GUIDELINES ON THE 'FRAGRANCE ALLERGENS' REQUIREMENTS

07/11/2023
Contact person: Pamina Mika Suzuki, psuzuki@cosmeticseurope.eu
Gerald Renner, grenner@cosmeticseurope.eu
Maxime Jacques, mjacques@cosmeticseurope.eu

Table of Contents

Background

The new 'fragrance allergens' labelling regulation (Commission Regulation (EU) 2023/1545 of 26 July 2023 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products) aims to protect allergic individuals through providing them labelling information that allows them to make a proper choice when buying products. This Commission Regulation sets out new obligations for the labelling of an extended list of so called 'fragrance allergens' in addition to the one set by directive 2003/15/CE. The date of the entry into force of the new regulation is 16 August 2023. However, for new restrictions a transition period is foreseen until 31 July 2026 for placing products on the market, and until 31 July 2028 for withdrawal of products from the market.

At present, 24 so called 'fragrance allergens' (26 initially, but two are banned now[1]) are to be listed in the list of ingredients even if they are constituents of a perfume, aroma or complex ingredient. Labelling is mandatory if the substance is present in the cosmetic product above specific threshold concentrations, which are different for leave-on and rinse-off products. The new regulation expands this list to 80+ allergens[2]. Note that the purpose of this additional labelling is to inform those sensitised individuals who have been tested and know which ingredients to avoid. It will tell them whether the substance to which they are sensitised is present in the product. **The formula has not changed.** There is no requirement to remove these substances and no need to consider reformulating out of these ingredients. The overwhelming majority of cosmetic users will not experience any undesirable effects associated with the presence of these substances.

The expansion of the list of allergens introduced new regulatory and implementation challenges, such as:

- Many complex names to be memorised by allergic consumers for the same type of allergen.
- Issue of space on labels due to very long list of ingredients.

To address these issues, a new annex III regulatory approach had to be developed in the new regulation, allowing substances with the same cross-sensitising properties to be listed under a common group name rather than the individual substance name.

A third challenge linked to the expansion of the list of allergens is the need to secure globally compatible labels. To reduce the impact at international level and facilitate the acceptance of the new EU labelling requirements globally, INCI names were allocated to those substances that had none and to the newly created group names. More details on the expected impacts are provided in the annex.

Purpose

The main purpose of this guidance document is to help companies to understand and correctly interpret the 'fragrance allergens' labelling requirements and adapt its practices to ensure continued compliance. The guidelines were developed with the aim to complement the general COLIPA Guidelines on Cosmetic Product Labelling of 15 December 2011 and provide a regulatory analysis of the sometimes quite complex labelling scenarios which were either introduced by the new regulation or encountered with the implementation of the past 'fragrance allergens' provisions. At the end of the guidelines – in chapter 4.1 and 4.2 - there are tables summarising the requirements with practical examples.

[1] Lilial (CAS 80-54-6) banned since March 2022; Lyral (CAS 31906-04-4, 51414-25-6) banned since August 2019.
[2] The entries containing requirements on the 80+ allergens are entries 45, 46, 67, 69 to 78, 80 to 82, 84 to 92, , 109, 114, 122, 124, 131, 133, 154,157,175,196, 324 and 327 to 371

Chapter 1: List of ingredients: labelling of cosmetic ingredients vs 'fragrance allergens'

Ingredients are substances that are intentionally added in the manufacturing process of a cosmetic product - this includes all extracts, perfume blends, emulsifiers, thickeners, essential oils, fragrance materials like geraniol, etc. Article 19.1(g) of Regulation (EC) No 1223/2009 requires that:

- A list of ingredients is indicated on the packaging of the cosmetic product.
- All cosmetic ingredients - defined as '*any **substance or mixture intentionally used** in the cosmetic product **during** the process of **manufacturing**'* - are to be labelled in the ingredient list of the packaging.
- Perfume and aromatic compositions and their raw materials are to be referred to by the terms 'parfum' or 'aroma' in the list of ingredients.

In addition, article 19.1(g) requires that the list of ingredients is complemented by substances the mention of which is required under the column h ('Other') in Annex III to that Regulation.

For the labelling of an allergen, the article states that it is the presence of the substance regardless of whether it has been added to a perfume mixture, NCS (Natural Complex Substance) or is present in other raw materials as cosmetic ingredient, that triggers the labelling, provided that the concentration exceeds the Labelling Threshold (LT). This is specified:

- in article 19.1(g): *'Moreover, **the presence of substances, the mention of which is required under the column 'Other' in Annex III, shall be indicated in the list of ingredients** in addition to the terms parfum or aroma.'*.
- in the wording used under column h ('Other') of the Annex III allergens entries: '***The presence of the substance [or substances] shall be indicated in the list of ingredients** referred to in Article 19(1), point (g), when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products'*.

Chapter 2: Different types of sources of the 80+ allergens in cosmetic products.

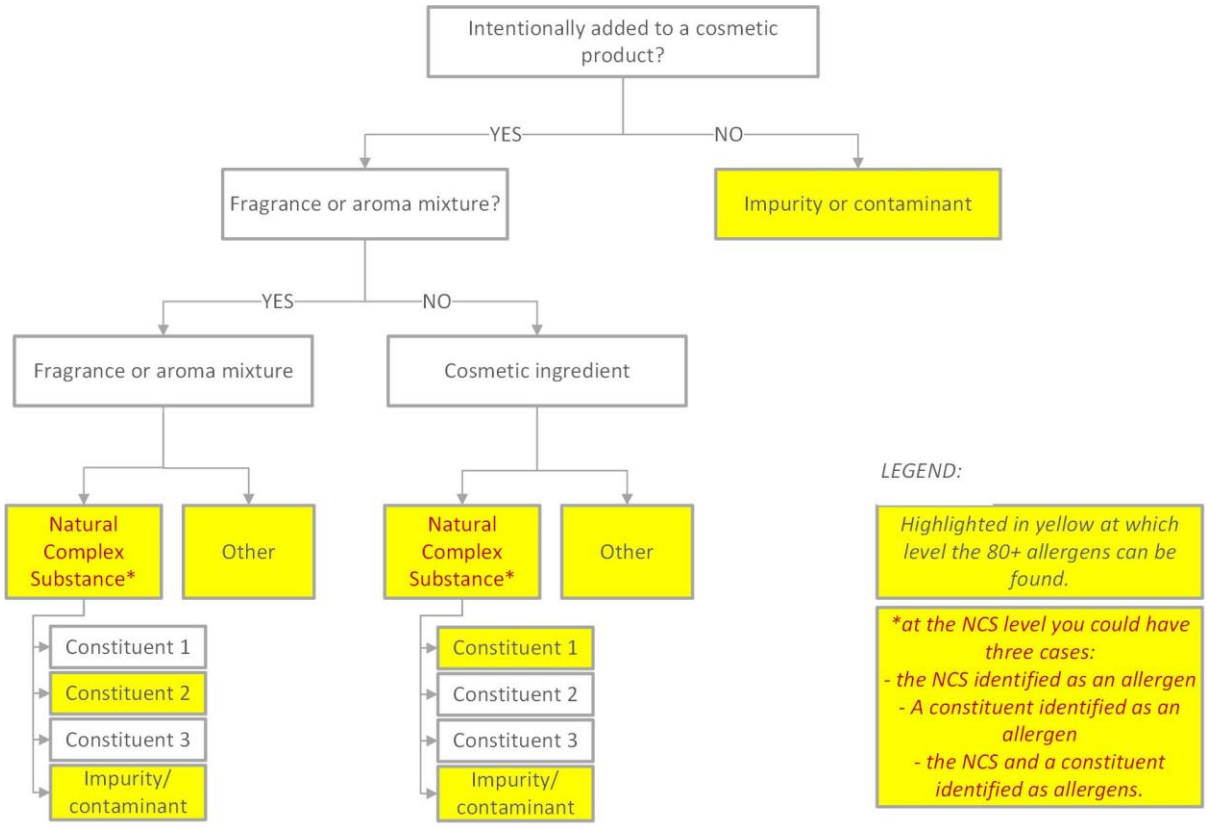
The term 'fragrance allergens' is a misnomer used to refer to contact allergens that are usually present in fragrance compositions. The new regulation itself uses the term 'fragrance allergens'. Given that no definition is given to this term in the regulation, its use in the regulatory context could lead someone to think that the new labelling requirements apply only if the source of the allergen is in a fragrance mixture, which is not correct. **The presence of the 80+ allergens[3]** (i.e. the substances in the scope of entries 45, 46, 67, 69 to 78, 80 to 82, 84 to 92, 109, 114, 122, 124, 131, 133, 154,157,175,196, 324 and 327 to 371) **is to be labelled regardless of its source.**

[3] For the purpose of this guidance document the term '80+ allergens' refers also to certain pre-haptens and pro-haptens identified by the SCCS and taken in Annex III of the Regulation. According to the SCCS, pre-haptens and pro-haptens are chemicals that are not allergens themselves but need to be activated either through abiotic activation (pre-haptens) and/or through biotic (enzyme mediated) mechanisms (pro-haptens) to acquire skin sensitisation potential. This type of activation occurs after the product is applied by the consumer. The prehaptens and prohaptens listed in table 13-6 of SCCS/1459/11 are included in the annex III labelling requirements. Recital 7 of the new adopted regulation provides the regulatory rational for their inclusion in annex III: "*fragrance substances, such as prehaptens and prohaptens, that can be transformed to known contact allergens via air oxidation or bioactivation should be treated as equivalent to fragrance allergens and be subject to the same restrictions and other regulatory requirements*".

An allergen can be present in a cosmetic product due to:

a) Its presence in the fragrance or aroma mixture either added directly or as part of a natural complex substance (e.g., essential oil, botanical extract)
b) Its presence as constituent of a natural complex substance (NCS) (e.g., essential oil, botanical extract)
c) Its presence as an impurity or contaminant
d) A combination of two or more of the above (no contribution as cosmetic ingredient)
e) Its intentional addition as a cosmetic ingredient (i.e., not a fragrance or aroma mixture)
f) Combination of (e) and one or more of the above

Figure 1. Graphic illustration showing at which levels of the decision tree the 80+ allergens can be found.
NB: this decision tree is not a labelling guideline and does not indicate how to label. The guidance documnet tells how to label.



In the legislation this general allergen labelling requirement is addressed in different ways. If some cases are already covered by the application of article 19.1(g) – e.g. scenario e, others require the application of the annex III labelling requirements - case a, b, c.

The following sub-chapters analyse, in more detail, each scenario listed above. For simplification the following sub-chapters refer to stand-alone and grouped allergens (further described under chapter 4) as 'allergen' in singular, regardless of whether it refers to one substance (= allergen) or more substances with cross-sensitisation properties. Under chapter 4 the below 'simplified scenarios' are combined with the Grouped and Standalone concept applied in the legislation.

a) Presence of the allergen as constituent in a fragrance or aroma mixture

This is the most straightforward case. The allergen is only present in the fragrance mixture. The Responsible Person needs to look at the concentration of the allergen in the final cosmetic product and if it exceeds the labelling threshold (LT), the allergen is to be labelled. The concentration in the final cosmetic product is calculated based on the information provided by the fragrance supplier (e.g., information exchange document with IFRA[4]).

In case variations in the concentration are expected (e.g., seasonal variation of the composition of a natural raw material), it is recommended to apply a worst-case assumption to define if the concentration of the allergen can exceed the LT.

b) Presence of the allergen as constituent of a natural complex substances (essential oil, botanical extract)

The same logic as under scenario (a) applies. Based on the information provided by the supplier regarding the concentration of the allergen in the raw material[5], the Responsible Person of the cosmetic company should determine the concentration in the final product. If the concentration of the allergen in the final cosmetic product exceeds the LT, the allergen is to be labelled.

Some of the 80+ allergens are NCS. Hence, they need to be labelled if their concentration exceeds the LT. Some of them contain as a natural constituent another allergen that also belongs to the 80+ allergens. In the case of an allergen that is constituent of another allergen (natural complex substance), if their individual concentrations (considered separately) exceed the LT, the legislation requires the label of both allergens - the natural complex substance and the constituent in question.

In case variations in the concentration are expected (e.g., seasonal variation of the composition of a natural raw material), it is recommended to apply a worst-case assumption to define if the concentration of the allergen can exceed the LT.

c) Impurities or contaminants

The unintended presence of one of the 80+ allergens, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, or migration from packaging (although very unlikely) is to be mentioned in the list of ingredients, if the concentration of the allergen in question exceeds the LT.

In case variations in the concentration are expected (e.g., seasonal variation of the composition of a natural raw material), it is recommended to apply a worst-case assumption to define if the concentration of the allergen can exceed the LT.

d) Presence of the allergen as a combination of two or more of the above cases (i.e., no contribution as cosmetic ingredient)

The Responsible Person needs to consider all the contributions of each of the sources and if the total concentration exceeds the LT, the allergen is to be labelled.

---

[4] Guidelines on exchange of information between fragrance suppliers and cosmetic manufacturers, compliance with the product information requirements of article 11 of the EU Cosmetics Regulation 1223/2009, Cosmetics Europe and International Fragrance Association (IFRA), Revised Version 2014

[5] A guideline exists on the information exchange between suppliers and cosmetic companies regarding the 24 allergens (see footnote 4). This guideline should also be applied to the extended list of allergens. We expect that the guideline will be updated in this respect.

e) Direct use of the allergen as a cosmetic ingredient

The general provisions of article 19.1(g) cosmetics ingredients labelling requirement prevails over the specific provisions set out in the annexes.

Therefore, when the allergen is used directly as cosmetic ingredient its presence is to be labelled regardless of the concentration.

f) Direct use of the allergen as a cosmetic ingredient and presence of the allergen as a combination of one or more of the above cases

Similarly to case (e), the direct use of the allergen as a cosmetic ingredient requires its labelling regardless of the concentration of the allergen in the product.

Chapter 3: other relevant regulatory principles not specific for labelling of allergens

Chapter 3.1: Order of declaration

According to article 19.1(g), '*The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.*'

Legally speaking, the listing of the presence of a substance is not part of the general ingredient listing. From a regulatory point of view, one can either apply the approach for ingredient listing (i.e. consider their concentration to define the position in the ingredient list) or put the allergens names at the end, since the allergens information is supplementary information to the ingredient list. The company can decide the approach they prefer. What would not be correct is to label the allergen in a random place in the ingredient list among those ingredients having a concentration >1%, as that would indicate a wrong concentration of the substance in the cosmetic product and can be considered as misleading the consumer.

Chapter 3.2: Scope of an annex III entry

Especially for natural ingredients, the exact scope of an Annex III requirements is not always obvious from the wording of the entry.

In principle, the scope of an Annex III entry is defined by four columns (b to e) that are listed under the heading 'Substance identification':

b) Chemical Name

c) Name of Common Ingredient Glossary

d) CAS Number

e) EC Number

In case of single, stand-alone substances (e.g., Isoeugenol), these four columns are usually fully consistent with each other, i.e., each column providing a unique identifier for the same single substance.

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
73	Phenol, 2-methoxy-4-(1-propenyl) (E)-2-methoxy-4-(prop-1-enyl)phenol; (trans-Isoeugenol) (Z)-2-methoxy-4-(prop-1-enyl)phenol; (cis-Isoeugenol)	Isoeugenol	97-54-1 5932-68-3 5912-86-7	202-590-7 227-678-2 227-633-7	(a) Oral products (b) Other products	(b) 0,02 %	(a) (b) The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products.	

However, in cases there are inconsistencies between columns, it is column b) 'chemical name' that should be considered to define the scope.

An example to illustrate this principle would be Cinnamomum cassia leaf oil. The labelling requirements laid down under column h ('Other') only apply to Cinnamomum cassia leaf oil.

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
X [OP: please replace with the next consecutive number]	Cinnamomum cassia leaf Oil*	Cinnamomum Cassia Leaf Oil	8007-80-5/ 84961-46-6	-/ 284-635-0			The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products.	

Other ingredients obtained from Cinnamomum cassia, such as Cinnamomum cassia extract, Cinnamomum cassia bark, Cinnamomum cassia bark powder, Cinnamomum cassia bark extract are out of the scope of the labelling requirements.

Note, however, that 'Cinnamomum cassia oil' which does not specify the plant part from which the oil is obtained, would be considered as covered by the labelling requirement because it cannot be excluded that the oil was obtained from the leaves.

Furthermore, in case where one Annex III entry covers several substances, it is possible that the identification in column b) 'chemical name' is broader than the specific substances listed in column c) to d), which are based on the existing INCI names at that time[6]. Also in this case, the scope of the entry is ultimately defined by column b). The other columns should be considered as examples of specific substances that are in scope, but not as an exhaustive list.

[6] Note that the Commission is not systematically updating column c when new INCI names are introduced.

Chapter 4: Two approaches for naming of allergens: Standalone and Grouped

In the regulation there are two regulatory approaches for the naming of allergens in annex III, which are referred to in the document as '**Standalone**' and '**Grouped**'.

The **Standalone allergen entry** approach is the usual regulatory approach used in the past for the 24 allergens: i.e., one allergen = one substance = 1 Glossary/INCI name. In stand-alone allergen entries the labelling requirement is set out by specifying under column h ('Other') the LT and under column c ('Glossary') the labelling name to be used. Figure 1 provides an example of stand-alone allergen entry.

Figure 1: example of Standalone allergen entry – Geraniol.

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
78	2,6-Octadien-1-ol, 3,7-dimethyl-, (2E)-	Geraniol	106-24-1	203-377-1			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

One Single Name under column c.

No Group Name under column h.

Therefore, if geraniol is present in the finished product in a concentration above 0.001% for leave-on and 0.01% for rinse-off, the ingredient has to be added to the list of ingredients as 'geraniol'.

The **Grouped allergen entry** approach is a new regulatory approach which was developed to solve the issue of the length of ingredient lists which would have made the label too long and complicated, and therefore not consumer friendly (especially for allergic people). During the decision-making process, the overarching goal of the industry was to provide consumers with simple information. For grouped allergens the allergic person only needs to know if the group of those substances with the same cross-sensitisation property is present (> LT). Thus, instead of forcing the allergic person to memorise the whole list of substances belonging to the same cross-sensitisation group, only one name for each group is to be memorised by the concerned allergic consumers. That is the so called '**Group Names' (GN)**, which in the legislation is provided under column h. All GN are recognised INCI names.

It is important to outline that if the sum of the concentrations of the substances belonging to the same group is above the LT, the use of the GN is mandatory. As regards Single Names (SN – i.e., the glossary name provided under column c of the entry) of the substance that belongs to the same group, its labelling in addition to the GN is not mandatory. A company can however decide to provide the SN as additional information, since the legislation does not forbid indicating additional information in the ingredient list. Note that the guidance on the order of declaration under chapter 3.1 would apply.

An example of grouped allergen entry is provided in Figure 2. The characteristics of such entry are the following:

- The scope of the entry covers all substances with the same cross-sensitisation property (broad column b scope).
- The mandatory labelling of the allergen is triggered if the **sum of the concentrations of the substances** covered by the same entry exceeds the thresholds of 0,001 % in leave-on products or 0,01 % in rinse-off products (referred to as '**Labelling Threshold'** or **'LT'** throughout this document);
- The labelling name to be used to identify the allergen (**Group Name**) is specified under column h (not c, as for Standalone allergens entries).

Figure 2: example of grouped allergens entry – Citrus Aurantium Flower Oil.

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
X [OP: please replace with the next consecutive number]	Citrus Aurantium Amara and Dulcis Flower oil*	Citrus Aurantium Amara Flower Oil Citrus Aurantium Dulcis Flower Oil	72968-50-4 8028-48-6/ 8016-38-4	277-143-2 232-433-8/ -			The presence of the substance or substances shall be indicated as 'Citrus Aurantium Flower Oil' in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products.	

More than one Single Name under column c.

Group Name provided under column h.

In this case, if a leave-on product contains 0,0008 % of citrus aurantium amara flower oil and 0,002 % of citrus aurantium dulcis flower oil, their sum exceeds the LT for leave-on products. Thus, the two allergens are to be labelled by using the GN 'Citrus aurantium flower oil'. If the company wish to also add the SNs 'Citrus aurantium amara flower oil' and 'Citrus aurantium dulcis flower oil' as additional information, that is possible, but it is not mandatory.

Below a list of the grouped substances is provided and their group names included in the regulation, for easier reference. However, please refer to the regulation text for the requirements.

Reference number	Chemical name/INN	Name of Common Ingredients Glossary	Group Name (column H of Annex III)
70	3,7-Dimethyl-2,6-octadienal (E)-3,7-dimethylocta-2,6-dienal (Z)-3,7-dimethylocta-2,6-dienal	Citral Geranial Neral	Citral

109	*Pinus mugo* leaf and twig oil and extract	Pinus Mugo Leaf Oil; Pinus Mugo Twig Leaf Extract; Pinus Mugo Twig Oil	Pinus Mugo
114	*Pinus pumila* leaf and twig oil and extract	Pinus Pumila Needle Extract; Pinus Pumila Twig Leaf Extract; Pinus Pumila Twig Leaf Oil	Pinus Pumila
122	*Cedrus atlantica* oil and extract	Cedrus Atlantica Bark Extract; Cedrus Atlantica Bark Oil; Cedrus Atlantica Bark Water; Cedrus Atlantica Leaf Extract; Cedrus Atlantica Wood Extract; Cedrus Atlantica Wood Oil	Cedrus Atlantica Oil/ Extract
154	*Myroxylon balsamum* var. *pereirae*; extracts and distillates; Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)	Myroxylon Balsamum Pereirae Balsam Extract; Myroxylon Balsamum Pereirae Balsam Oil; Myroxylon Pereirae Oil; Myroxylon Pereirae Resin Extract; Myroxylon Pereirae Resin	Myroxylon Pereirae Oil/ Extract
157	1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one 1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (Z)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (E)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one	Alpha-Damascone cis-Rose ketone 1 trans-Rose ketone 1 Rose ketone 4 (Damascone) Rose ketone 3 (delta-Damascone) trans-Rose ketone 3 cis-Rose ketone 2 (cis-beta-Damascone) trans-Rose ketone 2 (trans-beta-Damascone)	Rose Ketones
347	Cananga odorata flower oil and extract; Ylang Ylang flower oil and extract	Cananga Odorata Flower Extract; Cananga Odorata Flower Oil	Cananga Odorata Oil/Extract
350	Citrus aurantium amara and dulcis flower oil	Citrus Aurantium Amara Flower Oil Citrus Aurantium Dulcis Flower Oil	Citrus Aurantium Flower Oil
351	Citrus aurantium amara and dulcis peel oil	Citrus Aurantium Amara Peel Oil Citrus Aurantium Dulcis Peel Oil; Citrus Sinensis Peel Oil	Citrus Aurantium Peel Oil
354	Cymbopogon citratus / schoenanthus/	Cymbopogon Schoenanthus Oil Cymbopogon Flexuosus Oil	Lemongrass Oil

	flexuosus oils	Cymbopogon Citratus Leaf Oil	
355	Eucalyptus globulus oil	Eucalyptus Globulus Leaf Oil; Eucalyptus Globulus Leaf/Twig Oil	Eucalyptus Globulus Oil
356	Eugenia caryophyllus oil	Eugenia Caryophyllus Leaf Oil Eugenia Caryophyllus Flower Oil Eugenia Caryophyllus Stem oil Eugenia Caryophyllus Bud oil	Eugenia Caryophyllus Oil
357	Jasminum grandiflorum / officinale oil and extract	Jasminum Grandiflorum Flower Extract; Jasminum Officinale Oil; Jasminum Officinale Flower Extract	Jasmine Oil/Extract
358	Juniperus virginiana oil	Juniperus Virginiana Oil; Juniperus Virginiana Wood Oil	Juniperus Virginiana Oil
360	Lavandula hybrida oil/extract; Lavandula intermedia oil/extract; Lavandula angustifolia oil/extract	Lavandula Hybrida Oil; Lavandula Hybrida Extract; Lavandula Hybrida Flower Extract; Lavandula Intermedia Flower/Leaf/Stem Extract; Lavandula Intermedia Flower/Leaf/Stem Oil; Lavandula Intermedia Oil Lavandula Angustifolia Oil; Lavandula Angustifolia Flower/Leaf/Stem Extract	Lavandula Oil/ Extract
363	Narcissus poeticus/pseudonarcissus/jonquilla/tazetta extract	Narcissus Poeticus Extract Narcissus Pseudonarcissus Flower Extract Narcissus Jonquilla Extract Narcissus Tazetta Extract	Narcissus Extract
366	Rosa damascena flower oil/extract; Rosa alba flower oil/extract; Rosa canina flower oil; Rosa centifolia oil/extract; Rosa gallica flower oil; Rosa moschata flower oil; Rosa rugosa flower oil	Rosa Damascena Flower Oil; Rosa Damascena Flower Extract Rosa Alba Flower Oil; Rosa Alba Flower Extract Rosa Canina Flower Oil Rosa Centifolia Flower Oil; Rosa Centifolia Flower Extract Rosa Gallica Flower Oil Rosa Moschata Flower Oil Rosa Rugosa Flower Oil	Rose Flower Oil/Extract

How do I recognise if the entry is a Standalone or Grouped allergen entry?

You need to look to whether a name (i.e., Group Name) is provided or not under column h:

- if **column h specifies the name to be used**, then that is a **Grouped allergen entry**,
- if **column h does not specify the name**, then that is a **Standalone allergen entry**.

The next subchapters delve more into deep as regards the complexities of cases that could be encountered when applying the allergens labelling requirements and aim at tackling the different complex cases from al the three perspectives described under chapter 2 (source of the allergen), 3 (order of declaration) and 4 (standalone vs grouped allergens).

Chapter 4.1: Stand-alone allergen – examples of potential scenarios:

The following table could be used as template to combine the concepts described in the previous chapters (labelling and allergen source) for stand-alone allergens. Every company will need to assess their own specific scenarios, ingredients, and concentrations. Few scenarios are described but more could be encountered.

Note that some of these examples in the table are just theoretical examples provided to cover as many cases as possible and not real examples.

Cases – examples of an allergen in a rinse-off product originating from:				
(a) fragrance or aroma mixture	**(b) NCS (essential oil, botanical extract)**	**(c) impurity or contaminant**	**(e) its intentional addition as cosmetic ingredient**	**Allergen to be labelled? (LT for rinse-off product = 0.01%)**
Geraniol: 0.001% **(<LT)**	none	none	none	**No**: the concentration is < LT
Geraniol: 0.1 % **(>LT)**	none	none	none	**Yes**: 'Geraniol' is to be labelled as its concentration is > LT
none	none	none	**Geraniol**	**Yes:** 'Geraniol' is to be labelled regardless of its concentration, as the general labelling requirements for cosmetic ingredients set out in art 19.a(g) applies in this case.
Geraniol: 0.002% **(< LT)**.	none	none	**Geraniol**: 0.007% **(<LT).**	**Yes**: Even though geraniol is present in the rinse-off product at a concentration <LT (tot. 0.009%), the ingredient Geraniol is to be labelled according to the general labelling requirements for cosmetic ingredients.
none	**Geraniol** is a natural **constituent in Melissa Officinalis Oil (not part of 80+)**. **Melissa Officinalis Oil** (**NCS**) is used as cosmetic ingredient at 0.5% (contains 3.79% geraniol). The contribution of Geraniol as constituent of this NCS in the final product is 0.019% **(>LT)**.	none	none	**Yes:** Geraniol is to be labelled as its concentration is >LT. *(Note: Melissa Officinalis Oil has to be labelled because it is added as cosmetic ingredient.)*

Cases – examples of an allergen in a rinse-off product originating from:				
(a) fragrance or aroma mixture	**(b) NCS (essential oil, botanical extract)**	**(c) impurity or contaminant**	**(e) its intentional addition as cosmetic ingredient**	**Allergen to be labelled? (LT for rinse-off product = 0.01%)**
Lavandula Hybrida Oil: 1,3 % **(>LT)** **Linalool** (45% contained in Lavandula Hybrida Oil used in Fragrance Mixture): 0,585 % **(>LT)**	none	None	none	**Yes**: both 'Lavandula Oil/Extract' and 'Linalool' are to be labelled as their respective concentrations are both above the corresponding LTs to those two allergens.
Lavandula Oil/Extract 0,013 % **(>LT)** **Linalool** (45% contained in Lavandula Oil/Extract used in Fragrance Mixture): 0,0058% **(<LT)**	none	none	none	**Yes**: Only 'Lavandula Oil/Extract' is to be labelled as its concentration is >LT. **No**: 'Linalool' is not to be labelled as <LT.
none	none	**Linalool** % **> LT**.	none	**Yes**
none	none	**Linalool** % **< LT**	none	**No**

Cases – examples of an allergen in a rinse-off product originating from:				
(a) fragrance or aroma mixture	**(b) NCS (essential oil, botanical extract)**	**(c) impurity or contaminant**	**(e) its intentional addition as cosmetic ingredient**	**Allergen to be labelled? (LT for rinse-off product = 0.01%)**
Linalool: 0.008% **(< LT)**.	none	**Linalool** : 0.004% **(<LT)**	none	**Yes:** as total concentration of Linalool in the rinse-off product is 0.012% (**> LT**)
Linalyl Acetate:0.008% **(<LT)**	**Linalyl acetate** (28.63% contained in Citrus aurantium bergamia peel oil) : 0.0086% **(<LT)**	none	**Citrus Aurantium Bergamia Peel Oil**: 0.03% **(>LT)**	**Yes:** Both allergens ('Citrus Aurantium Bergamia Peel Oil' and 'Linalyl Acetate') need to be labelled as their concentrations in the cosmetic products are > LT: Citrus Aurantium Bergamia Peel Oil = 0.03%; Linalyl Acetate: 0.0166%.

Chapter 4.2: Grouped allergens – examples of potential scenarios:

The following table could be used as template to combine the concepts described in the previous chapters (labelling and allergen source) for grouped allergens. Every company will need to assess their own specific scenarios, ingredients, and concentrations. Few scenarios are described but more combinations are possible.

Note that some of these examples in the table are just theoretical examples provided to cover as many cases as possible and not real examples.

Concentration of the allergen in a rinse-off product originating from:				**On the label:**	
(a) fragrance or aroma mixture	**(b) NCS (essential oil, botanical extract)**	**(c) impurity or contaminant**	**(e) its intentional addition as cosmetic ingredient**	**Group Name (GN) to be labelled?**	**Single Name (SN) to be labelled?**
Narcissus Poeticus Extract **(<LT)**			Narcissus Pseudonarcissus Flower Extract **(<LT)**	Sum < LT : GN not mandatory.	Since the ingredient is used as cosmetic ingredient the company must label either with the **SN ('Narcissus Pseudonarcissus Flower Extract) OR** with the **GN (Narcissus Extract').**
Narcissus Poeticus Extract **(<LT)**			Narcissus Pseudonarcissus Flower Extract **(<LT)**	Sum > LT: Yes, mandatory to label with '**Narcissus Extract'**	No*
none	none	none	Narcissus Poeticus Extract 0,008% AND Narcissus Pseudonarcissus Flower Extract = 0,008% **∑=0.016% (>LT)**	Yes: '**Narcissus Extract'**	No*

Concentration of the allergen in a rinse-off product originating from:				On the label:	
(a) fragrance or aroma mixture	**(b) NCS (essential oil, botanical extract)**	**(c) impurity or contaminant**	**(e) its intentional addition as cosmetic ingredient**	**Group Name (GN) to be labelled?**	**Single Name (SN) to be labelled?**
Rose ketone 4= 0,004% AND Rose ketone 3= 0,005% **∑=0,009% (<LT)**	none	none	none	No	No
none	none	none	Citrus Aurantium Amara Flower Oil = 0,004% AND Citrus Aurantium Dulcis Flower Oil = 0,005% **∑=0,009% (<LT)**	As the concentration of the allergens is <LT, there is no obligation to label with the GN. A company can decide to use either the SN or the GN to fulfil the general labelling requirement for cosmetic ingredients (art. 19.1(g)). All GNs are INCI names. GNs could be used as synonym of SN.	
Citrus Aurantium Amara Flower Oil = 0,008% AND Citrus Aurantium Dulcis Flower Oil = 0,008% **∑=0,016% (>LT)**	none	none	none	Yes: **'Citrus Aurantium Flower Oil'**	No*

* The regulation does not require to label with the SN, but also does not prohibit to add additional information in the ingredient list. If, in this case, a company wish to add the SN (in addition to the GN), that could be provided as additional information.

ANNEX: International impact of the new EU allergen labelling requirements

An important challenge linked to the expansion of the list of allergens is the impact at international level, and the need to secure globally compatible labels for cosmetics. Indeed, regulatory discrepancies in labelling requirements fragment the market and create supply chain complexities and unnecessary additional cost.

It is crucial that the new allergen labelling requirements implemented in the EU are explained to global authorities to ensure their acceptance of the new labels and avoid unjustified re-notification or re-registration of products already on the market.

Several international regulatory issues and scenarios need to be considered:

INCI Nomenclature

To increase the compatibility of the labels following the new EU labelling requirements, INCI names, have been allocated by the globally accepted[7] International Nomenclature Committee (INC), for all individual allergens as well as for the newly created groups that will have to be mentioned on EU labels. Especially in countries where labelling of fragrance allergens is not mandatory, the use of INCI nomenclature will facilitate regulatory tolerance as 'additional information' for sensitized consumers about the presence of specific allergens in the product above the thresholds. In countries where a local nomenclature for cosmetic ingredients exists (e.g., China, Korea or Japan), the industry may have to ensure the update of the respective local nomenclature if they have to / want to indicate the fragrance allergens on the local packaging or over-stickered label.

Countries with similar labelling requirements to the EU

As of September 2023, about 50 countries are either directly referring to the EU cosmetics ingredient annexes in their local cosmetic regulation, or continuously adapting their annexes to mirror EU ingredients regulation locally. Consequently, at least 27 countries have implemented similar allergens labelling requirements for 24/26 substances, like it was done in the EU[8]. It can therefore be anticipated that many countries will either automatically link to the new EU labelling requirements or will mirror them sooner or later in their own regulation and/or ingredient inventory/database. For these countries, it will be paramount to ensure authorities' awareness and correct understanding not only of the correct scope of labelling but most importantly also of industry's need of time for analysis, information gathering from suppliers, labelling update, and stock depletion. Implementing the new fragrance labelling requirement too early could lead to technical challenges and important supply chain disruptions.

Countries without requirements for fragrance allergen labelling

Nevertheless, countries which do not / will not require fragrance allergen labelling historically allow the listing of the allergens on pack. These countries understand that their presence in the ingredient list is an EU requirement that provides additional safety information to sensitized consumers. In these

[7] As of today, at least 48 countries recognize or request listing of cosmetic ingredients using INCI names, in addition to the EU.

[8] According to the international cosmetic associations surveyed by Cosmetics Europe during the first half of 2023.

countries, it is particularly important to explain that the new labelling is simply an extended scope of an existing provision. All the clarification should be provided on the fact that the newly labelled allergenic substances or group of substances have always been present in the product, and that the evolution of the label does not reflect a change of formula. Such explanations could prevent the need to re-notify or re-register existing products in some countries.

In the case of China, which has a comprehensive positive list approach to cosmetic ingredients (Inventory of Existing Cosmetic Ingredients in China, IECIC), the lack of understanding could further lead to cumbersome regulatory requirements that would ultimately impede the access of EU products to the Chinese market. Even if it is accepted that the new labelling is not a formulation change, and that the allergens are not 'new ingredients', it may be necessary to submit a copy of the new label/ingredient list to update existing product notifications/registrations.

Countries not allowing listing of fragrance allergens in the ingredient list

In very rare cases, countries may not allow, under the local legislation, the listing of fragrance allergens on cosmetic products. For imported products, this may lead to differences between the ingredients list on the original packaging (with fragrance allergens) and the local label/sticker (without fragrance allergens).

These countries may formally require explanatory information to be provided to clarify this difference. For instance, for imported products in China, as of current practice a precautionary statement ''*this product contains XYZ*'' has to be made on the Chinese labeling when the names of allergens XYZ are present in the ingredient list of original packaging. Informing the Chinese regulatory authorities about the evolving EU labelling requirements is essential to ensure the extension of the current practice to all the newly disclosable allergens/group of substances.

Outreach to international regulatory bodies

Mindful of the potential challenges ahead, the EU cosmetic industry is preparing an explanatory paper to be shared with international regulators to help clarify the new regulatory requirements in the EU and introduce the allergen guideline.

This paper is aiming to ensure global authorities understand:

- that these additionally labelled substances/group of substances **were already present in the product** under the ingredient 'PARFUM' or 'FRAGRANCE' or as a substance/constituent of the existing ingredient and have not been newly added.
- thus, that the extension of the allergens list of the product is made to comply with new EU labelling requirements and **does not reflect a change of formula**.
- that all these substances and groups of substances are labelled with a **recognized INCI name**.
- **that there are implementation timelines** ('placing on the market' and 'making available') which are important for the industry because they need to conduct the assessment for each product and adapt the labelling in compliance with the new regulation.
- that allergens are labelled **to inform sensitized consumers about their presence in the product above the safety thresholds**. Asking the exact percentage of each allergen present in the formula is not appropriate since it does not accurately predict the risk of an allergic reaction and can thus be misleading.