



# IFRA GUIDELINES ARE CHANGING

Lucky for you, Lebermuth is here to help

We'll help you understand revisions to the IFRA 49<sup>th</sup> amendment



FRAGRANCES

# IFRA GUIDELINES ARE CHANGING



## WHAT YOU WILL LEARN IN THIS GUIDE:

- What is IFRA & The Code of Practice?
- What is changing?
- When the change takes affect
- How Lebermuth will support you



# IFRA & THE CODE OF PRACTICE



The [International Fragrance Association \(IFRA\)](#) Code of Practice is the fragrance industry's commitment to providing products that are safe for consumers and respect the environment. The IFRA Standards form the basis of the Code of Practice, which is a globally recognized and self-regulated management system for the safe use of fragrance materials. The Code of Practice encompasses rules around both the standards for the raw materials of fragrance themselves, as well as standards around how those materials may be used in consumer products. Nearly 200 fragrance materials are impacted by the Standards. The Standards themselves comprise of:



## PROHIBITIONS

Bans on the use of some raw materials in fragrance



## RESTRICTIONS

Rules on the quantity or maximum dosages of some materials in fragrance or the types of consumer products they may be used in, implemented by the Quantitative Risk Assessment (QRA)



## SPECIFICATIONS

Other conditions on the properties, purity or type of material which can be used as fragrance raw material

# STANDARDS



The Standards for the fragrance materials are set by three independent organizations which are following the following steps before the change clock begins:

## **SUBMISSION OF NEW MATERIAL**

IFRA sends fragrance material information to the [Research Institute of Fragrance Materials \(RIFM\)](#) including exposure situation (usage concentration, variety of use, volume of use), chemical composition, olfactory profile, and olfactory potential.

## **TESTING**

RIFM prepares a comprehensive dossier on the material, including all available safety data (CREME Usage Model diagram on page 6). If necessary, RIFM initiates and organizes safety studies to fill gaps in knowledge about the materials.

## **EVALUATION**

The Independent Expert Panel evaluates the data. It checks whether the data supports current use levels that pose no risk to consumers. If the safety assessment does not support current use, the Panel instructs IFRA to issue a Standard for a material.

## **ISSUE STANDARD**

IFRA prepares a Standard in the line with its process which results in a draft Prohibition, Restriction, or Specification for the material.



# STANDARDS



## CONSULTATION

Next is the consultation phase. The draft Standard is sent to IFRA members and stakeholders for consultation. The consultation period allows members and stakeholders to provide IFRA with additional data or scientific studies that may be needed to consider in setting the final Standard.

## PUBLICATION AND IMPLEMENTATION

If no additional information is received during the consultation phase, the final Standard is published as a part of an Amendment to the IFRA Code of Practice. Following publication of the Letter of Notification on January 10, 2020, members will have a specified period to change internal systems and apply the new Standard.



# CREME RIFM USAGE MODEL



The Creme RIFM model includes detailed usage data for over 36,000 consumers representing the European and US populations. The database contains detailed usage information on the following products:

Category	Product Type
Body Lotion	Mass Market, Prestige
Deodorant	Deodorant/Anti-Perspirant Spray, Deodorant/Anti-Perspirant Non-Spray, Body Spray
Oral Care	Toothpaste, Mouthwash
Cosmetic Styling	Lipstick, Liquid/Makeup Foundation, Hair Styling Products (Non-Spray), Hair Spray
Hydroalcoholics	Eau de Toilette, Eau de Parfum, After Shave/Cologne (Splash-on)
Shower Products	Shower Gel/Body Wash, Shampoo, Rinse-Off Conditioner, Moisturizers, Face Moisturizer, Hand Cream
Moisturizers	Face Moisturizer, Hand Cream
Soaps	Bar Soap, Liquid Hand Soap
Air Care	Air Freshener (Aerosol), Air Freshener (Plug-in), Scented Candles

# CREME RIFM USAGE MODEL



For QRA Use Standards, human exposure information for fragrance materials are calculated by the type of consumer product it will be used in. For example, a consumer using a body lotion applied daily with the palms over most of the body will be exposed to a different amount of fragrance than a consumer who simply picks up a candle with their fingertips and puts it on a shelf. Using real-world studies, in a combination with usage models, it is possible to model the consumer's exposure to fragrance materials based on how products are used and how much fragrance is typically in the products.

With this data it is possible to place the products into categories based on expected exposure models assessments. Further, based on the chemical, cellular and molecular understanding of dermal sensitization and the overall toxicology of materials, it is possible to conduct an exposure based QRA for consumers' exposure to fragrances, and determine safe use levels of fragrance ingredients in each usage category.



# THE 49<sup>TH</sup> AMENDMENT CHANGE



The underlying exposure and endpoint model for the QRA is continuously being refined, forming the next evaluation of QRA 2. Significant developments have been incorporated in the way dermal sensitization risk assessments are conducted for fragrance ingredients. The recent new developments specifically address the elements of exposure-based risk that are unique to the induction of dermal sensitization, while being consistent with the principles of general toxicology risk.

## QRA RISK FORMULA = HAZARD x EXPOSURE

Importantly, they include **the determination of the aggregate overall exposure a consumer has to a product fragrance over a 24-hour period.** This will directly affect personal care and household products and will result in refined acceptable use levels of fragrance ingredients in these products. These advancements are included in the new QRA 2.

As a result, the 49<sup>th</sup> Amendment to the IFRA Code of Practice is revising and harmonizing dermal sensitization and systemic toxicity endpoints under QRA 2. The update will expand the major IFRA categories from 11 to 12, with inclusion of some subcategories, it will bring the final total to 16. Due to these expansions, fragrance companies will need to make several changes in order to continue to provide IFRA certificates, as not all products in the current 11 categories will stay in the same category within QRA 2.





# THE 49<sup>TH</sup> AMENDMENT CHANGE



For example, in QRA 2 there is no longer a distinction between hydroalcoholic products designed for shaved skin (QRA category #3) and unshaved skin (QRA category #4) -they are all grouped together in QRA 2 category #4. All products in the new QRA 2 category 12 come from QRA category 11, but not all products in QRA category 11 have been moved to new category 12, such as reed diffusers, floor waxes, and certain laundry treatment items, which will be in QRA 2 category 10A.

As for changes for the raw materials themselves, there are 25 new Standards, 35 revised Standards, and 3 revised specification Standards. Numerous Standards have been reworded, clarified or reformatted for greater clarity.



# NOW WHAT?



Due to the scope of the changes in the 49<sup>th</sup> Amendment, the typical 14 to 19 month transitional compliance period for existing fragrance creations, has been extended to 25 months. The 2 to 7 month compliance period for new fragrance has been extended to 13 months.

Both clocks start after January 10, 2020 when the Letter of Notification is released (step 6 of the process). The Consultation Phase (step 5 of the process) has ended as of July 21, 2019. Any data collected will now be submitted to the Expert Panel for Fragrance Safety for evaluation.



# LEBERMUTH IS HERE TO HELP



These upcoming changes do not only impact Lebermuth, they affect the entire fragrance industry. We here at Lebermuth recognize the importance of being integrated within the technical and political fragrance community. Not only is Lebermuth part of RIFM and IFRA associations, Lebermuth CEO & President Rob Brown is a [Fragrance Creators Association™ \(FCA\)](#) board member. It is vital to be incorporated within the industry to understand it's future predictability so we can best serve our customers.



FRAGRANCE CREATORS  
ASSOCIATION™

## STEPS LEBERMUTH MUST TAKE, AND WHEN:

**STEP 1:** Update regulatory software to follow the new Standards; timeline is 13 months from Letter of Notification date.

**STEP 2:** Formulate new fragrances within the new Standards and provide IFRA certificates that reflect the new Standards for new fragrances; timeline is 13 months from Letter of Notification date.

**STEP 3:** Update existing fragrance formulations & IFRA certificates, as needed, to reflect the new Standards; timeline is 25 months from Letter of Notification date.

**As always, we are here to help, if you have questions please contact your Sales Executive or Customer Support at 800-648-1123 for more information.**

### Sources:

1. <https://www.rifm.org/>
2. <https://ifrafragrance.org/>
3. <https://www.cremeglobal.com/creme-rifm/>

Since 1908, Lebermuth has been a leader in the Essential Oil, Fragrance, and Flavor industries.

Over a century of sensory experience.



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