

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

Cc: RIFM

Customer Associations Members of the JAG

July 10, 2015

CORRIGENDUM

NOTIFICATION OF IFRA STANDARDS No. 13

48th Amendment to the IFRA Code of Practice

Dear Colleagues,

Since the notification of the 48th Amendment to the IFRA Code of Practice on June 10 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

We recognized some minor issues which nevertheless do justify to publish a corrigendum.

The National Associations are requested to circulate this Corrigendum without any delay to their member companies.

To prevent any confusion about the correct version along with this letter we do send all the elements of the 48th Amendment, also those not affected by changes.

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The most relevant changes are all related to the Methyl eugenol Standard, for which we had adapted the restriction level for non-skin products in all applications to 0.01% in the finished consumer product. When removing the category 'other non cosmetic products not covered above' to harmonize the category 11 from the Standard, we overlooked that this terminology was also used for some products in category 9 and 10 and was also used in the Standard for Estragole.

The following adaptations for further harmonization of approaches where therefore agreed:

- use the wording 'non-skin, incidental skin contact products' for category 11 and those products in category 9 and 10 that before were described as 'other non cosmetic' in the colums for Methyl eugenol and Estragole in table 4 of the QRA booklet;
- harmonize all levels across category 9, 10 and 11 for product types now described as 'non-skin, incidental skin contact' to 0.01% (100 ppm) for Methyl eugenol. This is now completely conform with the approach taken for the Estragole Standard (where the level is 0.2%);
- adapt the language in the Estragole Standard which was talking about 'non-skin and non cosmetic products' to 'non-skin, incidental skin contact'.

Further we recognized that, in the QRA booklet:

- 'Scent pack' products were missing from Category 11;
- Table 4 in the booklet was missing details for 'fragranced face masks (not intended to be used as medical device)' in category 9. We use this opportunity to further better describe what is meant by this terminology precising that the fragranced face masks covered by the QRA booklet are not intended to be used as medical device.

In addition some typos we had overlooked in the Index have been corrected.

As none of the changes has an impact that is more severe or restrictive than what was communicated on June 10, the actual date of the notification remains unchanged. Nevertheless, understanding that this corrigendum might cause a delay in the preparation of IFRA certificates, the general period by which those should be in the hands of the customers is extended by 4 weeks (i.e. August 10, 2015).

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

Hoping for your understanding,

Matthias Vey IFRA Scientific Director

Enclosed:

- IFRA Standards part of the 48th Amendment to the IFRA Code of Practice
- Index of IFRA Standards
- Annex I and II to the IFRA Standards
- QRA booklet v7.1.
- Standard Operating Procedure (SOP) for handling Amendments to the IFRA Code of Practice.
- Annex 8 to the Code of Practice: Introduction to the IFRA Standards.