

Matthias Vey, Dr.-Ing
Scientific Director
6, Avenue des Art
B - 1210 BRUSSELS
☎ +32-2/214 2061 - 📠 +32-2/214 20 69

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

Cc: RIFM
Customer Associations
Members of the JAG

July 7, 2009

NOTIFICATION OF IFRA STANDARDS No. 9

44th Amendment to the IFRA Code of Practice

Dear Colleagues,

IFRA notifies the 44th Amendment to the IFRA Code of Practice consisting of:

1. 11 new Standards, based on the QRA
2. 1 revised Standard, based on the QRA (capped)
3. 1 revised Standard with reference to potential nitrosamine formation
4. 3 new Standards with reference to potential nitrosamine formation
5. 7 new Standards prohibiting materials due to insufficient data
6. New Standard prohibiting musk xylene due to environmental endpoint
7. New Standard restricting estragole due to systemic toxicity
8. Revised Standard on HMPCC introducing pragmatic restrictions independent of the QRA
9. Revision of Standard on Pseudomethyl Ionones to ensure all materials concerned are covered
10. Publication of a revised Standard for Rose Ketones to include additional CAS numbers
11. Publication of Allyl Ester Standard in new format
12. SOP for implementation of IFRA Standards and revised versions of Annex I, Index of Standards and QRA Information booklet

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 usually enter into force
 - one month after the date of the letter of notification for new creations
 - 13 months after the date of the letter of notification for existing creations.Exceptions to this rule are possible and the actual **timelines for the 44th Amendment are summarized on page 5 of this document.**
- c) The Standards being part of the 44th Amendment will be published on the IFRA website 7 months after the date of the letter of notification.
- d) The National Associations are requested to circulate this letter without any delay to their member companies.

1. 11 new Standards, based on the QRA

CAS No	Name	Status
56973-85-4	1-(5,5-Dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one	NEW RESTRICTED (QRA)
93-53-8	2-Phenylpropionaldehyde (Hydratropic aldehyde)	
5462-06-6	4-Methoxy- α -methyl benzenepropanal	
7493-74-5	Allyl phenoxyacetate	
100-52-7	Benzaldehyde	
4364-06-1	Cinnamic aldehyde dimethyl acetal	
103-50-4	Dibenzyl ether	
8014-71-9 84082-61-1	Melissa oil*	
6658-48-6	p-Isobutyl- α -methyl hydrocinnamaldehyde	
121-33-5	Vanillin	
117-98-6 62563-80-8 68917-34-0 73246-97-6 84082-84-8	Vetiveryl acetate**	

*Melissa oil had been prohibited before due to insufficient data; data has now been provided.

**The former specification Standard on Vetiveryl acetate (Acetylated vetiver oil) is replaced by the new QRA Standard.

2. 1 revised Standard, based on the QRA

The existing IFRA Standard for this material has been revised to incorporate QRA. For this Standard only QRA limits equal to or lower than the already existing IFRA restrictions will be introduced. Category 11 and oral care products are excluded from these measures. These categories were not covered by the former IFRA Standard and were only included with the introduction of the QRA.

CAS No	Name	Status
1604-28-0	6-Methyl-3,5-heptadiene-2-one (Methyl heptadienone)	REVISED RESTRICTED (QRA)

3. 1 revised Standard with reference to potential nitrosamine formation

The IFRA AWG (Analytical Working Group) has confirmed that Methyl N-methylantranilate has the potential to form nitrosamines under specific conditions of use. This risk of nitrosamine formation is indicated in the Standards and requested to be communicated to the customer.

CAS No	Name	Status
85-91-6	Methyl N-methylantranilate	REVISED

4. 3 new Standards with reference to potential nitrosamine formation

The IFRA AWG (Analytical Working group) has confirmed that the following materials have the potential to form nitrosamines under specific conditions of use. This risk of nitrosamine formation is indicated in the Standards and requested to be communicated downstream the supply chain.

CAS No	Name	NEW STANDARDS
19343-78-3	1,2,3,4-Tetrahydro-4-methylquinoline	
65505-24-0	Isobutyl N-methylantranilate	
91-61-2	p-Methyltetrahydroquinoline	

5. 7 new Standards prohibiting materials due to insufficient data

The materials have been reviewed by the RIFM Expert Panel with the conclusion that they should not be used as or in fragrance ingredients until additional data is available and considered sufficient to support their safe use.

CAS No	Name	PROHIBITED DUE TO INSUFFICIENT DATA
2363-88-4	2,4-Decadienal	
5910-85-0	2,4-Heptadienal	
80466-34-8	2,4-Hexadienal	
6750-03-4	2,4-Nonadienal	
13162-46-4	2,4-Undecadienal	
8022-81-9	Boldo oil	
98-00-0	Furfuryl alcohol	

6. New Standard prohibiting musk xylene due to environmental endpoint

The safety data available for musk xylene have been reviewed by the RIFM Expert Panel with the conclusion that due to the critical effects mentioned in the Standards, the material should not be used as or in fragrance ingredients, unless otherwise specified in the Standard.

CAS No	Name	PROHIBITED DUE TO SPECIFIC ENDPOINT
81-15-2	Musk Xylene	

7. New Standard restricting estragole due to systemic toxicity

The safety data available for estragole have been reviewed by the RIFM Expert Panel with the conclusion that due to the critical effects mentioned in the Standards, the material should be restricted as specified in the Standard.

CAS No	Name	RESTRICTED DUE TO SPECIFIC ENDPOINT
140-67-0	Estragole	

8. Revised Standard on HMPCC introducing pragmatic restrictions independent of the QRA

HMPCC is one of the few fragrance ingredients for which the observed frequency of sensitization is greater than 2% in patients with eczema reporting to dermatology clinics in Europe (Schnuch et al., 2007). While this high frequency is not seen in other geographic regions, the fragrance industry is very concerned about these observations in Europe.

In 2008, IFRA published a revised standard for HMPCC based on the QRA, further restricting its use in certain product categories. We believe that, had the QRA been available and implemented earlier, the level of HMPCC sensitization in patients in Europe might never have reached the level reported today. IFRA firmly believes and continues to support the development of Standards for recognized fragrance allergens based on induction of sensitization rather than elicitation. However, given the exceptional situation in Europe, IFRA has elected to implement more stringent restrictions on HMPCC.

There is strong indication from dermatological reports that antiperspirant and deodorant products are more problematic with respect to HMPCC sensitization than other product types (Jorgensen et al, 2007). Therefore, a lower restriction on HMPCC is proposed to lower its use to a level which would be expected to effectively reduce the frequency of sensitizations observed. As these products fall into IFRA category 2, this category has received the strictest limitation (together with category 1, containing lip products). The RIFM Expert Panel further recommended having the very strict restriction also in category 7.

Hydroalcoholic products also result in robust levels of exposure to fragrance materials, as reflected by reports from dermatologists. As such, it is proposed that this category of products also be further restricted to protect consumers and patients.

Use levels for all other categories have been aligned to the same level as for hydro alcoholics to ensure the greatest likelihood of reducing the frequency of sensitization.

These significant additional restrictions are independent of the QRA methodology and are selected only to promote a decrease in the frequency of sensitization observed in eczema patients in Europe. It demonstrates the seriousness of the fragrance industry's commitment for responsible action to protect consumers according to the mission of IFRA.

9. Revision of Standard on Pseudomethyl ionones to ensure all materials concerned are covered

When transferred to the new format this Standard lost part of its original scope. The revised version in this Amendment will correct this.

CAS No	Name	REVISED STANDARD
26651-96-7 72968-25-3 1117-41-5	Pseudo Methylionones	

10. Publication of a revised Standard for Rose Ketones to include two additional CAS numbers

IFRA felt that two additional materials should be named on the Standard to ensure that all materials intended to be covered by this Standard are actually under its scope.

CAS No	Name	REVISED STANDARD
35044-68-9 23726-93-4, etc.	Rose Ketones	

11. Publication of Allyl Ester Standard in new format

The new format features a number of changes such as providing more details and identification data about the materials covered by the Standard. It does not affect the contents of the IFRA Standard. For more information about the new format of the Standards see IFRA IL 701.

CAS No	Name	NEW FORMAT SPECIFICATION
N/A	Allyl Esters	

12. Other updated documentation

QRA Information Booklet Version 4.1 Final 2009 (including guidance on classes for IFRA Certificate)	Revised
Annex 1 to the IFRA Standards which has been updated with contributions from other sources for benzaldehyde, estragole, methyl eugenol and vanillin	Revised
Index (list of all IFRA Standards)	Revised
SOP for implementation of IFRA Standards	Unchanged

COMPLIANCE TIMELINES

Ingredient(s)	Date for Standards entering into force for new submissions	Date for Standards entering into force for existing fragrance compounds
QRA-based Standards (new as well as revised)	1 month after the date of the letter of notification	25 months after the date of the letter of notification
HMPCC pragmatic Standard	1 month after the date of the letter of notification	25 months after the date of the letter of notification
Rose ketones	Same timing as for QRA Standards (see above)	Same timing as for QRA Standards (see above)
Pseudo methyl ionones	1 month after the date of the letter of notification	13 months after the date of the letter of notification
Standard on Methyl-N-methyl anthranilate and related materials	1 month after the date of the letter of notification	13 months after the date of the letter of notification
Standard restricting the use of estragole	1 month after the date of the letter of notification	13 months after the date of the letter of notification
Standards prohibiting the use of ingredients	1 month after the date of the letter of notification	13 months after the date of the letter of notification
Changes (new categories and re-categorization) in the QRA booklet	Same timing as for QRA Standards (see above)	Same timing as for QRA Standards (see above)
Changes and updates in Annex 1	Same timing as for QRA Standards (see above)	Same timing as for QRA Standards (see above)

The prolonged IFRA compliance time of the QRA Standards for existing fragrance compounds has been granted once again because of the number of Standards and the level of impact assessment required as well as the potential need for reformulations.

An existing fragrance compound is a compound currently sold or already the subject of evaluation for performance in a defined consumer product.

New submission: Any fragrance, new or existing, which does not fall within the definition of an existing fragrance compound.

The period of time permitted for achieving compliance with a new or revised Standard applies only to that compound in that defined consumer product.

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

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.

Matthias Vey

IFRA Scientific Director

Enc: QRA Information Booklet Version 4.1 Final 2009 07 02
Index of IFRA Standard
Annex I to IFRA Standards
SOP for implementation of IFRA Standards