INTERNATIONAL FRAGRANCE ASSOCIATION

To: Member Associations (FOR ACTION)
Members of the Scientific Committee

Cc: RIFM
Customer Associations
Members of the JAG

June 10th, 2013

**NOTIFICATION OF IFRA STANDARDS No. 12**

**47th Amendment to the IFRA Code of Practice**

Dear Colleagues,

IFRA notifies the 47th Amendment to the IFRA Code of Practice consisting of:

1. **Six new Standards, based on the dermal sensitization QRA**
2. **Four revised Standards, based on the dermal sensitization QRA**
3. **New Standard restricting the use of Furfural**
4. **New Standard prohibiting the use of 2,4-Dienals (group Standard replacing Standards for individual materials)**
5. **Eleven revised Standards taking the contributions of Schiff Bases into account**
6. **One Standard, based on the dermal sensitization QRA, with a corrected maximum use level**
7. **Other updated information**

Please note the following:

a) The compliance with the Standards of the IFRA Code of Practice is mandatory for all companies belonging to an IFRA member association.

b) The IFRA Standards enter into force as follows:

   i. IFRA Standards of restriction and prohibition:
   - 2 months after the date of the letter of notification for new submissions
   - 14 months after the date of the letter of notification for existing fragrance compounds

   ii. IFRA Standards with a purity criterion
   - 7 months after the date of the letter of notification for new submissions
   - 19 months after the date of the letter of notification for existing fragrance compounds

c) The National Associations are requested to circulate this letter without any delay to their member companies.

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## 1. Six new Standards, based on the dermal sensitization QRA

| CAS | Name | Status |
|---|---|---|
| 122-03-2 | Cuminaldehyde | NEW RESTRICTED (DERMAL SENSITIZATION QRA) |
| 103-95-7 | Cyclamen aldehyde | |
| 106-02-5 | Cyclopentadecanolide | |
| 4748-78-1 | p-Ethylbenzaldehyde | |
| 123-11-5 | p-Methoxybenzaldehyde | |
| 529-20-4<br>620-23-5<br>104-87-0<br>1334-78-7 | o,m,p-Tolualdehydes and their mixtures | |

## 2. Four revised Standards, based on the dermal sensitization QRA

| CAS | Name | Status |
|---|---|---|
| 119-84-6 | Dihydrocoumarin | REVISED RESTRICTED (DERMAL SENSITIZATION QRA) |
| 8021-36-1<br>9000-78-6<br>93384-32-8 | Opoponax | |
| 116-26-7 | 2,6,6-Trimethylcyclohex-1,3-dienyl methanol (Safranal) | |
| 8046-19-3<br>8024-01-9<br>94891-27-7<br>94891-28-8 | Styrax | |

- Opoponax: All forms of this material (including rectified oils) are covered by a dermal sensitization QRA Standard capped at 0.6%. In addition, and in cases where Opoponax is produced by pyrolysation, a fragrance material specification limits the PAH content to 1 ppb in the fragrance product.
- Styrax: All qualities of Styrax (except crude gums) are covered by a dermal sensitization QRA Standard capped at 0.6% in the finished product to not go beyond the maximum limit of the previous Standard. The Standard keeps the same fragrance material specification as reported in the prior Standard limiting the natural sources that can be used to produce the Styrax extracts. There is also a specific requirement covering Styrax pyrolysate that limits PAH content to 1 ppb in the fragrance product.
- The IFRA Standards covering Birch Wood pyrolysate and Cade oil have been modified to take into account the possible presence of PAH traces in Styrax and Opoponax. However, this modification is purely technical and does not imply the re-notification of these Standards.

## 3. New Standard restricting the use of Furfural (CAS 98-01-1)

Furfural (CAS No 98-01-1 and EC No 202-627-7) has widespread use in cosmetic products as a perfumery ingredient. This material has been classified as a CMR carcinogen Cat. 2 under the EC Regulation No 1272/2008. The European Scientific Committee on Consumer Safety (SCCS) recently issued a new opinion on Furfural (SCCS/1461/12) that is largely built on information submitted by the fragrance industry. The SCCS concluded that a concentration of 10 ppm in all finished cosmetic products can be regarded as safe. This restriction is currently being discussed for inclusion in the EU Cosmetics Regulation (1223/2009).

As this restriction is the result of an exchange between the European Authorities and the fragrance industry, IFRA regards it essential that an IFRA Standard on Furfural reflect the risk management measure proposed at the European level. The new Standard provides only two categories: skin contact and non-skin contact products. The first category, as outlined above, sets a limit of 10 ppm in the finished product while the limitation for non-skin contact products is set at 500 ppm.

## 4. New Standard prohibiting the use of 2,4-Dienals (group Standard)

All 2,4-Dienals that had use reported in the past in fragrance compounds were previously reviewed by the RIFM Expert Panel and consequently banned due to lack of adequate data (Dermal DNA Adduct study). This risk management measure may be revised in case additional data is available and considered sufficient to support the use of these fragrance ingredients. The presence of a structural alert justifies that the entire family of 2,4-Dienal's be prohibited and not only the discrete materials already covered by IFRA Standards. For this reason, and instead of issuing individual IFRA Standards for each material, it has been decided to introduce a Standard prohibiting the use of the entire group of 2,4-dienals for use in perfumery applications. Consequently, the individual IFRA Standards issued for 2,4-hexadienal, 2,4-heptadienal, 2,4-octadienal, 2,4-nonadienal, 2,4-decadienal, and 2,4-undecadienal are all replaced by this Standard.

| CAS | Name | Status |
|---|---|---|
| 764-40-9<br>142-83-6<br>80466-34-8<br>5910-85-0<br>30361-28-5<br>6750-03-4<br>2363-88-4<br>13162-46-4<br>21662-16-8<br>25152-84-5<br>30361-29-6<br>4313-03-5<br>… | 2,4-Dienals (group of materials) | PROHIBITED |

## 5. Eleven revised Standards taking the contributions of Schiff Bases into account

The IFRA Scientific Committee examined the physicochemical properties of Schiff bases and concluded that, based on the available information, these materials should be considered in contributions from other sources. By default, the stoichiometric presence of the constituents of the Schiff bases is taken into account assuming 100% dissociation. This information is now reported under Annex II to the IFRA Standards. The IFRA Standards of alpha-Amyl cinnamic aldehyde, p-tert-Butyl-alpha-methylhydrocinnamic aldehyde (BMHCA), Benzaldehyde, Citral, Cinnamic aldehyde, Dimethylcyclohex-3-ene-1-carbaldehyde (Triplal), alpha-Hexyl cinnamic aldehyde, Hydroxycitronellal, 3 and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde (HMPCC or Lyral), 4-Methoxy-α-methylbenzenepropanal (Canthoxal or Fennaldehyde) and α-Methyl-1,3-benzodioxole-5-propionaldehyde (MMDHCA or Helional) are modified respectively.
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.

## 6. One Standard, based on the dermal sensitization QRA, with a corrected maximum use level

In its periodical review of existing IFRA Standards, the IFRA Scientific Committee observed that one of the maximum use levels set for p-Mentha-1,8-dien-7-al (Perilla aldehyde, CAS 2111-75-3) is incorrect. The maximum use level for Category 7 should read 0.05% instead of 0.1% and the Standard has been corrected. With this letter, Perilla aldehyde is now re-notified with appropriate periods of time to implement this change.

## 7. Other updated documentation

Annex I to the IFRA Standards has been updated with regard to the new Standards of the 47th Amendment. In particular, contributions from other sources for Cuminaldehyde, Cyclamen aldehyde, Cyclopentadecanolide, Dihydrocoumarin and p-Methoxybenzaldehyde are now reported in this document.

Annex II to the IFRA Standards has been created to handle the specific problem of Schiff bases hydrolysis.

The Index of IFRA Standards has also been updated.

## COMPLIANCE TIMELINES

| Ingredient(s) | Date for Standards entering into force for new creations | Date for Standards entering into force for existing fragrance compounds |
|---|---|---|
| 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 element | 7 months after the date of the letter of notification | 19 months after the date of the letter of notification |

## DEFINITIONS

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

A new submission means any fragrance, new or existing, which does not fall within the definition of an existing fragrance compound.

The timelines refer to the mixture of fragrance ingredients, the so-called “fragrance compound” (fragrance oil), and not to the finished consumer product.

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**The Member Associations are kindly requested to distribute this information without delay to their individual members.**

If you have any questions, please do not hesitate to contact the IFRA Secretariat (mvey@ifraorg.org or flebreux@ifraorg.org).

Matthias Vey
IFRA Scientific Director

Enclosed:

IFRA Standards part of the 47th Amendment to the IFRA Code of Practice

Index of IFRA Standards

Annex I to the IFRA Standards

Annex II to the IFRA Standards