



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

Cc: RIFM  
Customer Associations  
Members of the JAG

June 10, 2015

## **NOTIFICATION OF IFRA STANDARDS No. 13**

### **48<sup>th</sup> Amendment to the IFRA Code of Practice**

Dear Colleagues,

IFRA notifies the 48<sup>th</sup> Amendment to the IFRA Code of Practice consisting of:

- 1. Three new Standards based on the dermal sensitization QRA**
- 2. One revised Standard, based on the dermal sensitization QRA, with a corrected maximum pragmatic use level**
- 3. Two new Standards prohibiting the use due to insufficient data for safety assessment**
- 4. Revised policy on combined use of four phototoxic ingredients and clarification on the application scope of all phototoxicity Standards**
- 5. Revised Standard on Methyl eugenol on the restriction level for non-skin products**
- 6. Three Standards revised for clarification**
- 7. Three revised Standards due to the addition of new CAS Numbers**
- 8. Other updated information**

Please note the following:

- a) The compliance with the Standards of the IFRA Code of Practice is mandatory for all IFRA member 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. Three new Standards based on the dermal sensitization QRA**

CAS	Name	Status
33704-61-9	6,7-Dihydro-1,1,2,3,3-pentamethyl-4(5H)-indanone (DPMI)	NEW RESTRICTED (DERMAL SENSITIZATION QRA)
62518-65-4	3-(m-tert-Butylphenyl)-2-methylpropionaldehyde (m-BMHCA)	
144020-22-4 28371-99-5	Acetic acid, anhydride, reaction products with 1,5,10- trimethyl-1,5,9-cyclododecatriene	

**2. One revised Standard, based on the dermal sensitization QRA, with a corrected maximum pragmatic use level**

CAS	Name	Status
80-54-6	p-tert-Butyl-alpha-methylhydrocinnamic aldehyde (p-BMHCA)	REVISED RESTRICTED (DERMAL SENSITIZATION QRA)

The restriction levels are now expressed with 2 decimal places. In addition, according to the application of pragmatic levels, the category 9 level has been corrected to 5.00 %.

**3. Two new Standards prohibiting the use due to insufficient data for safety assessment**

CAS	Name	Status
111-28-4 17102-64-6	2,4-Hexadien-1-ol	PROHIBITED DUE TO LACK OF DATA
18485-38-6	2,4-Dodecadien-1-ol, (2E, 4E)	

**2,4-Hexadienon-1-ol** and **2,4-Dodecadien-1-ol, (2E, 4E)** are prohibited due to lack of data to address concerns about long term toxicity effects.



#### 4. Revised policy on combined use of four phototoxic ingredients and clarification on the application scope of all phototoxicity Standards

- Revised policy on combined use of 4 phototoxic ingredients:

CAS	Name	Status
15323-35-0	5-Acetyl-1,1,2,3,3,6-Hexamethyl indan (AHMI)	REVISED POLICY ON COMBINED USE OF PHOTOTOXIC INGREDIENTS
85-91-6	Methyl-N-methylantranilate	
93-08-3	Methyl $\beta$ -naphthyl ketone	
91772-29-1 8016-84-0	Tagetes oil and absolute	

The policy of combination of phototoxic effects will be suspended for all cases where the effect does NOT result from furocoumarin content (i.e. where the materials are not likely to induce phototoxicity by a common mechanism, as opposed to furocoumarins which are assumed to act via a common mechanism). In consequence the 'note on phototoxic ingredients' as it was contained in the Introduction to the IFRA Standards as well as a number of Standards based on phototoxic effects has been deleted.

- Clarification on the application scope of all phototoxicity Standards:

CAS	Name	Status
15323-35-0	5-Acetyl-1,1,2,3,3,6-Hexamethyl indan (AHMI)	CLARIFICATION ON THE APPLICATION SCOPE OF ALL PHOTOTOXICITY STANDARDS
8015-64-3	Angelica root oil	
908007-75-8	Bergamot oil expressed	
68916-04-1 72968-50-4	Bitter orange peel oil expressed	
Not available	Citrus oils and other furocoumarins containing essential oils	
8014-13-9	Cumin oil	
8016-20-4	Grapefruit oil expressed	
8008-56-8	Lemon oil cold expressed	
8008-26-2	Lime oil expressed	
85-91-6	Methyl-N-methylantranilate	
93-08-3	Methyl $\beta$ -naphthyl ketone	
8014-29-7	Rue oil	
91772-29-1 8016-84-0	Tagetes oil and absolute	



A reference to Table 4 of the QRA booklet has been added in the Note box of all Phototoxicity Standards.

### 5. Revised Standard on Methyl eugenol on the restriction level for non-skin products

CAS	Name	Status
93-15-2	Methyl eugenol	REVISED STANDARD

**Methyl eugenol (CAS 93-15-2):** the restriction level for non-skin products has been adapted (0.02% in the fragrance oil is changed to 0.01% in the finished consumer products) in order to be consistent with the restriction levels of the other categories, which are based on the finished product and not the fragrance oil. Furthermore, the category *“other non-cosmetic products not covered above”* will be removed from the revised Standard. The new timelines in the Standard only applies to the new limit in non-skin contact products and not to the measures that are already in place.

### 6. Three Standards revised for clarification

CAS	Name	Status
117-98-6 62563-80-8 68917-34-0 73246-97-6 84082-84-8	Acetylated Vetiver oil	REVISED STANDARD
103-95-7	Cyclamen aldehyde	
98-00-0	Furfuryl alcohol	

**Acetylated Vetiver oil:** due to recent developments (see IFRA IL990) IFRA has removed the material specifications information and renamed the Vetiveryl acetate Standard to **‘Acetylated Vetiver oil’**. Moreover, the structure and the empirical formula have also been removed. IFRA will update the Standard in the future based on the outcome of the evaluation of the material by the SCCS.

**Cyclamen aldehyde:** *“Cyclamen aldehyde should not contain more than 1.5% of Cyclamen alcohol”* has been added to the material specifications section in the Standard.

**Furfuryl alcohol:** IFRA has been informed about the presence of Furfuryl alcohol in Cade essential oils. The known minor presence of Furfuryl alcohol in coffee extracts and the resulting exposure was already assessed by the RIFM Expert Panel and considered safe. The new information about the presence of Furfuryl alcohol in Cade oils did not change the outcome of the assessment. The following sentence will therefore be added in the contributions from other sources section: *“Contributions from other sources like Coffee extracts or certain types of Cade oil have been evaluated. On the basis of the established*



maximum level of Furfuryl alcohol in these commercially available natural sources, exposure to this substance from the use of these oils and extracts is not significant and not regarded of concern from a consumer safety point of view”.

## 7. Three revised Standards due to the addition of new CAS Numbers

CAS	Name	Status
105-13-5 1331-81-3	Anisyl alcohol	REVISED STANDARDS
54814-64-1 51154-96-2	Massoia lactone	
1335-46-2 127-42-4 127-43-5 127-51-5 7779-30-8 79-89-0	Methyl ionone, mixed isomers	

**Anisyl alcohol:** the CAS number 1331-81-3 is also covered by the Standard.

Accordingly to the QRA booklet v7.0 published with the 48<sup>th</sup> Amendment, the restriction levels of the Anisyl alcohol Standard are now expressed with 2 decimal places. The implementation timeline apply to those restriction levels which have changed compared to the previous version of the Standard.

**Massoia lactone:** the CAS number 51154-96-2 is also covered by the Standard.

**Methyl ionone, mixed isomers:** the CAS number 79-89-0 is also covered by the Standard.

Accordingly to the QRA booklet v7.0 published with the 48<sup>th</sup> Amendment, the restriction levels of the Methyl ionone, mixed isomers Standard are now expressed with 2 decimal places. The implementation timeline apply to those restriction levels which have changed compared to the previous version of the Standard.

In addition, for increased transparency and to ensure a better link between the prohibition of pseudo methyl ionone and the permitted impurities in Methyl ionones, IFRA will add the following sentence to the material specifications section in the Methyl ionone, mixed isomers Standard: *“Pseudo methyl ionones (CAS numbers 26651-96-7, 72968-25-3, 1117-41-5) should not be used as fragrance ingredient as such, but a level of up to 2% as an impurity in methyl ionones is accepted”*.

For these 3 revised Standards, the implementation dates for new submissions and existing fragrance compounds do only apply to the changes introduced with the 48<sup>th</sup> Amendment.



### 8. Other updated documentation

- The Annex I to the IFRA Standards has been revised to comply with the new NCS nomenclature system introduced by RIFM and IFRA (IL971, IL973, IL978).
- The Index of IFRA Standards has been updated.
- The new version of the QRA booklet provides updated information on the definition of IFRA product categories and guidance on preparing IFRA certificates.
- The Introduction to the IFRA Standards (Annex 8 of the IFRA Code of Practice) has been revised.
- An updated Standard Operating Procedure (SOP) for handling Amendments to the IFRA Code of Practice. This document is intended to help companies implement Amendments to the IFRA Code of Practice, which consists of new or revised Standards.

### 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](mailto:mvey@ifraorg.org)).

Matthias Vey  
IFRA Scientific Director



Enclosed:

- IFRA Standards part of the 48<sup>th</sup> Amendment to the IFRA Code of Practice
- Index of IFRA Standards
- Annex I and II to the IFRA Standards
- QRA booklet v7.0.
- Standard Operating Procedure (SOP) for handling Amendments to the IFRA Code of Practice.
- Annex 8 to the Code of Practice: Introduction to the Standards.