



INTERNATIONAL
FRAGRANCE ASSOCIATION

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

Cc: RIFM
Customer Associations
Members of the JAG
Members of IFRA Committees

July 16, 2008

NOTIFICATION OF IFRA STANDARDS No. 8

43rd Amendment to the IFRA Code of Practice

Dear Colleagues,

IFRA notifies:

1. **Publication of 8 new Standards, based on the QRA**
2. **Publication of 10 revised Standards, based on the QRA**
3. **Introduction of an additional purity requirement in the Standards on Oak moss extracts and Tree moss extracts**
4. **Publication of a revised Standard on Methyl ionone due to re-adjusted NESIL by REXPAN**
5. **Publication of 14 revised QRA Standards published first time as part of the 42nd Amendment**
6. **Publication of 26 individual Standards for the materials so far contained in the list of materials with non supported use ("other materials")**
7. **Publication of a revised Standard for 7-Methoxycoumarin to account for presence in naturals**
8. **Updated version of the QRA booklet and other documents**

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 43rd Amendment are summarized on page 5 of this document.**
- c) The Standards being part of the 43rd Amendment will be published on the 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. 8 new Standards, based on the QRA

CAS No	Name	
91-64-5	Coumarin	NEW RESTRICTED (QRA)
103694-68-4	2,2-Dimethyl-3-(3-methylphenyl)propanol (Majantol)	
54464-57-2	OTNE (1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone)	
2563-07-7	2-Ethoxy-4-methylphenol	
99-49-0 2244-16-8 6485-40-1	Carvone	
8006-81-3 68606-83-7 83863-30-3	Ylang Ylang (various extracts)	
8022-96-6 8024-43-9 90045-94-6 84776-64-7	Jasmine absolute (Grandiflorum)	
91770-14-8	Jasmine absolute (Sambac)	

2. 10 revised Standards, based on the QRA

For these materials previous IFRA Standards existed, which are newly revised to incorporate the QRA. For these Standards only QRA limits equal to or lower than the already existing IFRA restrictions are introduced (so called 'Capping'). Category 11 and oral care products are excluded from these measures. Oral care products were not covered by the former IFRA Standards and were only included with the introduction of the QRA (see also IFRA IL 749). Therefore, the limits as determined by the QRA will remain in place, even if they are higher than the limits in the original Standards. For more details see item 5 below or IFRA IL 801.

CAS No	Name	
1885-38-7 4360-47-8	Cinnamyl nitrile	REVISED RESTRICTED (QRA)
17373-89-6	alpha-Hexylidene cyclopentanone	
31906-04-4 51414-25-6	3 and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde (HMPPC)	
2111-75-3	para-Mentha-1,8-dien-7-al (Perilla aldehyde)	
68683-20-5	Menthadiene-7-methyl formate	
17369-59-4	3-Propylidene phthalide	
90028-68-5 9000-50-4 68917-10-2	Oakmoss extracts	
90028-67-4 68648-41-9 68917-40-8	Treemoss extracts, Cedar moss extracts	
111-12-6	Methyl heptine carbonate	
111-80-8	Methyl octine carbonate	

3. Introduction of an additional purity requirement in the Standards on Oak moss extracts and Tree moss extracts

Following a risk assessment carried out by RIFM and reviewed by REXPAN, besides the introduction of lower restrictive levels for certain categories as determined by the QRA an additional purity requirement resulted, requiring the levels of atranol and chloroatranol to each be below 100 ppm in the respective extracts.

In consequence of introducing this new purity requirement, the Standards on Oak moss and Tree moss extracts will follow a different implementation timing (see section on compliance timelines below).

4. Re-issuing the Standard on Methyl ionone due to re-adjusted NESIL by REXPAN

REXPAN has recommended a slight adjustment to the NESIL that is the basis for the QRA Standard on Methylionone, mixed isomers (first published as part of the 42nd Amendment) from 71000 µg/cm² to 70000 µg/cm². This is only due to rules on rounding up or down and not linked to any new safety data and leads only to minor adjustments of the permitted use levels in the various categories.

5. 14 revised QRA Standards published first time as part of the 42nd Amendment

As outlined in IL 801, stakeholders have expressed concerns about the possibility of increased numbers of elicitation reactions in cases where the QRA level exceeds the restriction level of a material already having a Standard. Therefore, for all the materials listed below, which were already contained in the 42nd Amendment, maximum use levels in the QRA categories will be 'capped' at the level of the previous IFRA Standard on a temporary basis until the end of a 5 year monitoring phase. At the end of those 5 years, the position will be re-evaluated. This excludes category 11 (non-skin contact products) as well as oral care products, which had no IFRA restriction before the introduction of the QRA. Therefore, for oral care products the limits as determined by the QRA will remain in place even if they are higher than the limits in the original Standards.

It should be emphasized that this measure of 'capping' is based on concerns about already sensitized people, therefore linked to elicitation and does not in any way reflect a concern about the validity of the QRA methodology, which was developed to prevent induction of contact allergy to fragrance ingredients (for further details see IL 801).

CAS No	Name	
18127-01-0	p-tert-Butyl-dihydrocinnamaldehyde (Bourgeonal)	AMENDED RESTRICTED (QRA)
80-54-6	p-tert-Butyl-alpha-methylhydrocinnamic aldehyde (BMHCA)	
104-54-1	Cinnamic alcohol	
104-55-2	Cinnamic aldehyde	
97-53-0	Eugenol	
6728-26-3	trans-2-Hexenal	
107-75-5	Hydroxycitronellal	
68527-77-5	Isocyclogeraniol	
97-54-1	Isoeugenol	
86803-90-9	Methoxy dicyclopentadiene carboxaldehyde (Scentenal)	
93-51-6	2-Methoxy-4-methylphenol	
2442-10-6	1-Octen-3-yl acetate	
8007-00-9	Peru balsam extracts and distillates	

57378-68-4 43052-87-5 24720-09-0 23696-85-7 23726-92-3 23726-91-2 23726-94-5 39872-57-6 71048-82-3 33673-71-1 70266-48-7 35087-49-1	Rose ketones	
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6. Introduction of individual Standards for the materials so far contained in the list of materials with non supported use (“other materials”)

The materials contained in the list of “materials with non supported use” (“Other materials”) are prohibited for use in fragrance compounds not because of a negative outcome of a risk assessment by REXPAN but because of a review by REXPAN concluding insufficient data to carry out an adequate risk assessment. These materials should not be used as or in fragrance ingredients until additional data is available and considered sufficient to support their safe use in fragrances.

This conclusion is based on:

- 1) presence of structural alerts as defined in the RIFM Human Health Criteria Document (Ford et al., 2000) and/ or
- 2) adverse data on the material itself and/or
- 3) adverse data for a structurally related material.

So far all those materials were only contained in the so called list of “Other materials”. For the sake of easier identification of the individual materials as being prohibited, individual Standards have been developed and are made part of this 43rd Amendment to the IFRA Code of Practice. This is just a change of the format of the Standards, not of their status. In consequence the list of “Other materials” will be disbanded.

7. Revised Standard on 7-Methoxycoumarin to account for presence of naturals

The material had already been prohibited. Based on new test data provided for traces resulting from contributions from natural sources (as exemplary listed in the Standard) a maximum limit of 100 pm in the finished product was approved by REXPAN.

CAS No	Name	
531-59-9	7-Methoxycoumarin	REVISED PROHIBITED

8. Updated QRA booklet ad other documents

The following documents do make part of the notification of the 43rd Amendment:

QRA Information Booklet Version 3.4	Revised
Annex 1 to the IFRA Standards	Revised*
Index (list of all IFRA Standards)	Revised
SOP for implementation of IFRA Standards	Unchanged
Enclosure 1 to Guidance document on IFRA Certificate	Revised**

*New entries or updates to Annex 1 are highlighted in the Annex

** For more information on definition of classes etc. please see IFRA IL 768

COMPLIANCE TIMELINES

Ingredient(s)	Date for Standards entering into force for new creations	Date for Standards entering into force for existing fragrance compounds
QRA-based Standards (whether new or revised) except for Standards on Oak moss and Tree moss extracts	1 month after the date of the letter of notification	25 months after the date of the letter of notification
QRA Standards for Oak and Tree Moss extracts + Purity Standard combined.	7 months after the date of the letter of notification	31 months after the date of the letter of notification
7-Methoxycoumarin	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)

The prolonged IFRA compliance time of the QRA Standards for existing creations is once again granted because of the high number of Standards and the level of impact assessment required as well as potential need for reformulations. An ‘existing creation’ is a fragrance compound (oil) that has already been placed on the market (in a consumer product) or is already in the development pipeline. The period of time permitted to achieve compliance with a new or revised Standard applies only to that compound in that defined consumer product.

With regard to new creations the compliance timeline follows the regular IFRA timelines. ‘New creations’ are defined as any fragrance compound (oil) for which the brief has been issued after the publication date of the Amendment. This does not include fragrance compounds that were already in development or in the hands of either fragrance supplier or consumer product manufacturer, before the date of the Amendment (the latter are referred to as ‘pipeline fragrances’ and are treated like ‘existing creations’).

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

The different implementation times for Oak moss and Tree moss extracts result from the revised Standard not only introducing the QRA but also a purity requirement.

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

Attachment: IL 801
QRA Information Booklet Version 3.4
Index of IFRA Standards
Annex I to the IFRA Standards
SOP for implementation of IFRA Standards
Enclosure 1 to Guidance document on IFRA Certificate