GUIDANCE FOR THE USE OF IFRA STANDARDS

December 12, 2019

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Preamble

The International Fragrance Association (IFRA), founded in 1973, represents the interests and is the voice of the fragrance industry worldwide. It promotes the safety and benefits of the fragrance industry's products through stakeholder dialogue on a global basis.

When warranted by concerns regarding the safe use of a specific ingredient identified by the RIFM safety assessment program, IFRA will issue an IFRA Standard as part of an IFRA Amendment. IFRA Standards can either prohibit, restrict or set purity requirements for specific ingredients. The safety of ingredients, whether the subject of an IFRA Standard or not, remains the responsibility of IFRA members. Compliance with IFRA Standards is therefore necessary for compliance with the IFRA Code of Practice, but may not be sufficient to ensure regulatory compliance and the safety of fragrance mixtures or ingredients.

The IFRA Standards and related documents are subject to regular changes as new information relevant to the safety of fragrance ingredients become available. All these changes are part of an IFRA Amendment, which is designed pursuant to an inclusive procedure and is subject to a broad consultation of all relevant stakeholders before its Notification. The process for setting the Standards has been documented in detail and was broadly consulted with the membership. A summary of this process is provided in Section 2.

For the 49th Amendment, IFRA Standards reflect the introduction of several improvements of the risk assessment methodology. As already communicated to the membership by IL1032 and by the several webinars organized by IFRA and RIFM ahead of the consultation, these improvements specifically relate to the revised methodology of Quantitative Risk Assessment for fragrance ingredients (hereafter QRA2) and a new way to assess systemic toxicity based on an aggregate exposure model.

QRA2 is the outcome of the work undertaken by industry, academia, and other stakeholders under the IDEA multi-stakeholder forum to improve the QRA methodology used until now. This includes the review of the Safety Assessment Factors (SAFs) and the use of the RIFM/Creme model for aggregate exposure. For more details, please visit the IDEA website (http://ideaproject.info/) and consult the QRA2 publications (www.fragrancematerialsafetyresource.elsevier.com/).

As a result, the following improvements have been included in the 49th Amendment:

- The revision of the SAFs and the inclusion of aggregate exposure within QRA2 has led to different categories compared to QRA1. Thus, all the new and existing IFRA Standards for the Dermal Sensitization endpoint are based on QRA2 and include 12 QRA2 categories.
- The categories for Standards based on systemic toxicity, have been reviewed according to the aggregate exposure. The IFRA categories for systemic toxicity have been harmonized with the IFRA categories for QRA2. Moreover, the upper concentration levels derived from QRA2 have been checked for the systemic toxicity endpoint. Thus, the upper concentration levels reflected in the Standards are the lowest upper concentration level between QRA2 and systemic toxicity.

It is important that fragrance suppliers and users globally are fully informed about the above-mentioned changes, the implementation of this new approach and its impact. The main impact relates to the identification of acceptable levels of fragrance ingredients in different product types and how this will be managed on a practical basis through grouping of certain product types into product categories with specific limitations. The consultation and implementation period described below will enable the above-mentioned companies to fully take account of and manage that impact.

For the first time, this Guidance for the use of IFRA Standards combines the following documents that were previously distributed separately:

- Introduction to the IFRA Standards.
- IFRA-RIFM QRA information booklet.
- Standard Operating Procedure for the implementation timelines of Amendments to the IFRA Standards.

In addition, this Guidance for the use of IFRA Standards contains:

- A summary of the procedure for setting IFRA Standards.
- How the risk assessment of fragrance ingredients is performed and its consequences for setting IFRA Standards.
- Frequently Asked Questions about the application of IFRA Standards.

Compliance timelines for Amendments

The compliance timelines for the Standards that will be introduced in the 49th Amendment is detailed in the Notification Letter. The former compliance timeline applied to previous Amendments is reported in Table 1. As part of the review of the Standard setting process and due to the scope of the 49th Amendment including the introduction of new tools, the timelines for the 49th Amendment will be extended as specified in

Table 2 and Figure 1.

An existing mixture is a mixture currently sold or already the subject of evaluation for performance in (a) defined consumer product(s). The period of time permitted for achieving compliance with a new or revised Standard applies only to that mixture in that defined consumer products.

The timelines refer to the mixture of fragrance ingredients and not to the finished consumer product(s).

"**New creations**" are defined as any fragrance mixture for which the brief has been issued after the completion of the information exchange across the supply chain period (i.e. update of IT systems, bilateral information exchange between fragrance houses and information exchange between fragrance houses and customers as a total of 7 months – see also Figure 1).

In practice, this means that briefs received after the Notification can only be verified for compliance with the requirements of the new Amendment once companies are fully operational.

"**Existing creations**" are those fragrance mixtures that have already been placed on the market in (a) consumer product(s) or are already in the development phase at the time the completion of information exchange comes to its end. This includes:

- fragrance mixtures for which a brief has been received prior to the date of the Notification of the Amendment;
- fragrance mixtures for which the brief has been received during the period of information exchange across the supply chain; and
- fragrance mixtures that are already in development by the fragrance manufacturer or even in the hands of the consumer product manufacturer.

Table 1: Former compliance timeline for previous IFRA Amendments (excluding IFRA 49th Amendment)

IFRA Standards	Date for Standards entering into force for new creations	Date for Standards entering into force for existing creations
Standards prohibiting or restricting the use of ingredients	2 months after the date of the letter of Notification	14 months after the date of the letter of Notification
Standards introducing a specification on the use of the fragrance ingredient	7 months after the date of the letter of Notification	19 months after the date of the letter of Notification

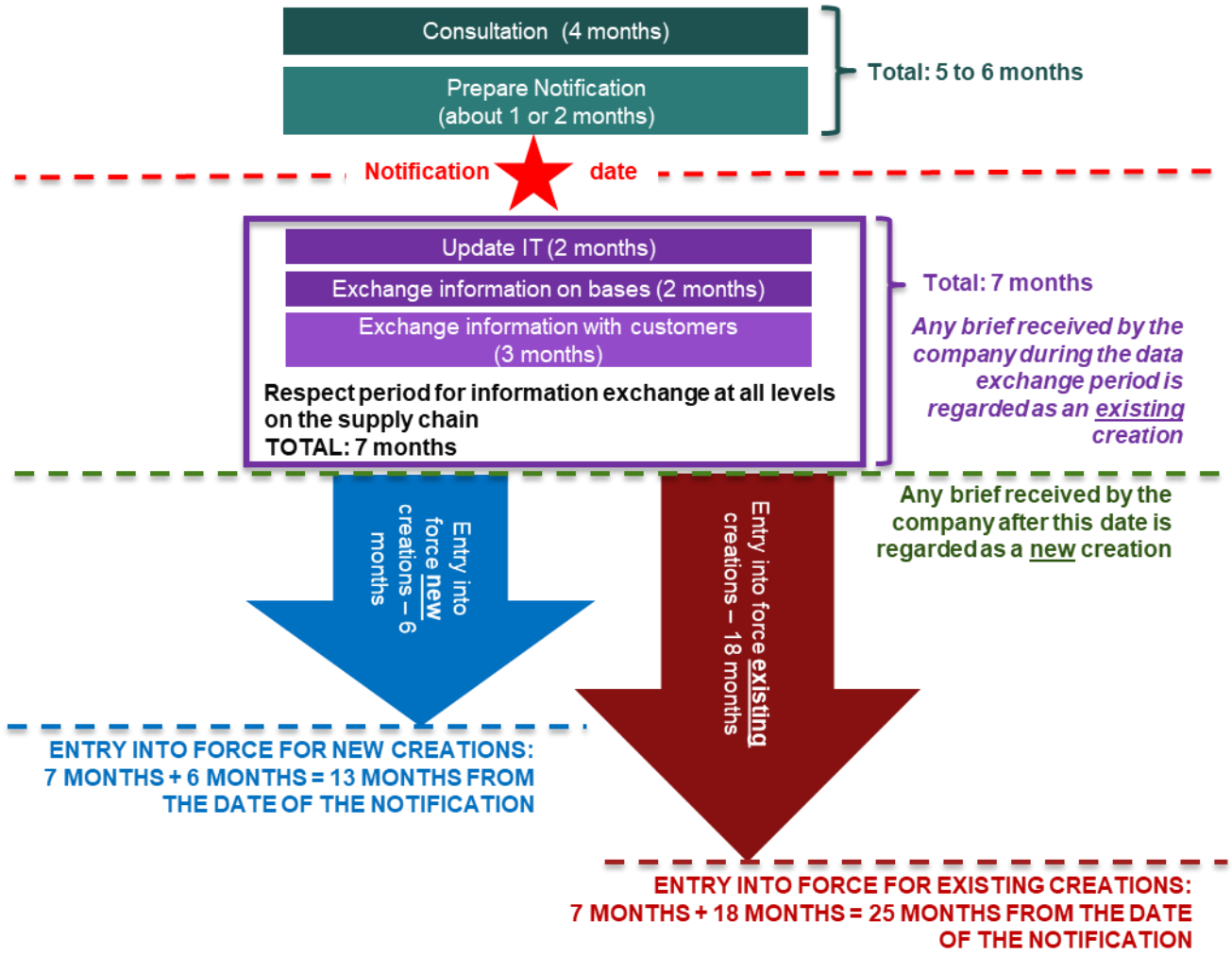
Table 2: Timeline applicable specifically for the 49th Amendment

IFRA Standards	Date for Standards entering into force for new creations	Date for Standards entering into force for existing creations
Standards prohibiting or restricting the use of ingredients	6 months after the completion of the information exchange across the supply chain period (which is 7 months after the Notification date). In total, this is 13 months after the date of the Notification.	18 months after the completion of the information exchange across the supply chain period (which is 7 months after the Notification date). In total, this is 25 months after the date of the Notification.
Standards introducing a specification on the use of the fragrance ingredient	Exceptionally for the 49th Amendment there is no difference of timeline for Specification Standards. Therefore, the timeline for Specification Standards is also 13 months after the date of the letter of Notification.	Exceptionally for the 49th Amendment there is no difference of timeline for Specification Standards. Therefore, the timeline for Specification Standards is also 25 months after the date of the letter of Notification.

Figure 1: Representation of the timeline applicable for the 49th Amendment. A 7-month period is granted after the date of the Notification to ensure adequate information exchange across the supply chain.

The entry into force of the 49th Amendment for new creations is 13 months after the date of the Notification.

The entry into force of the 49th Amendment for existing creations is 25 months after the date of the Notification.



1. Introduction to the IFRA Standards

The IFRA Standards form the basis for the globally accepted and recognized risk management system for the safe use of fragrance ingredients and are part of the IFRA Code of Practice. This is the self-regulating system of the industry, based on risk assessments carried out by an independent Expert Panel for Fragrance Safety (http://fragrancesafetypanel.org/). The Expert Panel for Fragrance Safety is an independent panel of experts that reviews the activities of the Research Institute for Fragrance Materials (RIFM). They determine safety of use for fragrance ingredients through consideration of available information and active generation of additional data. If the Expert Panel for Fragrance Safety determine that a restriction of use is necessary for consumer and environmental protection, an IFRA Standard will be published.

1.1 Definitions

Fragrance or Fragrance mixture: A mixture of fragrance ingredients and functional components formulated to impart an odour/flavour or for its malodour coverage/taste masking*.

**in the case of oral care and related products, please see respective explanations and requirements in Section 1.6.2 of this Guidance.'*

Existing creations: are those fragrance mixtures that have already been placed on the market in (a) consumer product(s) or are already in the development phase at the time the completion of information exchange comes to its end. This includes:

- fragrance mixtures for which a brief has been received prior to the date of the Notification of the Amendment;
- fragrance mixtures for which the brief has been received during the period of information exchange across the supply chain; and
- fragrance mixtures that are already in development by the fragrance manufacturer or even in the hands of the consumer product manufacturer.

Fragrance ingredient/material: Any basic substance (raw material) used for its odor properties or malodor coverage as a component of a fragrance mixture.

Fragrance functional component: Any basic substance necessary for the functionality and/or, stability of a fragrance ingredient or mixture (e.g. antioxidant, preservative, diluents, solvent, etc.).

Fragrance manufacturer: A company engaged in the production of a fragrance including processing, mixing, packaging and labelling.

Fragrance material manufacturer: A company engaged in the production of any basic substance used as a fragrance material for its odor properties or malodor coverage.

New creation: Is defined as any fragrance mixture for which the brief has been issued after the completion of the information exchange across the supply chain period (i.e. update of IT systems, bilateral information exchange between fragrance houses and information exchange between fragrance houses and customers).

Quality: Conformity of a fragrance material with its olfactory, physical and chemical specifications and conformity of its production and control with the basic standards of Good Manufacturing Practice.

Toy: Toys under the scope of IFRA Standards follow the definition as contained in the EU Toy Directive (2009/48/EC) and the American National Standard ASTM F963, in its latest version.

1.2 Scope of IFRA Standards

All fragranced consumer products are in the scope of the IFRA Standards with the exception of products clearly not covered in the RIFM Safety Assessments, such as:

- medical devices,
- prescriptive drugs,
- aromatherapy applications,
- consumer products used in occupational settings (e.g. shampoos applied in hair salons, hand sanitizers applied in hospitals, etc.)

Certain types of Over the Counter (OTC) products are also out of the scope of the IFRA Standards unless those products are regarded as cosmetic products under certain cosmetic product regulation worldwide. An example would be sun protection products, which are e.g. regarded as OTC in the United States or Australia but are considered as cosmetic products e.g. in Europe.

A detailed list of the products covered under the scope of the IFRA Standards is provided in Table 12. In case a final product application is not included therein, it remains the responsibility of the final consumer product manufacturing company to adequately categorize this final product application in order to comply with the requirements of the IFRA Standards.

1.3 Types of IFRA Standards

The IFRA Standards can trigger:

- A restriction by a quantitative limit on the use of fragrance materials.

IFRA Standards that impose a quantitative limit on the use of fragrance materials are expressed as an upper concentration of fragrance material in the finished consumer product. This is based on the combined knowledge of the concentration of restricted fragrance materials in the mixture and the concentration of the mixture in the final consumer product. Fragrance suppliers are therefore required to inform manufacturers of consumer products, who use or intend to use a fragrance mixture, that due to the presence of a restricted ingredient, the mixture should only be used up to a specified maximum concentration. This can either be a maximum for a number of applications (driven by the most restrictive one) or in the form of an individual listing of maximum concentrations for well-defined applications, thereby being in compliance with IFRA Standards. Alternatively, a Certificate of Conformity of fragrance mixtures with IFRA Standards can be prepared with a reference to the actual end use and use level when known by the fragrance house (see item 0). Unless otherwise specified, concentrations are expressed in weight-per-weight percent.

From the 49th Amendment on, the Standards limiting ingredients due to sensitization are based on the refined Quantitative Risk Assessment for dermal sensitizers (QRA2) including revised product categories. More information on how the dermal sensitization QRA2 works in detail is available in Section 3.

- A prohibition of the use of the fragrance ingredients in any final product application.

An IFRA Standard may ban the use of a substance when it is intended to be used as such in a fragrance mixture. The ban applies to all final product applications, including non-skin contact applications.

- A specification on the use of a fragrance ingredient, such as purity requirements.

Certain fragrance ingredients are considered safe for their use in final product application but with a defined level of impurities (e.g. traces of solvents) or reaction products or defined procedures for extraction and/or production.

1.4 Contributions from other sources

1.4.1 Contributions from natural complex substances (NCS)

Restricted Substances

IFRA Standards establishing use restrictions for specific fragrance materials in final consumer products shall apply regardless of whether the restricted substance is added directly or indirectly to the fragrance mixture. Indirect contributions from other sources e.g. presence in natural complex substances (NCS) must be taken into account in the calculation of the levels of the restricted substance.

Annex I to the IFRA Standards provides indicative levels of restricted substances in a non-exhaustive list of various fragrance ingredients of complex composition, including essential oils and other natural extracts. These indicative levels should be taken into account when determining the compliance of a fragrance mixture under its conditions of use as outlined above. The indicative concentration levels provided in Annex I are applied based on a typical/representative composition of a given NCS (noting that in practice, such composition varies for each NCS), which is assessed by a group of experts based on the typical/representative qualities of NCS's in the market. However, if actual analytical data show that the level of the limited substance in a specific NCS is not the same as the indicative level given in Annex I, then the fragrance manufacturer can use its analytical data instead of the indicative level provided in Annex I.

Fragrance manufacturers are invited to:

(a) Also use for the purpose of calculation additional information they may have on levels of the restricted substances in any other essential oil, extract, etc. used as fragrance ingredients, but not already mentioned in Annex I to the IFRA Standards;
(b) Provide to IFRA (info@ifraorg.org) information on those substances and levels.

Prohibited Substances

An IFRA Standard may ban the use of a substance when it is intended to be used as such in a fragrance mixture. However, this does not necessarily exclude the use of a natural fragrance material which contains the prohibited substance as a component or contaminant, or a synthetic material which contains the prohibited substance as a contaminant i.e. added indirectly, provided that in the judgment of the Expert Panel for Fragrance Safety there is sufficient data supporting the safe use of the fragrance material and that it is not being used to provide an alternative, indirect source of the banned substance.

One source of prohibited substances is the small amounts of organic solvents that might be carried over into a synthetic fragrance ingredient or an organic extract during the manufacturing process. There are specific steps within a synthetic pathway that are designed to remove minor amounts of solvents, but these steps are inevitably not completely successful in removing traces of the substances. These processes may result in extremely low, technically unavoidable traces of substances in the final fragrance material. Where feasible, IFRA develops guidance regarding upper concentration levels for these substances that have been reviewed and approved by the Expert Panel for Fragrance Safety.

In general, fragrance materials which are single chemicals or essential oils (in any form) should be analyzed to identify components or impurities (especially those that are prohibited) at levels that allow a meaningful safety assessment.

Every IFRA member becoming aware of IFRA prohibited materials in fragrance ingredients at levels not addressed by the respective IFRA Standards (in the Standard or as an impurity), shall inform IFRA (as required in the IFRA Code of Practice), so that an adequate safety evaluation by the Expert Panel for Fragrance Safety can be carried out. Certain essential oils may act as a second source from which the banned substance cannot be removed. If the Expert Panel for Fragrance Safety finds the presence of a banned substance in other fragrance materials (either a synthetic chemical or natural complex substance) cannot be supported based on a risk assessment, the chemical or NCS will itself be prohibited from use.

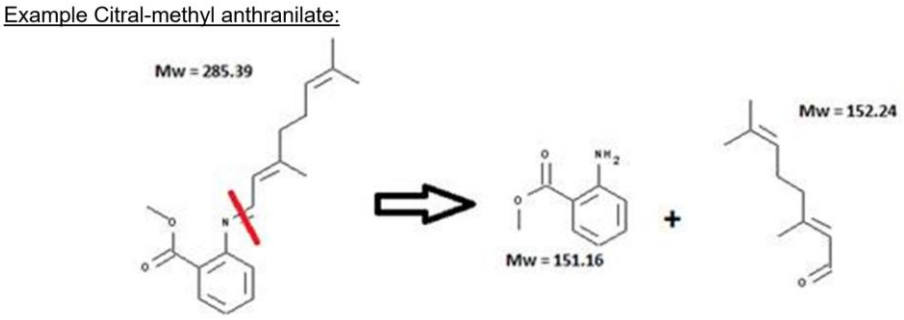
However, if the levels of the banned substance can be reduced to a safe use level, then an IFRA Standard will be established to allow the use of the chemical or natural complex substance by setting a limit for the presence of the banned substance (e.g. Atranol and Chloroatranol in Oakmoss and Treemoss, or Toluene as a solvent residue).

1.4.2 Schiff bases

Schiff Bases are condensation products from aldehyde and (primary) amines, resulting in a (true) "Imine" with a C=N double bound. Due to the concern that this could affect some of the restricted ingredients by IFRA Standards present in fragrance mixtures/finished products and based on the available information e.g. on physicochemical properties information, these materials are considered under contributions from other sources in a precautionary approach. By default, the stoichiometric presence of the aldehydes of the Schiff bases is taken into account assuming 100% dissociation. An indicative list of Schiff bases incorporating aldehydes covered by an IFRA Standard of restriction is reported in Annex II of the IFRA Standards. These Schiff bases must be taken into account for determination of the upper concentration level of the respective aldehydes.

Annex II provides an example calculation for the Schiff bases used in the fragrance industry and listed therein (Figure 2).

Figure 2: Example of calculation for the Schiff bases used in the fragrance industry as reported in Annex II of the IFRA Standards: Citral-methyl anthranilate.



152.24 / 285.39 namely 53.34 % of the Schiff base mass has to be assigned to Citral.

Contributions of restricted aldehydes from all other Schiff bases should be calculated in the same way, as detailed in Figure 2. Please note that the hydrolysis rate of 100% might be replaced by a lower value if robust data on the specific Schiff base in the specific end product exist.

1.5 IFRA Standards for environmental protection

IFRA sets-up the IFRA Environmental Standards of fragrance materials on the following two principles:

- Evaluation for aquatic risk following the RIFM Framework (Salvito, Senna, and Federle; 2002)
- Identification of ingredients with properties for Persistence, Bioaccumulation and (eco)Toxicity (PBT or vPvB).

The criteria and approaches described within the RIFM Framework are used to assess that all relevant consumer uses of fragrance materials associated with perfumery are safe for the environment. Following this RIFM Framework, and using the periodic IFRA Volume of Use (VoU) survey to estimate exposure, the industry may need to implement risk management measures by issuing an IFRA Standard.

For PBT and vPvB identification, the screening assessment is based on current criteria defined in the EU REACH legislation (Annex XIII). Materials identified by IFRA as PBT or vPvB shall be banned and an IFRA Standard issued.

1.6 Important information for the application of IFRA Restriction Standards

1.6.1 Phototoxic ingredients

The IFRA Standards on phototoxic ingredients have been set based on:

- The phototoxicity potential of the fragrance ingredient itself (Table 3). Due to the inclusion of a restriction level for rinse-off products in the Standard Tagetes oil and absolute, the IFRA policy of phototoxicity considerations has been revised in the scope of the 49th Amendment. Additional details are provided in Section 1.6.1.1.
- The phototoxicity potential of furocoumarins present in certain essential oils (Table 4). No changes are introduced with the 49th Amendment on the IFRA policy on Furocoumarins. Additional details on this policy are provided in Section 1.6.1.2.

Table 3: List of IFRA Standards on phototoxic ingredients based on the phototoxicity potential of the fragrance ingredient itself.

CAS number	IFRA Standard
15323-35-0	5-Acetyl-1,1,2,3,3,6-Hexamethyl indan (AHMI)
85-91-6	Methyl-N-methylanthranilate
93-08-3	Methyl β-naphthyl ketone
91772-29-1 8016-84-0 91770-75-1 90131-43-4	Tagetes oil and absolute
41270-80-8	Methyl 2-(formylamino)benzoate

Table 4: List of IFRA Standards on phototoxic ingredients based on the phototoxicity potential of furocoumarins present in certain essential oils.

CAS number	IFRA Standard
8015-64-3	Angelica root oil
908007-75-8	Bergamot oil expressed
68916-04-1 72968-50-4	Bitter orange peel oil expressed
Not available	Citrus oils and other furocoumarins containing essential oils
8014-13-9	Cumin oil
8016-20-4	Grapefruit oil expressed
8008-56-8	Lemon oil cold expressed
8008-26-2	Lime oil expressed
8014-29-7	Rue oil

1.6.1.1 Revised policy on phototoxicity considerations implemented with the 49th Amendment

The scope of application of restrictions based on phototoxic effects includes any product that is applied on body areas reasonably expected to be exposed to sunlight. For non-skin contact consumer products (i.e. Category 12), phototoxicity considerations do not apply and therefore IFRA Standards do not set a restriction on them.

Compared to the previous Amendments, the IFRA 49th Amendment introduces the following changes:

- Introducing a restriction level to rinse-off products in the Standard of Tagetes oil and absolute.

- Subcategorization of Category 7 in A and B to take into account the presence of rinse-off and leave-on products included in this category.
- Consideration of potential phototoxicity for all product types included in Category 8 (even if there is no expected exposure to sunlight).
- Subcategorization of Category 11 in A and B to take into account the presence of rinse-off and leave-on products included in this category.

This is explained in more detail in the following sections.

a) Introducing a restriction level to rinse-off products in the Standard of Tagetes oil and absolute.

Traditionally, phototoxicity considerations for rinse-off products were not applied and this was reflected by an absence of restriction in the respective IFRA Standards (e.g. Methyl N-methylanthranilate). With the 49th Amendment, a restriction limit for rinse-off products has been introduced for the first time in the Standard of Tagetes oil and absolute.

This leads to a significant change in the rationale to attribute phototoxicity considerations to finished consumer products. In order to take into account the fact that some Standards include a restriction limit for rinse-off products, the rationale included in Table 12 has been adapted as shown in Table 5.

Table 5: Change of the rationale applied for phototoxicity considerations introduced with the 49th Amendment and comparison with the rationale used in previous IFRA Amendments.

Rationale in previous Amendments	Rationale introduced with the 49th Amendment
Applicable	Applicable (leave-on products)
Not applicable	Applicable (rinse-off products)
Not applicable	Not applicable (leave-on products without UV exposure)
Not applicable	Not applicable (non-skin contact products)

b) Subcategorization of Category 7 in A and B to take into account the presence of rinse-off and leave-on products included in this category.

Category 7 contains leave-on and rinse-off products for which phototoxicity considerations are applicable.

In line with the goal to harmonize the IFRA Categories with the former IFRA Classes used in the Certificates, Category 7 is therefore divided into Categories 7A (rinse-off products) and 7B (leave-on products). This approach is similar to the one taken for the division of categories 5 and 10 due to systemic toxicity considerations.

c) Consideration of potential phototoxicity for all product types included in Category 8 (even if there is no expected exposure to sunlight).

Potential phototoxic effects are taken into consideration for Category 8 (Products with significant anogenital exposure), for reasons of conservativism to take into account some uses of the products that could include UV exposure (e.g. baby wipes).

d) Subcategorization of Category 11 in A and B to take into account the presence of rinse-off and leave-on products included in this category.

Category 11 contains leave-on products for which phototoxicity considerations are either applicable or not, depending on the likeliness of UV exposure.

In line with the goal to harmonize the IFRA Categories with the former IFRA Classes used in the Certificates, Category 11 is now divided into Categories 11A (Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure) and 11B (Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure). This approach is similar to the one taken for the division of Categories 5 and 10 due to systemic toxicity considerations.

Moreover, Category 11A contains products which are applicable to the skin but without UV exposure. As a consequence, the applicability of phototoxicity considerations becomes irrelevant for the products of Category 11A. This is translated in IFRA Standards by an absence of restriction for the products included in this subcategory.

A summary of the restrictions applicable to Standards based on phototoxicity considerations is presented in Table 6.

Table 6: Outline of the revised rationale on phototoxicity considerations introduced with the 49th Amendment and its application to the Standards of Tagetes oil and absolute and Methyl N-methylanthranilate.

Category	Product type	Phototoxicity considerations	Restriction for Tagetes oil and absolute[1]	Restriction for Methyl N-methylanthranilate[2]
1	Products applied to the lips	Applicable (leave-on)	0.01%	0.1%
2	Products applied to the axillae	Applicable (leave-on)	0.01%	0.1%
3	Products applied to the face/body using fingertips	Applicable (leave-on)	0.01%	0.1%
4	Products related to fine fragrance	Applicable (leave-on)	0.01%	0.1%
5	Products applied to the face and body using the hands (palms), primarily leave-on:			
5A	Body lotion products applied to the body using the hands (palms), primarily leave on	Applicable (leave-on)	0.01%	0.1%
5B	Face moisturizer products applied to the face using the hands (palms), primarily leave on	Applicable (leave-on)	0.01%	0.1%
5C	Hand cream products applied to the hands using the hands (palms), primarily leave on	Applicable (leave-on)	0.01%	0.1%
5D	Baby Creams, baby Oils and baby talc	Applicable (leave-on)	0.01%	0.1%
6	Products with oral and lip exposure	Applicable (leave-on)	0.01%	0.1%
7	Products applied to the hair with some hand contact			
7A	Rinse-off products applied to the hair with some hand contact	Applicable (rinse-off)	0.1%	No Restriction
7B	Leave-on products applied to the hair with some hand contact	Applicable (leave-on)	0.01%	0.1%
8	Products with significant anogenital exposure	Applicable (leave-on)[3]	0.01%	0.1%
9	Products with body and hand exposure, primarily rinse off	Applicable (rinse-off)	0.1%	No Restriction
10	Household care products with mostly hand contact:			
10A	Household care excluding aerosol products (excluding aerosol/spray products products)	Applicable (rinse-off)[4]	0.1%	No Restriction
10B	Household aerosol/spray products	Applicable (leave-on)	0.01%	0.1%
11	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate			
11A	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure	Not applicable (leave-on without UV exposure)[5]	No Restriction	No Restriction
11B	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure	Applicable (leave-on)	0.01%	0.1%
12	Products not intended for direct skin contact, minimal or insignificant transfer to skin	Not applicable (non-skin contact)	No Restriction	No Restriction

[1] The upper concentration level allowed by the IFRA Standard for Tagetes oil and absolute is 0.01% in leave-on products and 0.1% in rinse-off products.
[2] The upper concentration level allowed by the IFRA Standard for Methyl N-methylanthranilate is 0.1% in leave-on products. There is no restriction applicable to rinse-off products.
[3] Potential phototoxic effects are taken into consideration for Category 8 (Products with significant anogenital exposure), for reasons of conservativism to take into account some uses of the products that could include UV exposure (e.g. baby wipes).
[4] Category 10A includes rinse-off products and products with limited skin contact. As a conservative approach, all the products included in Category 10A are treated as rinse-off products for phototoxicity considerations.
[5] Category 11A contains products which are applicable to the skin but without UV exposure. As a consequence, the applicability of phototoxicity considerations becomes irrelevant for the products of Category 11A.

1.6.1.2 IFRA policy on Furocoumarins

The IFRA policy on Furocoumarins remains unchanged with the 49th Amendment.

Combination effects of phototoxic ingredients are only taken into consideration for furocoumarin containing fragrance ingredients (extracts).

If combinations of furocoumarin-containing phototoxic fragrance ingredients (extracts) are used, the use levels must be reduced accordingly. The sum of the concentrations of all furocoumarin-containing phototoxic fragrance ingredients (extracts), expressed in % of their recommended upper concentration level in the consumer product shall not exceed 100.

If the level of furocoumarins is unknown, the restriction level specified in the respective IFRA Standards for the specific essential oils as listed in the Standard of Citrus oils and other furocoumarins containing essential oils applies (see the list of essential oils in

Table 4).

1.6.2 Oral Care Products and other products with the potential of ingestion

1.6.2.1 Products with the potential of ingestion in the scope of the IFRA Standards

In general, IFRA Standards are applicable for fragrance mixtures used in non-food products.

Depending on the regulatory framework, ingredients used in oral care and similar products could either be regarded as fragrance or flavor applications. For the purpose of the IFRA Code of Practice, when referring to single ingredients and mixtures we talk about fragrance ingredients and fragrance mixtures (perfume) respectively, even if the ingredients and mixtures in the end are fulfilling flavor requirements and are in fact produced as flavor mixtures and could thus be legitimately termed “flavor”. Therefore, all oral care products that carry a fragrance, like any other fragranced product, must follow the IFRA Standards and general guidelines as contained in the IFRA Code of Practice.

Mouthwash and toothpaste are the principal oral care products currently identified in the respective category. Other oral care products as/like toothpowder, strips, mouthwash tablets are also in scope. The introduction of aggregate exposure with the 49th Amendment implies that simultaneous usage of e.g. a toothpaste and a mouthwash (two products from the same category) is assessed, but not the concomitant use as a flavor ingredient in food.

Exposure limits for oral care products resulting from the QRA process are established to reduce the risk of peri-oral skin sensitization.

Besides oral care products there are certain other products containing fragrance materials that are not intended for ingestion but have the possibility of ingestion of minute amounts of the fragrance ingredients, like lip products of all types (solid and liquid lipsticks, balms etc.) or specific types of toys. Due to the possibility of ingestion of small amounts of fragrance ingredients from the use of the aforementioned allowable product categories (such as oral care, lip products or certain types of

toys), materials present in the fragrance mixture must comply not only with IFRA Standards but must also have an approved flavor material status as defined by the IOFI[1] Code of Practice. Such materials are those that meet one or more of the following requirements:

- Accepted by the authoritative body the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as acceptable flavoring materials that "pose no safety concerns at current levels of intake";
- Have been evaluated and found, using the same or similar methodology as used by JECFA, to present "no safety concern under conditions of intended use" by authoritative bodies such as the European Food Safety Authority (EFSA) or the Japanese Food Safety Authority (FSC);
- Deemed to be Generally Recognized As Safe (GRAS) or approved food additives by the US Food and Drug Administration (FDA) including GRAS determinations published by the independent Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA);
- Are compliant with appropriate national/regional regulation covering the use of flavorings 'for local use' and respective product uses as outlined above.

Materials without an approved flavor status according to the criteria above are not permitted in products where incidental oral ingestion may occur.

The above-mentioned products (e.g. oral care or lipsticks), which are under the scope of the IFRA Standards, are not designed and therefore not intended to be ingested, even so accidental ingestion can occur.

1.6.2.2 Products with the potential of ingestion outside the scope of the IFRA Standards

The safety of (fragrance) ingredients or mixtures present in products intended for ingestion (like 'ingestible perfumes or deodorants, fragrances for odorizing potable water, cleaning products intended for food contact') is outside the scope of RIFM's and IFRA's current risk assessment and management process.

It is the responsibility of the companies to assess the safe use of these products based on the specific use conditions and the legal requirements applicable in the respective country/region. Therefore, this safety assessment is key for decision and is prevailing above any type of other considerations like material status (e.g. approved flavor material food grade status). In conclusion, IFRA cannot incorporate them in the IFRA products categorization.

[1] http://www.iofi.org/

1.6.3 Use of fragrance ingredients in toys (or other children's products)

Toys under the scope of IFRA Standards follow the definition as contained in the EU Toy Directive (2009/48/EC)[2] and the American National Standard ASTM F963[3], in its latest version.

1.6.3.1 Prohibition of use of fragrance ingredients in toys or other children's products where there is the likelihood of mouth contact (independently of whether exposure data is available or not)

IFRA prohibits the use of fragrance materials and mixtures in toys or other children's products where there is the likelihood of mouth contact. Following the criteria established by the toy industry, these include:

1) toys for children less than 3 years of age;
2) any toy designed and intended to go into the mouth; and/or
3) those toys for which mouth contact is reasonably foreseeable.

1.6.3.2 Restriction of use of fragrance ingredients in toys or other children's products where there is no likelihood of mouth contact and for which there is no exposure data available

IFRA restricts the use of fragrance materials and mixtures in toys or other children's products where there is no likelihood of mouth contact. Following the criteria established by the toy industry, these include:

1) toys for children older than 3 years of age;
2) any toy not designed and not intended to go into the mouth; and/or
3) those toys for which mouth contact is not reasonably foreseeable.

Although there is absence of exposure data, these toys have been placed in Category 1 (leave-on products generally applied to the lips) due to the potential of ingestion of minute amounts of fragrance ingredients. Should exposure data become available, these product types may be re-categorized.

1.6.3.3 Toys for which there is no foreseeable exposure

Considering feedback received during the Consultation of the 49th Amendment, the product type of "Olfactive Board Games" has been assessed by the QRA Expert Group. Due to non-foreseeable exposure, Olfactive Board Games have been categorized in Category 12.

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0048
[3] https://www.astm.org/toys.html

2. IFRA Standards setting procedure

The IFRA Standards form the basis of the globally recognized risk management system for the safe use of fragrance ingredients as outlined in the IFRA Code of Practice. This document summarizes the process followed for setting and reviewing the IFRA Standards. A more detailed and specific description of the process is available from IFRA (info@ifraorg.org).

2.1 IFRA Commitment to safety

The **International Fragrance Association (IFRA)** and its members are committed to providing fragrances that are safe to use in consumer products.

The **IFRA Code of Practice** requires that member companies are responsible to ensure safety and regulatory compliance for the use of fragrance ingredients and mixtures. This includes the requirement to follow the IFRA Standards.

The **IFRA Standards** are set to protect consumers and the environment from potential adverse effects when fragrances are present in consumer products.

2.2 Key principles of the IFRA Standards

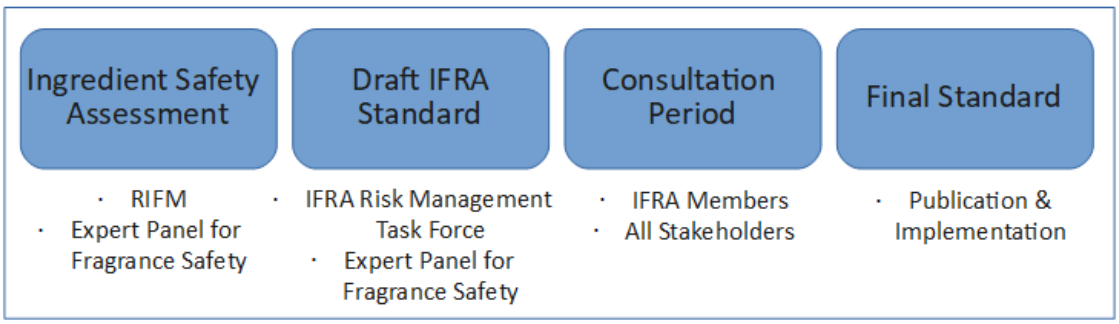
- Where there are concerns over the safe use of a fragrance ingredient, IFRA will issue an IFRA Standard.
- Consequently, not all fragrance ingredients are subject to IFRA Standards.
- IFRA Standards may prohibit, restrict or set purity requirements for specific ingredients.
- Each member company is ultimately responsible for ensuring the fragrance ingredients or mixtures they supply are compliant with applicable laws and are safe for intended uses.

2.3 The IFRA Standards setting process

The IFRA Standards are set to ensure effective risk management of fragrance ingredients. As explained further below, the IFRA Standards are set based on materials identified by the RIFM safety assessment program. IFRA then introduces risk management measures through an inclusive process (described below) which includes a consultation open to all relevant stakeholders to ensure all comments and data are considered. A robust summary of the final safety assessment forming the basis of the Standard is also published by RIFM.

The four key steps in this process and the stakeholders involved at each stage are illustrated in the Figure 3 and summarized in the next sections.

Figure 3: Illustration of the procedure for setting IFRA Standards.



2.3.1 Identification of an ingredient to be considered for a Standard

A risk for a potential adverse effect may be identified during the safety assessment of a fragrance ingredient. A draft safety assessment is prepared by the **Research Institute for Fragrance Materials (RIFM)** following a published set of criteria (**RIFM Criteria Document II**). This assessment reviews nine toxicological endpoints as well as the environmental safety of the ingredient.

The draft safety assessment undergoes independent review by the **Expert Panel for Fragrance Safety** prior to finalization. Robust summaries of the finalized safety assessments are published and available through the open-access **Food and Chemical Toxicology Fragrance Material Safety Assessment Center.**

2.3.2 Proposed Risk Management Measures (Draft IFRA Standard)

Once an ingredient is identified as a potential concern under the current use conditions, a draft Standard is prepared by IFRA through the IFRA Risk Management Task Force. This is based on the safety assessment conclusions of the Expert Panel for Fragrance Safety.

The Risk Management Task Force consists of Industry regulatory experts and the IFRA Secretariat. This group may consult other IFRA expert groups where necessary in drafting the Standard. For example, to determine presence of materials in natural extracts, confirmation of CAS numbers or any specific uses of ingredients in the market.

The draft Standard, once completed, is shared with the Expert Panel for Fragrance Safety for approval.

2.3.3 Stakeholder Consultation

Draft IFRA Standards are circulated and open for comment to the IFRA membership and stakeholders for, typically, a 3-6 months commenting period. Stakeholders include IFRA and RIFM membership (including national association members), trade association partners and other interested stakeholders.

All comments are reviewed and may result in a revised draft or, in the case of new data, referred back to RIFM and the Expert Panel for Fragrance Safety to review. A Standard may be deferred if, during consultation, it is informed that new data are expected within 6 months of the proposed date of Notification of the Standard and that the new data is expected to change the safety assessment outcome.

Following Consultation, an ‘End of Consultation Letter’ is provided to all Stakeholders explaining how comments were considered and any impact on the Standard.

2.3.4 Adoption of the IFRA Standard and Publication

Following the Consultation process, the final standards are adopted and are published by IFRA on the public website (https://ifrafragrance.org/). All Stakeholders are informed through a ‘Letter of Notification’ which includes the timelines for the implementation of the Standard.

2.3.5 Reviewing Existing Standards

RIFM safety assessments are reviewed whenever new toxicological and/or exposure data becomes available. Exposure information is also surveyed among the membership on a regular basis. This may lead to the need for updating or setting a new IFRA Standard.

2.3.6 Participation in the IFRA Standard-Setting Process

The IFRA Standard setting process is intended to be open and transparent. It has been reviewed from an antitrust perspective and has been designed to be as inclusive as possible. IFRA members (directly or via national associations) may apply to participate in the IFRA Task Forces engaged in the process and all Stakeholders may participate in the exposure surveys, provision of data to RIFM and commenting during the Consultation period. Any interest to participate should be addressed directly to IFRA (info@ifraorg.org) or a member association.

2.3.7 Additional information

International Fragrance Association (IFRA): https://ifrafragrance.org

IFRA Code of Practice: https://ifrafragrance.org/self-regulation/ifra-code-of-practice

IFRA Standards: https://ifrafragrance.org/self-regulation/introduction

RIFM: www.rifm.org

RIFM Criteria Document II:
http://fragrancematerialsafetyresource.elsevier.com/sites/default/files/Criteria_Document_Final.pdf

Expert Panel for Fragrance Safety: http://fragrancesafetypanel.org/

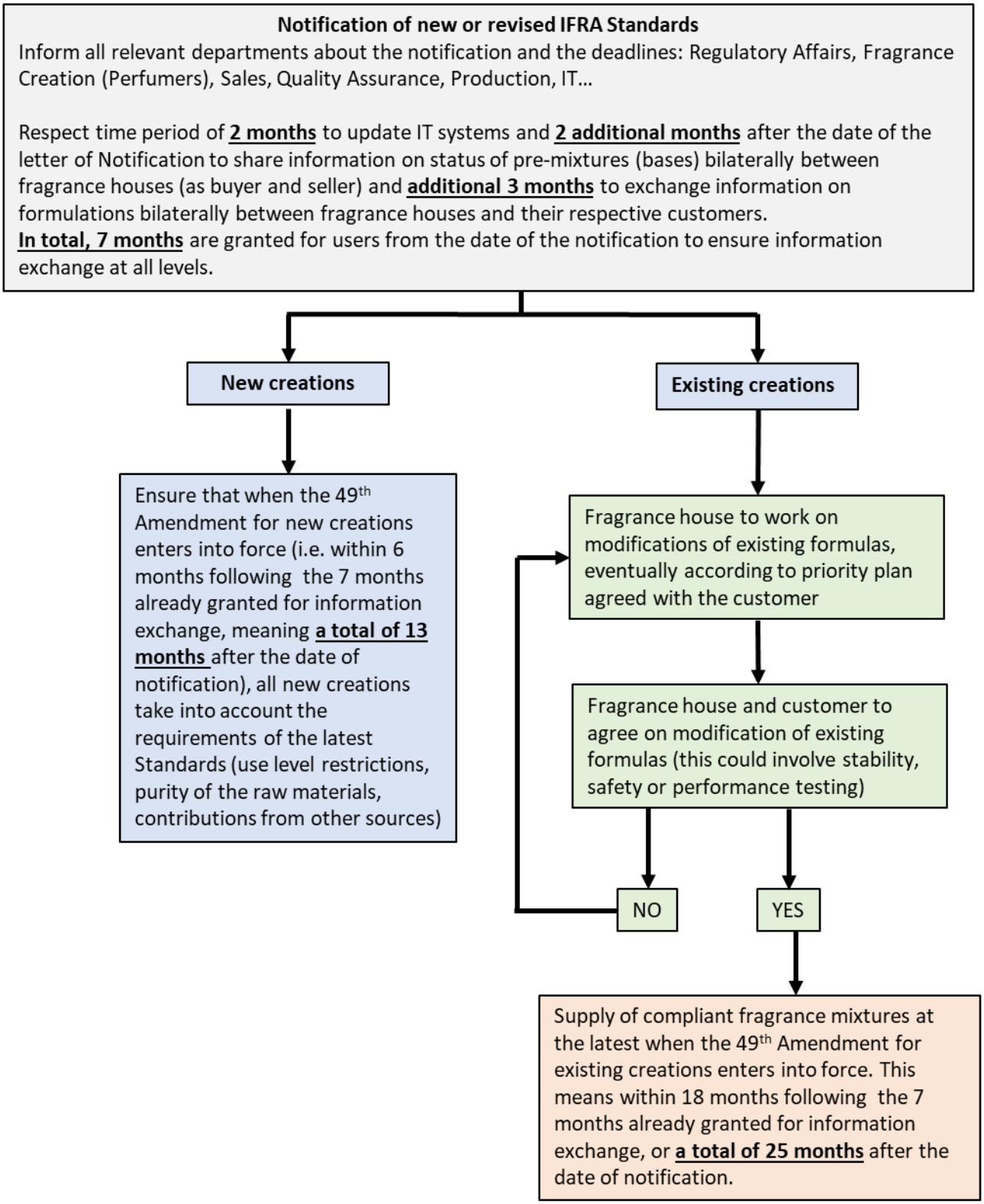
Food and Chemical Toxicology Fragrance Material Safety Assessment Center:
http://fragrancematerialsafetyresource.elsevier.com/

2.4 Standard Operating Procedure for handling Amendments to the IFRA Code of Practice

The Standard Operating Procedure (SOP) is intended to help companies implement Amendments to the IFRA Code of Practice, which consists of new or revised Standards.

As mentioned above, due to the scope of the 49th Amendment including the introduction of new tools, the timelines for the 49th Amendment will deviate. A revised specific operation procedure including the exceptional timeline of the 49th Amendment is provided in Figure 4.

Figure 4: Specific operation procedure including the exceptional timeline of the 49th Amendment.



3. Quantitative Risk Assessment for fragrance ingredients

3.1 Introduction to the Quantitative Risk Assessment (QRA and QRA2) for fragrance ingredients

Although some substances in common use today may have the potential to cause dermal sensitization, they can still be formulated into consumer products at safe levels. This is the case for fragrance ingredients. Based on the chemical, cellular and molecular understanding of dermal sensitization, it is possible to conduct an exposure-based Quantitative Risk Assessment (QRA) to determine safe use levels of fragrance ingredients in a variety of consumer product types.

Significant developments have been incorporated in the way dermal sensitization risk assessments are conducted for fragrance ingredients. This methodology is a reflection of evolving risk assessment processes taking into account the latest scientific developments. It specifically addresses the elements of exposure-based risk assessment that are unique to the induction of dermal sensitization, while being consistent with the principles of general toxicology risk assessment (Api *et al*., 2008). The QRA methodology as it exists today does not cover occupational use of consumer products, mainly due to missing exposure data to build into the risk assessment.

In a brief overview, key steps of the QRA process are the determination of benchmarks for the induction potential (No Expected Sensitization Induction Level or NESIL); application of sensitization assessment factors (SAF) and calculation of consumer exposure (CEL) through product use. Using these parameters, an acceptable exposure level (AEL) can be calculated and compared with the consumer exposure level (CEL). The ratio of the AEL to CEL must be favourable to support the safe use of the skin sensitizer. This ratio must be calculated for the skin sensitizer in each product type. The detailed methodology is under preparation for peer-reviewed publication.

Based on the recommendation of the Expert Panel for Fragrance Safety and beginning with the 40th Amendment to the IFRA Code of Practice in May 2006, RIFM and IFRA formally adopted the QRA approach as the core strategy for primary prevention of dermal sensitization to these materials in consumer products. This methodology is now being used to determine global fragrance industry product management practices (IFRA Standards) for potentially sensitizing fragrance ingredients on an ongoing basis.

Further to the development of the QRA, and to its initial use for determining IFRA Standards, refinements have now been made to the QRA process to include:

1. Determination of aggregate exposure of consumers to fragrances used in personal care and household care products (Comiskey *et al*., 2015; Comiskey *et al.*, 2017), and use of the results from the aggregate exposure calculations to refine acceptable use levels of fragrance ingredients in products (and thus to define IFRA Standards) (QRA submissions)
2. Discussion and refinement of SAFs used in the QRA process (Basketter and Safford, 2016).

The QRA process for dermal sensitization incorporating these refinements, referred to as QRA2, is the outcome of the multi-stakeholder platform 'International Dialogue for Evaluation of Allergens' (IDEA)[4].

The use of aggregate exposure represents a key advancement in determining acceptable levels of use in IFRA Standards. This ensures that the levels take into account the overall exposure of

[4] IDEA QRA2 report: http://www.ideaproject.info/uploads/Modules/Documents/qra2-dossier-final--september-2016.pdf

consumers to any particular fragrance from use of multiple products as part of their normal daily routine. Aggregate exposure is determined using the Creme RIFM model, a Monte Carlo based model which uses extensive consumer survey data from a number of countries (Comiskey *et al*., 2015; 2017). The process of determining acceptable levels incorporates the following steps:

1. Calculate the acceptable level of a fragrance in each product type using conservative deterministic CEL values and the fragrance NESIL, as previously used.
2. Incorporate these acceptable levels into the Creme RIFM Exposure model and calculate aggregate exposure to the fragrance (CEL_{agg}) for each body area.
3. Identify body areas for which the AEL/CEL_{agg} ratio is less than 1. If there are none go to step 7.
4. Apply an adjustment factor to reduce the acceptable levels for products used on the body area with the lowest AEL/CEL_{agg} ratio. The adjustment factor for each product was calculated based on its contribution to exposure on that body area (i.e. products with a higher contribution were reduced the most).
5. Determine aggregate exposure as in Step 2 using these modified acceptable levels.
6. Follow steps 3-5 until the AEL/CEL_{agg} ratio for all body areas is equal or greater than 1 (in Step 3).
7. Determine the final acceptable levels for each product by applying the appropriate adjustment factor to the values determined in Step 1.

The adjustment factors have been calculated using this methodology for one fragrance material only. It follows that the adjustment factors are the same for all fragrances since they are a function of product exposure, which is always the same regardless of the fragrance material. Thus, exposure to a given fragrance material is calculated as the product exposure multiplied by the concentration of fragrance material in the consumer product. The initial acceptable levels calculated in the method (Step1) are a function of the product exposure and the NESIL, so although they will vary with the NESIL value, the relative values between products will not change.

As part of the refinements described above, particularly with respect to incorporating aggregate exposure, product categories have been redefined to better reflect consumer use of the products (e.g. rinse-off/leave-on, general area of use). Upper concentration levels used in the IFRA Standards are defined by category and driven by the product with the lowest acceptable level in that category.

Table 7 provides the SAF and product type that drives the IFRA QRA2 category consumer exposure levels. These data are used with the NESIL to calculate the acceptable exposure levels to individual fragrance ingredients.

Table 7: SAF and product type that drive the IFRA QRA2 category Consumer Exposure Levels (CEL).

IFRA QRA2 category	SAF	Calculated Consumer Exposure Level (CEL) (mg/cm^2/day)	QRA2 Aggregate Adjustment factor	Product type that drives the category Consumer Exposure Level (CEL)
Category 1 – products applied to the lips	100	11.8	0.91	Lip products
Category 2 – Products applied to the axillae	300	9.1	0.63	Solid deodorants/antiperspirants
Category 3 – Products applied to the face using fingertips	100	2.17	1.00	Eye products
Category 4 – Fine fragrance products	100	2.21	0.95	Fine fragrance products
Category 5 – Products applied to the face and body using the hands (palms), primarily leave-on	100	3.02	0.33	Insect repellent (intended to be applied to the skin)
Category 6 – Products with oral and lip exposure	100	1.27	0.32	Toothpaste
Category 7 – Products applied to the hair with some hand contact	30	2.2	0.58	Hair sprays
Category 8 – Products with significant anogenital exposure	300	7.4	NA*	Baby wipes
Category 9 – Products with body and hand exposure, primarily rinse off	300	0.2	0.50	Bar soap
Category 10 – Household care products with mostly hand contact	100	0.2	0.60	Hand dishwashing detergent
Category 11 – Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate	300	0.2	NA*	Feminine hygiene liners
Category 12 – Products not intended for direct skin contact, minimal or insignificant transfer to skin	NA*	NA*	NA*	NA*

* Not Applicable (NA) – the product types in these categories are not included in the Creme RIFM model, and aggregate exposure is not taken into account when calculating the acceptable levels of fragrance ingredients.

3.2 Example: Coumarin

Coumarin has been chosen as an example to demonstrate the practical application of the principles of QRA2. This material is one of the four fragrance ingredients that were part of the 40th Amendment to the IFRA Code of Practice for which Standards have been set based on the QRA approach. The dermal sensitization data on Coumarin include the availability of robust animal sensitization data, confirmatory human sensitization data as well as diagnostic patch test studies.

Table 8 shows the practical application of the dermal sensitization QRA approach for fragrance ingredients, in products in the 12 IFRA QRA categories. It lists the calculated upper concentration levels for Coumarin in each IFRA QRA category.

Table 8: Calculation of the aggregate exposure adjusted upper concentration levels for Coumarin using the aggregate adjustment factors from Table 7 (Coumarin: NESIL of 3500 µg.cm^{-2}).

Category	Product type driving the QRA2 upper concentration levels	Max QRA 2 unadjusted use level by category (%)	QRA 2 aggregate adjustment factor	QRA 2 aggregate exposure adjusted upper concentration levels (%)**
1	Lip products	0.297	0.91	**0.27**
2	Deodorants and antiperspirants of all types including fragranced body sprays	0.128	0.63	**0.080**
3	Eye products	1.613	1.00	**1.6**
4	Fine fragrance (eau de toilette, parfum etc.)	1.584	0.95	**1.5**
5	Insect repellent (intended to be applied to the skin)	1.159	0.33	**0.38**
6	Toothpaste	2.756	0.32	**0.88**
7	Hair sprays	5.303	0.58	**3.1**
8	Baby wipes	0.158	NA*	**0.16**
9	Bar soap	5.833	0.50	**2.9**
10	Hand dishwashing detergent	17.500	0.60	**11**
11	Feminine hygiene conventional pads, liners, interlabial pads	5.833	NA*	**5.8**
12	Products not intended for direct skin contact, minimal or insignificant transfer to skin	Not Restricted		

* Not Applicable (NA) – the product types in these categories are not included in the Creme RIFM model, and aggregate exposure is not taken into account when calculating the acceptable levels of fragrance ingredients.

** Expressed with two significant digits.

4. Systemic toxicity

Endpoints related to systemic toxicity (genotoxicity/carcinogenicity, reproductive and developmental toxicity and repeated dose toxicity) are evaluated according to the Criteria II document (Api *et al*., 2015).

For systemic toxicity assessment, in order to define upper concentration levels in products, aggregate exposure is determined for total body exposure, as all fragrance material that is absorbed through the skin becomes systemically available independently of the body site on which the fragrance material was applied. This approach is therefore different from the one used for skin sensitization (QRA2), which considers body sites.

4.1 Calculation of upper concentration levels based on systemic toxicity considerations

For consideration of concerns related to **systemic toxicity** of a given material, several pieces of key information are needed. In order to determine the maximum acceptable use levels based on systemic toxicity, the Optimization Tool in the Creme RIFM Aggregate Exposure Model is used.

For the given systemic product categories, the model provides concentration limits (maximum acceptable use levels), such that the 95th percentile (P95) of aggregate exposure to each material stays below the designated reference dose (RfD). The RfD is approved by the Expert Panel. Maximum acceptable use level distribution follows the use level pattern reported to RIFM by the industry. This is achieved in reply to RIFM concentration of use surveys, where fragrance compounders report the use levels of a given fragrance ingredient in fragrance compounds (intended for a specific product type). These data are combined with the use concentrations of fragrance compounds in product types as reported by the consumer product manufacturers directly to Creme Global. The P95 exposure data are calculated using the Creme RIFM Aggregate Exposure Model for each product type and this ratio between different product types is used in the Optimization Tool to distribute the allowable maximum use levels between product categories.

Therefore, all the concentrations resulting from the RIFM concentration of use surveys are used as starting point in the optimization tool. In case there is no reported use for a product category the default used in the optimization tool is 10 ppm, unless there is another reported use for another product that is below 10 ppm, which will then become the starting point for running the Optimization Tool.
Other key data used in the optimization tool are skin absorption data. The calculated skin absorption data used are based on the skin absorption model (SAM) developed by RIFM (Shen *et al.*, 2014) unless measured data are available.

When there is a need for an IFRA Standard based on another adverse effect (typically dermal sensitization), the upper concentration levels (e.g. from QRA2) will be compared to the upper concentration levels based on the material's systemic effects (see Section 6).

4.2 IFRA categories based on systemic toxicity considerations

In order to take into account systemic toxicity considerations, the following IFRA categories subdivisions are applied:

- **Category 5** has been divided into 5A (body lotion), 5B (face moisturizer), 5C (hand cream) and 5D (baby products).

  The exposure data for Categories 5D, 8 and 11, if available, is often limited to regional studies and are so far not regarded reliable enough to be used in the Creme-RIFM model. The RIFM aggregate exposure Core Team therefore agreed that the upper concentration level of Category 5D should be derived from the lowest upper

concentration level from Categories 5A, 5B and 5C. To account for the uncertainty regarding the exposure information, the level will be divided by 3. The upper concentration levels of Categories 8 and 11 should be the same as Category 5D. Consequently, **the upper concentration levels of Categories 5D, 8 and 11 are derived by taking the lowest upper concentration level from Categories 5A, 5B and 5C divided by 3.**

- **Category 10** has been divided into 10A (household care products with mostly hand contact) and 10B (aerosol spray/air freshener).

  No exposure data on household care products with hand contact (Category 10A) are yet included in the aggregate exposure model. As a consequence, Category 9 (bar soaps, thus with hand contact) is used as a surrogate for Category 10A and therefore, **the upper concentration levels for Categories 9 and 10A are identical.**

The final IFRA categories, including dermal sensitization (QRA2), phototoxicity and systemic toxicity considerations are reflected in Table 9.

Table 9: IFRA Standard categories by product type.

Category	Product type
1	Products applied to the lips
2	Products applied to the axillae
3	Products applied to the face/body using fingertips
4	Products related to fine fragrance
5	Products applied to the face and body using the hands (palms), primarily leave-on:
5A	Body lotion products applied to the body using the hands (palms), primarily leave on
5B	Face moisturizer products applied to the face using the hands (palms), primarily leave on
5C	Hand cream products applied to the hands using the hands (palms), primarily leave on
5D	Baby Creams, baby Oils and baby talc
6	Products with oral and lip exposure
7	Products applied to the hair with some hand contact
7A	Rinse-off products applied to the hair with some hand contact
7B	Leave-on products applied to the hair with some hand contact
8	Products with significant anogenital exposure
9	Products with body and hand exposure, primarily rinse off
10	Household care products with mostly hand contact:
10A	Household care excluding aerosol products (excluding aerosol/spray products)
10B	Household aerosol/spray products
11	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate
11A	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure
11B	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure
12	Products not intended for direct skin contact, minimal or insignificant transfer to skin

Coumarin has been chosen as an example to demonstrate the practical application of setting upper concentration levels based on systemic toxicity. The material is a weak sensitizer with a NESIL of 3500 µg/cm² and the reference dose 160 µg/kg/day. The comparison of the systemic exposure and the QRA2-derived upper concentration levels is provided in Table 10 (page 35).

5. Environment

To support the IFRA Environmental Standards, a screening level risk assessment is performed following the RIFM Environmental Framework (Salvito,2002) that provides three tiered levels of screening for aquatic risk.

- In Tier 1 only the material's regional volume of use, log Kow and molecular weight are needed to estimate a conservative risk quotient (RQ) expressed as the ratio: Predicted Environmental Concentration/Predicted No Effect Concentration (PEC/PNEC)). In Tier 1 a general QSAR for fish toxicity is used with a high uncertainty factor as discussed in Salvito *et al.*, 2002.
- In Tier 2 the model ECOSAR (providing chemical class specific ecotoxicity estimates) is used allowing for a lower uncertainty factor to be applied to the PNEC.
- Finally, if necessary, Tier 3 is conducted using measured biodegradation and ecotoxicity data to refine the RQ, thus allowing for lower PNEC uncertainty factors.

A screening-level hazard assessment is also performed using EPISUITE[5] using a material's structure and physical-chemical properties. This screening level hazard assessment considers the potential for a material to be persistent and bioaccumulative and toxic or very persistent and very bioaccumulative. The screening criteria currently applied are those used in the European Union for REACH as per their guidance document of 2012. For persistence, if the EPISUITE models BIOWIN 2 or BIOWIN 6 <0.5 and BIOWIN 3 <2.2, then the material is considered as potentially persistent. A material would be considered potentially bioaccumulative if the EPISUITE model BCFBAF predicts a fish BCF ≥ 2000 L/kg. Ecotoxicity is determined in the screening level risk assessment.

Should additional assessment be required, based on these model outputs, a weight-of-evidence based review is performed. This review considers available data on the material's physical-chemical properties, environmental fate (e.g., OECD Guideline biodegradation studies or die-away studies), fish bioaccumulation, and higher tier model outputs (e.g., USEPA's BIOWIN and BCFBAF found in EPISUITE).

[5] Last version released of EPISUITE: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

6. IFRA Standard categories

6.1 Introduction to the IFRA categories

For practical reasons, IFRA Standards are set per product category, each covering a range of product types which can be grouped together based on risk assessment considerations. Groupings have been derived for the skin sensitization endpoint resulting from the application of QRA2 and have been compared to groupings fitting with phototoxicity and systemic toxicity considerations.

With the new approach of combining the QRA2, phototoxicity and systemic toxicity assessment in one exercise, the number of categories in the IFRA Standard has changed from 11 categories for dermal sensitization Standards and 4 for systemic toxicity based Standards to 12 (Table 9). Product categorization is achieved by grouping consumer product types based on functional type, and major factors in habits and practices of consumers such as area of use (head, face, axillae, etc.) and whether they are rinse-off or leave-on applications. This represents a change from the categorization used in previous amendments but was considered necessary to fully implement aggregate consumer exposure into the process.

The final list of IFRA categories is shown in Table 9 (page 31).

6.2 General approach for deriving the upper concentration levels for IFRA categories

The upper concentration levels reported in the Standards are the lower values of upper concentration levels derived from the comparison of the dermal sensitization and the systemic toxicity endpoints risk evaluation. When there is a need for an IFRA Standard based on several adverse effects (typically dermal sensitization and systemic toxicity) the upper concentration levels (maximum acceptable exposure levels) for dermal sensitization (e.g. by QRA2) will be compared to the upper concentration levels based on the material's systemic effects. **For each product category, the lowest maximum acceptable exposure level (based on systemic toxicity, dermal sensitization or any other endpoint) will be used**.

It is possible that for some materials the upper concentration level based on sensitization effects (i.e. derived by QRA2) is lower than that derived for systemic toxicity for a given product category, but not all categories. As a result, the use level will be restricted to the respective QRA2 limit for such product category. The resulting lowered total systemic exposure from all such product categories combined will be used to deploy the Creme-RIFM Aggregate Exposure Model's Optimization Tool once again to derive refined upper concentration levels for all other remaining product categories. In this way, a given proportion of the maximum acceptable aggregated exposure can be redistributed to those product categories that are not limited by the QRA2, i.e. this allows for higher upper concentration levels in such categories. If in a product category the upper concentration level reaches 100% (most likely in IFRA Standard category 12), the level is fixed to 100% and the optimization tool is applied again to allow redistribution of exposure over remaining not yet fixed categories. This process may have to go through several iterations to achieve the maximum allowable distribution amongst the different product categories. Table 10 (page 35) uses the example of Coumarin to demonstrate how this is accomplished.

In the cases where the **threshold of toxicological concern (TTC)** is used in the endpoint assessment, it will not be treated as a no effect level, meaning that no risk management measures will be recommended based on the TTC values alone (as long as the current use is below the TTC), i.e., IFRA will not set Standards based on the TTC. **In those cases, the upper concentration levels reported in the Standard are derived solely from the dermal sensitization endpoint evaluation**. A monitoring system is in place at RIFM to ensure that the current use does not exceed the TTC. This system re-surveys concentration data every 5 years for any fragrance ingredient that has a safety assessment which used either the TTC or the Dermal Sensitization Threshold (DST). If the monitoring system indicates that the current use levels are no

longer supported by the current RIFM safety assessment, a re-evaluation is conducted, and the safety assessment is revised. This process could result in a new IFRA Standard.

The upper concentration levels are expressed in the Standard with two significant digits.

6.3 Specific cases for deriving the upper concentration levels for IFRA categories

In some cases, specific ingredients have been the object of an ingredient defense activity in the context of regulatory developments (e.g. SCCS dossiers for the European Commission). In their defense, industry may have provided upper concentration levels, which have been reflected in the application of the optimization tool as fixed values. This is the case, for example, of **Acetylated Vetiver oil** and **p-tert-Butyl-alpha-methylhydrocinnamic aldehyde (p-BMHCA)**, where the upper concentration levels for cosmetic product categories, as provided to the SCCS, have been implemented in these Standards. This approach will also be used for any ingredient in a similar situation in the future.

There are a few cases where existing IFRA Standard limits have been taken as fixed limits in the optimization tool as in the case of **3- and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde (HMPCC), Oakmoss and Treemoss** as described below.

The Standard on **3- and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde (HMPCC)** was not based on QRA1 but on a pragmatic approach establishing a restriction based on consideration of elicitation information instead of induction information (which is the one considered for Standards addressing dermal sensitization). As a result, the IFRA Scientific Committee (in charge of IFRA Standards at that time) recommended to the Expert Panel for Fragrance Safety to limit the use of HMPCC to 0.02% in lip products, deodorants and antiperspirants and 0.2% in other cosmetic products except oral products. As such, when transferring the Standard to QRA2, the fixed levels were transferred to the different categories depending on the products included within each of the categories.

For **Oakmoss and Treemoss**, the restrictions in the Standards are directly linked to the presence of Atranol and Chloroatranol in the finished products. To ensure that those remain below trace levels, the upper concentration levels have not been increased (compared to QRA1).

6.4 Important information relevant to the product types included in each category

There are several key considerations regarding the product types and categories that must be noted:

- The QRA2 addresses the protection of human health and is specifically aimed at reducing as much as possible the induction of dermal sensitization to fragrance ingredients under their conditions of use. The fragrance industry QRA approach defined for dermal sensitization should not be applied to other toxicological effects or usage patterns as it is specific for dermal sensitization.
- The products described are all retail consumer products. As such upper use levels are determined for consumer use of these products only. End uses that are not listed in this Guidance document have not been reviewed by RIFM in their risk assessment process and therefore not included in the IFRA risk management.
- The QRA2 methodology and systemic toxicity risk assessment do not cover occupational use of consumer products, mainly due to missing exposure data to build into the risk assessment.
- Upper use levels of fragrance mixtures in medical devices and prescriptive drugs have not been determined. This is mainly due to the potential or intended application on compromised or diseased skin and therefore a different risk benefit consideration than for typical consumer products is needed. In addition, these product types are under the scope of specific regulations with defined safety assessment requirements.

- In cases where a finished consumer product is marketed for applications that cross several uses, the most stringent restriction should apply.

Table 10: Combining QRA2 and systemic toxicity acceptable levels for Coumarin

Category	Product	QRA2 acceptable % in final product	Systemic acceptable % in final product	Combined systemic and QRA2 % in final product (this can be the result from various iterations in the optimization tool)
1	Products applied to the lips	0.27	0.089	0.089
2	Products applied to the axillae	0.080	0.080	0.080
3	Products applied to the face/body using fingertips	1.6	0.089	0.089
4	Products related to fine fragrances	1.5	1.5	1.5
5 (5A)	Products applied to the body using the hands (palms), primarily leave-on (Body lotion)	0.38	0.38	0.38
5 (5B)	Products applied to the face using the hands (palms), primarily leave-on (Face moisturizer)	0.38	0.11	0.11
5 (5C)	Products applied to the hands using the hands (palms), primarily leave-on (Hand cream)	0.38	0.16	0.16
5 (5D)	Products applied to babies using the hands (palms), primarily leave-on (Baby cream, oil, talc)	0.38	NA*	0.035
6	Products with oral and lip exposure	0.88	0.0024	0.0024
7 (7A)	Rinse-off products applied to the hair with some hand contact	3.1	0.18	0.18
7 (7B)	Leave-on products applied to the hair with some hand contact	3.1	0.18	0.18
8	Products with significant anogenital exposure (tampon)	0.158	NA*	0.035
9	Products with body and hand exposure, primarily rinse off	2.9	0.52	0.52
10 (10A)	Household care products with mostly hand contact (excluding aerosol/spray products)	11	NA*	0.52
10 (10B)	Household care products with mostly hand contact (household aerosol/spray products)	11	1.6	1.6
11 (11A)	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure	5.8	NA*	0.035
11 (11B)	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure	5.8	NA*	0.035
12	Other air care products not intended for direct skin contact, minimal or insignificant transfer to skin	100	33	33

* Not Applicable (NA) – the product types in these categories are not included in the Creme RIFM aggregate exposure model, and aggregate exposure is not taken into account when calculating the acceptable levels of fragrance ingredients.

- The target of the RIFM Safety Assessments is humans and their safety while handling the finished consumer products. Some finished products applied to pets are listed in Table 12, being covered by the IFRA Standards (animal sprays or shampoos). However, the categorization of such products only relates to the human exposure during the application of such products, not to the exposure of the product on the pet. As a consequence, the assessment of safety of such finished consumer products with regard to animals is outside the scope of IFRA/RIFM and is the responsibility of the manufacturer.
- Product types are placed into IFRA product categories on the basis of their way of use (leave on or rinse off) and the area of the body on which they are used. This method of categorization was adopted to fit in with the use of aggregate exposure to derive acceptable levels in the QRA2 process and adjusted for systemic exposure considerations. It is not possible to list every conceivable type of product in this document. Several product types have been placed in specific IFRA categories even in the absence of exposure data by taking into account how the product is used and the body area on which it is used. However, should consumer product exposure data become available; these product types may be re-categorized. Also, if additional relevant exposure data become available on any product type, this may also result in re-categorization of the product type.
- The NESIL is expressed in two significant figures and rounded down as a conservative approach. For example, a calculated NESIL of 3564 will be rounded to 3500.
- It should be noted that the AELs will be expressed as accurate to two decimal places unless the NESIL is low enough that the AEL needs to be expressed to three decimal places. 1ppm (0.0001%) will be lowest level reported as AEL.
- In cases, where a product is not currently categorized and/or there are newly available data on consumer product exposure or surface area, then it is incumbent on the fragrance supplier to submit these data without undue delay. Data should be sent to IFRA (mvey@ifraorg.org) and RIFM (amapi@rifm.org). RIFM and IFRA have developed a form for providing all the necessary information. The form can be found at IFRA Information Letter 796 and also on the RIFM[6] and IFRA[7] websites. When the provided information is sufficiently robust, modification of this information booklet will be done and the IFRA membership and stakeholders would be adequately informed about the change(s).

6.5 Important information relative to specific products

6.5.1 Aerosols

Pressurized aerosols:

When calculating fragrance ingredient concentration in pressurized aerosols, to determine compliance with an IFRA Standard (determining the concentration reaching the skin), the limit is the one in the finished product, including the propellant.

Specially concentrated products:

For any concentrated product, Standards for maximum concentrations of restricted materials have been based on upper levels of consumer exposure from published surveys. In cases where specially concentrated products have been specifically designed to ensure lower delivery of the concentrated product, proportionately higher levels of restricted materials than those specified in the Standards may be used providing that the manufacturer certifies to fragrance suppliers the

[6] https://www.rifm.org/publications-detail.php?id=48
[7] https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/background-scientific-information-and-guidelines/qra-data-categorization-form.pdf?sfvrsn=f47ca8fd_0

exact degree to which exposure has been reduced. (For an example see the note on concentrated aerosol products below)

Concentrated aerosol products:

For aerosol products to be applied to the axillae, Standards for maximum concentrations of restricted materials have been based on upper levels of consumer exposure from published surveys (e.g. deodorant products with a product exposure of 9.1 mg/cm^2/day [Cowan- Ellsberry *et al.*, 2008]). In cases where concentrated aerosol products in this category have been specifically designed to ensure lower product delivery (e.g. lower spray rate), proportionately higher levels of restricted materials than those specified in the Standards may be used providing that the manufacturer certifies to fragrance suppliers the exact degree to which exposure has been reduced.

Incidental aerosol skin contact:

Incidental skin contact from aerosol products (e.g. aerosol air freshener) as defined in Category 10 relates to those aerosol products that are not intended for skin contact, but their use may result in skin contact. This excludes deodorant/antiperspirants, hair styling aids and sprays, which are part of other categories.

Concentrated aerosol air fresheners:

These air fresheners are differentiated from other aerosol air fresheners by the following two characteristics:

- These air fresheners are part of a device that either delivers the fragrance automatically or the device has an activation mechanism that is not located near where the aerosol is discharged, so there is essentially no dermal exposure from activation and at best incidental through exposure. Such concentrated aerosol air fresheners deliver a metered spray (typically 0.05 – 0.5 ml/spray) and are placed in Category 12.
- Other aerosol air fresheners deliver a continuous spray at 1-1.5 ml/second spray for as long as the consumer manually pushes the activation button, which is typically 2 to 10 seconds for a total volume of 2 – 15 ml/spray. Those products are placed in Category 10, as they are typically manually activated by a push button near the spray, which can result in some dermal exposure.

6.5.2 Aftershaves

Products marketed as aftershave products are all included in Category 4 along with other fine fragrance products. Some aftershave products are cream and lotion products and may actually be categorized as a face moisturizer (Category 5B). It is recommended that the fragrance supplier and the customer company consult on the appropriate category for these types of aftershave products.

6.5.3 After sun and self-tanning products

After sun and self-tanning creams, lotions, foams and other product applications are not addressed separately, but are included in the appropriate major product types (e.g. facial cream, body cream) in line with other sun care products. Products used on mildly sunburned skin are also expected to fit into the appropriate major product categories without amendment to their QRA which is already sufficiently conservative. Use of products for severely sunburned skin could constitute a different exposure scenario, but since these borders on needing professional medical advice for treatment, this is considered to be outside the scope of this QRA activity.

6.5.4 Sunscreens

Products that contain sunscreen or sunblock are not listed separately but are included in the appropriate major product type (e.g. lip creams containing sunscreen are included in the lip products category).

6.5.5 Animal sprays:

The target of the RIFM Safety Assessments is humans and their safety while handling the finished consumer products. Some finished products applied to pets are listed in Table 12, being covered by the IFRA Standards (animal sprays or shampoos). However, the categorization of such products only relates to the human exposure during the application of such products, not to the exposure of the product on the pet. Therefore, the assessment of safety of such finished consumer products with regard to animals is outside the scope of IFRA/RIFM and is the responsibility of the manufacturer.

Animal sprays (or pet sprays) are categorized in Category 10. For this specific type of product (where there is no direct application to humans) it is not necessary to differentiate between aerosol and pump applications.

6.5.6 Body sprays (including body mists)

Although Category 2 targets products that are mainly applied to the axillae, body sprays (including body mists) have been placed in this category as, in many regions, the intended and/or foreseeable use does actually go beyond the application on the body only.

If a body spray (body mist) is clearly labelled that it should not be applied to the axillae (meaning it should not be used as a deodorant), then this product can be considered under Category 4. It is recommended that the fragrance supplier and the customer company consult on the appropriate category for each specific body spray (body mist) product.

6.5.7 Body and face paint (for adults and children)

Due to insufficient habits and practice information that would allow a differentiation of these products, body and face paint (for adults and children, which sometimes are even marketed as one product for both applications) are included in Category 3.

6.5.8 Children's toys

As stated in Section 1.6.3, IFRA prohibits the use of fragrance materials and mixtures in toys or other children's products where there is the likelihood of mouth contact. Following the criteria established by the toy industry, these include:

1) toys for children less than 3 years of age;
2) any toy designed and intended to go into the mouth; and/or
3) those toys for which mouth contact is reasonably foreseeable.

If these conditions do not apply, fragrance ingredients may be used according to the upper concentration levels described in the Category 1 of IFRA Standards. These toys have been placed in Category 1 (leave-on products generally applied to the lips) due to the potential of ingestion of minute amounts of fragrance ingredients. Should exposure data become available, these product types may be re-categorized.

Due to non-foreseeable exposure, Olfactive Board Games have been categorized in Category 12.

6.5.9 Dental products

Toothpaste and Mouthwash Products:

With the implementation of the QRA approach, the IFRA Standards will include oral care products. Mouthwash and toothpastes are the principal oral care products currently identified in IFRA Category 6. Exposure limits for these products are established to reduce the risk of peri-oral dermal sensitization and as such, are not related to considerations of safe levels for ingestion.

See section 1.6.2 'Oral care products and other products with the potential of ingestion' for specifics related to the flavor material status needed for fragrances used in oral care products.

Denture adhesives and tooth whiteners:

These are regulated globally as medical devices. Since medical device regulations include separate safety assessment guidelines, these product types are not included in the IFRA categorization.

6.5.10 Oral intake of products:

The IFRA policy on the inclusion of fragrance ingredients in consumer products with the potential of ingestion is described in Section 1.6.2..

6.5.11 Diapers, feminine hygiene pads, liners and tampons:

As with all other product types, levels of fragrance ingredients in diapers and feminine hygiene products are based on the final product. It is recognized that assembled products such as these (versus formulated products) involve special considerations because the fragrance mixture is included in the final product based on weight rather than percent concentration.

6.5.12 Scent pads and foil packs:

Scent pads and foil packs are two types of fragrance sampling technology that contain the hydroalcoholic product on a pad or in a foil pack. As such these product types are categorized in Category 4.

6.5.13 Scent strips:

The concentration of the fragrance mixture, that is used for IFRA compliance review of a fragrance, to be used in a scent strip product (a sampling technology that potentially gets rubbed on the skin) should be the same concentration that is used for the related fragrance oil (or fragrance mixture) in the consumer product for which the scent strip is meant to be a sampled. For example, if the consumer product is a hydroalcoholic product containing 15% fragrance mixture, then the concentration of the fragrance mixture to be used in the scent strip should be 15% for review in Category 4.

6.5.14 Tissues *vs*. wipes:

Tissues or facial tissues are soft (dry) tissues (Category 11) that are usually contained in boxes. Wipes or refreshing tissues (Category 3) are moist towels and are usually contained in (re)sealable plastic packages.

6.5.15 Wheat bags:

Heating pads of various shapes or size filled with grain to be applied on different areas of the body and presented as providing soothing effect by applying it either warm or cold.

6.5.16 Attars and attar-type fragrances

On a global scale, it has been determined that ***attar*** has a broad definition as a concentrated fragrance oil format with various uses by consumers (similar to an oil, lotion or spray format), rather than a single specific use in one product type [recognizing it being described as such[8]].

Because it is free from the ethanol used in traditional colognes and EdTs, undiluted attar is preferred by various religious groups as a personal fragrance product. It may be applied in very small amounts to small skin surface areas like a fine fragrance on pulsation points or in larger amounts over a more extensive body surface like body oil. Most often attar is used neat. However, the term “attar type fragrance” is also used to describe diluted products. For example, when religious concerns about ethanol are not an issue, Attar can be diluted for typical fine fragrance or Eau de Toilette uses or as a fabric spray.

Attar can also be used in/as air care products. Examples include incense or reed diffusors. The smoke from the incense may be used to fragrance clothing or the air.

Therefore, user exposure can vary based on the actual use pattern of the product as/in which the Attar is used.

Because of the various potential uses of consumer products labelled as attar or “attar type fragrances” (as outlined above) and the wide range of potential exposures, it is not feasible to assign it to a single QRA category. It is therefore up to the final product manufacturer to select the proper IFRA category for a compliance assessment. The decision criteria should include the intended or reasonably foreseeable use of the product (body part, amount used etc.). Both dose per unit area for the dermal QRA and total daily exposure for systemic risk assessment should be considered. Possible options are included in Table 11.

Table 11: Possible categorization of Attar products depending on the potential uses of consumer products labelled as Attar or “Attar type fragrances”

Type of finished consumer product	Proposed categorization
Fine fragrance type use	4
EDT use (oil with alcohol)	4
Body oil/lotion like use	5A
With intimate exposure	8
Fabric Spray / reed diffuser	10A
Incense / other non-skin	12

IFRA recommends using the most stringent outcome of the safety assessment (in terms of dermal and systemic effects) in case no clear end product for the use of attar is specified.

[8] Garry Dix, Perfumer and Flavorist, Vol. 40, 38-43, Jan. 2015

6.6 IFRA categories: list of finished consumer products per category

Table 12 gives the products placed in the 12 IFRA Categories and subcategories with detailed comments for specific product types.

Table 13 is an alphabetical list of product types and their corresponding IFRA Category.

Table 14 provides a summary of the changes of product categorization introduced with the 49th Amendment i.e. based on QRA2 (compared to the product categorization in previous Amendments i.e. based on QRA1).

Table 12: List of IFRA categories and subcategories with corresponding product

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Category 1	**Leave on products generally applied to lips**					
Lip Products of all types (solid and liquid lipsticks, balms, clear or colored, etc.)	Products that contain sunscreen or sunblock are not listed separately and are included in the major product type (e.g. lip creams containing sunscreen are included in the lip products category).		YES	Applicable (leave-on products)	Category 1	Category 1
Children's toys	This product type has been placed in Category 1 based on the absence of exposure data. Should exposure data become available, these product types may be re-categorized.		YES	Applicable (leave-on products)	Category 1	Category 1
Category 2	**Leave on products generally applied to axillae**					
Deodorant and antiperspirant products of all types including any product with intended or reasonably foreseeable use on the axillae or labelled as such (spray, stick, roll-on, under-arm, deo-cologne, etc.)			NO	Applicable (leave-on products)	Category 2	Category 2 (Deodorant and Antiperspirant Products of all types), Category 4 (Body Sprays)
Body sprays (including body mist)			NO	Applicable (leave-on products)	Category 2	Category 4 (body mist not intended to be applied in the axillae) and Category 2 (body mist with the potential of application in the axillae)
Category 3	**Products generally applied to the face using fingertips**					
Eye products of all types (eye shadow, mascara, eyeliner, eye make-up, eye masks, eye pillows, etc.) including eye care and moisturizer			NO	Applicable (leave-on products)	Category 3	Category 3
Facial make up and foundation			NO	Applicable (leave-on products)	Category 3	Category 5 (women facial make-up)
Make-up remover for face and eyes			NO	Applicable (leave-on products)	Category 3	Category 8
Nose pore strips			NO	Applicable (leave-on products)	Category 3	Category 2

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Wipes or refreshing tissues for face, neck, hands, body	These product types have been placed in Category 3 based on the absence of exposure data, but it is recognized that these products are generic to males and females and have similarities with the product types in this category. Should exposure data become available, these product types may be re-categorized.		NO	Applicable (leave-on products)	Category 3	Category 5
Body and face paint (for children and adults)	This product type has been placed in Category 3 based on the absence of exposure data, with the assumption that this product is applied with fingertips and not with the palms. Should exposure data become available, this product type may be re-categorized.		NO	Applicable (leave-on products)	Category 3	Category 3 (body paint for children) and Category 4 (body paint for adults)
Facial masks for face and around the eyes			NO	Applicable (leave-on products)	Category 3	Category 5 (Facial masks for face, lips and around the eyes).
Category 4	**Fragrancing products generally applied to neck, face and wrists**					
Hydroalcoholic and non-hydroalcoholic fine fragrance of all types (Eau de Toilette, Parfum, Cologne, solid perfume, fragrancing cream, aftershaves of all types, etc.)			NO	Applicable (leave-on products)	Category 4	Category 3 (hydroalcoholic products applied to shaved skin), Category 4 (hydroalcoholic products applied to unshaved skin, solid perfumes, fragrancing cream)
Fragranced bracelets	These product types have been placed in Category 4 based on the absence of exposure data and on assumptions which include the leave on use on the wrists. Should exposure data become available, this product type may be re-categorized.		NO	Applicable (leave-on products)	Category 4	Category 2
Ingredients of perfume kits and fragrance mixtures for cosmetic kits			NO	Applicable (leave-on products)	Category 4	Category 4
Scent pads, foil packs			NO	Applicable (leave-on products)	Category 4	Category 4
Scent strips for hydroalcoholic products	These product types have been placed in Category 4 based on the absence of exposure data, but it is recognized that these products have similarities to hydroalcoholic products applied to unshaved skin. Should exposure data become available, these product types may be re-categorized.		NO	Applicable (leave-on products)	Category 4	Category 4
Category 5	**Leave on products applied to the face and body using the hands (palms)**					
Body creams, oils, lotions of all types	Products that contain sunscreen or sunblock are not listed separately and	A	NO	Applicable (leave-on products)	Category 5A	Category 4

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Foot care products (creams and powders)	are included in the major product type (e.g. lip creams containing sunscreen are included in the lip products category).	A	NO	Applicable (leave-on products)	Category 5A	Category 4
Insect repellent (intended to be applied to the skin)		A	NO	Applicable (leave-on products)	Category 5A	Category 7
All powders and talc (excluding baby powders and talc)		A	NO	Applicable (leave-on products)	Category 5A	Category 8
Facial toner		B	NO	Applicable (leave-on products)	Category 5B	New
Facial moisturizers and creams		B	NO	Applicable (leave-on products)	Category 5B	Category 3 (Men's facial creams and balms) and Category 5 (women facial creams)
Hand cream		C	NO	Applicable (leave-on products)	Category 5C	Category 5
Nail care products including cuticle creams, etc.		C	NO	Applicable (leave-on products)	Category 5C	Category 8
Hand sanitizers		C	NO	Applicable (leave-on products)	Category 5C	Category 5
Baby cream/lotion, baby oil, baby powders and talc		D	NO	Applicable (leave-on products)	Category 5D	Category 3 (Baby creams and lotions) and Category 5 (Baby powders and talc)
Category 6	**Rinse off products with lip and oral exposure**					
Toothpaste	Exposure limits for these products are established to reduce the risk of peri-oral skin sensitization and as such, are not related to considerations of safe levels for ingestion. For the systemic toxicity assessment, only incidental ingestion is considered.		YES	Applicable (leave-on products)	Category 6	Category 6
Mouthwash, including breath sprays			YES	Applicable (leave-on products)	Category 6	Category 6
Toothpowder, strips, mouthwash tablets			YES	Applicable (leave-on products)	Category 6	New
Category 7	**Products applied to hair with hand contact**					
Hair permanent or other hair chemical treatments (rinse-off) (e.g. relaxers), including rinse-off hair dyes	Fragrance ingredients in hair permanent and other hair chemical treatments have been placed in Category 7. There are no exposure data on these product types. It is recognized that these product types involve repeated low frequency exposure. In order to define a per diem exposure, a conservative surrogate product has been chosen, which is leave-on conditioners. Should exposure data become available, these product types may be re-categorized.	A	NO	Applicable (rinse-off products)	Category 7A	Category 5 (hair permanent or other hair chemical treatments (e.g. relaxers) and Category 8 (hair dyes)
Hair sprays of all types (pumps, aerosol sprays, etc.)		B	NO	Applicable (leave-on products)	Category 7B	Category 4
Hair styling aids non sprays (mousse, gels, leave- on conditioners)		B	NO	Applicable (leave-on products)	Category 7B	Category 8

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Hair permanent or other hair chemical treatments (leave-on) (e.g. relaxers), including leave-on hair dyes	Fragrance ingredients in hair permanent and other hair chemical treatments have been placed in Category 7. There are no exposure data on these product types. It is recognized that these product types involve repeated low frequency exposure. In order to define a per diem exposure, a conservative surrogate product has been chosen, which is leave-on conditioners. Should exposure data become available, these product types may be re-categorized.	B	NO	Applicable (leave-on products)	Category 7B	Category 5 (hair permanent or other hair chemical treatments (e.g. relaxers) and Category 8 (hair dyes)
Shampoo - Dry (waterless shampoo)		B	NO	Applicable (leave-on products)	Category 7B	Category 5
Hair deodorizer		B	NO	Applicable (leave-on products)	Category 7B	Category 4
Category 8	**Products with significant anogenital exposure**					
Intimate wipes			NO	Applicable (leave-on products)*	Category 8	Category 7
Tampons			NO	Applicable (leave-on products)*	Category 8	Category 3
Baby wipes			NO	Applicable (leave-on products)*	Category 8	Category 7
Toilet paper (wet)			NO	Applicable (leave-on products)*	Category 8	Category 9 (toilet paper)
*For the 49th Amendment, phototoxic effects are taken into consideration for Category 8 (Products with significant anogenital exposure), for reasons of conservativism to take into account potential uses of the products that could include sun exposure (e.g. baby wipes).						
Category 9	**Rinse off products with body and hand exposure**					
Bar soap			NO	Applicable (rinse-off products)	Category 9	Category 9
Shampoo of all type			NO	Applicable (rinse-off products)	Category 9	Category 9
Cleanser for face (rinse-off)			NO	Applicable (rinse-off products)	Category 9	Category 9
Conditioner (rinse-off)			NO	Applicable (rinse-off products)	Category 9	Category 9
Liquid soap			NO	Applicable (rinse-off products)	Category 9	Category 9
Body washes and shower gels of all types			NO	Applicable (rinse-off products)	Category 9	Category 9
Baby wash, bath, shampoo			NO	Applicable (rinse-off products)	Category 9	Category 9
Bath gels, foams, mousses, salts, oils and other products added to bathwater			NO	Applicable (rinse-off products)	Category 9	Category 9

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Foot care products (feet are placed in a bath for soaking)			NO	Applicable (rinse-off products)	Category 9	Category 4
Shaving creams of all types (stick, gels, foams, etc.)			NO	Applicable (rinse-off products)	Category 9	Category 9
All depilatories (including facial) and waxes for mechanical hair removal			NO	Applicable (rinse-off products)	Category 9	Category 9
Shampoos for pets	It was assumed that the exposure to humans from shampoos for pets could be expected to be similar to hand dishwashing liquids.		NO	Applicable (rinse-off products)	Category 9	Category 10
Category 10	**Household care products with mostly hand contact**					
Hand wash laundry detergent (including concentrates)		A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Laundry pre-treatment of all types (e.g. paste, sprays, sticks)		A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Hand dishwashing detergent (including concentrates)	In an abundance of caution, the exposure for liquid soaps (0.2 mg/cm2/day) is being used for the Hand Dishwash Liquid products (the HERA value is 0.01 mg/cm2/day). This this takes into account consumers who use hand dishwash liquids as a liquid soap.	A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Hard surface cleaners of all types (bathroom and kitchen cleansers, furniture polish, etc.)		A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Machine laundry detergents with skin contact (e.g. liquids, powders) including concentrates		A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Dry cleaning kits		A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Toilet seat wipes		A	NO	Applicable (rinse-off products)	Category 10A	Category 10
Fabric softeners of all types including fabric softener sheets		A	NO	Applicable (rinse-off products)	Category 10A	Category 10

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Household cleaning products, other types including fabric cleaners, soft surface cleaners, carpet cleaners, furniture polishes sprays and wipes, leather cleaning wipes, stain removers, fabric enhancing sprays, treatment products for textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics)		A	NO	Applicable (rinse-off products)	Category 10A	Category 10 (household cleaning products, other types including fabric cleaners, soft surface cleaners, carpet cleaners, furniture polishes sprays and wipes, leather cleaning wipes, stain removers, fabric enhancing sprays) and Category 11 (treatment products for textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics)
Floor wax		A	NO	Applicable (rinse-off products)	Category 10A	Category 11
Fragranced oil for lamp ring, reed diffusers, pot-pourri, liquid refills for air fresheners (non-cartridge systems), etc.		A	NO	Applicable (rinse-off products)	Category 10A	Category 11
Ironing water (Odorized distilled water)		A	NO	Applicable (rinse-off products)	Category 10A	Category 11
Animal sprays – sprays applied to animals of all types		B	NO	Applicable (leave-on products)	Category 10B	Category 11
Air freshener sprays, manual, including aerosol and pump		B	NO	Applicable (leave-on products)	Category 10B	Category 9 (Other aerosols (including air freshener sprays and air freshener pump sprays, but not including deodorant/antiperspirants, hairy styling aids sprays))
Aerosol/spray insecticides		B	NO	Applicable (leave-on products)	Category 10B	Category 9 (Other aerosols (including air freshener sprays and air freshener pump sprays, but not including deodorant/antiperspirants, hairy styling aids sprays))
Category 11	**Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate**					
Feminine hygiene conventional pads, liners, interlabial pads		A	NO	Not applicable (leave-on products without UV exposure)	Category 11A	Category 9
Diapers (baby and adult)		A	NO	Not applicable (leave-on products without UV exposure)	Category 11A	Category 10
Adult incontinence pant, pad		A	NO	Not applicable (leave-on products without UV exposure)	Category 11A	New

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Toilet paper (dry)		A	NO	Not applicable (leave-on products without UV exposure)	Category 11A	Category 9 (toilet paper)
Tights with moisturizers		B	NO	Applicable (leave-on products)	Category 11B	Category 10
Scented socks, gloves		B	NO	Applicable (leave-on products)	Category 11B	Category 10
Facial tissues (dry tissues)		B	NO	Applicable (leave-on products)	Category 11B	Category 9
Napkins		B	NO	Applicable (leave-on products)	Category 11B	Category 9
Paper towels		B	NO	Applicable (leave-on products)	Category 11B	Category 9
Wheat bags		B	NO	Applicable (leave-on products)	Category 11B	Category 9
Facial masks (paper/protective) e.g. surgical masks not used as medical device		B	NO	Applicable (leave-on products)	Category 11B	Category 9
Fertilizers, solid (pellet or powder)		B	NO	Applicable (leave-on products)	Category 11B	New
Category 12	**Products not intended for direct skin contact, minimal or insignificant transfer to skin**					
Candles of all types (including encased)	Due to the expected negligible skin exposure from such products the risk of induction of dermal sensitization through the normal formulation and use of such products is considered to be negligible. As such, the concentration of fragrance ingredient is not restricted in the finished product.		NO	Not applicable (non-skin contact products)	Category 12	Category 11
Laundry detergents for machine wash with minimal skin contact (e.g. Liquid tabs, pods)			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Automated air fresheners and fragrancing of all types (concentrated aerosol with metered doses (range 0.05-0.5mL/spray), plug-ins, closed systems, solid substrate, membrane delivery, electrical, powders, fragrancing sachets, incense, liquid refills (cartridge), air freshening crystals)			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Air delivery systems			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Cat litter			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Cell phone cases			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Deodorizers/maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders)			NO	Not applicable (non-skin contact products)	Category 12	Category 11

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub-category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48th Amendment)
Fuels			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Insecticides (e.g. mosquito coil, paper, electrical, for clothing) excluding aerosols/sprays			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Joss sticks or incense sticks			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Dishwash detergent and deodorizers – for machine wash			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Olfactive board games			NO	Not applicable (non-skin contact products)	Category 12	New
Paints			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Plastic articles (excluding toys)			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Scratch and sniff			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Scent pack			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Scent delivery system (using dry air technology)			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Shoe polishes			NO	Not applicable (non-skin contact products)	Category 12	Category 11
Rim blocks (Toilet)			NO	Not applicable (non-skin contact products)	Category 12	Category 11

Table 13: IFRA categories and subcategories arranged alphabetically by product type.

Product Type	IFRA Category
Adult incontinence pant, pad	Category 11A
Aerosol/spray insecticides	Category 10B
Air delivery systems	Category 12
Air freshener sprays, manual, including aerosol and pump	Category 10B
All depilatories (including facial) and waxes for mechanical hair removal	Category 9
All powders and talc (excluding baby powders and talc)	Category 5A
Animal sprays – sprays applied to animals of all types	Category 10B
Automated air fresheners and fragrancing of all types (concentrated aerosol with metered doses (range 0.05-0.5mL/spray), plug-ins, closed systems, solid substrate, membrane delivery, electrical, powders, fragrancing sachets, incense, liquid refills (cartridge), air freshening crystals)	Category 12
Baby cream/lotion, baby oil, baby powders and talc	Category 5D
Baby wash, bath, shampoo	Category 9
Baby wipes	Category 8
Bar soap	Category 9
Bath gels, foams, mousses, salts, oils and other products added to bathwater	Category 9
Body and face paint (for children and adults)	Category 3
Body creams, oils, lotions of all types	Category 5A
Body sprays (including body mist)	Category 2
Body washes and shower gels of all types	Category 9
Candles of all types (including encased)	Category 12
Cat litter	Category 12
Cell phone cases	Category 12
Children's toys	Category 1
Cleanser for face (rinse-off)	Category 9
Conditioner (rinse-off)	Category 9
Deodorant and antiperspirant products of all types including any product with intended or reasonably foreseeable use on the axillae or labelled as such (spray, stick, roll-on, under-arm, deo-cologne, etc.)	Category 2
Deodorizers/maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders)	Category 12
Diapers (baby and adult)	Category 11A
Dishwash detergent and deodorizers – for machine wash	Category 12
Dry cleaning kits	Category 10A
Eye products of all types (eye shadow, mascara, eyeliner, eye make-up, eye masks, eye pillows, etc.) including eye care and moisturizer	Category 3
Fabric softeners of all types including fabric softener sheets	Category 10A
Facial moisturizers and creams	Category 5B
Facial toner	Category 5B
Facial make up and foundation	Category 3
Facial masks (paper/protective) e.g. surgical masks not used as medical device	Category 11B
Facial masks for face and around the eyes	Category 3

Product Type	IFRA Category
Facial tissues (dry tissues)	Category 11B
Feminine hygiene conventional pads, liners, interlabial pads	Category 11A
Fertilizers, solid (pellet or powder)	Category 11B
Floor wax	Category 10A
Foot care products (creams and powders)	Category 5A
Foot care products (feet are placed in a bath for soaking)	Category 9
Fragranced bracelets	Category 4
Fragranced oil for lamp ring, reed diffusers, pot-pourri, liquid refills for air fresheners (non-cartridge systems), etc.	Category 10A
Fuels	Category 12
Hair deodorizer	Category 7B
Hair permanent or other hair chemical treatments (leave-on) (e.g. relaxers), including leave-on hair dyes	Category 7B
Hair permanent or other hair chemical treatments (rinse-off) (e.g. relaxers), including rinse-off hair dyes	Category 7A
Hair sprays of all types (pumps, aerosol sprays, etc.)	Category 7B
Hair styling aids non sprays (mousse, gels, leave- on conditioners)	Category 7B
Hand cream	Category 5C
Hand dishwashing detergent (including concentrates)	Category 10A
Hand sanitizers	Category 5C
Hand wash laundry detergent (including concentrates)	Category 10A
Hard surface cleaners of all types (bathroom and kitchen cleansers, furniture polish, etc.)	Category 10A
Household cleaning products, other types including fabric cleaners, soft surface cleaners, carpet cleaners, furniture polishes sprays and wipes, leather cleaning wipes, stain removers, fabric enhancing sprays, treatment products for textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics)	Category 10A
Hydroalcoholic and non-hydroalcoholic fine fragrance of all types (Eau de Toilette, Parfum, Cologne, solid perfume, fragrancing cream, aftershaves of all types, etc.)	Category 4
Ingredients of perfume kits and fragrance mixtures for cosmetic kits	Category 4
Insect repellent (intended to be applied to the skin)	Category 5A
Insecticides (e.g. mosquito coil, paper, electrical, for clothing) excluding aerosols/sprays	Category 12
Intimate wipes	Category 8
Ironing water (Odorized distilled water)	Category 10A
Joss sticks or incense sticks	Category 12
Laundry detergents for machine wash with minimal skin contact (e.g. Liquid tabs, pods)	Category 12
Laundry pre-treatment of all types (e.g. paste, sprays, sticks)	Category 10A
Lip Products of all types (solid and liquid lipsticks, balms, clear or colored, etc.)	Category 1
Liquid soap	Category 9
Machine laundry detergents with skin contact (e.g. liquids, powders) including concentrates	Category 10A
Make-up remover for face and eyes	Category 3
Mouthwash, including breath sprays	Category 6
Nail care products including cuticle creams, etc.	Category 5C
Napkins	Category 11B

Product Type	IFRA Category
Nose pore strips	Category 3
Olfactive board games	Category 12
Paints	Category 12
Paper towels	Category 11B
Plastic articles (excluding toys)	Category 12
Rim blocks (Toilet)	Category 12
Scent delivery system (using dry air technology)	Category 12
Scent pack	Category 12
Scent pads, foil packs	Category 4
Scent strips for hydroalcoholic products	Category 4
Scented socks, gloves	Category 11B
Scratch and sniff	Category 12
Shampoo - Dry (waterless shampoo)	Category 7B
Shampoo of all type	Category 9
Shampoos for pets	Category 9
Shaving creams of all types (stick, gels, foams, etc.)	Category 9
Shoe polishes	Category 12
Tampons	Category 8
Tights with moisturizers	Category 11B
Toilet paper (dry)	Category 11A
Toilet paper (wet)	Category 8
Toilet seat wipes	Category 10A
Toothpaste	Category 6
Toothpowder, strips, mouthwash tablets	Category 6
Wheat bags	Category 11B
Wipes or refreshing tissues for face, neck, hands, body	Category 3

Table 14: Summary of changes of product types from QRA1 (old) categories (as per the 48th Amendment) to the new IFRA categories (as per the 49th Amendment). The product types highlighted in red have changed IFRA Category in the 49th Amendment.

QRA1 (old) Category 1
Lip products of all types (solid and liquid lipsticks, balms, clear etc.)
Children's toys

QRA1 (old) Category 2
Deodorant and antiperspirant products of all types including any product with intended or reasonably foreseeable use on the axillae or labelled as such (spray, stick, roll-on, underarm, deo-cologne and body spray, etc.)
Nose pore strips *to new IFRA Category 3*
Fragranced bracelets *to new IFRA Category 4*

QRA1 (old) Category 3
Hydroalcoholic products applied to recently shaved skin (includes aftershave) *to new IFRA Category 4* *In the new IFRA Categorization (QRA2), there is no further distinction between shaved and unshaved skin for hydroalcoholic products. They are grouped together in Category 4 under "Hydroalcoholic and non-hydroalcoholic fine fragrance of all types (Eau de Toilette, Parfum, Cologne, solid perfume, fragrancing cream, aftershaves of all types, etc.).". Regarding aftershave, please refer to Section 6.5.2, page 37.*
Eye products of all types (eye shadow, mascara, eyeliner, eye make-up, eye masks, eye pillows, etc.) including eye care (and moisturizer)
Men's facial creams, balms *to new IFRA Category 5B* *In the new IFRA Categorization (QRA2), there is no longer the distinction between Men's and women's facial creams and balms. They are grouped together in Category 5B under "Facial moisturizers and creams".*
Tampons *to new IFRA Category 8*
Baby creams, lotions, oils *to new IFRA Category 5D* *In the new IFRA Categorization (QRA2), "Baby creams, lotions, oils" have been moved to Category 5D under the name "Baby cream/lotion, baby oil, baby powders and talc".*
Body paint for children *In the new IFRA Categorization (QRA2), Body paint for adults and children is included in Category 3. The reason is that there is insufficient habits and practice information that would allow a differentiation of these products.*

QRA1 (old) Category 4
Hydroalcoholic products applied to unshaved skin (includes aqueous based, alcoholic based and hydroalcoholic) like Cologne, Eau de Cologne, Eau de Parfum or Parfum *In the new IFRA Categorization (QRA2), there is no longer the distinction between shaved and unshaved for hydroalcoholic products. They are grouped together in Category 4 under "Hydroalcoholic and non-hydroalcoholic fine fragrance of all types (Eau de Toilette, Parfum, Cologne, solid perfume, fragrancing cream, aftershaves of all types, etc.).". Regarding aftershave, please refer to Section 6.5.2, page 37.*
Hair styling aids, hair sprays of all types (pumps, aerosol sprays, etc.) *to new IFRA Category 7B*
Body creams, oils, lotions of all types (except baby creams and lotions) *to new IFRA Category 5A*
Fragrancing creams
Body sprays (including body mist) with no intended or reasonably foreseeable use on the axillae *to new IFRA Category 2* *The QRA 1 product type "Body sprays (including body mist) with no intended or reasonably foreseeable use on the axillae" is with the new IFRA Categorization (QRA2) included in Category 2 under the name "Body sprays (including body mist)". See more details in Section 6.5.6, page 38.*
Solid perfumes
Ingredients of perfume kits
Fragrance compounds (mixtures) for cosmetic kits
Scent pads, foil packs
Scent strips for hydroalcoholic products
Foot care products *to new IFRA Category 5A (for leave-on) and Category 9 (for rinse-off)*
Hair deodorant *to new IFRA Category 7B*
Body paint (except those for children) *to new IFRA Category 3* *In the new IFRA Categorization (QRA2), Body paint for adults and children is included in Category 3. The reason is that there is insufficient habits and practice information that would allow a differentiation of these products.*

QRA1 (old) Category 5
Women's facial creams/Facial make-up *to new IFRA Category 5B (Women's facial creams) and to new IFRA Category 3 (Facial make-up)* *In the new IFRA Categorization (QRA2), there is no longer the distinction between Men's and women's facial creams and balms. They are grouped together in Category 5B under "Facial moisturizers and creams".* *In the new IFRA Categorization (QRA2), all the make-up products are included in Category 3.*
Hand cream *to new IFRA Category 5C*

QRA1 (old) Category 5
Hand sanitizers *to new IFRA Category 5C*
Facial masks *to new IFRA Category 3*
Baby powder and talc *to new IFRA Category 5D*
Hair permanent and other hair chemical treatments (e.g. relaxers) but not hair dyes *to new IFRA Category 7B*
Wipes or refreshing tissues for face, neck, hands, body *to new IFRA Category 3*
Dry shampoo or waterless shampoo *to IFRA Category 7B*

QRA1 (old) Category 6
Mouthwash, including breath sprays
Toothpaste

QRA1 (old) Category 7
Intimate wipes *to new IFRA Category 8*
Baby wipes *to new IFRA Category 8*
Insect repellent (intended to be applied to the skin) *to new IFRA Category 5A*

QRA1 (old) Category 8
Make-up removers of all types (not including face cleansers) *to new IFRA Category 3* *In the new IFRA Categorization (QRA2), all the make-up products are included in Category 3.*
Hair styling aids non-spray of all types (mousse, gels, leave-in conditioners, etc.) *to new IFRA Category 7B.*
Nail Care *to new IFRA Category 5C*
Powders and talc, all types (except baby powders and talc) *to new IFRA Category 5A*
Hair dyes *to new IFRA Category 7A (rinse-off hair dyes) and to new IFRA Category 7B (leave-on hair dyes)*

QRA1 (old) Category 9
Bar soap (toilet soap)
Bath gels, foams, mousses, salts, oils and other products added to bathwater
Body washes of all types (including baby washes) and shower gels of all types
Conditioner (rinse-off)
All depilatories (including waxes for mechanical hair removal)
Face cleansers of all types (washes, gels, scrubs, etc.)
Facial tissues *to new IFRA Category 11B*
Feminine hygiene – pads, liners *to new IFRA Category 11A*
Fragranced face masks (not intended to be used as medical device) *to new IFRA Category 11B*
Liquid soap
Napkins *to new IFRA Category 11B*
Paper towels *to new IFRA Category 11B*
Shampoos of all types (including baby shampoos)
Shaving creams of all types (stick, gels, foams, etc.)
Toilet paper *to new IFRA Category 11A (Dry toilet paper) and to new IFRA Category 8 (Wet toilet paper)*
Wheat bags *to IFRA Category 11B*
Other aerosols (including air freshener sprays and air freshener pump sprays, but not including deodorant/antiperspirants, hairy styling aids sprays) *to new IFRA Category 10B*

QRA1 (old) Category 10
Handwash laundry detergents of all types including concentrates *to new IFRA Category 10A*
Fabric softeners of all types including fabric softener sheets *to new IFRA Category 10A*

QRA1 (old) Category 10
Household cleaning products, other types (fabric cleaners, soft surface cleaners, carpet cleaners, etc.) *to new IFRA Category 10A*
Machine wash laundry detergents (liquids, powders, tablets, etc.) including laundry bleach and concentrates *to new IFRA Category 10A*
Hand dishwashing detergent including concentrates *to new IFRA Category 10A*
Hard surface cleaners of all types (bathroom and kitchen cleansers, furniture polish, etc.) *to new IFRA Category 10A*
Diapers *to new IFRA Category 11A*
Shampoos for pets *to new IFRA Category 9*
Dry cleaning kits *to new IFRA Category 10A*
Toilet seat wipes *to new IFRA Category10A*
Scented gloves, socks, tights with moisturizers *to new IFRA Category 11B*

QRA1 (old) Category 11
All product types in new IFRA Category 12 come from QRA 1 Category 11, however not all QRA 1 Category 11 product types have been moved to the new IFRA Category 12. The new IFRA Category 11 contains no product types from QRA 1 Category 11.
Air fresheners and fragrancing of all types (*concentrated aerosol with metered doses (range 0.05-0.5 mL/spray)*, plug-ins, solid substrate, membrane delivery, electrical) *to new IFRA Category 12*
Air delivery systems *to new IFRA Category 12*
Animal sprays (all types) *to new IFRA Category 10B*
Candles *to new IFRA Category 12*
Cat litter *to new IFRA Category 12*
Cell phone cases *to new IFRA Category 12*

QRA1 (old) Category 11
Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) *to new IFRA Category 12*
Floor wax *to new IFRA Category 10A*
Fragranced lamp ring *to new IFRA Category 10A*
Fuels *to new IFRA Category 12*
Insecticides (e.g. mosquito coil, paper, electrical, for clothing) excluding aerosols/sprays *to new IFRA Category 12*
Joss sticks or incense sticks *to new IFRA Category 12*
Liquid refill for air fresheners (cartridge systems) *to new IFRA Category 12*
Machine dishwash detergent and deodorizers *to new IFRA Category 12*
Machine-only laundry detergent (e.g. liquitabs) *to new IFRA Category 12*
Odored distilled water (that can be added to steam irons) *to new IFRA Category 10A*
Paints *to new IFRA Category 12*
Plastic articles (excluding toys) *to new IFRA Category 12*
Pot-pourri, powders, fragrancing sachets, liquid refills for air fresheners (non-cartridge systems), reed diffuser *to new IFRA Category 10A (pot-pourri, reed diffuser and liquid refills for air fresheners (non-cartridge systems)) and to new IFRA Category 12 (powders, fragrancing sachets)*
Scratch and sniff (sampling technology) *to new IFRA Category 12*
Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization) *to new IFRA Category 12*
Scent pack *to new IFRA Category 12*
Shoe polishes *to new IFRA Category 12*

QRA1 (old) Category 11
Toilet blocks *to new IFRA Category 12*
Treatment products for textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics) *to new IFRA Category 10A*

6.7 Certificate of Conformity of fragrance mixtures with IFRA Standards

The certificate of conformity of fragrance mixtures with IFRA Standards hereafter "Certificate of Conformity" declares compliance with the requirements expressed in the IFRA Standards, and confirms that a specific fragrance mixture up to a certain concentration can be used in a specified consumer product in compliance with up to and including a specific Amendment (the number and the Notification date of the Amendment should be stated in the Certificate). The Certificate of Conformity does not replace a safety assessment. Additional information can also be provided by the supplier on a voluntary basis, such as the concentration in the fragrance mixture or the finished consumer product of the ingredients subject to IFRA Standards being part of the fragrance mixture.

IFRA classes were used in the past to define the group of consumer products for which the fragrance mixture can be used at the upper concentration level determined by the Certificate of Conformity. Such classes took into account systemic toxicity and phototoxicity considerations. Today, with the 49th Amendment, IFRA Categories already consider skin sensitization, systemic toxicity and phototoxicity considerations. As a consequence, the nomenclature of ‘classes’ becomes obsolete, as they already match with the IFRA categories (see also Table 12). The Certificate of Conformity is a document established by the fragrance mixture manufacturer and based on a trust relationship between the fragrance supplier and its customer (fragrance supplier or finished product manufacturer). IFRA is not involved in its preparation and takes on no responsibility with respect to the content or format of any such Certificate of Conformity.

Figure 5 provides an example of a Certificate of Conformity. This template is also available at the IFRA website:

https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/ifra-certificate-template/certificate-of-conformity-to-ifra-standards-template-december-12-2019.doc?sfvrsn=20664815_2

Previous information letters on Certificates of Conformity (i.e. IL768 and IL896) are becoming obsolete and the information is replaced by what is contained in this Guidance for the use of IFRA Standards.

Figure 5: Example of Certificate of Conformity of fragrance mixtures with IFRA Standards.

[Logo of the CERTIFYING PARTY]

CERTIFICATE OF CONFORMITY OF FRAGRANCE MIXTURES WITH IFRA STANDARDS

This Certificate assesses the conformity of a fragrance mixture with IFRA Standards and provides restrictions for use as necessary. It is based only on those materials subject to IFRA Standards for the toxicity endpoint(s) described in each Standard.

CERTIFYING PARTY:
Name of the fragrance supplier delivering the certificate
Address of the fragrance supplier

CERTIFICATE DELIVERED TO:
Customer: Name of the fragrance supplier or finished product manufacturer

SCOPE OF THE CERTIFICATE:
Product: Name of the product/fragrance mixture

COMPULSORY INFORMATION:

We certify that the above mixture is in compliance with the Standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA), up to and including the xx Amendment to the IFRA Standards (published *Month, Year*), provided it is used in the following category(ies) at a maximum concentration level of:

IFRA Category(ies) [see Table 12 in Guidance for the use of IFRA Standards for details]	Level of use (%)*
Category 4	***12%***
Category 5.C	***2.1%***

**Actual use level or maximum use level*

For other kinds of application or use at higher concentration levels, a new evaluation may be needed; please contact (name of the fragrance supplier).

(OPTIONAL INFORMATION):

Information about presence and concentration of fragrance ingredients subject to IFRA Standards in the fragrance mixture (name of the product) is as follows:

Materials under the scope of IFRA Standards:	CAS number(s):	Recommendation from IFRA Standard:	Concentration (%) in fragrance mixture or finished product:
trans-2-Hexenal (example)	*6728-26-3 (example)*	*Restriction (example)*	*to be completed*
Citral (example)	*5392-40-5 (example)*	*Restriction (example)*	*to be completed*
……...	……...	……...	*to be completed*

Disclaimer: This Certificate provides restrictions for use of the specified product based only on those materials restricted by IFRA Standards for the toxicity endpoint(s) described in each Standard. This Certificate does not provide certification of a comprehensive safety assessment of all product constituents. This certificate is the responsibility of the fragrance supplier issuing it. It has not been prepared or endorsed by IFRA in anyway.

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[Logo of the CERTIFYING PARTY]

Materials under the scope of IFRA Standards:	CAS number(s):	Recommendation from IFRA Standard:	Concentration (%) in fragrance mixture or finished product:
Toluene (example)	*108-88-3 (example)*	*Specification: level that should be lower than 100ppm in fragrance mixture (example).*	*to be completed*
Safrole, Isosafrole, Dihydrosafrole (example)	*94-59-7* *120-58-1* *94-58-6 (example)*	*Specification: level should be lower than 0.01% in finished consumer product, only if such level is due to natural contributions containing Safrole, Isosafrole and/or Dihydrosafrole (example).*	*to be completed*

Signature *(If generated electronically, no signature)* Date

Disclaimer: This Certificate provides restrictions for use of the specified product based only on those materials restricted by IFRA Standards for the toxicity endpoint(s) described in each Standard. This Certificate does not provide certification of a comprehensive safety assessment of all product constituents. This certificate is the responsibility of the fragrance supplier issuing it. It has not been prepared or endorsed by IFRA in anyway.

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7. Frequently asked questions

7.1 Why was QRA2 developed?

The QRA approach was initially defined to address limitations in the historical methodology that related to the more qualitative nature of the dermal sensitization risk assessments and the definition of only two product categories (skin contact and non-skin contact). QRA2 was developed to further refine the QRA process by incorporating:

1. Discussion and refinement of SAFs used in the QRA process. This process involved individual experts from industry and academia as well as independent experts from the fields of dermatology, contact allergy and risk assessment.
2. Aggregate exposure to fragrances from a range of personal and household care products.

This approach, particularly the inclusion of aggregate exposure estimation, is seen as a step change in the risk assessment of fragrance ingredients and will ensure a more robust process for determining IFRA Standard upper concentration levels.

7.2 Do I have to calculate the NESIL and AELs for each of my fragrance ingredients?

In the context of setting IFRA Standards, NESILs and AELs are already determined by RIFM and approved by the Expert Panel for Fragrance Safety. This information is included in the RIFM safety assessments publicly available (http://fragrancematerialsafetyresource.elsevier.com/). Exceptionally for the 49th Amendment, it could happen that the safety assessment of a specific ingredient covered by an IFRA Standard is not yet publicly available in the Fragrance Material Safety Resource website. If this is the case, please contact RIFM (amapi@rifm.org) to request a copy of the final draft safety assessment.

If a company would like to use fragrance ingredients that are not part of the RIFM Safety Assessment process, it remains the responsibility of the company to ensure a safe use of the ingredient. In the case of the skin sensitization endpoint, QRA2 may be used to derive safe use levels.

More details on the scope of the RIFM Safety Assessment program are available at www.rifm.org.

7.3 Will the NESILs and AELs ever change requiring reformulation as a result of a revised QRA?

While highly improbable it is not impossible that a fragrance ingredient NESIL once defined would be changed. However, the additional data would need to provide significant additional perspective for such a change to be necessary. It is more likely that the AEL could change on the basis of additional relevant exposure data becoming available. Such changes would be incorporated into future IFRA Amendments.

7.4 Where can I get help in understanding the QRA approach, including QRA2, and making the appropriate procedural changes?

This Guidance document is the first interface for global fragrance suppliers and users. For more in-depth understanding of the approaches now used, the following documents should be consulted:

QRA1:

Api *et al*., (2008), Dermal sensitization Quantitative Risk Assessment (QRA) for fragrance ingredients. Regulatory Toxicology and Pharmacology, 52; 3-23.

Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients, Technical Dossier, March 15, 2006, Revised June 22, 2006, is also still available on the IFRA and RIFM websites (http://rifm.org/publications-sort-title.php and http://www.ifraorg.org/en-us/guidelines/).

QRA2:

IDEA project (International Dialogue for the Evaluation of Allergens) Final Report on the QRA2: Skin Sensitisation Quantitative Risk Assessment for Fragrance Ingredients, September 30, 2016 (http://www.ideaproject.info/uploads/Modules/Documents/qra2-dossier-final--september-2016.pdf).

Refinements of SAFs:

Basketter, D. and Safford B. (2016). Skin sensitization quantitative risk assessment: A review of underlying assumptions. Regul Toxicol Pharmacol. 74; 105-16.

Aggregate exposure:

Comiskey *et al.*, (2015). Novel database for exposure to fragrance ingredients in cosmetics and personal care products. Regulatory Toxicology and Pharmacology. 72(3); 660-72.

Comiskey, *et al.*, (2017). Integrating habits and practices data for soaps, cosmetics and air care products into an existing aggregate exposure model. Regulatory Toxicology and Pharmacology, 88:144-156.

Safford *et al.*, (2017). Application of the expanded Creme RIFM consumer exposure model to fragrance ingredients in cosmetic, personal care and air care products. Regulatory Toxicology and Pharmacology 86; 148-156.

Safford *et al.*, (2015). Use of an aggregate exposure model to estimate consumer exposure to fragrance ingredients in personal care and cosmetic products. Regulatory toxicology and pharmacology, 72; 673-682.

7.5 Why was the Optimization Tool for systemic toxicity developed?

The total safety profile of a fragrance material must be taken into consideration when deriving acceptable exposure levels.

Most fragrance materials are weak or extremely weak sensitizers. As such, the NESIL values will be higher which in turn will result in higher acceptable levels than for stronger sensitizers.

If the material has a safety profile with a lower reference dose, then the acceptable levels derived from the sensitization risk assessment may not be acceptable systemically. As such it is important to compare the acceptable exposure levels from all endpoints. To allow the distribution of safe use levels from a systemic point of view in the context of aggregate exposure, RIFM has developed an approach which is based on the reported exposure of the respective fragrance ingredient. This approach, which is happening through the Creme-RIFM aggregate exposure model, is called the Optimization Tool. Through iteration, this Optimization Tool distributes the acceptable use levels across the different IFRA Categories depending on the exposure reported.

The reported exposure of the respective fragrance ingredient is provided by companies participating in the RIFM concentration of use surveys. Should you like to receive such surveys, please contact RIFM (amapi@rifm.org). Companies participation to this survey is strongly encouraged in order to obtain an adequate representation of the current uses of fragrance ingredients (including their contributions from naturals).

For more details on the Optimization Tool, please refer to Sections 4.1.

7.6 Where can I consult the RIFM safety assessments that drive the IFRA Standards?

As explained in Section 2, the RIFM safety assessments are the basis for deriving IFRA Standards as industry self-regulatory risk measures.

The Expert Panel for Fragrance Safety reviews and approves the RIFM safety assessments, which are then made publicly available in the website Fragrance Materials Safety Resource (http://fragrancematerialsafetyresource.elsevier.com/). Exceptionally for the 49th Amendment, it could happen that the safety assessment of a specific ingredient covered by an IFRA Standard is not yet publicly available in the Fragrance Material Safety Resource website. If this is the case, please contact RIFM (amapi@rifm.org) to request a copy of the final draft safety assessment.

7.7 How do the IFRA Classes relate to the IFRA Standards categories?

In the past, the IFRA Classes have been established to take into account considerations of all types of IFRA restrictions (skin sensitization, phototoxicity and systemic toxicity) that can apply to ingredients in a fragrance mixture. With the 49th Amendment, a harmonization has been carried out, and the IFRA Standard Categories are identical to the IFRA classes. Therefore, there is no further need to differentiate them and to keep the specific terminology of classes.

The IFRA Categories are summarized in Table 12.

7.8 What happens if I have a product that is not in an IFRA Category?

Table 12 and Table 13 contain a non-exhaustive illustrative list of consumer products available in the market. Given the diversity and variety of existing consumer products and new types introduced into the market, IFRA cannot provide a detailed list of product categorization for all consumer products.

It is recommended that the fragrance supplier and the customer company consult on the appropriate category for consumer products which are not included in any of the IFRA Categories.

If a stakeholder wishes a product type to be officially included in the IFRA Standard Categories (and therefore in this Guidance), it requires the engagement of the QRA Expert Group. It is indispensable that a detailed dataset (including exposure information) is provided in order to allow the QRA Expert Group to decide on the categorization of the product. The data form can be downloaded from IFRA website[9] and should be sent to RIFM (rifm@rifm.org) with copy to IFRA (mvey@ifraorg.org).

7.9 Are any other oral care products included in IFRA Category 6?

Mouthwash and toothpaste are the principal oral care products currently identified in the respective category. Other oral care products as/like toothpowder, strips, mouthwash tablets are also in the scope.

Other oral care products such as tooth whiteners and denture adhesives were considered but were specifically excluded from the QRA approach. This is because these products are regulated globally as medical devices and regulations covering such products include specific safety assessment guidelines.

Exposure limits for mouthwash and toothpastes resulting from the QRA process are established to reduce the risk of peri-oral skin sensitization. Regarding systemic exposure based on incidental ingestion, only the use of the ingredient from oral care products is considered (i.e. concomitant use as flavor ingredient in food is not considered).

[9] https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/background-scientific-information-and-guidelines/qra-data-categorization-form.pdf?sfvrsn=f47ca8fd_0

7.10 How are naturals covered by the IFRA Standards and what is the role of Annex I?

Annex I to the IFRA Standards provides indicative levels of restricted substances in a non-exhaustive list of various fragrance ingredients of complex composition, including essential oils. The IFRA NCS TF is in charge of agreeing on the typical levels of constituents in Natural Complex Substances (NCSs) representative of the current market.

These typical levels should be taken into account when determining the compliance of a fragrance mixture under its conditions of use. However, if the company is in possession of detailed analytical data for the specific quality of NCS that will be part of the mixture, this data can be used instead of the typical levels provided in Annex I.

Additionally, some natural substances have their own IFRA Standard. In this case, the Standard on the natural substance itself as well as the IFRA Standards applicable to its constituents should be applied.

7.11 How do I determine a safe use level for an NCS?

Two cases can apply regarding NCS:

- An NCS is part of the fragrance mixture and this NCS contains constituents that are covered by IFRA Standards.

The company should know at which concentration the constituents covered by an IFRA Standard are present in the NCS. This information is provided by Annex I or by analytical data derived by the company. Once the respective concentrations are known, the company should calculate the maximum allowed use of NCS in the finished consumer product (and consequently in the fragrance mixture) to ensure that the concentration of constituents in the finished consumer product do not exceed the upper concentration levels established by the IFRA Standards, for a specific IFRA Category.

For example, a customer has requested a perfumer to create a fragrance mixture intended to be used in a fine fragrance at 20%. The perfumer would like to use Hay absolute as a fragrance ingredient in this mixture. Annex I report the presence of 8% Coumarin in Hay absolute. Coumarin can be used at a maximum use level of 1.3% in Category 4.

As there is a dilution factor of 5, the total amount of Coumarin in the fragrance mixture should not exceed 6.5% to reach such level (assuming there are no other sources of Coumarin in the mixture), the concentration of Hay absolute in the mixture should be lower than 16.25%

In this example, the NCS only contains one constituent covered by an IFRA Standard. If more than one constituent is covered by an IFRA Standard, this exercise should be repeated for each of them. The lowest resulting maximum permitted use level of the NCS will drive its use in the mixture.

- An NCS is covered by an IFRA Standard (e.g. Ylang ylang).

In this case, there are two restrictions to take into account: the one resulting from the constituent approach and the one resulting from the NCS itself. Both need to be compared, and the lowest one will drive the maximum allowed use of the NCS in the fragrance mixture.

7.12 How do I apply the IFRA policy of Furocoumarins?

The IFRA Standards on phototoxic ingredients have been set based on:

- The phototoxicity potential of the fragrance ingredient itself (see Table 3).
- The phototoxicity potential of furocoumarins present in certain essential oils (see
- Table 4).

The IFRA policy on Furocoumarins only applies to the fragrance ingredients listed in Table 3 (page 16) of this Guidance and only for those finished consumer product applications that are exposed to the sunlight (see Table 12).

For such fragrance ingredients (individually or in combination), the total amount of the furocoumarin marker 5-MOP (this can come from one or several extracts containing furocoumarins – a non-exhaustive list is provided in the Standard) should not exceed 15ppm. The amount of Furocoumarins can be analytically quantified – IFRA has a method in the guidelines section of the public website.

In case the concentration of 5-MOP is unknown, the upper concentration levels indicated in the individual Standards apply.

7.13 What does the Certificate of Conformity of fragrance mixtures with IFRA Standards mean and what not?

The Certificate of Conformity of fragrance mixtures with IFRA Standards is a document established by the companies creating fragrance mixtures and based on a trust relationship between the fragrance supplier and its customer. It means that, by using this Certificate, a fragrance supplier assures to its customer that the product they supply is in compliance with the requirements set by the IFRA Standards for an intended use.

The Certificate of Conformity confirms that a specific fragrance mixture up to a certain concentration can be used in a specified consumer product in compliance with up to and including a specific Amendment to the IFRA Code of Practice (the number and the Notification date of the Amendment should be stated in the Certificate).

The Certificate of Conformity declares compliance with the requirements expressed in the IFRA Standards, it does not replace a safety assessment.

The Safety Assessment reflects the internal expertise of the company with regards to the full safety assessment of all ingredients in the fragrance mixture (i.e. not just those with IFRA Standards). It cannot be issued in the name of IFRA but follows its compliance philosophy as reflected in the IFRA Code of Practice (i.e. all substances used in a fragrance have justification which supports its safe use).

As stated in the IFRA Code of Practice, it is the responsibility of each IFRA member to ensure that the fragrance mixtures or ingredients they supply comply with applicable laws and are safe for their intended uses. Thus, IFRA does not elaborate the Certificates of Conformity and there is no certifying company providing Certificates of Conformity on behalf of IFRA.

Figure 5 (page 61) provides an example of a Certificate of Conformity of fragrance mixtures with IFRA Standards. This template is also available at the IFRA website:

https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/ifra-certificate-template/certificate-of-conformity-to-ifra-standards-template-december-12-2019.doc?sfvrsn=20664815_2

7.14 Who can issue a Certificate of Conformity of fragrance mixtures with IFRA Standards?

The Certificate of Conformity is a document established by the fragrance mixture manufacturer and based on a trust relationship between the fragrance supplier and its customer. IFRA is not involved in its preparation of a Certificate of Conformity of fragrance mixtures with IFRA Standards and takes on no responsibility for the Certificates issued by companies.

The Certificate of Conformity can be issued by anybody who is familiar with the Code of Practice and the associated Standards. It can therefore also be used by **non-members** to declare that they comply with the IFRA Standards.

Computational software solutions from third parties are commercially available to provide support for individuals and companies to issue Certificates of Conformity.

7.15 What is the scope of the Certificate of Conformity of fragrance mixtures with IFRA Standards?

The Certificate of Conformity is only applicable for fragrance ingredients and/or fragrance mixtures intended to be directly included in a finished consumer product. In practice, the Certificate of Conformity is also used by fragrance suppliers to fragrance suppliers for the acquisition of fragrance materials and/or bases.

The requirements to comply with the IFRA Standards are less onerous for raw material suppliers compared to fragrance compounders, as most of the Standards restrict the use of ingredients in the finished consumer product. Nevertheless, there is a number of Standards that establishes Specification requirements that apply to individual raw materials.

Raw material suppliers are encouraged to collaborate with the fragrance houses by providing the composition of the essential oil if required by them, in particular for those constituents that have an IFRA Standard. However, if their fragrance ingredients (essential oils) are used as such in the final consumer product, the supplier should ensure that the NCS's constituents which have an IFRA Standard do not exceed the concentration limit in the finished consumer product established by the Standard. For this purpose, the raw material supplier can use its own analytical data or use the data provided in Annex I as approximative concentration information.

7.16 How to establish the level of use of a fragrance mixture intended to be used in different applications?

If a finished consumer product is marketed for applications that cross several uses, the most stringent restriction should apply.

7.17 Are products in compliance with IFRA Standards safe for pets?

The target of the RIFM Safety Assessments is humans and their safety while handling the finished consumer products. Some finished products applied to pets are listed in Table 12, being covered by the IFRA Standards (animal sprays or shampoos). However, the categorization of such products only relates to the human exposure during the application of such products, not to the exposure of the product on the pet. As a consequence, the assessment of safety of such finished consumer products with regard to animals is outside the scope of IFRA/RIFM and is the responsibility of the manufacturer.

8. Abbreviations

AEL	Acceptable Exposure Level
AISE	International Association for Soaps, Detergents and Maintenance Products
AWG	IFRA Analytical Working Group
CEL	Consumer Exposure Level
CoP	Code of Practice
DST	Dermal Sensitization Threshold
EdT	Eau de Toilette
EFSA	European Food Safety Authority
ETC	IFRA Executive Technical Committee
EU	European Union
FAQ	Frequently Asked Question
FDA	US Food and Drug Administration
FEMA	US Flavor and Extract Manufacturers Association
FSC	Food Safety Commission of Japan
GRAS	Generally Recognized As Safe
IDEA	International Dialogue for Evaluation of Allergens
IFRA	International Fragrance Association
IOFI	International Organization of the Flavor Industry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NA	Not applicable
NCS	Natural Complex Substance
NCS TF	IFRA Natural Complex Substances Task Force
NESIL	No Expected Sensitization Induction Level
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OECD	Organization for Economic Co-operation and Development
OTC	Over the Counter
PBT	Persistent, Bioaccumulative, Toxic
PCPC	US Personal Care Products Council
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
QRA	Quantitative Risk Assessment
QSAR	Quantitative Structure–Activity Relationship
REACH	Registration, Evaluation, Authorization of Chemicals

RfD	Reference Dose
RIFM	Research Institute for Fragrance Materials
RMTF	IFRA Risk Management Task Force
RQ	Risk quotient
SAF	Sensitization Assessment Factor
SAM	Skin Absorption Model
SOP	Standard Operating Procedure
TTC	Threshold of Toxicological Concern
VoU	Volume of Use
vPvB	Very Persistent, very Bioaccumulative
WoE	Weight of Evidence

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