



APPENDIX 8 TO THE IFRA CODE OF PRACTICE

Introduction to the IFRA Standards

Restrictions for the protection of human health

Standards that impose a quantitative limit on the use of fragrance materials are expressed as a maximum concentration of fragrance material in the consumer product. This implies knowledge of the concentration of the restricted fragrance material in the compound and the concentration of the compound in the final consumer product. Fragrance suppliers are therefore required to inform manufacturers of consumer products, who use or intend to use a fragrance compound, that due to the presence of a restricted ingredient, the compound 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. Unless otherwise specified, concentrations are expressed in weight-per-weight percent.

From the 40th Amendment on, the Standards limiting ingredients due to sensitization are based on the Quantitative Risk Assessment for dermal sensitizers (QRA). The QRA methodology for fragrance ingredients is a refined risk assessment approach for dermal sensitizers, which currently identifies individual limitations for 11 specific product categories (based on similar Safety Assessment Factors and exposure). More information on how the dermal sensitization QRA works in detail is available from IFRA or RIFM.

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.

Fragrance compounds in medical devices, OTC drugs and topical drugs are not covered by the current QRA methodology. This is mainly due to the potential or intended application on compromised or diseased skin and 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.

Phototoxic Ingredients

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

The scope of application of restrictions based on phototoxic effects excludes certain skin contact applications where the area of the body where the product will be applied would not reasonably be expected to be exposed to light (e.g., tampons or intimate wipes). The comprehensive list of product applications within the scope is contained in Table 4 of the QRA booklet, which is distributed with each Amendment.



Contributions from Other Sources

Prohibited Substances

An IFRA Standard may ban the use of a substance when it is intended to be used as such in a fragrance compound. However, this does not necessarily exclude the use of a fragrance material (natural or synthetic) which contains the same substance as a component or contaminant provided, in the judgment of the RIFM Expert Panel (REXPAN), there are 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 maximum accepted limits for these substances that have been reviewed and approved by the RIFM Expert Panel.

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), is obliged to inform IFRA/RIFM, so that an adequate safety evaluation by REXPAN can be carried out. Certain essential oils may act as a second source from which the banned substance cannot be removed.

If REXPAN based on a risk assessment of the presence of a banned substance in other fragrance materials (either a synthetic chemical or natural complex substance) finds this presence cannot be supported, the chemical or natural complex substance will itself be prohibited from use.

However, if the levels of the banned substance as such are assessed as being of no concern or can be reduced to a safe 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).

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. Those contributions from other sources 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. These indicative levels should be taken into account when determining the compliance of a fragrance compound under its conditions of use. However, if actual analysis has shown that the level of the limited substance in a specific fragrance ingredient is not the same as the indicative level given in Annex I, then the analyzed level can be used instead of the indicative level.



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/RIFM information on those substances and levels.

Aerosol Products (Skin Contact)

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

Aerosol skin contact: Skin contact from aerosol products (e.g. aerosol air freshener) as defined in dermal sensitization QRA Category 9 relates to those aerosol products that are not intended for skin contact, but their use may result in incidental skin contact. This excludes deodorant/antiperspirants, hair styling aids and sprays, which are included in other QRA categories.

Fragrance use in Toys

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.

Oral Care Products and other products with the potential of ingestion

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

To avoid confusion, for the purpose of the IFRA Code of Practice, when referring to single ingredients and mixtures we talk about fragrance ingredients and fragrance compounds (perfume) respectively, even if the ingredients and mixtures in the end are fulfilling flavour requirements and are in fact produced as flavour compounds and could thus be legitimately termed "flavour".

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.

Standards for oral care products, when based on the dermal sensitization QRA, only address the issue of the endpoint of sensitization.

Mouthwash and toothpaste are the principal oral care products currently identified in the respective category resulting from the QRA. 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.

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 compound must not only comply with IFRA Standards but must also have an approved flavour materials status as defined by the IOFI Code of Practice. Such materials are those that meet one or more of the following requirements:

- (a) 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”;
- (b) 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);
- (c) 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);
- (d) 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 safety of (fragrance) materials present in products intended for ingestion (like ‘ingestible perfumes or deodorants’) is outside the scope of IFRA’s risk assessment process.

‘Non-Skin-Contact Products’ vs ‘Incidental skin-contact products’ in IFRA Category 11

With the 48th Amendment, all IFRA Standards addressing dermal sensitization have been converted to the QRA format. In addition, the Methyl eugenol Standard was modified. As a result, it is no longer necessary to make a distinction between the previous categories of non-skin and incidental skin contact products.

All products in Category 11 of the QRA can be regarded ‘non-skin contact products’ independent of the endpoint addressed by the Standard.