

Notice to interested parties - Proposal to amend the *Cosmetic Regulations*

Dear Stakeholder

This notice to interested parties seeks stakeholder's comments and feedback regarding potential amendments to the *Cosmetic Regulations* (CR).

Health Canada is considering:

1. adding a requirement to disclose specific fragrance allergens on labels of cosmetic;
2. allowing flexibility for the disclosure of ingredients and specific fragrance allergens on labels of small packages; and
3. improving oversight of cosmetics by:
 - clarifying terminology and improving the level of detail for information submitted in a cosmetic notification, in order to facilitate its use for risk management purposes;
 - enhancing compliance and enforcement oversight with regard to who is responsible for responding to evidence of safety requests for cosmetics; and
4. addressing administrative changes

The main objective of this regulatory initiative would be to better inform consumers about the presence of specific fragrance allergens in cosmetics that are currently captured on labels under the word "parfum". Disclosure of this information on labels of cosmetics would help strengthen consumer decision-making and help to protect their health.

The feedback received during this pre-consultation will be considered in the development of a regulatory proposal, which includes performing a cost-benefit analysis to support regulatory decisions. Following the publication of proposed amendments to the *Cosmetic Regulations* in *Canada Gazette*, Part 1, there will be an additional comment period.

Background

It is Health Canada's mandate to help protect Canadian consumers from health risks associated with the use of cosmetics marketed in Canada.

For the purposes of the *Food and Drugs Act* (FDA), cosmetics are defined as "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". Products in this category include moisturizers, cleansers, make-up products, hair products (shampoo and styling) and nail products.

Health Canada uses a post-market approach to regulate the safety of cosmetics in Canada. The Department does not approve cosmetic products or ingredients before they are made available on the Canadian market. Rather, cosmetics manufactured, imported, advertised and sold in Canada are subject to the FDA and its *Cosmetic Regulations* (CR). This legislation stipulates that no person can sell any cosmetic that has in it any substance that may cause injury to the health of the user when the cosmetic is used according to the directions on the label and under normal conditions of use (see section 16 of the FDA, a provision that Health Canada refers to as the “general prohibition”).

In addition, under section 30 of the CR, manufacturers and importers must notify Health Canada within 10 days of first sale of a cosmetic (i.e., at the latest, 10 days after they first sell a cosmetic in Canada), and provide information about the product such as its formulation, area of application, form and function.

The last significant amendments to the CR came into force in 2007, when among other things, the disclosure of ingredients on labels of cosmetics became mandatory. This disclosure allows consumers to identify ingredients that they may be sensitive to or wish to avoid in order to help protect their health. This requirement helps consumer decision-making concerning the protection of their health. It is mandatory to disclose all cosmetic ingredients on the product label using the International Nomenclature (of) Cosmetic Ingredients (INCI). This is the same naming convention used in the European Union (EU), and similar requirements apply in the United States (US). The use of these universally recognized terms provides consumers around the world with valuable information concerning the composition of cosmetics, thereby allowing for more informed decisions regarding product purchase and use.

Fragrance ingredients are commonly used in cosmetics, and are added to the product to produce or mask a particular odour. Fragrances may be individual ingredients but are generally complex mixtures of many different ingredients. The composition of fragrances is typically proprietary. There are more than 3,000 unique fragrance ingredients used to create various fragrance mixtures¹.

Under subsection 21.4(3) of the CR, it is permitted to use the word “parfum” at the end of the ingredient listing to indicate that a fragrance ingredient, or mixture of ingredients, is present in the product. Therefore, some individual fragrance ingredients might not appear on a product label if the word “parfum” is used. This labelling practice for fragrance ingredients is used globally.

Issues to be addressed

In the past decade, there has been significant public interest with respect to increased transparency regarding the use of fragrance ingredients in cosmetics. Certain fragrance

¹ IFRA. The Socio-Economic Impact of Fragrance Technologies in Europe. Available at: [https://ifrafragrance.org/docs/default-source/policy-documents/23341_pp_2013_10_07_the_socio-economic_impact_of_fragrance_technologies_in_europe-\(5\).pdf?sfvrsn=4e602dfd_0](https://ifrafragrance.org/docs/default-source/policy-documents/23341_pp_2013_10_07_the_socio-economic_impact_of_fragrance_technologies_in_europe-(5).pdf?sfvrsn=4e602dfd_0)

ingredients are known to cause or lead to allergic contact dermatitis when used on the skin, resulting in irritations, such as redness of the skin or rashes. Allergic contact dermatitis caused by fragrances is the most common reaction among consumers of cosmetics² and may affect up to at least 1% of the general adult population³. These fragrance ingredients have been identified as fragrance allergens by the scientific community.

The CR do not require that the names of specific fragrance allergens appear on the label of cosmetics if these fragrance ingredients are captured by the word “parfum”. Health Canada is considering amendments to the CR that would require specific fragrance allergens to be disclosed on product labels in order to strengthen consumer decisions regarding product purchase and use, in order to better protect their health. This is especially important for people who are sensitive to particular fragrance ingredients. Furthermore, in the case where a consumer consults a health professional following an adverse reaction to a cosmetic, this expanded ingredient list could help them to identify potential ingredient(s) that may have triggered the reaction.

Health Canada is also considering flexibilities for the disclosure of ingredients (including specific fragrance allergens) on small packages, as well as amendments aimed at improving the oversight of cosmetics, and to support compliance actions.

1. Adding a requirement to disclose specific fragrance allergens on labels of cosmetic

Under the European Commission’s (EC) Cosmetics Regulation, the disclosure of certain fragrance allergens on labels has been in place since 2005. These fragrance allergens must be disclosed within the ingredient list on the label of the cosmetic when their concentration exceeds 0.01% in rinse-off products and 0.001% in leave-on products⁴.

In June 2012, the Scientific Committee on Consumer Safety (SCCS)⁵ of the EC recommended that European consumers be informed of 62 additional fragrance allergens on the label of cosmetics. The SCCS recommended 87 fragrance allergens for disclosure. The EC completed an [impact assessment study](#) to address options for disclosing of the additional fragrance allergens identified in the 2012 SCCS opinion. A [regulatory proposal](#) to address this recommendation is anticipated for the last quarter of 2021.

² Milam EC, Cohen DE. Contact Dermatitis: Emerging Trends. *Dermatol Clin*. 2019 Jan;37(1):21-28.

³ Van Oosten E J, Schuttelaar M L, Coenraads P J. Clinical relevance of positive patch test reactions to the 26 EU-labelled fragrances. *Contact Dermatitis* 2009; 61: 217-223.

⁴ Easy to read summaries of scientific opinions – Fragrance allergens. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/citizens_fragrances_allergens_en.pdf

⁵ Scientific Committee on Consumer Safety (SCCS) Opinion on Fragrance allergens in cosmetic products. Available at : https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

The proposal

Health Canada is considering a requirement for regulated parties to inform consumers of the presence of specific fragrance allergens in cosmetics currently captured by the word “parfum”, through mandatory disclosure on product labels.

The list of specific fragrance allergens (see Appendix 1) being considered is based on the 2012 SCCS opinion and would align with the EC’s consultation on this topic in 2014. The disclosure of a fragrance allergen would be required on the label of the cosmetic when its concentration exceeds 0.01% in rinse-off products, or 0.001% in leave-on products.

The information about the presence and concentration of fragrance allergens, would also need to be reflected in the cosmetic notification provided to the Department’s Consumer and Hazardous Products Safety Directorate (CHPSD) as per section 30 of the CR. Specific fragrance allergens would be identified and listed individually, as other ingredients, in the cosmetic notification.

2. Allowing flexibility for the disclosure of ingredients and specific fragrance allergens on labels of small packages

Subsection 18(b) of the CR states that the information required on the labels of cosmetics must be clearly legible. However, for cosmetics whose immediate containers or outside packages are too small to disclose the list of ingredients in a legible manner, the CR allows regulated parties to display this information on a tag, tape, or card attached to the container at the time of purchase (see CR section 21.5). Generally speaking, cosmetics within the scope of section 21.5 might include eyeliner pencils, lipsticks or nail enamels.

The proposal

Health Canada recognizes that there are considerations and impacts for industry when adding new labelling requirements. This presents a particular challenge for regulated parties that have cosmetics in small packages with limited space.

To provide flexibility and allow for innovative ways for industry to inform consumers, Health Canada is exploring the addition of an option to use electronic-labelling (e-labelling) of all ingredient information for cosmetics within the scope of section 21.5. This could allow regulated parties to provide consumers with required information about product ingredients including specific fragrance allergens via their website with a prompt on the label.

Considering that not all consumers may have internet access, the required information would also need to be available in an alternative manner, such as a toll-free number. This would ensure that all consumers have access to information about the ingredients, including and specific fragrance allergens, used in the cosmetic product.

3. Improving oversight of cosmetics

Health Canada is considering additional amendments to the CR to:

- clarify terminology and improve the level of detail for information submitted in a cosmetic notification, in order to facilitate its use for risk management purposes; and
- enhance compliance and enforcement oversight with regard to who is responsible for responding to evidence of safety requests for cosmetics.

Health Canada anticipates that the regulatory amendments being considered will enhance its oversight of cosmetics. Details for each proposal are provided in the sections below.

(a) Update the definition of “manufacturer”

The CR defines the term “manufacturer” as “a person, a partnership or an unincorporated association that sells, or manufactures and sells, a cosmetic under its own name or under a trademark, design, tradename or other name or mark owned or controlled by it”. Health Canada is considering whether to modernize and update the definition of “manufacturer” so that it would reflect more accurately its role in the supply chain. Health Canada is considering whether the definition for manufacturer could be simplified so that it would refer to a person who fabricates or processes a cosmetic in Canada for the purpose of sale.

(b) Clarify the term “importer”

The CR does not define the term “importer”, although the term is used in various sections of the CR. Health Canada is considering whether to add precision or include a definition for the term “importer”, so the regulated parties have a better understanding of, and subsequently compliance with, the regulations. For example, in order to decrease ambiguity about the meaning of “importer”, it could be considered that an importer is a person who imports a cosmetic into Canada.

(c) Considerations regarding the term “distributor”

The term “distributor” is currently only used in paragraph 30(2)(f), where the name and address in Canada of the manufacturer, importer or distributor is required to be provided in the cosmetic notification. The term “distributor” is commonly understood to be a person in Canada who sells a cosmetic to another person for the purpose of further sale by that other person.

In modern supply chains, a manufacturer or importer may have multiple distributors, which may change throughout the lifespan of a product. Health Canada is considering whether the term “distributor” is necessary for paragraph 30(2)(f), and whether contact

information about the manufacturer or importer in Canada would be sufficient for compliance and enforcement purposes.

(d) Strengthen the notification requirement

Subsection 30(1) outlines the requirement that a cosmetic notification must be submitted within 10 days of first sale in Canada. Similarly, if a change is made to the information provided in the cosmetic notification, a revised notification must be submitted within 10 days of the change, as per paragraph 31(a). Additionally, further information may be requested about the notification, as per paragraph 31(b).

Health Canada is considering an amendment to specify that if section 30 or 31 are not met, the sale of a cosmetic must stop. This proposal would provide effective tools to support compliance and enforcement activities, in order to help protect the health and safety of Canadians.

(e) Add a requirement to identify whether the product is “rinse-off” or “leave-on” in the cosmetic notification

In the cosmetic notification, manufacturers and importers are already required to identify the product function and form as per paragraphs 30(2)(c) and 30(2)(e). In order to help protect the health of Canadians during the screening of cosmetic notifications and to determine if disclosure requirements for specific fragrance allergens are met, Health Canada is considering a requirement for manufacturers and importers to specify in the cosmetic notification whether a product is rinse-off or leave-on for all notified products.

(f) Require that ingredient names be identified by their INCI names in the cosmetic notification

As per paragraph 30(2)(d) of the CR, the ingredient name must be provided in the cosmetic notification. This information is important for Health Canada to identify the ingredient and help determine if there is a concern with the cosmetic. This contributes to Health Canada’s goal of protecting the health and safety of Canadians from unsafe cosmetics.

Health Canada is considering having notifiers identify all the ingredients provided in their cosmetic notifications with their INCI names, or if there is no INCI name, using the chemical name. The CR already require ingredients to be disclosed on the product label using the INCI names. As such, in Health Canada’s view, this step would not represent additional burden for manufacturers and or importers when completing the cosmetic notification.

This proposed amendment would align the information present on the label with the information in the cosmetic notification submitted to Health Canada, and would facilitate risk management actions.

(g) Revise the table of concentration ranges for cosmetic notification

As per paragraph 30(2)(d) of the CR, a list of the cosmetic ingredients and, for each ingredient, either its exact concentration or corresponding concentration range must be provided in the cosmetic notification. The [table](#) in paragraph 30(2)(d) outlines concentration ranges which may be used instead of an exact concentration when the formulation of the cosmetic is provided in the cosmetic notification.

Some of the current concentration ranges in the table are very broad. Broad concentration ranges pose a challenge when Health Canada conducts risk assessments of certain ingredients under the FDA and the Chemicals Management Plan. For example, risk assessors will typically assume the worst-case scenario during exposure calculations, which are used to help inform subsequent risk management actions. In the absence of exact concentrations, the higher concentration from a concentration range will be used by default for exposure calculations. In these cases, the final assessment may be overly conservative, and may not reflect the actual exposure to the ingredient through its cosmetic use.

Health Canada is considering narrower concentration ranges compared to the current requirements. The number of concentration ranges would increase from the current 7 to 13. Narrower ranges would provide more precise information which would facilitate the screening of cosmetic notifications and enhance the risk assessments conducted by Health Canada. This may reduce the number of clarification requests sent to regulated parties during the screening of cosmetic notifications. The ranges Health Canada is considering are presented below:

Item	Concentration range	Corresponding number
1	More than 80% up to 100%	1
2	More than 65% but no more than 80%	2
3	More than 50% but no more than 65%	3
4	More than 40% but no more than 50%	4
5	More than 30% but no more than 40%	5
6	More than 20% but no more than 30%	6
7	More than 10% but no more than 20%	7
8	More than 3% but no more than 10%	8
9	More than 1% but no more than 3%	9
10	More than 0.3% but no more than 1%	10
11	More than 0.1% but no more than 0.3%	11
12	More than 0.001% but no more than 0.1%	12
13	More than 0% but no more than 0.001%	13

(h) Broadening who can be contacted for evidence of safety information

Section 29 authorizes Health Canada to, among other things, request evidence to establish the safety of a cosmetic, under the recommended or normal conditions of use, from the Canadian manufacturer of the cosmetic.

Most cosmetics sold in Canada are imported. Health Canada is considering amending section 29 so that the provision would apply to manufacturers in Canada as well as importers. This will strengthen the oversight of cosmetics and provide Health Canada with additional tools to help protect the health and safety of Canadians.

4. Administrative changes

Health Canada is considering updates to the CR's definition for ICI Dictionary (meaning the International Cosmetic Ingredient Dictionary and Handbook) and to revise ingredient names in the Schedule to the CR. Revisions to the layout of the Schedule will be explored to better reflect its purpose with respect to the bilingual terms to use on labels.

- In the definition, the publisher of the ICI dictionary, "The Cosmetic, Toiletry, and Fragrance Association Inc.", would be replaced with "the Personal Care Products Council (PCPC)". The 10th edition (2004) would be replaced with the current edition (2016).
- The Schedule outlines a list of ingredients that may be listed one of two ways: either by its EU trivial name set out in column 1 of the Schedule or by the appropriate English and French equivalents set out in columns 2 and 3 (as described in paragraph 21.2(4)). It is also acceptable for all three names to be used together. Health Canada is also considering an update to the format of the Schedule. The current format does not present the information in an intuitive manner. For example, the column order could be changed to better indicate that if an English equivalent of an INCI name is used, its French equivalent is also required.
- Ingredients listed in the Schedule would be revised to reflect the current EU trivial names. For example, the EU trivial name "Bombyx" should be replaced by "Bombyx Lipida".

How to participate

To participate in this pre-consultation, please submit your comments and feedback on the potential amendments being considered for the *Cosmetic Regulations* by email to: hc.cosmetics.sc@canada.ca.

We have prepared specific questions to guide your feedback. These are provided in a separate attachment for your convenience

This pre-consultation is open for comment to the general public and stakeholders from July 16, 2021 until August 30, 2021 (**45** calendar days).

Interested parties are encouraged to provide comments and suggestions by August, 30 2021.

Appendix 1: Fragrance allergens

The list of fragrance allergens proposed to be disclosed in the list of ingredients separate from under the word “parfum”, when they exceed a concentration of 0.01% in rinse-off products and 0.001% in leave-on products. This list is based on the 2012 SCCS opinion and would align with the EC’s [consultation](#). Fragrance ingredients denoted with an asterisk (“*”) are fragrance allergens that must currently be disclosed in the European Union (EU).

	INCI Name of fragrance allergen	CAS number
1.	Acetylcedrene	32388-55-9
2.	Amyl cinnamal *	122-40-7
3.	Amylcinnamyl alcohol *	101-85-9
4.	Amyl salicylate	2050-08-0
5.	Anethole	4180-23-8
6.	Anise alcohol *	105-13-5
7.	Benzaldehyde	100-52-7
8.	Benzyl alcohol *	100-51-6
9.	Benzyl benzoate *	120-51-4
10.	Benzyl cinnamate *	103-41-3
11.	Benzyl salicylate *	118-58-1
12.	Butylphenyl methylpropional *	80-54-6
13.	Camphor	76-22-2; 464-49-3
14.	beta-caryophyllene	87-44-5
15.	Carvone	99-49-0; 6485-40-1; 2244-16-8
16.	Cinnamal *	104-55-2
17.	Cinnamyl alcohol *	104-54-1
18.	Citral*	5392-40-5
19.	Citronellol *	106-22-9; 1117-61-9; 7540-51-4
20.	Coumarin *	91-64-5
21.	(Damascenone) Rose Ketone-4	23696-85-7

	INCI Name of fragrance allergen	CAS number
22.	Alpha-Damascone (TMCHB)	43052-87-5; 23726-94-5
23.	cis-beta-Damascone	23726-92-3
24.	delta-Damascone	57378-68-4
25.	Dimethylbenzyl carbiny acetate (DMBCA)	151-05-3
26.	Eugenol*	97-53-0
27.	Eugenyl acetate	93-28-7
28.	Farnesol *	4602-84-0
29.	Geranial	141-27-5
30.	Geraniol *	106-24-1
31.	Geranyl acetate	105-87-3
32.	Hexadecanolactone	109-29-5
33.	Hexamethylindanopyran	1222-05-5
34.	Hexyl cinnamal *	101-86-0
35.	Hydroxycitronellal *	107-75-5
36.	Isoeugenol *	97-54-1
37.	Isoeugenyl acetate	93-29-8
38.	alpha-isomethyl ionone *	127-51-5
39.	(DL)-Limonene *	138-86-3
40.	Linalool *	78-70-6
41.	Linalyl acetate	115-95-7
42.	Menthol	1490-04-6; 89-78-1; 2216-51- 5
43.	6-methyl coumarin	92-48-8
44.	Methyl 2-octynoate *	111-12-6
45.	Methyl salicylate	119-36-8
46.	3-Methyl-5-(2,2,3-trimethyl-3-cyclopentenyl)pent-4-en-2-ol	67801-20-1
47.	Alpha-Pinene; beta-pinene	80-56-8; 127-91-3

	INCI Name of fragrance allergen	CAS number
48.	Propylidene phthalide	17369-59-4
49.	Salicylaldehyde	90-02-8
50.	alpha-Santalol; beta-santalol	115-71-9; 77-42-9
51.	Sclareol	515-03-7
52.	Terpineol (mixture of isomers)	8000-41-7
53.	Alpha-terpinene	99-86-5
54.	alpha-Terpineol	10482-56-1 ; 98-55-5
55.	Terpinolene	586-62-9
56.	Tetramethyl acetyloctahydronaphthalenes	54464-57-2 ;54464-59-4 ;68155-66-8 ; 68155-67-9
57.	Trimethyl-benzenepropanol (Majantol)	103694-68-4
58.	Vanillin	121-33-5
Natural extracts		
59.	<i>Cananga Odorata Flower Extract; Cananga Odorata Flower Oil</i>	83863-30-3; 8006-81-3
60.	<i>Cedrus Atlantica Bark Extract; Cedrus Atlantica Bark Water; Cedrus Atlantica Leaf Extract; Cedrus Atlantica Wood Extract; Cedrus Atlantica Wood Oil; Cedrus Atlantica Bark Oil</i>	92201-55-3; 8000-27-9
61.	<i>Cinnamomum Cassia Leaf Oil</i>	8007-80-5
62.	<i>Cinnamomum Zeylanicum Bark Oil</i>	84649-98-9
63.	<i>Citrus Aurantium Amara Flower Oil; Citrus Aurantium Amara Peel Oil</i>	8016-38-4; 72968-50-4
64.	<i>Citrus Bergamia Peel Oil Expressed</i>	89957-91-5
65.	<i>Citrus Limon Peel Oil</i>	84929-31-7
66.	<i>Citrus Sinensis Peel Oil Expressed; Citrus Aurantium Dulcis Peel Oil Expressed; Citrus Aurantium Dulcis Peel Oil</i>	97766-30-8; 8028-48-6
67.	<i>Cymbopogon Citratus Leaf Oil; Cymbopogon Schoenanthus Oil</i>	89998-14-1; 8007-02-1; 89998-16-3

	INCI Name of fragrance allergen	CAS number
68.	<i>Eucalyptus Species</i> Leaf Oil; <i>Eucalyptus Globulus</i> Leaf Oil	92502-70-0; 8000-48-4
69.	<i>Eugenia Caryophyllus</i> Leaf Oil; <i>Eugenia Caryophyllus</i> Flower Oil	8000-34-8
70.	<i>Evernia Furfuracea</i> Extract *	90028-67-4
71.	<i>Evernia Prunastri</i> Extract *	90028-68-5
72.	<i>Jasminum Grandiflorum</i> Flower Extract; <i>Jasminum Officinale</i> Flower Oil; <i>Jasminum Officinale</i> Oil	84776-64-7; 90045-94-6; 8022-96-6
73.	<i>Juniperus Virginiana</i> Oil; <i>Juniperus Virginiana</i> Wood Oil;	8000-27-9; 85085-41-2
74.	<i>Laurus Nobilis</i> Oil; <i>Laurus Nobilis</i> Leaf Oil	8002-41-3; 8007-48-5; 84603-73-6
75.	<i>Lavandula Hybrida</i> Herb Oil	91722-69-9
76.	<i>Lavandula Officinalis</i> Flower Oil; <i>Lavandula Angustifolia</i> Oil	84776-65-8; 800-28-0
77.	<i>Mentha Piperita</i> Oil	8006-90-4; 84082-70-2
78.	<i>Mentha Spicata</i> Herb Oil; <i>Mentha Viridis</i> Extract	84696-51-5
79.	<i>Myroxylon Pereirae</i> Balsam Extract; <i>Myroxylon Balsamum Pereirae</i> Balsam Oil	8007-00-9;
80.	<i>Narcissus Poeticus</i> Extract; <i>Narcissus Poeticus</i> Flower Extract	Diverse
81.	<i>Pelargonium Graveolens</i> Flower Oil	90082-51-2; 8000-46-2
82.	<i>Pinus Mugo</i> Leaf Oil; <i>Pinus Mugo</i> Twig Leaf Extract; <i>Pinus Mugo</i> Twig Oil; <i>Pinus Pumila</i> Twig Leaf Extract; <i>Pinus Pumila</i> Twig Leaf Oil	90082-72-7; 97676-05-6
83.	<i>Pogostemon Cablin</i> oil	8014-09-3 ; 84238-39-1
84.	<i>Rosa Alba</i> Flower Extract; <i>Rosa Canina</i> Flower Oil; <i>Rosa Centifolia</i> Flower Oil; <i>Rosa Damascena</i> Flower Oil; <i>Rosa Gallica</i> Flower Oil; <i>Rosa Moschata</i> Oil; <i>Rosa Rugosa</i> Flower Oil	Diverse
85.	<i>Santalum Album</i> oil; <i>Santalum Album</i> Wood Oil;	84787-70-2 ; 8006-87-9
86.	Turpentine (oil, gum)	8006-64-2 ; 9005-90-7 ; 8052-14-0

	INCI Name of fragrance allergen	CAS number
87.	<i>Lippia Citriodora</i> Leaf/Flower Oil; <i>Lippia Citriodora</i> Oil (Verbena Absolute (<i>Lippia Citriodora</i> Kunth.))	8024-12-2