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Overview of the Canadian Regulatory Framework for Cosmetics and Recent Updates

Magdalena Jurkiewicz and Nibal Saikali

Consumer and Hazardous Products Safety Directorate

Health Canada

Canadian Association of Professionals in Regulatory Affairs (CAPRA)

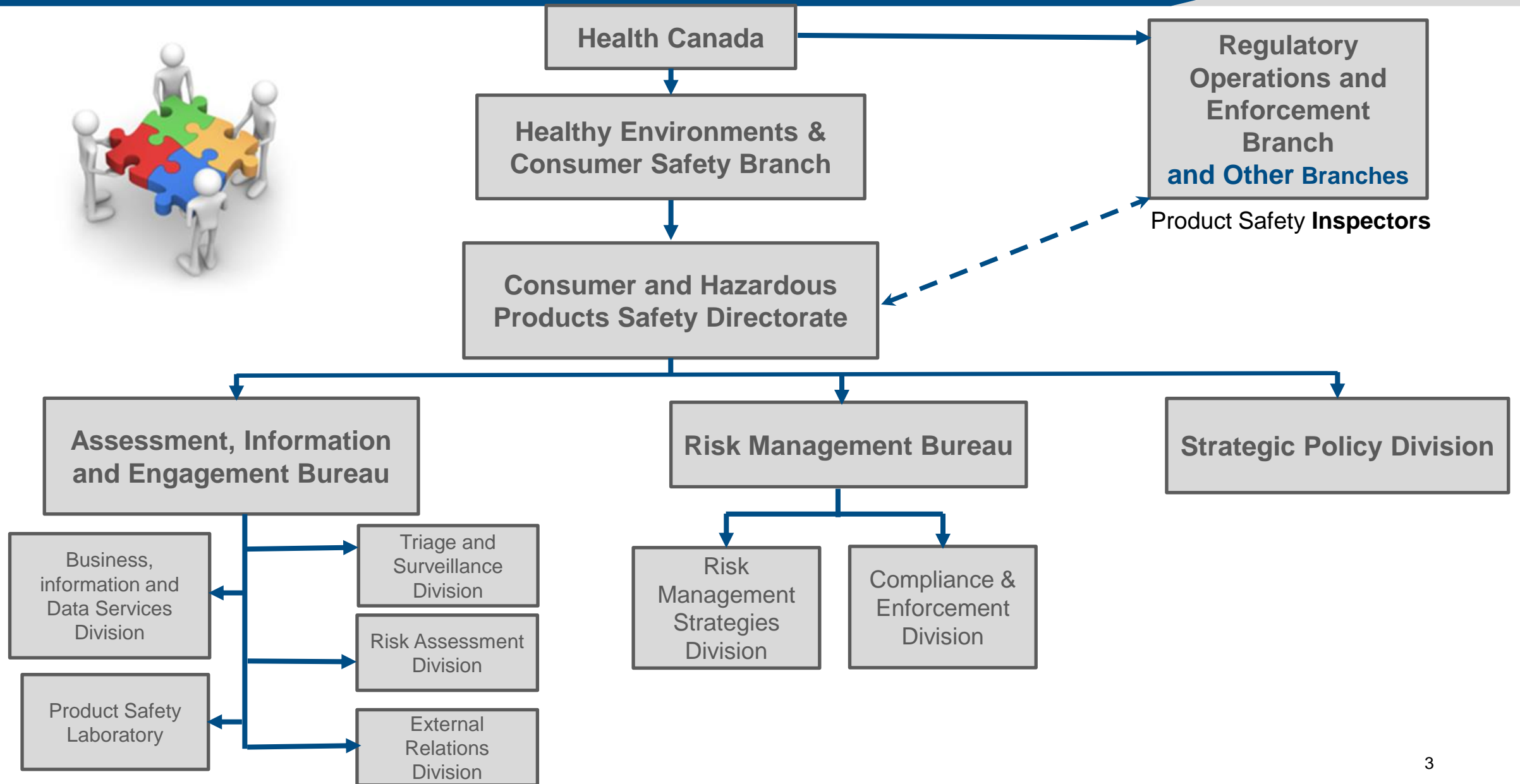
Webinar

March 20, 2024

Outline

- **Overview of the Canadian Regulatory Framework for Cosmetics**
- **Regulatory Proposal Concerning Cosmetics**
- **Updates to the Cosmetic Ingredient Hotlist**
- **Cosmetic Animal Testing Ban**

How we are organized



How Cosmetics are Regulated in Canada

Health Canada's mandate is:

To maintain and improve the health of people in Canada

For cosmetics, it is accomplished by minimizing health risks associated with the use of cosmetics marketed in Canada

Legislative authority to regulate cosmetics lies within:

- The ***Food and Drugs Act (F&DA)*** and
- The ***Cosmetic Regulations (CR)***



How Cosmetics are Regulated in Canada *(continued)*

Cosmetics are also subject to :

- *Consumer Packaging and Labelling Act (CPLA)** and Regulations
 - Net weight declaration and false and misleading claims
- *Canadian Environmental Protection Act (CEPA, 1999) **
 - New and existing cosmetic ingredients



*This legislation is not under the purview of the Consumer Product Safety Program (CPSP)

Food and Drugs Act (FDA)

- **Defines cosmetic, drug, food and medical device (s.2):**
 - “**Cosmetic**” includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.
- **Provides general safety requirement for cosmetics (General Prohibition)(s.16):**

No person shall sell any cosmetic that

 - » has in or on it any substance that may cause injury to the health of the user
 - » contains any “filthy or decomposed” substance or foreign matter
 - » was manufactured, prepared, preserved, packaged or stored under unsanitary conditions
- **Gives authority to inspectors to enter premises, take samples, seize products, etc.**
- **Includes Regulations under the Act:** *Cosmetic Regulations, Food and Drug Regulations**, *Natural Health Products Regulations** and others*.

*The products governed by these regulations are not under the purview of the Consumer Product Safety Program (CPSP)

The *Cosmetic Regulations* (CR) Outline Requirements for:

- **Importation**

- **Labelling**

- Product identity and the responsible company
- Directions for safe use and warnings
- Requirements for cosmetics in pressurized containers
- Special packaging for certain cosmetics or ingredients
- Disclosure of ingredients using INCI (International Nomenclature of Cosmetic Ingredients)
- Bilingual requirements

- **Notification**

- Within 10 days of first sale of the product in Canada
- Required for new products, amendments to original notification such as formulation changes and discontinued products
- No fee
- [Online form](#)
- Instructions on how to complete the form can be found here: Guidance document: [How to complete a Cosmetic Notification Form](#)

Submission of the Cosmetic Notification Form does not constitute approval for sale by Health Canada, agreement that the product is classified as a cosmetic nor that the product complies with all legislative requirements.



Regulatory Proposal Concerning Cosmetics

(Regulations Amending Certain Regulations Concerning the Disclosure of Cosmetic Ingredients)

Background Information

- Fragrance ingredients are commonly used in cosmetics and are added to produce or mask a particular odour.
- Currently, fragrance ingredients can be listed as follows:
 - Individually in the list of ingredients; or
 - The term “**parfum**” can be included at the end of the list of ingredients.
- Certain fragrance ingredients are known to cause or lead to allergic contact dermatitis when used on the skin. Common symptoms include irritation and rashes. This may affect 1 to 9% of the general population.
 - ❑ The lack of disclosure of fragrance allergens on cosmetic labels can negatively impacts the health and safety of people in Canada.



Government Commitments and Stakeholder's Engagement

- **Summer 2021:** A pre-consultation was published on Health Canada's website seeking feedback on a proposal to disclose fragrance allergens on cosmetic labels and to strengthen the regulatory oversight for cosmetics.
- Government of Canada commitment :
 - December 2021: [Mandate letter to the Minister of Health](#) highlights intent to increase the transparency of chemical labelling in a variety of consumer products, including cosmetics.
- Pre-publication published in [Canada Gazette, Part I on February 11, 2023](#). The comment period closed on April 22, 2023.

The Objectives of the Proposed Regulations

- The objectives are to:
 - introduce a requirement to **disclose certain fragrance allergens** on cosmetic labels;
 - add greater flexibility for the disclosure of ingredients for cosmetics sold in small packages;
 - **improve the oversight of cosmetics** by clarifying terminology, strengthening the cosmetic notification requirements and enhancing compliance and enforcement tools; and
 - address changes of administrative nature.



Introduce a Requirement to Disclose Certain Fragrance Allergens on Cosmetic Labels

- The **objective** is to:
 - Help consumers identify ingredients that they may be **allergic or sensitive** to or wish to avoid
 - Allow consumers to make more **informed health decisions** regarding product purchase and use
- Require the disclosure of certain fragrance allergens on cosmetic labels **within the list of ingredients**, when its concentration exceeds 0.001% in leave-on products or 0.01% in rinse-off products.
 - ❖ **Align** with the European Commission with regard to the list of fragrance allergens that would require disclosure.
 - ❖ Incorporation by reference of the fragrance allergens within **Annex III** of the [European Commission's Cosmetic Products Regulation](#), including the transition period set out in that Annex, to address future updates to substances identified for disclosure.
 - ❖ Include fragrance allergens as ingredients in the Cosmetic Notification.
 - ❖ This requirement would come into force two years after the registration of the final Regulations.

Greater Flexibility for Disclosure of Ingredients for Cosmetics Sold in Small Packages

- Currently, cosmetics available in small packages that cannot meet the legibility requirement, the list of ingredients can appear on a tag, tape or card **affixed** to the container or package.
- It is proposed to add the option to use a **website** to disclose the list of ingredients for cosmetics sold in **small packages**, provided that there is a **statement** specifying that the list of ingredients appears on that website and include the location of the website.

Statement Examples:

Pour la liste des ingrédients / For the list of ingredients: www.websitename.ca

Ingrédients /Ingredients: www.websitename.ca

Improving the Regulatory Oversight for Cosmetics

- Adding or clarifying terminology used in the *Cosmetic Regulations* (adding “importer”, “rinse-off” and “leave-on” and clarifying “manufacturer”)
- The proposal would **strengthen the Cosmetic Notification (CN) requirements**, as follows:
 - ❖ Require ingredients to be identified using International Nomenclature of Cosmetic Ingredients;
 - ❖ Require to identify whether the product is leave-on or rinse-off;
 - ❖ The Canadian distributor information would no longer be required
 - ❖ Revise the table of concentration ranges from 7 to 13 ranges;
 - ❖ Add the **ability to request evidence of safety from the importer** (in addition to the manufacturer); and
 - ❖ Add a provision to **allow Health Canada to stop the sale of a product** if the notification requirements are not met, or the information requested is not provided and clarify that a discontinuation is a change to the CN.
- **Modernize** the contact information present on the label - Allow a telephone number, email address, website, postal address or any other information for consumer questions be indicated on the label.

Amendments of Administrative Nature

- Amendments of administrative nature are as follows:
 - Update the publisher and edition of the INCI Dictionary;
 - Update the Schedule for outdated ingredient names;
 - Update the format of the Schedule to facilitate its understanding:
 - ❖ English version:
 - The heading of column 1, “EU Trivial Name” ⇒ “EU Technical Name”;
 - The heading of column 2, “English Equivalent” ⇒ “INCI Name”;
 - ❖ French version:
 - The heading of column 1, “Nom trivial attribué par l’UE” ⇒ “Nom technique attribué par l’UE”;
 - The heading of column 3, “Équivalent anglais” ⇒ “Appellation INCI”;
 - Clarify that for ingredients included in the schedule, **all three terms** listed for the same ingredient, for example: “Water / Eau / Aqua” can be used on the label.

Consequential Amendments to the *Cannabis Regulations*

- Updates are made to ensure terminology for the labelling of cannabis topicals remains consistent with the terminology to be used for cosmetics.
- As a result of the change to the columns headings in the Schedule, consequential amendments to the *Cannabis Regulations* are proposed, as follows:
 - Subsection 130(1) is amended to reflect the change made to the heading of column 1 in the Schedule;
 - Subparagraph 132.17(1)(c)(iv) is amended to reflect the changes made to the headings of column 1 and column 2 in the Schedule.



Path Forward and Next Steps

In summer 2023, the [European Commission](#) adopted its expanded list of fragrance allergens (Annex III).

- As a result, Health Canada conducted a targeted cost-benefit survey to determine if there are additional costs for industry with respect to the disclosure of the expanded list of fragrance allergens.

Publication in *Canada Gazette, Part II* is anticipated for 2024:

- Amendments related to disclosure of fragrance allergens would come into force **two years after** the registration of the final Regulations;
- All other amendments would come into force **180 days after** the registration of the final Regulations.



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Updates to the Cosmetic Ingredient Hotlist

Cosmetic Ingredient Hotlist

- The **Hotlist** is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the FDA, may contravene one or more provisions of the CR, or may otherwise be inappropriate for use in cosmetics.
 - Two tables: prohibited ingredients, restricted ingredients
 - Reviewed and updated as new scientific data becomes available
 - Not exhaustive – general prohibition applies at all times
- The latest version of the Hotlist (2022) can be found [here](#).
- Proposed updates to the Hotlist published on July 13, 2023 can be found [here](#).
- Health Canada can take actions at any time to enforce the FDA and CR, regardless of whether a substance is included on the Hotlist.

Cosmetic Ingredient Hotlist

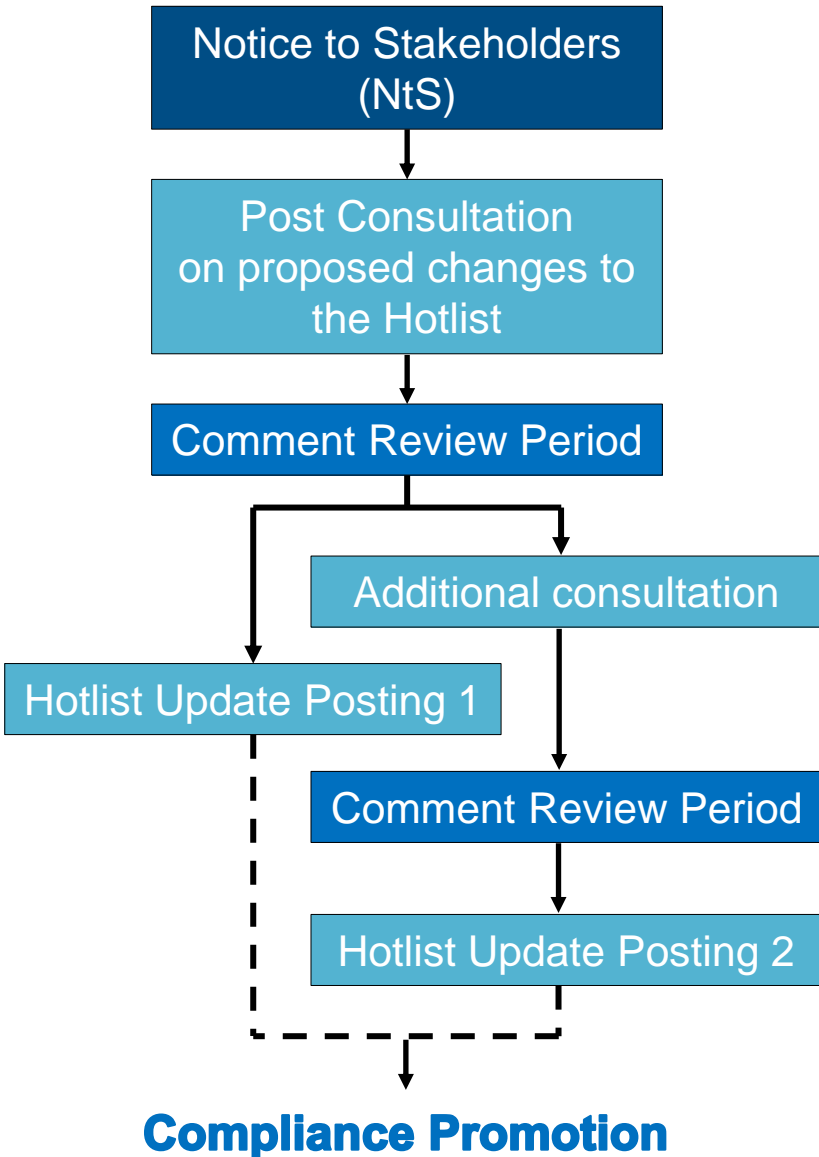
The latest update to the [Hotlist](#) was published on August 26, 2022.

From July 13 to October 11, 2023, the [Consultation on proposed updates to the Cosmetic Ingredient Hotlist](#) was posted. Additions or changes for the following ingredients were proposed:

Prohibited List	
<i>Proposed Additions</i>	<i>Proposed Revisions</i>
<ul style="list-style-type: none"> Basic Green 4 (known as Malachite Green, CAS 569-64-2) 	<ul style="list-style-type: none"> Mixed cresols and derivatives
<ul style="list-style-type: none"> Thioglycolic acid esters 	<ul style="list-style-type: none"> Dialkanolamines, secondary

Restricted List	
<i>Proposed Additions</i>	<i>Proposed Revisions</i>
<ul style="list-style-type: none"> Benzophenone 	<ul style="list-style-type: none"> Alpha-Hydroxy Acids
<ul style="list-style-type: none"> p-Chloro-m-cresol 	<ul style="list-style-type: none"> Aluminum chlorohydrat and its associated complexes
<ul style="list-style-type: none"> Retinal 	<ul style="list-style-type: none"> Peroxide and peroxide-generating compounds
<ul style="list-style-type: none"> Solvent Violet 13 	<ul style="list-style-type: none"> Benzoyl peroxide
	<ul style="list-style-type: none"> Hydroquinone
	<ul style="list-style-type: none"> P-Hydroxyanisole
	<ul style="list-style-type: none"> Retinol and its esters
	<ul style="list-style-type: none"> Talc

Current Hotlist Update



November 2022 – NtS

- Notice of posting sent to Cosmetics Mailing List and email address provided by notifiers

July 13 - October 11, 2023 – Consultation posted (90 days)

- Notice of posting sent to Cosmetics Mailing List and email addresses provided by notifiers

Winter 2023/2024 – Comment Review

- Health Canada reviews the information provided during the consultation and responds to comments received.

Spring 2024 – Additional consultation

- Additional consultation for certain ingredients shared through the Cosmetics Mailing List on March 11, 2024.

Spring 2024 – Hotlist Update 1

- Hotlist will be updated with proposed changes that did not require additional consultation. Efforts will be made to contact notifiers that may be affected by the Hotlist changes

Fall 2024 – Hotlist Update 2

- Final Hotlist update posting expected in Fall 2024

Health Canada prioritizes compliance & enforcement based on:

- Level of risk posed by a product; and
- Any complaints/incidents received.

Current Hotlist Update

Hotlist Update 1: Spring 2024

- Basic Green 4 (Malachite Green)
- Dialkanolamines, secondary
- Benzophenone
- p-Chloro-m-cresol
- Solvent Violet 13
- Alpha-Hydroxy Acids
- Hydroquinone
- P-Hydroxyanisole
- Talc

Hotlist Update 2: Fall 2024 (Anticipated)

- Retinal
- Retinol and its esters
- Peroxide and peroxide-generating compounds
- Benzoyl peroxide
- Aluminum chlorohydrate and its associated complexes
- Thioglycolic acid esters
- Mixed cresols and derivatives

- Following the final Hotlist publications, a notice of posting to be sent to Cosmetics Mailing List and email addresses provided in notifications.
- Notifiers affected by the Hotlist changes will be contacted by Health Canada.

Chemicals Management Plan

Assessments have been published for the following ingredients under the Chemicals Management Plan (CMP) and may be of interest to cosmetics stakeholders.

Proposed Conclusions* Published:

- Acyclic, Monocyclic, and Bicyclic Monoterpenes Group
- Alcohols Group
- Monocyclic and Bicyclic Sesquiterpenes Group
- Parabens Group
- Salicylates Group

*(may change following comment period)

Final Conclusions Published:

- Coumarin 1
- Other Polymers Group

Updates on the [publication of documents/consultations under the CMP](#).

Ban on Cosmetic Animal Testing



Ban on Cosmetic Animal Testing – General Information

- The Minister of Health's 2021 [mandate letter](#) included a commitment to introduce legislation to end testing on animals and the Government remains committed to this goal.
- In [Budget 2023](#), the Government reaffirmed its commitment to ban cosmetic testing on animals by introducing amendments to the *Food and Drugs Act* to prohibit:
 - testing cosmetics on animals in Canada;
 - selling cosmetics that rely on animal testing data to establish the product's safety, with some exceptions; and
 - false or misleading labelling pertaining to the testing of cosmetics on animals.
- [Bill C-47](#) received royal assent on June 22, 2023. The amendments to the *Food and Drugs Act* relating to the animal testing of cosmetics came into force on December 22, 2023.



Ban on Cosmetic Animal Testing – Compliance by Industry

- These provisions were informed by discussion with the cosmetics industry and key animal advocacy groups.
 - Very little animal testing for cosmetics currently occurs in Canada, so manufacturers were already voluntarily reducing their reliance on animal testing data when it was possible to do so.
- To meet the new requirements, industry needs to:
 - **Not test any cosmetics on animals in Canada** for the purposes of establishing the cosmetic's safety under the *Food and Drugs Act* or any other country's cosmetic requirements;
 - Ensure that the **safety** of any new cosmetic product sold in Canada can be **established relying strictly on allowable data** (i.e., data not derived from animal testing, or data satisfying the relevant exceptions); and
 - Ensure that any **claims** relating to the cosmetic not being tested on animals **can be validated**.
- Health Canada is adopting **reactive compliance and enforcement approach** to these prohibitions, meaning any enforcement of these prohibitions will focus on complaints and incident reports.

Guidance to Help You

- [The Guide for Completing Cosmetic Notification Form](#)
- [Cosmetic Ingredient Hotlist](#)
- [Industry Guide for the labelling of cosmetics](#)
- [Guide to Cosmetic Ingredient Labelling](#)
- [Labelling Requirements for Cosmetics in Pressurized Containers](#)
- [Guidance on the Classification of Products at the Cosmetic-Drug Interface](#)
- [Guidance document: Animal testing ban on cosmetics](#) **"New"**
- [Act](#) and [Regulations](#), etc.

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics.html>

Contact Us

cosmetics@hc-sc.gc.ca

Contact your designated Regional Product Safety Office:

<https://www.canada.ca/en/health-canada/corporate/contact-us/regional-product-safety-offices.html>

or

via telephone 1-866-662-0666

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