

## **Attachment to IFRA IL 1121**

### Guidance for the use of IFRA Standards

#### Updated text Section 1.4 on *Prohibited Substances*

An IFRA Standard may prohibit the use of a material 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 (Natural Complex substance, NCS), which contains the prohibited material as a constituent or impurity, or the use of a synthetic, chemically defined material, which contains the prohibited material as an impurity (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 prohibited material.

It is important to recognize that, due to scientific advancements and the evolution of analytical methods, previously undetectable levels of unwanted impurities in raw materials may now be detectable. Even with state-of-the-art sourcing and best manufacturing practices, these unwanted prohibited substances may appear at trace levels in finished consumer products. The concept of acceptable traces of prohibited substances is addressed in several regulatory frameworks e.g. the section on impurities within the Guidance Document for the preparation of Safety Assessments under the Cosmetics Regulation (see [EUR-Lex - 32013D0674 - EN - EUR-Lex \(europa.eu\)](#)) require that the presence of traces of prohibited substances should be kept as low as reasonably achievable (ALARA) under good manufacturing practices.

However, even though the concept of “traces of technically unavoidable substances in finished product” is mentioned in several regulations across the globe as a parameter that must be addressed in the safety assessment, this concept does not benefit from any internationally recognized common interpretation and therefore remains the responsibility of the producer of raw materials and mixtures in co-operation with the finished product manufacturer.

One source of prohibited substances may be small amounts of organic solvents that could be carried over into a synthetic fragrance material or an NCS during the manufacturing process. There are specific steps within a manufacturing process designed to remove minor amounts of solvents, but these steps may not always be completely successful in removing the prohibited substance and therefore result in extremely low, technically unavoidable traces of substances in the finished product.

In general, fragrance materials which are synthetic materials or NCS (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 the presence of IFRA prohibited materials in fragrance ingredients, not already addressed by the respective IFRA Standard (or Annex 1 to the Standards), shall

inform IFRA, so that an adequate assessment by the Expert Panel for Fragrance Safety can be carried out.

If the Expert Panel for Fragrance Safety finds the presence of a prohibited substance in other fragrance materials (either a synthetic chemical or NCS) cannot be supported based on a risk assessment, the chemical or NCS will itself be prohibited from use.

However, there may be situations in which an IFRA Standard could be established by setting a limit level for a prohibited substance as an impurity in a synthetic material or as a component in an NCS based on an assessment by RIFM and validated by the Expert Panel for Fragrance Safety.

If a safe limit level for a prohibited material is not established by RIFM and the Expert Panel for Fragrance Safety, as expressed in an IFRA Standard, it remains the responsibility of the fragrance house in co-ordination with the consumer product manufacturer, to ensure that the material is not present as an impurity at a level posing a safety concern for the use of the consumer product. Such an assessment should be based on generally accepted principles of toxicology and risk assessment and can, as one element, refer to assessments of the material in question made by a recognized authoritative body.

New text for Prohibition Standards with no defined trace levels in the Expert Panel rationale:

The material xxx has been reviewed by the Expert Panel for Fragrance Safety with the conclusion that it cannot be safely used as a fragrance ingredient. If the substance is found as an impurity in other fragrance ingredients, leading to trace level presence in finished products, please check the latest version of the Guidance to the IFRA Standards for the respective IFRA procedure.

New text for the section 'Contribution from other sources' of the Standards:

None to consider beyond traces (see also the section on contributions from other sources in chapter 1 of the Guidance for the use of IFRA Standards).