDA's notice Procedures of Filing Management for First Import non-special Use Cosmetics through Shanghai Pudong New Area for the time being.

Regarding the inspection report of the first imported non-special use cosmetics, overseas enterprises must comply with the requirements under "Notice of Inspection Report Requirements and Related Matters of First Imported Non-Special Cosmetics for Pudong Pilot Filing Management".

Please note that as of this notice the data requirements for filing are the same as for registration, which includes animal testing.

Environmental Updates

Section 71 Survey for Certain Quaternary Ammonium Compounds

On November 17, 2018, a Section 71 survey for certain quaternary compounds in Canadian commerce – Phase 1 was released as part of the CMP-3 assessment of the QUATS Grouping. The notice applies to 800 inanimate (chemical) substances. The purpose of this Notice will be to serve as an initial inventory review to identify and focus assessment activities on those QUATS that are likely to be in commerce in relatively significant volumes and in applications of potential greatest concern from an exposure perspective.

Cosmetics Alliance strongly recommends that you review and engage in this Section 71 survey as it will help shape and direct corresponding risk assessment and risk management efforts. CA will also be reviewing the substances to determine any implications it may have to membership.

The list of approximately 800 substances can be found in Schedule 1 of the CG1 notice.

There are also two additional Schedules:

- Schedule 2: Outlines the requirements of stakeholders' activities to provide information.
- Schedule 3: Outlines the information required if you meet the activities listed in Schedule 2

As with all Section 71 Notices, information collected through this Notice may be made available through public summaries. However, written requests for confidentiality can be requested in writing upon submission of responses.

Reponses can be submitted to ECCC'S Single Window and if you need guidance on completing the sections of the notice please refer to the Guidance Manual for Completing the Notice with Respect to Certain Quaternary Ammonium Compounds in Canadian Commerce – Phase 1 or manually by submitting data to HC.chemicalsubstances-chimiques.SC@canada.ca

If you have any questions or would like discuss this notice further please reach out to regulatory@cosmeticsalliance.ca.

Consultation on the Pollution Prevention Planning for Triclosan in Certain Products

Environment and Climate Change Canada (ECCC) published the final proposed P2 planning Notice in Canada Gazette. There is a 60-day consultation period closing on January 23, 2019. Cosmetics Alliance will be reviewing the notice and will send out a detailed communication to membership. In the meantime, please review the notice and send your comments to regulatory@cosmeticsalliance.ca by no later than January 14, 2018.

Draft Screening Assessment for Epoxides and Glycidyl Ethers Groups

The draft screening assessment of Epoxides and Glycidyl Ethers Group was released on November 24, 2018. Environment and Climate Change Canada and Health Canada have assessed 5 substances in the Epoxides and Glycidyl Ethers Group, which are listed as follows:

CAS RN	Domestic Substances List name	Common name (Acronym)
106-92-3[a]	Oxirane, [(2-propenyloxy)methyl]-	Allyl glycidyl ether (AGE)
1139-30-6	5-Oxatricyclo[8.2.0.04,6]dodecane, 4,12,12-trimethyl-9-methylene-, [1R-(1R,4R,6R,10S)]-	Beta-caryophyllenoxide (BCPO)
2210-79-9[a]	Oxirane, [(2-methylphenoxy)methyl]-	o-Cresol glycidyl ether (o-CGE)
2451-62-9[a]	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(oxiranylmethyl)-	Triglycidyl isocyanurate (TGIC)
120547-52-6[b]	Oxirane, mono[(C12-13-alkyloxy)methyl] derivs.	Alkyl (C12-C13) glycidyl ether (C12-C13 AGE)

a This substance was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered a priority on the basis of other human health concerns.

b This CAS RN is a UVCB (unknown or variable composition, complex reaction products or biological materials).

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to the environment from AGE, BCPO, o-CGE, TGIC and C12-C13 AGE. It is proposed to conclude that AGE, BCPO, o-CGE, TGIC and C12-C13 AGE do not meet the criteria under paragraphs 64(a) or (b) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Based on the information presented in this draft screening assessment, it is proposed to conclude that AGE, BCPO, o-CGE, TGIC, and C12-C13 AGE do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that AGE, BCPO, o-CGE, TGIC, C12-C13 AGE do not meet any of the criteria set out in section 64 of CEPA.

Strategy On Zero Plastic Waste – ECCC News Release

In November, Environment Ministers agreed to work collectively toward a common goal of zero plastic waste. The Strategy outlines areas where changes are needed across the plastic lifecycle from design to collection, clean-up and value recovery and underscores the economic and business opportunities resulting from long-lasting and durable plastics. On November 23, 2018 Environment and Climate Change Canada (ECCC) released the Strategy on Zero Plastic Waste report. The Minister of Environment and Climate Change Canada, Catherine McKenna, joined by provincial and territorial counterparts agreed to push forward on a Canada-wide zero-plastic waste strategy. The strategy outlines a vision to keep plastics in the economy and out of the environment through solution to better prevent, reduce, reuse and clean up plastic waste. With its circular-economy approach, the strategy addresses the plastics throughout their life cycle. Two of the objectives key to stakeholders are part of this reduction initiative is to ensure all plastic products and packaging are designed for greater durability, reuse and recycling throughout the value chain and working with companies that make products containing plastics or using plastic packaging to shift responsibility to them for the improvement of plastic-waste collection, management systems and infrastructure across Canada.

Chemicals Management Plan Stakeholder Advisory Council

The Chemicals Management Plan (CMP) Stakeholder Advisory Summary Report for May 2018 was published. The purpose of the Chemicals Management Plan (CMP) Stakeholder Advisory Council (SAC) meeting is to provide stakeholders the opportunity to offer advice and input to Government on the implementation of the CMP, and to foster dialogue on issues pertaining to the CMP between stakeholders and government, and among different stakeholder groups. The objective of the May 2018 CMP SAC meeting was to:

- seek views on how to better communicate a strategy on Endocrine Disrupting Chemicals (EDCs), and
- hear directly from a panel of Canadians about the impacts of chemicals exposure for vulnerable groups in order to learn from their perspectives, and to seek views on how the approach to vulnerable populations (VP) under the CMP going forward could be strengthened

The Summary Report of the CMP Stakeholder Advisory Council Meeting can be found here.

Consultation on the Definition of Vulnerable Population with Chemicals Management Plan (CMP)

The Chemicals Management Plan released the proposed definition of vulnerable populations within the context of chemicals management. This is a first step towards the development of a

policy framework focussed on enhancing the protection of vulnerable populations through the assessment and management of risks associated with certain chemicals, in particular under the Canadian Environmental Protection Act, 1999 (CEPA 1999). The Government is committed to continuously improving the consideration of vulnerable populations in the assessment and management of chemicals. It is an opportune time to further consider vulnerable populations as the Government is setting new directions and objectives for chemicals management post 2020. Although engagement with stakeholders has been ongoing throughout the CMP, more recent discussions have been focused on what a chemicals management program could encompass after the current CMP objectives are met. During these discussions, the Government has heard that enhancing consideration of vulnerable populations is a key area of interest for stakeholders. Please take the time to review the Defining Vulnerable Populations document. The consultation is open till January 21, 2019 and can be sent to hc.esrabdirector-directeurberse.sc@canada.ca.