

# The IFRA Standards - what's new in the 49th Amendment?

**IFRA webinar**  
15 January 2020

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*Welcome to this webinar*

## **The IFRA Standards - what's new in the 49th Amendment?**



**The webinar will last  
around 60 minutes**



**Please ask questions  
via the panel on  
GotoWebinar**



**The webinar is being  
recorded**



# IFRA Standards setting process and the 49th Amendment

**Matthias Vey**

*IFRA Scientific Director*

**IFRA webinar**

15 January 2020

# IFRA Standards Setting Process

- ▶ Establishment of usage Standards for fragrance ingredients: voluntary initiative.
- ▶ Based on safety assessments carried out by the Research Institute for Fragrance Materials (RIFM) and reviewed by the Panel for Fragrance Safety.
- ▶ IFRA Member companies must comply with the Standards.

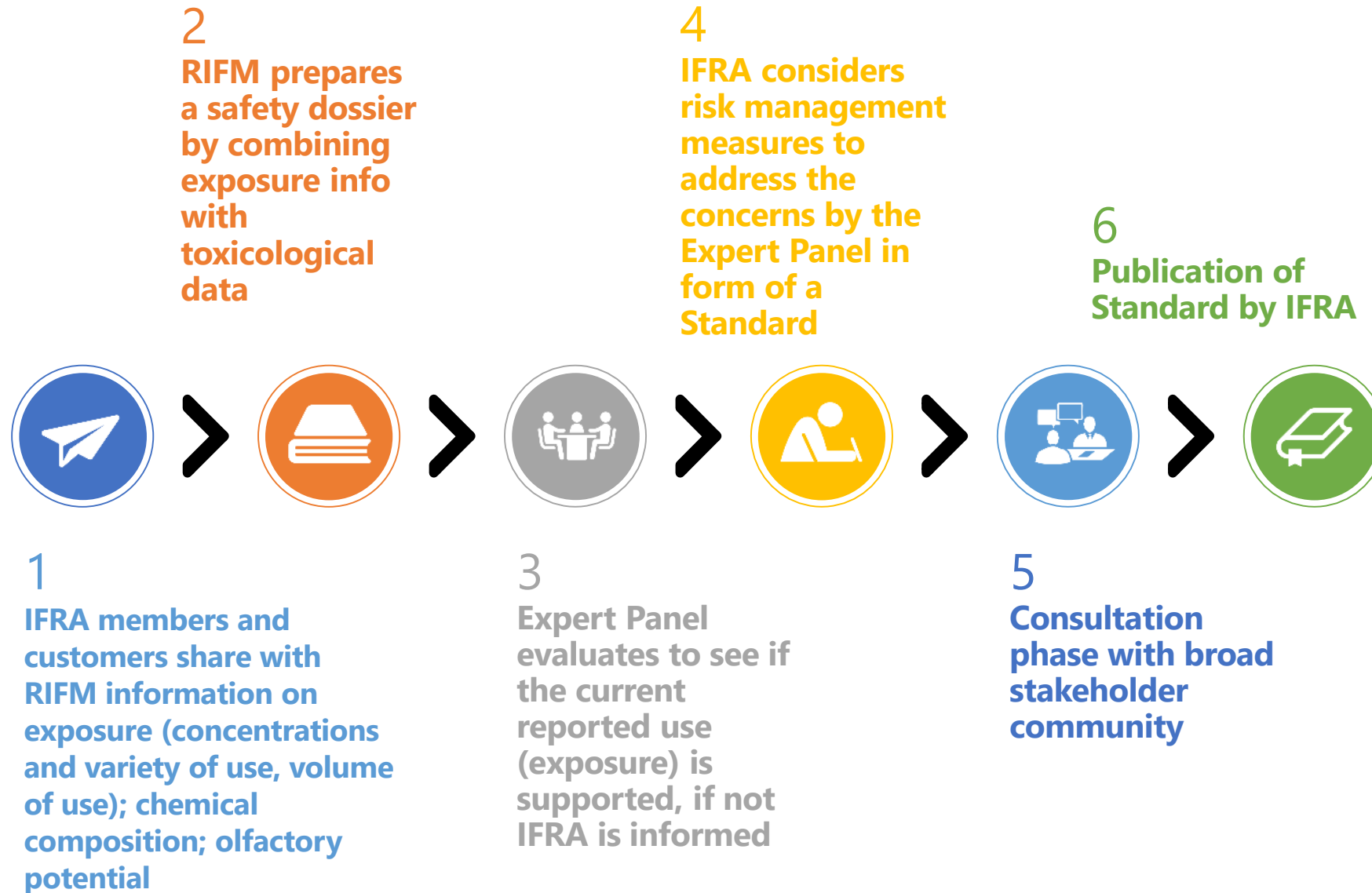
IFRA ([www.ifraorg.org](http://www.ifraorg.org)),

RIFM ([www.rifm.org](http://www.rifm.org)) and its

Expert Panel (<http://fragrancesafetypanel.org/>)

are at the heart of a multi-stakeholder Standard-setting process performed in close collaboration.

# IFRA Standards Setting Process



# IFRA Standards Setting Process

The Standards reflect the safe use levels determined from the RIFM Safety Assessments. RIFM's output is IFRA's input.

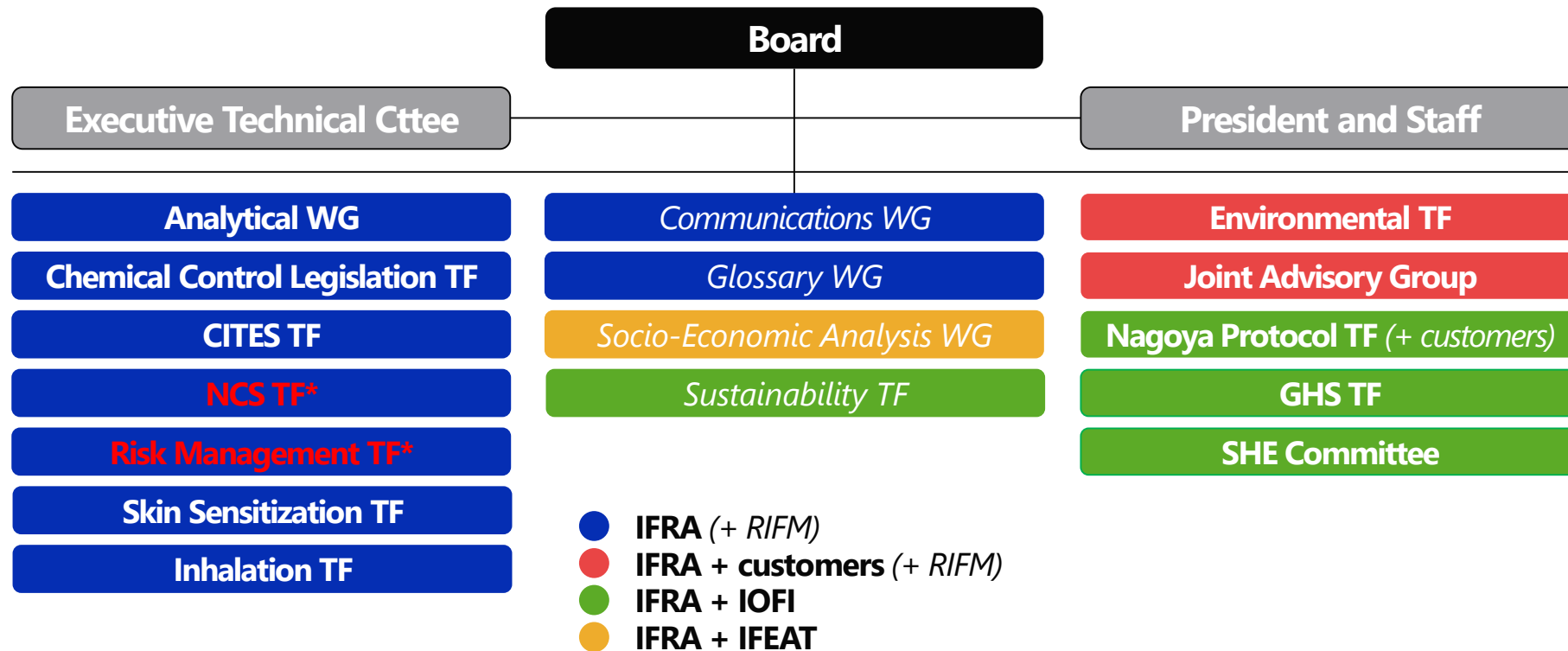
There are about 3000 materials in the current scope of RIFM assessment, including about 900 natural complex substances (NCS).

Those are the materials on the IFRA Transparency List, which is based on regular (4 – 5 years) Volume of Use surveys, thereby reflecting our understanding of the Perfumer's Palette.

There are about 450 'functional' materials (e.g. preservatives, solvents, colorants), which RIFM will not assess.

# IFRA Standards Setting Process

## IFRA's global Committees and Task Forces



\*directly engaged in Standard setting process



## Process documentation

### RIFM SAFETY ASSESSMENT PROCESS

Most recent SA assessment process description published as 'Criteria Document II' (Api et al, Food & Chemical Toxicology 82 (2015), S1 – S19).

- Substance and endpoint specific approach (irritation, sensitization, reprotoxicity, phototoxicity, etc.)
- Improvement of exposure information (aggregate exposure model)

### IFRA STANDARD SETTING PROCESS

Executive summary contained in Guidance for the Use of IFRA Standards, which was part of the Consultation and the Notification of the 49<sup>th</sup> Amendment.

Detailed description available to interested stakeholders on request.



*IFRA Standards*

# 49<sup>th</sup> Amendment

# It took some time, because...

... a large number of Standards have been included.

... we had to develop a process for setting Standards based on the new RIFM SA process:

- A new product categorization system.
- A new process to determine acceptable exposure levels.

... we had to test and validate the process.

... based on the feedback of the Consultation and learnings we had to adapt the process, then to reapply and verify.

**... our aim has been to deliver a high-quality product that honours the goal of the IFRA Standards to protect consumers and the environment while aiming to prevent unnecessary impact on the business.**

# Preparation and notification

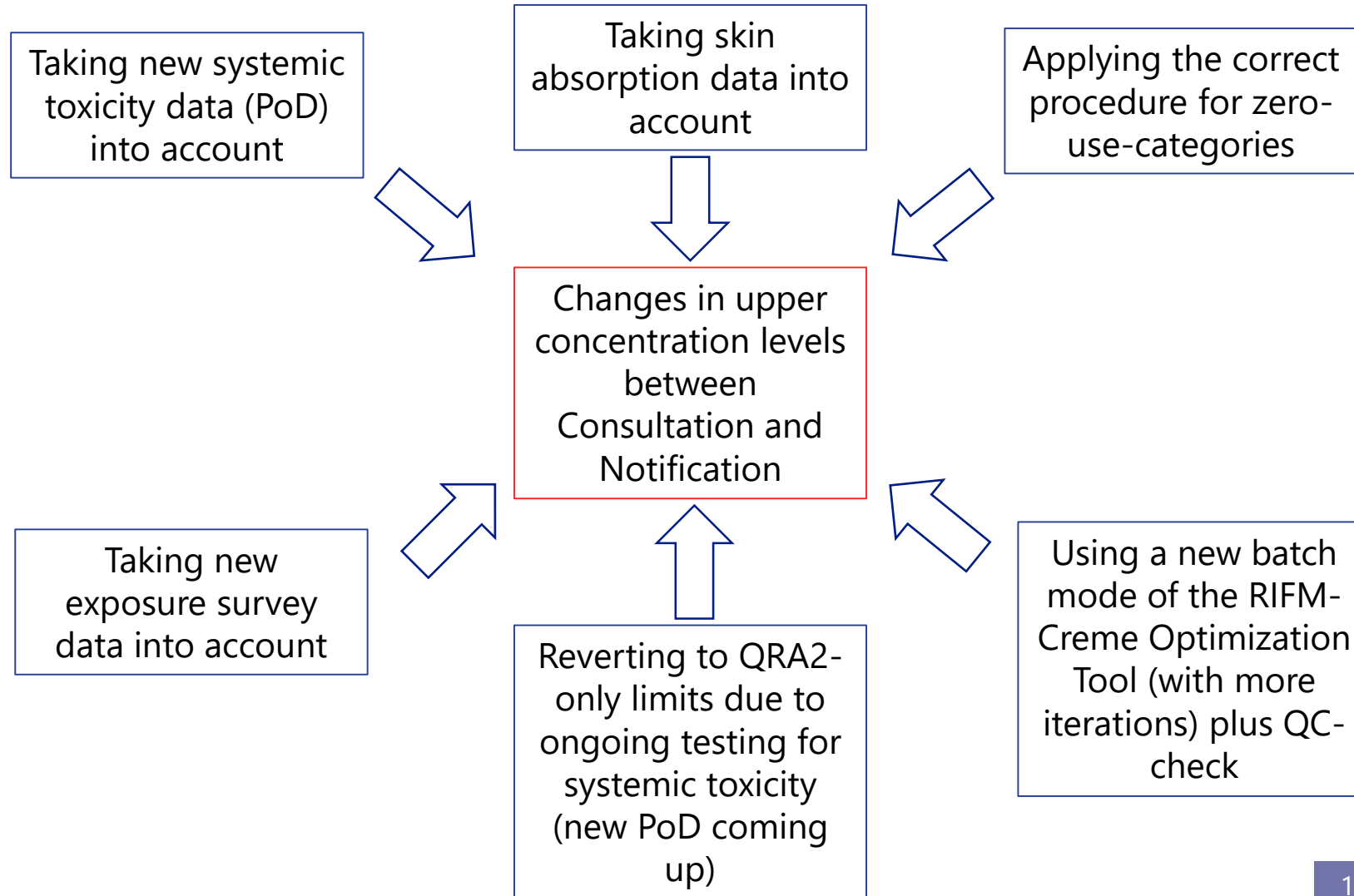
Feb/Mar 2019	Global Consultation period began
21 Jul 2019	Consultation period ended
Q3/Q4 2019	Synthesizing comments, finalizing Standards
18 Nov 2019	End of Consultation Letter sent
12 Dec 2019	Notification Letter sent
10 Jan 2020	Official Notification and publication in the IFRA website

## Addressing the comments received during the Consultation

IFRA and the RMTF were engaged in the analysis of all comments received during consultation and addressed them to the respective group(s) to deal and decide on which changes to implement for the **Notification**. These included:

- **IFRA** staff for simple issues like typos or CAS number corrections
- **RMTF** and **Legal Counsel** for questions on the procedure or guidance
- **NCS TF** for questions on Annex I
- **RIFM and the Expert Panel** in case of questions linked to the tools used by RIFM to derive the upper concentrations levels or the underlying data in the safety assessment.

## Addressing the comments received during the Consultation



## **48<sup>th</sup> Amendment:**

Dermal Sensitization = QRA1

Systemic toxicity and  
Phototoxicity = Specific  
Standards

Dermal Sensitization = 11 IFRA  
Categories

Systemic toxicity and  
Phototoxicity = IFRA Classes

## **49<sup>th</sup> Amendment:**

Dermal Sensitization = QRA2

- Aggregate exposure consideration
- Revised Safety Assessment Factors (SAFs)

Systemic toxicity and Phototoxicity:

- new RIFM safety assessment process (Criteria 2 document)
- Aggregate exposure consideration

Dermal Sensitization = 12 IFRA Categories

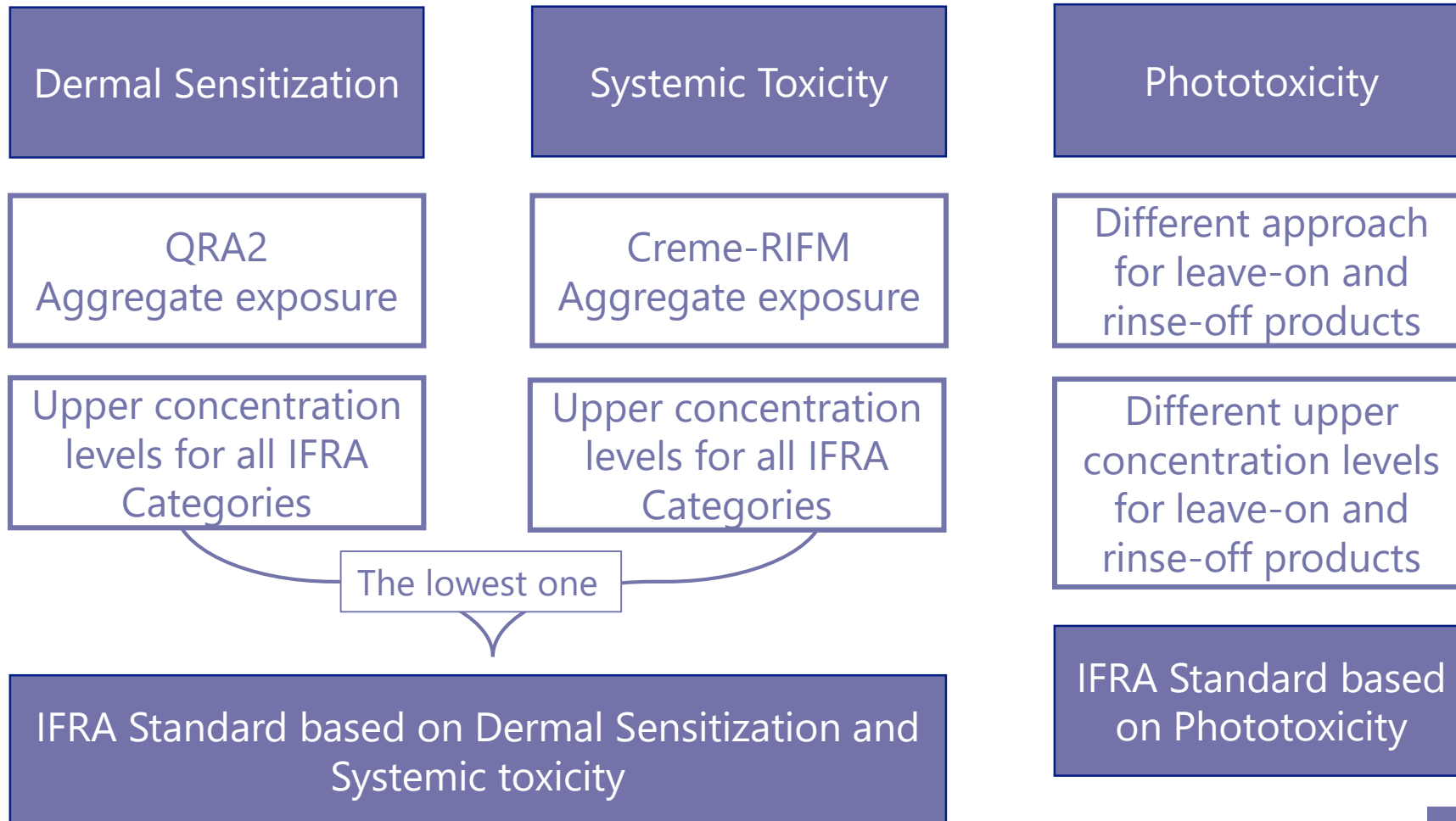
Systemic toxicity and Phototoxicity:

Subcategorization of IFRA Categories:

- Systemic toxicity (5A, 5B, 5C, 5D and 10A, 10B)
- Phototoxicity (7A, 7B and 11A, 11B)

# Critical new elements

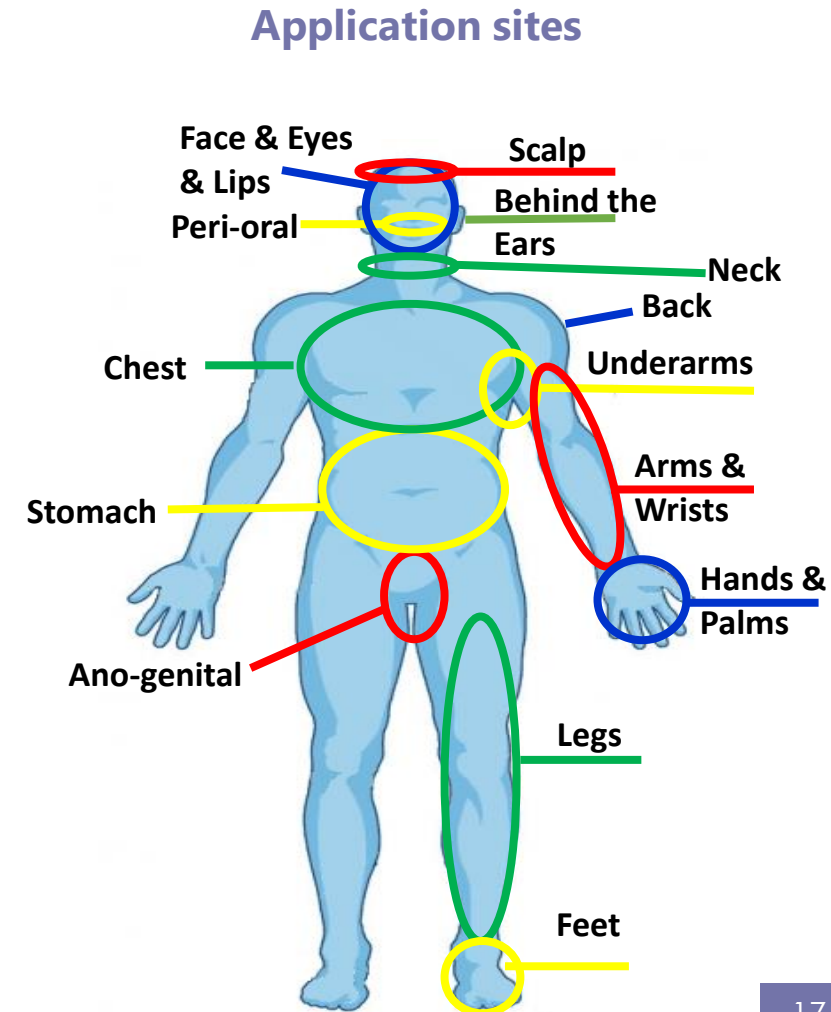
Expanding Standard scope  
Consideration of Systemic toxicity and Phototoxicity





# QRA2 – Aggregate Exposure

- ▶ Consumers use several products each day and some are applied on the same skin (body) site.
- ▶ **RIFM collaborated with Creme Global** (Dublin) to develop an aggregate exposure model for fragrance ingredients.
- ▶ Model is based on habits and practices data for more than 36000 consumers across EU & USA.
- ▶ QRA2 discussed as one item of IDEA (International Dialogue for the Evaluation of Allergens) – for more info see [ideaproject.info](http://ideaproject.info)



## Expanding Standard scope Consideration of Systemic toxicity

➤ **Lack of reliable exposure data for Categories 5D, 8 and 11**

The exposure data for Categories 5D, 8 and 11, if available, are often limited to regional studies and so far, are not regarded reliable enough to be used in the Creme-RIFM model.

$$\text{Category 5D, 8, 11A, 11B} = \text{MIN (Categories 5A, 5B, 5C) / 3}$$

➤ **Exposure data for household care products with hand contact (Category 10A) not yet included in the aggregate exposure model**

Therefore, Category 9 (bar soaps, thus with hand contact) is used as a surrogate for Category 10A.

$$\text{Category 9} = \text{Category 10A}$$

## Expanding Standard scope Consideration of Phototoxicity

- The IFRA 49<sup>th</sup> Amendment introduces a revised policy for phototoxicity.
- Traditionally:
  - The scope of application of restrictions based on phototoxic effects includes any product that is applied on body areas reasonably expected to be exposed to sunlight.
  - For non-skin contact consumer products (i.e. Category 12), phototoxicity considerations do not apply and therefore IFRA Standards do not set a restriction on them.
  - Phototoxicity considerations for rinse-off products were not applied and this was reflected by an **absence of restriction** in the respective IFRA Standards (e.g. Methyl N-methylantranilate).

## Expanding Standard scope Consideration of Phototoxicity

- The IFRA 49th Amendment introduces a **restriction level to some rinse-off products** (Standard of Tagetes oil and absolute).
- This leads to a significant change in the rationale to attribute phototoxicity considerations to finished consumer products:

Type of products	Rationale in previous Amendments	Rationale introduced with the 49 <sup>th</sup> Amendment
Leave-on products	Applicable	Applicable
<b>Rinse-off products</b>	<b>Not applicable</b>	<b>Applicable</b>
Leave-on products without UV exposure	Not applicable	Not applicable
Non-skin contact products	Not applicable	Not applicable

## Expanding Standard scope Consideration of Phototoxicity

This leads to changes in the categories as follows:

- **Category 7** is divided into:
  - Category 7A (rinse-off products)
  - Category 7B (leave-on products)
- **Category 11** contains leave-on products for which phototoxicity considerations are either applicable or not, depending on the likeliness of UV exposure:
  - Category 11A (Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure)
  - Category 11B (Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure)

Category	Product type	Phototoxicity considerations	Restriction for Tagetes oil and absolute	Restriction for Methyl N-methylantranilate
1	Products applied to the lips	Applicable (leave-on)	0.01%	0.1%
2	Products applied to the axillae	Applicable (leave-on)	0.01%	0.1%
3	Products applied to the face/body using fingertips	Applicable (leave-on)	0.01%	0.1%
4	Products related to fine fragrance	Applicable (leave-on)	0.01%	0.1%
5	Products applied to the face and body using the hands (palms), primarily leave-on:			
5A	Body lotion products applied to the body using the hands (palms), primarily leave on	Applicable (leave-on)	0.01%	0.1%
5B	Face moisturizer products applied to the face using the hands (palms), primarily leave on	Applicable (leave-on)	0.01%	0.1%
5C	Hand cream products applied to the hands using the hands (palms), primarily leave on	Applicable (leave-on)	0.01%	0.1%
5D	Baby Creams, baby Oils and baby talc	Applicable (leave-on)	0.01%	0.1%
6	Products with oral and lip exposure	Applicable (leave-on)	0.01%	0.1%
7	Products applied to the hair with some hand contact			
7A	Rinse-off products applied to the hair with some hand contact	Applicable (rinse-off)	0.1%	No Restriction
7B	Leave-on products applied to the hair with some hand contact	Applicable (leave-on)	0.01%	0.1%
8	Products with significant anogenital exposure	Applicable (leave-on)	0.01%	0.1%
9	Products with body and hand exposure, primarily rinse off	Applicable (rinse-off)	0.1%	No Restriction
10	Household care products with mostly hand contact:			
10A	Household care excluding aerosol products (excluding aerosol/spray products)	Applicable (rinse-off)	0.1%	No Restriction
10B	Household aerosol/spray products	Applicable (leave-on)	0.01%	0.1%
11	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate			
11A	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure	Not applicable (leave-on without UV exposure)	No Restriction	No Restriction
11B	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure	Applicable (leave-on)	0.01%	0.1%
12	Products not intended for direct skin contact, minimal or insignificant transfer to skin	Not applicable (non skin contact)	No Restriction	No Restriction

## Expanding Standard scope Consideration of Systemic toxicity and Phototoxicity

### In conclusion:

- When a limit for skin sensitization is introduced, the QRA2 derived level will be compared to levels derived from a systemic toxicity point assessment – the lower limit will drive the restriction in the Standard.\*
  - The systemic categories have been harmonized with QRA2 categories and, following feedback from the Consultation, with phototoxicity application considerations:
    - **IFRA categories = IFRA classes**
    - For the Certificates of conformity to the IFRA Standards, the term classes become obsolete.
- simplification for Certificates of conformity to the IFRA Standards

\*Deviating approach for Oak- and Tree moss and HMPCC

# Specific considerations

- The Standards for **Oakmoss extracts** (CAS numbers: 90028-68-5; 68917-10-2 and 9000-50-4) and **Treemoss extracts** (CAS numbers: 90028-67-4; 68648-41-9 and 68917-40-8) have Specification elements (e.g. for the presence of Atranol and Chloroatranol).  
QRA2 has been applied, but only levels lower compared to what was in place before (43rd Amendment) were implemented.
- **HMPCC** (Lyrar®)  
Given the specific situation for 3 and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde (CAS numbers 31906-04-4 and 51414-25-6) with regard to clinical reactions, this ingredient has been considered exceptional and the Standard is therefore not based only on induction considerations.  
Consequently, for pragmatic reasons, only upper concentration levels derived from dermal sensitization and/or systemic toxicity endpoints that are lower compared to the levels established by the Standard at its last publication (47th Amendment) have been introduced to the 49th Amendment.



214 IFRA Standards in total, including:



116

***New and revised  
Standards  
Plus a number of  
updated formats but  
unchanged content***



25

***New Standards***



91

***Revised Standards***  
*Details provided in notification letter*

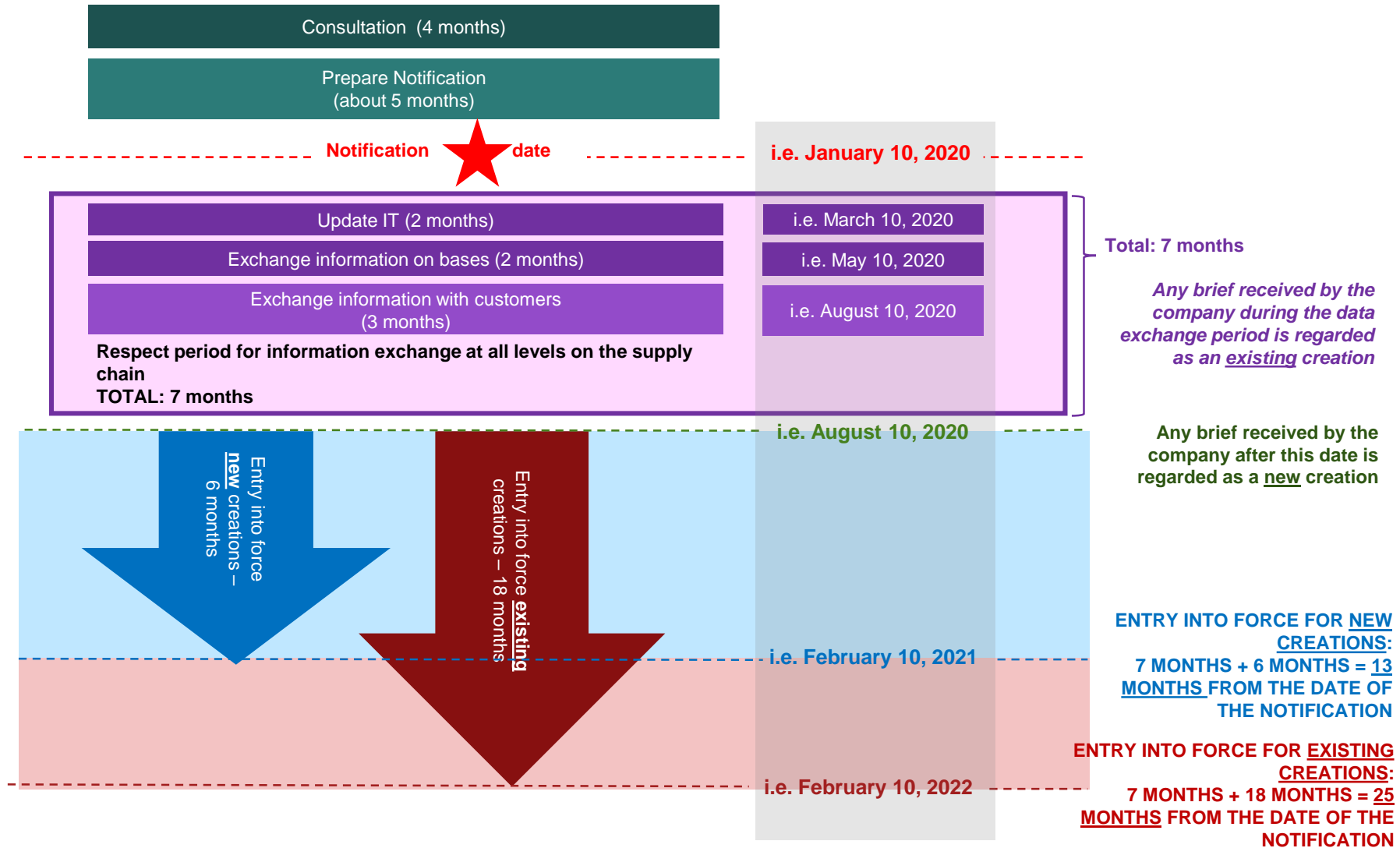
Example: The Standards 'Peru balsam crude' and 'Peru balsam extracts and distillates', published under the 42nd and 43rd Amendment respectively, have been merged for harmonization reasons into one single Standard with a Prohibition/Restriction recommendation: Peru balsam (CAS number: 8007-00-9).

The specific individual Standard for Peru balsam crude as published before has therefore been deleted.

# Clarification on policy for products with potential and those with intended ingestion

- Consumer products with a potential risk of ingestion (e.g. oral care or lipsticks), are in scope of the IFRA Standards, as they are not designed and therefore not intended to be ingested. Even so, accidental ingestion of minor amounts can occur.
- With the 49th Amendment, this policy remains unchanged.
- However, IFRA is introducing a clear distinction between consumer products containing fragrance ingredients with a potential risk of ingestion and those intended for ingestion.
- The safety of (fragrance) ingredients or mixtures present in products intended for ingestion (like 'ingestible perfumes or deodorants, fragrances for odorizing potable water, cleaning products intended for food contact') is outside the scope of RIFM's and IFRA's current risk assessment and management process.
- It is the responsibility of the companies to assess the safe use of these products based on the specific use conditions and the legal requirements applicable in the respective country/region.
- IFRA cannot incorporate products intended to be ingested in the IFRA products categorization scheme.

# Implementation timelines





THE INTERNATIONAL  
FRAGRANCE ASSOCIATION

**Thank you**

In case of questions  
[mvey@ifraorg.org](mailto:mvey@ifraorg.org)

# Communicating the Standards

**David O'Leary**

*IFRA Communications Director*

**IFRA webinar**

15 January 2020

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# We recognize the need to engage more with the public and highlight the benefits of the IFRA Standards

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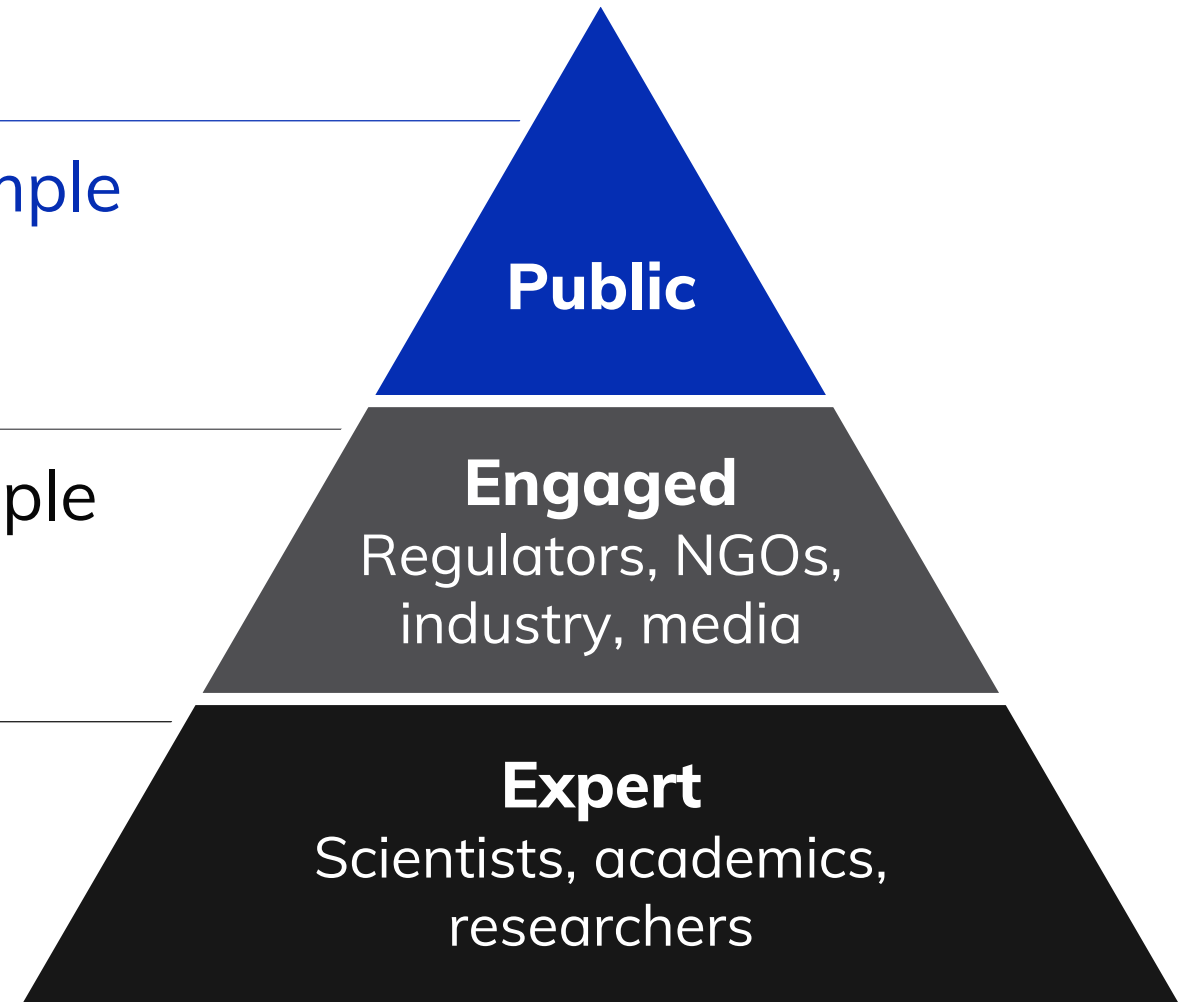
Addressing people directly with simple language, at website entry point

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Providing more detail, still with simple language

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Setting out data and details in technical and scientific language



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# Messaging on the Standards seeks to inspire confidence, provide reassurance and build trust – example of public messaging

## **The IFRA Standards – helping you to enjoy fragrance with confidence**

To ensure that you and your family can have **trust in fragranced products**, and to **respect our shared environment**, the fragrance industry has developed a system to manage the safe use of fragrance: the **IFRA Standards**.

## **Your well-being always comes first**

We see fragrance as a **safe and essential part of life**. The IFRA Standards, based on scientific evidence and overseen by independent experts, aim to make this vision a reality – **helping you to feel good about fragranced products and enjoy them with confidence**.

## **Bringing you creativity and confidence**

The IFRA Standards set the boundaries for fragrance creation – ensuring that **people can enjoy the art of perfumery with confidence**. We use scientific evidence and insights into how people use fragranced products to develop **fair rules to enhance your well-being and bring you the latest innovation**.

## **Working together for your well-being**

**Scientific evidence, consumer insights and partnership** are key elements of the IFRA Standards. Specialists assess ingredients objectively in a process overseen by independent experts, to develop a **comprehensive, global and responsive system**, so that everyone can enjoy fragranced products with confidence.



[SAFE USE](#)[INITIATIVES](#)[POLICY](#)[NEWS](#)[WHAT WE DO](#)[WHO WE ARE](#)

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# The IFRA Standards – helping you to enjoy fragrance with confidence

We see fragrance as a safe and essential part of life: it has the power to trigger a range of positive emotions and enhance lives. To ensure that you and your family can have trust in fragranced products, and to respect our shared environment, the fragrance industry has developed a system to manage the safe use of fragrance: the IFRA Standards.





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## Communications activities around the notification of the 49<sup>th</sup> Amendment – a milestone

- ≡ 12 Dec 2019 Notification to members
- ≡ 10 Jan 2020 **Formal notification of 49th Amendment**  
**Press release**  
**Briefing and messaging sent to members**  
**Website updated**
- ≡ 15 Jan 2020 Webinar
- ≡ **NB: send any media enquiries to IFRA!**



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# Ongoing communications activities around the IFRA Standards – a process

- ≡ **Training sessions:** Continue roadshow
- ≡ **Media:** continue outreach with interviews, briefings, developing third-party ambassadors
- ≡ **Website and social media:** ongoing improvement of the site, step-by-step guides, short videos with experts, possibly webchats, FAQ
- ≡ **Printed materials / toolkit:** factsheets and infographics
- ≡ *...and more to come – send us your needs and suggestions!*



# MORE ON THE IFRA STANDARDS AND OTHER HOT TOPICS

JOIN US IN SINGAPORE 1-2 APRIL 2020



*Sharing Ideas,  
Moving Forward*



Registration and information at  
[globalfragrancesummit.com](http://globalfragrancesummit.com)