THE INTERNATIONAL FRAGRANCE ASSOCIATION

Member Associations
Members of IFRA Committees
Cc: RIFM

March 2, 2021

Information Letter 1107
Clarifications related to the implementation of IFRA Standards and categorization of product types in the 49th Amendment.

Dear Colleagues,

Since the notification of the 49th Amendment we have received some comments and observations that led to the need for clarification, which we would like to communicate in this Information Letter. Where relevant, these clarifications will be incorporated in the next update of the Guidance document to be issued with the next regular Amendment.

Several questions and comments are linked to the new system of categorising products in the 49th Amendment.

Re: products with lip exposure and general categorization of multiple use products

There have been inquiries around several product types in Categories other than Category 1, which refer to application on the lips. IFRA together with RIFM concluded that Category 1 is for those products intentionally applied to the lips and which therefore have a potential for ingestion. There are other products where the exposure of fragrance ingredients to the lips is minimal with the products being wiped or rinsed off. For such cases where there may be incidental exposure to the lips, e.g., 'Make up remover for face and eyes' in category 3 or 'Cleanser for face' in Category 9, we consider the potential for ingestion to be negligible.
However, if a product is designed and clearly marketed for lips as well as for other application(s), then the product must follow the requirements of category 1 regarding its potential for ingestion. When it comes to determining the MAC, the rules for dual/multiple use as outlined below apply, meaning the category with the lowest MAC for a respective fragrance ingredient should be utilized.

The 49th Amendment to the IFRA Code of Practice included two major updates:
1) implementation of QRA2 and,
2) implementation of systemic toxicity considerations.

One or a combination of both can drive the maximum acceptable concentrations (MACs) derived from the RIFM Safety Assessments which have been approved by the Expert Panel for Fragrance Safety and presented in the IFRA Standards. As a result, many materials that had existing IFRA Standards have different MACs compared to their previously issued Standards. Some materials now have more restrictive limits in IFRA Categories, which could either be driven by QRA2 or systemic toxicity considerations. Given that the process is now more complex, it may be counterintuitive to the previously derived MACs in the Standards presented with the 48th Amendment which were derived from QRA1.

This is best explained by using examples. Utilizing QRA2 and solely taking into consideration dermal sensitization risk as the driver for a Standard, the allowable limit would be approximately 2x lower in Category 4 (Products Related to Fine Fragrance) vs. Category 7B (Leave-on Products Applied to the Hair with Some Hand Contact) based on differences in SAF's (100 vs 30) and adjustment factors (0.95 vs 0.58) respectively.

As an example, the Standard for **Longifolene CAS # 475-20-7** (based solely on dermal sensitization risk) provides the following limits:

Category 4 = 1.5%
Category 7B = 3.1%

On the other hand, the IFRA Standard for **1-(1,2,3,4,5,6,7,8 Octahydro-2,3,8,8-tetramethyl-2-naphthalenyl) ethanone (OTNE) CAS # 54464-57-2** (based on dermal sensitization and systemic toxicity risk), provides the following limits:

Category 4 = 20%
Category 7B = 0.67%
(for comparison, the MACs based on dermal sensitization only would be: Category 4 Fine Fragrance – 20.4% and for Category 7B Hair Care Products = 41.1%)

To categorize a product requested to be "dual use" such as a fine fragrance & hair mist it would be necessary to apply the more restrictive of the two different categories that such a product could be assigned to (Category 4 or 7B in these examples).

As done in the past when sensitization was the sole driver of standards, intuitively this would mean applying the more restrictive Category 4 level covering both uses of the dual use product as would be the case with Longifolene where 1.5% would then be the limit.

However, this does not hold when the Standard for a material is not driven solely by dermal sensitization, but rather driven by dermal sensitization ***and*** systemic toxicity. This can lead to lower limits in other IFRA Categories, that if solely based on dermal sensitization would be higher.
This is demonstrated with OTNE, where in the above case, the lower limit for Hair mist (Category 7B = 0.67%) would be applied as the overall Maximum Acceptable Concentration (MAC) for the dual use product.

The explanation lies in how the MACs for the different categories that you find in the Standard are derived when systemic toxicity is considered. Here the main driver that determines maximum use level is the distribution of the existing use levels of the material as reported to RIFM in the regular concentration surveys. Therefore, if the material has been reported to be used at higher levels in one category (e.g., Category 4) it is possible that the subsequent Standard limit (MAC) of this material is higher in this category compared to what one would expect to find for other categories with generally lower skin or systemic exposure (e.g., Category 7B). However, the maximum use level derived from systemic considerations can never exceed the upper use limit based on QRA2. This process is taking place at RIFM and the MACs reported in the Standard are the final outcome of this exercise. To follow the example from above with OTNE, the MAC in Category 4 is close to the QRA2 value because the systemic toxicity allows the level influenced by the 95th percentile reported use of the material in this category, which is 62% higher than the reported use in Category 7.

As such, it is extremely important for companies to report the concentration used for fragrance ingredients in the RIFM Concentration Surveys so that those uses will be represented, as they impact the attribution of permitted uses in the Standard. This means that reported exposures will accurately reflect real-life

exposures and that the MACs will be derived on those same real-life exposures. If a material is used in a product that has a dual use, the concentration should therefore be reported for both products.

To conclude, it is necessary to always take the following approach for dual use products: compare the limits in both categories the product shall be used in, for all ingredients within the fragrance, and identify the lowest limit for all ingredients in both categories to drive the overall MAC for the dual use product. The same principle and rules apply for products with more than 2 intended uses (in different product categories).

Re: Reed diffusers

Several other questions have been received regarding the recategorization of reed diffusers [Fragranced oil for lamp ring, reed diffusers, pot-pourri, liquid refills for air fresheners (non-cartridge systems), etc.]. With the implementation of QRA2 in the 49th Amendment, these products were placed in IFRA Category 10A. This more restrictive categorisation was chosen by IFRA and RIFM to reflect the potential exposure during manual handling of the soaked reed and/or the refill. Similar concerns exist for other product types sharing the same fate (like lamp oils). This decision was confirmed by the QRA Expert Team at RIFM.

Re: Sprays for facial masks (protective face coverings)

Questions have been addressed to IFRA and RIFM about how to categorize sprays for facial masks. It was determined that characterisation and assessing the safety of this product type adequately needs to be left to the responsibility of the producer.

Re: Updated Form to request Product Categorisation

We would further like to use this opportunity to remind you that for RIFM and IFRA to determine a product categorization, a minimum data set is required. An updated version of the Form for requesting Categorization of Product Types in the IFRA QRA Standard Categories (September 2020) can be found here:
https://ifrafragrance.org/standardsdocs

https://www.rifm.org/uploads/IFRA%20RIFM%20Categorization%20Form%20FINAL%20Draft%202020%2009%2015-Update.pdf

Re: Implementation timeline

There was a request for further clarification on the implementation timeline of an Amendment. We hope that the following paragraph provides sufficient clarity as it pertains to timelines of implementation for new amendments:
'The date for compliance of IFRA Amendments is for placing fragrance mixtures on the market, meaning them to leave a fragrance house. From a documentation point of view this should be considered to be the earliest of the following dates: the date of dispatch or the date of invoice.'

We hope you find this information helpful. If you have any further questions, please write to Matthias Vey (mvey@ifrafragrance.org) or Jennifer Dorts (jdorts@ifrafragrance.org)

Best regards,

IFRA