Heads Up!

Updates from IFRAFeb to Jun 2019



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Comments? Suggestions? Ideas?

We welcome any comments, suggestions or ideas for future editions of Heads Up! Please send your feedback to Marta Varela at mvarela@ifraorg.org



Policy and Regulation

Europe / Fragrance sector prepares follow-up to SCCS QRA2 opinion

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As reported in the previous edition of Heads Up!, the European Commission's Scientific Committee on Consumer Safety (SCCS) has provided its response to the fragrance industry's comments on the SCCS preliminary opinion on Skin Sensitization Quantitative Risk Assessment for Fragrance Ingredients (QRA2), and subsequently published its final opinion.

Following an agreement that there will not be a detailed response to the SCCS, the fragrance industry is currently preparing a publication on the basic principles of the QRA2, based on the original submission. This publication aims to address the points raised by the SCCS. The RIFM QRA Expert Team, led by Peter Cadby, has make progress on a draft publication, which has been shared with the IDEA Supervisory Group for comments.

Europe / SCCS final opinion on p-BMHCA

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As communicated in the IFRA Information Letter 1074, the European Commission's Scientific Committee on Consumer Safety (SCCS) has published its <u>final opinion (SCCS/1591/17) on p-BMHCA</u> (p-Butylphenyl methylpropional, CAS 80-54-6) on 10 May 2019.

The SCCS concluded that on individual product basis, BMHCA with alpha-tocopherol at 200 ppm can be considered safe when used as fragrance ingredient in cosmetic leave-on and rinse-off type products. However, considering the first-tier deterministic aggregate exposure arising from the combined use of different product types, BMHCA at the proposed concentrations was concluded as not safe.

RIFM has completed an aggregate exposure-based risk assessment on behalf of the fragrance industry that supports the continued safe use of BMHCA across both cosmetic and non-cosmetic product applications.

The opinion of the SCCS as such has no regulatory status. It remains to be seen whether and how it will be viewed by the EU regulators as a basis for regulatory measures under the EU Cosmetics Regulation. Any process of developing and consulting a regulatory measure will allow the industry to share further information about its own safety assessment, specifically the more refined consumer exposure assessment.

Europe / REACH update and related activities

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There are several activities taking place in regards with REACH (EU Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals.

After finishing the last registration phase-in period, REACH is entering the next phase. ECHA (the European Chemicals Agency) is now focusing on compliance checks and screening all registration dossiers to identify substances of concern (such as carcinogenic, mutagenic and reprotoxic substances, or CMRs).

ECHA is also working with the European Commission on a joint action plan for improving the compliance and



quality of REACH registration dossiers. The aim is to publish this plan over the summer. It seems that there will be a Commission regulation adding more substances than the legally required 5% per year to undergo compliance check (the current proposal is 20%). This plan is going through without increasing ECHA human resources. As result, ECHA is applying a more automated, 'check-box' approach.

Cefic and ECHA signed a Joint Statement last year to improve REACH implementation, particularly regarding safety information on chemicals. Cefic is finalizing a REACH Action Plan for Improvement of Dossiers to encourage and support companies in evaluating existing registration dossiers and implement follow-up actions.

The Commission published a document for comments on the application of certain registration and data sharing provisions of REACH, after the expiry of the final registration deadline for phase-in substances. The Substance Information Exchange Forums (SIEFs) under REACH will cease (but not the data-sharing obligations) after 31 December 2019. As result, pre-registrations will no longer be valid. All substances will therefore be regarded as new substances and the respective procedure must be followed (obligation to enquiry).

In May, ECHA published a new report on "<u>Mapping the chemical universe to address substances of concern</u>". According to the ECHA press release, this report presents a mapping of the registered substances that are on the EU market. This information helps authorities "to identify, plan and monitor progress on spotting and regulating substances of concern". The mapping results are the following so far:

- Around 270 substances are of high priority for risk management
- Around 1,300 substances are of high priority for data generation
- Around 450 substances are considered of low priority as already sufficiently regulated
- Around 500 substances have been concluded to be currently of low priority after assessment

Currently, the focus is on the 4,700 substances registered at above 100 tons per year. ECHA foresees that a significant number of them will undergo compliance checks or substance evaluation in the coming years. Lists of the substances belonging to the different pools of the chemical universe are not included in the report. ECHA plans to publish them on its website at the end of the year. Therefore, we could envisage more related activity, for instance, on CMRs and endocrine disruptors.

The Commission is now considering the REACH registration of polymers that were exempt from registration so far. Article 138 (2) of the REACH Regulation allows the Commission to start considering registration of polymers. As a result, the Commission's Directorate-General for the Environment is currently performing a study on "scientific and technical support for the development of criteria to identify and group polymers of concern for Registration/Evaluation under REACH and their impact assessment". This study will present conclusions and serve as evidence to the Commission for a future impact assessment.

The Commission is also working on an Implementing Regulation explaining the timing indication of "without undue delay" (Article 22) to update registration dossiers, which could help to clarify the duties concerning registration dossier updates.

The IFRA REACH Task Force has started work on the update of the Guidance document on REACH Exposure Scenarios for Substances and the Generic Exposure Scenarios for Mixtures Project. Ad hoc working sub-groups have been set-up for both activities. A draft revised Guidance for Substances has been issued for comments by the sub-working group.

Europe / EU CLP Regulation – publication of 12th ATP

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IFRA Information Letter 1073, disseminated in May, informed members about the publication of the 12th Adaptation to Technical Progress of the Classification, Labelling and Packaging Commission Regulation (EU CLP 12th ATP, EU 2019/521) in the EU Official Journal on 28 March 2019.

This Regulation, which implements sixth and seventh revision the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), has now entered into force and will apply from 17 October 2020.



Skin sensitizers and textiles / EU action on textile, leather, hide and fur articles containing skin sensitizing substances

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As reported in the previous edition of Heads Up!, a restriction dossier proposal by France/Sweden on skin sensitizers in textile products has been published for public consultation in mid-June. The proposal would restrict substances with harmonized classification as skin sensitizers in Category 1, 1A, or 1B in Annex VI to the CLP Regulation. The first deadline for comments is 19 August and the final deadline is 19 December 2019.

The articles covered by the restriction include:

- Cosmetic textiles or cosmetotextiles with microencapsulated solids or liquids intended to be released over time when the garment is in direct contact with the skin to give functions like fragrance or moisturizer, unless the microencapsulated solids or liquids are already covered by the ongoing restriction on microplastics;
- Disposable textile such as disposable napkins, tissues, sanitary towels and nappies.

IFRA will participate in the consultation in collaboration and coordination with the European textile industry association (EURATEX).

Endocrine disruptors / IFRA Europe contributes to EU consultation

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The European Commission published a Communication entitled 'Towards a comprehensive European Union framework on endocrine disruptors' on 7 November 2018. This Communication has been included in the Commission Work Programme for 2019.

On 12 June the European Commission released its roadmap on the Fitness Check on Endocrine Disruptors. This work takes place in the context of the Better Regulation approach and it is designed to assess the coherence of EU legislation in this area. It addresses the horizontal approach for the identification of endocrine disruptors (EDs) and the regulatory consequences for them across all product categories. The period for comments on the roadmap lasted until 10 July. IFRA Europe has prepared its contribution.

Regarding cosmetics, the EU Commission has proposed a priority list of 28 substances with potential ED properties used in cosmetic products. The 28 substances have been split into the two following groups:

- Group A, which consists of 14 substances that should be treated with higher priority for assessment since they are undergoing Substance Evaluation (SEV) under REACH for ED concerns or the SEV has already confirmed ED concerns;
- Group B, which consists of 14 substances where either no SEV has been initiated or the outcome of the SEV is of an environmental ED concern but not of a human health one. Group B also contains substances that have been recently evaluated by the SCCS and found safe, and/or substances that have been recently classified as CMRs under CLP where corresponding risk assessment/management measures are in place to ban/restrict their use in cosmetic products.

As next step, the Commission has launched a Call for Data on the 14 substances found in Group A. This call for data lasts until 15 October 2019.

Out of the nine substances on the Transparency List, three are fragrance materials (with a RIFM ID): resorcinol, benzyl salicylate, and benzophenone.

After analysis by both the IFRA Executive Technical Committee and the IFRA Europe Committee, IFRA will start actively working on the preparation of the dossier for benzyl salicylate, which is the only relevant fragrance ingredient. We are coordinating and liaising with Cosmetics Europe in preparing our input.



Butylated Hydroxytoluene/BHT is present and used in many hundreds of fragrance materials as an antioxidant or stabilizer and is also used directly in fragrance compounding. Therefore, despite BHT being a functional material, it is recognized that this regulatory development may have big impact on our industry.

Given the above, IFRA will contact the REACH Lead Registrant to raise awareness and learn about their intentions in regards their participation to the call for data.

For the other ingredients, companies may participate individually as IFRA is not going to organize any activity.

The European Parliament voted a Resolution on the 18 April 2019, at the very end of the legislature, asking the European Commission to come forward with a transversal legislative proposal on EDs not later than June 2020. Close to 90% of the Members present voted in favor of the Resolution. The Resolution asks for alignment with the CMRs and the introduction of the concept of categories (including suspected EDs). This would have a huge impact on our business. The Resolution also asks ECHA to make sure that REACH registrations are compliant by the end 2019.

France has started its own initiative, launching a public consultation on its national strategy on Eds on 14 January 2019. Despite the stated aim of helping the Commission's work, this French government initiative brings back several elements that were already rejected in discussions on biocides and pesticides at Commission level, specifically the concept of categories. The concern with this concept is the potential introduction of a category 3 'suspected' endocrine disruptors, where in the end many materials might end up.

Fragrance allergens / European Commission Impact Assessment on labelling

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In early December 2018, the European Commission published an inception impact assessment (roadmap) on labelling of fragrance allergens, open for feedback from stakeholders. IFRA Europe commented that the proposed document is an accurate description of the various options for providing information to consumers (no action, on-pack labelling or e-labelling).

An impact assessment is now being prepared and will compare the three different options in terms of costs and feasibility for the industry and consumers. The Commission has appointed a consultant who is contacting key stakeholders. IFRA Europe was interviewed on 11 June.

A public consultation will follow, probably starting between July and September for a 12-week period. No proposal for amendments to the legislative act can be expected before early 2021.

Microplastics and fragrance encapsulation / **EU consultation on potential microplastics restriction**

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At the request of the European Commission, the European Chemicals Agency (ECHA) has prepared a proposal for a <u>REACH Annex XV dossier restricting the use of intentionally added microplastics in finished consumer products</u>. This dossier has been built on a risk assessment and a socioeconomic impact on a potential restriction on microplastics.

ECHA is proposing to define microplastics as "composed of synthetic water-insoluble polymers with a shape between 5mm and 1nm dimension". ECHA has focused on persistence and biodegradability criteria, which could justify a derogation from the restriction proposal. ECHA is also establishing labelling and information reporting requirements as well as a five-year transition period for fragrance encapsulation.



The restriction proposal was finalized on 11 January 2019. The conformity check was presented and agreed by ECHA Risk Assessment and Socio-Economic Assessment Committees (RAC and SEAC) at their respective meetings on 6 and 13 March.

As a next step, ECHA launched on 20 March 2019 a six-month <u>public consultation on the Annex XV report</u> proposing a restriction of the use of intentionally added microplastics in finished consumer products. The deadline is set for 20 September 2019. ECHA has set two deadlines to provide comments in time for their consideration by the RAC (Risk Assessment Committee) and the SEAC (Socio-economic Assessment Committee): 20 May 20 (for the committees' June meetings) and 20 August (for the September meetings).

IFRA Europe met the first deadline for submission of comments to the ECHA public consultation. This input focuses on three main areas:

- 1. General comments on the Annex XV report, including:
 - a. the lack of recognition of the relatively small low impact of microplastics (and fragrance encapsulation in particular) on the environment resulting from plastics disposal;
 - b. the strong willingness of IFRA Europe to collaborate with ECHA in providing solutions for a fit for purpose restriction.
- 2. Biodegradability criteria: IFRA Europe has joined forces with A.I.S.E. (the International Association for Soaps, Detergents and Maintenance Products) to prepare a position paper providing suggestions and recommendations to ECHA to apply biodegradability criteria to the specific evaluation of fragrance encapsulation. Cosmetics Europe is an observer in this group.
- 3. A socio-economic analysis (SEA) of a potential impact of the ECHA restriction proposed on our industry.

Dr Karen Jenner, Chair of the IFRA Environmental Task Force, attended the RAC meeting on 4 June as an IFRA Europe expert. She had the opportunity to present to the RAC members the position and main concerns of the fragrance industry on the Annex XV report.

The respective subgroups, notably the one on SEA, will continue their work to prepare for the next deadline to submit comments, on 20 August 2019.

After the public consultation, the RAC and SEAC will prepare an opinion on the Annex XV report, based on the feedback received by ECHA from all stakeholders. In the meantime, IFRA Europe will continue its high engagement in advocacy activities regarding this ECHA Annex XV dossier. Activities are taking place in coordination with A.I.S.E. and Cosmetics Europe. IFRA Europe also participates in the cross-industry network organized by the European chemicals industry body, Cefic.

Europe / EU CLP Article 45: notifications to poison centers

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A draft delegated act for the amendments of Annex VIII (Poison Centers) has been prepared by the European Commission. At the request of various EU member states and stakeholders, it contains already an amendment for the postponement of one year (until 1 January 2021) for the entry into force of the notification for mixtures for consumer use. The draft was to be presented in CARACAL (Competent Authorities for REACH and CLP) at the start of July, as will be the norm with all delegated acts for CLP. From the Commission side it seems that the postponement is agreed.

In April ECHA announced the release of a new online submission portal for poison centers. This portal allows companies to prepare and submit information on hazardous mixtures that can be used by poison centers.

A proposal for a revised (version 2.0) 'Guidance on harmonized information related to emergency health response – Annex VIII to CLP' is being prepared and will be discussed at the CARACAL meeting in July 2019. Final comments were permitted until 5 July.



CMRs / Ingredients proposed for harmonized classification and labelling as CMRs in Europe

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A series of ingredients are currently undergoing a harmonized classification and labelling (CLH) procedure in the EU as potential CMRs (carcinogenic, mutagenic, or toxic for reproduction). Once these classifications are adopted, they are listed in Annex VI to the CLP Regulation and should be applied in the EU by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances at certain levels.

The IFRA CMR Working Group (under the umbrella of the IFRA Executive Technical Committee) is following up and managing the technical and regulatory aspects.

The ingredients under scrutiny are:

Methyl salicylate - CMR 1B by France: IFRA set-up an ad hoc Working Group, including client companies, to support the lead registrant and the IFRA leading company in preparing the comments to contribute to the public consultation on the CLH dossier for m-salicylate, launched on 12 November 2018. The strategy is to avoid the Reprotoxic 1B classification and keep it as Reprotoxic 2. The public consultation ended in January 2019. IFRA is now waiting for the publication of the consultation results. The next step is the discussion of the ECHA Risk Assessment Committee (RAC), which will take place this year.

Meanwhile, Cosmetics Europe has initiated a consortium to defend the use of m-salicylate before the SCCS. The IFRA team has joined the consortium as an observer. The objective of this consortium is to prepare the dossier needed to get an exemption under the Article 15 of the Cosmetic Regulation. Cosmetics Europe's activity is complementary to IFRA efforts to prevent the harmonized CMR 1B classification. The decision to set up the consortium is driven by the new CMR timelines, which are very short and do not give a possibility to get an exemption dossier ready if it is started only once the classification is in place.

Given this Cosmetics Europe initiative, IFRA will not organize any additional activity/consortium to prepare a SCCS dossier but will follow this subject through the Cosmetics Europe consortium.

Alpha-terpinene - CMR2 CLH by the Netherlands: IFRA participated in the ECHA RAC meeting together with an expert. The RAC did not agree with the CLH proposal to classify this substance as Rep 2.

Benzophenone – CMR2 CLH announced by Denmark: Denmark has submitted the CLH proposal as Car 2 to ECHA. The next step is the launching of the public consultation.

Hexyl salycilate – CMR2 CLH recommended by the Netherlands: following a Substance Evaluation, the Netherlands concluded that this ingredient should be classified as Rep 2. No action has been taken so far.

p-BMHCA - **CMR 1B draft opinion by the ECHA RAC:** the ECHA RAC voted for a more stringent classification as CMR 1B. IFRA organized a webinar on 29 March to explain more in depth the situation and important timelines. The slides from the webinar are available here.

As described in IL1066, the timing for the incorporation into regulation of the harmonized classification and labelling proposal in the 15th ATP is not yet defined. It has become even more difficult to anticipate the timing as the 14th ATP has not been adopted yet. That triggers the start of the discussions of the 15th ATP.

Also, it is important to highlight that the abovementioned regulatory events and activities are limited to EU and the use of BMHCA in cosmetic products outside the EU and in-home care products in general remains unaffected.

It is important to note that the current RIFM safety assessment of p-BMHCA also remains valid. The product does not represent a risk to human health when the scientifically derived maximum concentrations, as given in the current IFRA Standard, are followed.



Europe / Ingredients self-classified by industry as CMRs and other non-EU authorities

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The following ingredients have either a registration dossier with a CMR classification by a non-IFRA member or a self-classified as CMR by an IFRA-member. The IFRA CMR Working Group (under the umbrella of the IFRA Executive Technical Committee) is following-up and managing the technical-regulatory aspects.

Trans-2-Hexenal: Mut 2 self-classification under investigation.

Nerolidone: Rep 2 self-classification under investigation.

Lilial-methyl anthranilate: Rep 2 self-classification confirmed; will be included in the Labelling Manual 2019.

p-cymene: Rep 2 self-classification confirmed; will be included in the Labelling Manual 2019.

Isoeugenol: classified as a carcinogen by NICNAS (Australian authorities), as mentioned in a dossier for related esters. IFRA has contacted NICNAS and has submitted documentation justifying non-classification.

Europe / Limonene – harmonized classification proposal as Aquatic Chronic 3

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IFRA participated in the last European Chemicals Agency Risk Assessment Committee (RAC) meeting on limonene, together with EFEO (the European Federation of Essential Oils). The RAC concluded that d-limonene is readily biodegradable, therefore rapidly degradable and agreed to change the existing harmonized classification and labelling to Aquatic Chronic 3; H412 (instead of Aquatic Chronic 1; H410). This is a major achievement based on extensive battery of studies performed by EFEO.

The Skin Sensitization endpoint was also extensively discussed and the RAC concluded that the classification should apply to the substance itself rather than to any impurity or substance that result from chemical reactions by incidental contact with (such as air or water), and that the substance should therefore be classified as Skin Sens. 1B; H317.

Europe / Eurasian Economic Union

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IFRA is following the developments regarding the entry into force and implementation of REACH-like chemical regulation EAEU TR 041/2017 in the Eurasian Economic Area (EUEA - Russia, Belarus, Armenia, Kazakhstan and Kyrgyzstan). This regulation requires mandatory registration of mixtures including requirement for a risk assessment. It will enter into force on 2 June 2021. Additionally, two secondary pieces of legislation chemical legislation were expected to be published by now, but the situation is very unclear.

The implementation begins with the building of an EAEU inventory consisting of national parts managed by the five member states through an integrated Russian-language information system. There is contradictory and unclear information over the timing and other details. The Cefic Global Emerging Regulations network (GER) is preparing a list of questions to the EAEU authorities to get further clarification. However, we strongly advise companies to notify as many substances as possible to the inventory (i.e. the Transparency List) by December 2019 to be on the safe side. IFRA is monitoring the legislative development via the CEFIC GER network, which is chaired by Cristina Arregui.



Switzerland / Furocoumarins regulatory developments and activities

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As reported in the previous editions of Heads Up!, we learned in August 2018 that the Swiss Court case became obsolete as the legislation introduced in May 2017 (see IFRA Information Letter 1050 for background) was withdrawn and the Cassis de Dijon principle has been re-established. This happened on 3 January 2019 and the revised regulation, which contains more detail on the product types that will be in the scope of the 1 ppm furocoumarin limit, came into force on 3 February 2019.

Considering the developments in Switzerland and the potential impact on European regulation, IFRA has established a stakeholder group to investigate various options and develop a recommendation for future IFRA policy. The group includes experts from suppliers and customer industries and covers various fields of expertise (toxicology, regulatory, analytical, etc). The first face-to-face meeting took place on 28 August 2018 in Brussels.

A key decision taken was to have a critical look at the markers selected to be representative of furocoumarins and used them as reference in the analytical method looking into the feasibility of a science-based rationale for their selection, as well as evaluating the need for an updated safety dossier. Two subgroups will continue work in 2019.

Europe / Acetylated Vetiver Oil interested stakeholder group submission to SCCS

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Following the feedback received from the EU Scientific Committee on Consumer Safety (SCCS) in May 2017, a group of interested stakeholders made an additional submission to the SCCS in support of Acetylated Vetiver Oil, as the SCCS had not regarded previous submissions as sufficient. This was followed by further clarification in March 2018, upon a request from the SCCS Secretariat, about the material CAS numbers that would be covered by the submission.

In 2018 IFRA welcomed the SCCS Preliminary Opinion on Acetylated Vetiver Oil (SCCS/1599/18, adopted on 21-21 June 2018) which concludes that the material can be safely used under certain conditions. IFRA, on behalf of interested stakeholders, also participated in a public consultation.

After some consideration about whether to initiate additional studies without antioxidant to prevent the requirement of 1% alpha tocopherol to potentially being included in the regulatory proposal, members of the industry consortium decided not to do so and accepted the draft opinion.

Ultimately, the SCCS adopted a final opinion on Acetylated Vetiver oil, at its February 2019 plenary meeting, confirming the safe use levels of this material as provided in the dossier. It also states that the material needs to be stabilized with 1% alpha Tocopherol. The only unclear element remains the qualifier by the SCCS regarding aerosolized or sprayable application. It needs to be seen how this is going to be addressed in a regulatory proposal

The IFRA Risk Management TF (RMTF) agreed to only consider the 1% alpha tocopherol requirement for an IFRA Standard in case it would be part of a regulatory proposal.



Australia / NICNAS reform

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IFRA sent comments to the NICNAS (Australian National Industrial Chemicals Notification and Assessment Scheme) Consultation on proposed changes to Industrial Chemicals (General) rules arising from the passage of the Industrial Chemicals Act 2019. This was done in coordination and alignment with ACCORD (Australian hygiene, cosmetic and specialty products association).

Korea / K-REACH pre-registration deadline concluded

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The amended K-REACH entered into force on 1 January 2019. New substances below 100kg must be notified prior to manufacture/import (no hazard data requirement), while those above 100kg must be registered prior to manufacture/import (with a hazard evaluation required). Existing chemical substances of at least 1 ton per year needed to be pre-registered with the South Korean Ministry on Environment (MoE) by 30 June 2019.

Given the lack of clarification on certain key issues, the European Chemical Industry Council (Cefic), together with the national chemical industry councils of United States (ACC), Japan (JCIA) and Singapore (SCIC), sent to high level Korean officials some comments and concerns about K-REACH, the Chemicals Control Act and the Korea's Occupational Safety and Health Act (OSHA). IFRA contributed to this initiative via Cefic and SCIC.

Vietnam / New chemical inventory/database

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There is no information on the plans of the Vietnam Chemicals Agency (Vinachemia) regarding the introduction of chemicals legislation after the publication of the chemical inventory.

Australia / Ingredient defense: coumarin

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Coumarin is under review by National Therapeutic Goods Administration (TGA) for use in medicinal products in Australia. The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. The TGA revision includes some over-the-counter (OTC) product types (like sunscreens), which are cosmetics in other regions of the world.

IFRA, in close cooperation with ACCORD, has prepared comments, which were submitted to TGA at the start of April. ACCORD is the Australian national industry association representing manufacturers and marketers of hygiene, cosmetic and specialty products.



Argentina / First draft regulation on chemicals published

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The Argentinian Ministry of Production and Labor notified the World Trade Organization (WTO) about the Argentinian Chemical Draft Bill on 3 June 2019. The WTO notification was withdrawn on 17 June. Apparently, the notification of the Resolution on the WTO submission had differences in the text with the draft bill that was approved by the inter-ministerial committee. It should be highlighted that the resolution and the bill are different regulations and that the cancellation of the WTO notification of the resolution does not affect the process of approval of the bill in the congress (the law has a higher status).

On 11 June the Argentinian Secretary of Environment and Sustainable Development published the final version of the Argentinian Chemical Draft Bill. This is the law that will go to the Congress and will provide the framework to the management of chemicals. It seems this law would establish a national inventory and then each ministry (responsible for the non-exempt sectors) would establish the inventory process under their responsibility. In other words, different inventories under the responsibility of different ministries would form 'branches' of the national inventory foreseen in the law.

It has been drafted in alignment with Brazilian Draft Bill, but it will contain some differences such as:

- **Exemptions** (household products and cosmetics might be included in the inventory);
- Data protection for new substances no letter of access will be required;
- For new substances, there is not a minimum threshold to require tox/ecotox data and risk assessment and a letter of access is not required to make the registration;
- Notification in the national inventory of substances that are ingredient of imported mixtures will be required only for the hazardous substances.

The IFRA National Association in Argentina, CAFEPA, with the support of IFRA and IOFI, succeeded in getting an exemption for ingredients used in flavors/flavoring mixtures. Furthermore, CAFEPA will monitor together with the national chemical association (CIQyP) the evolution of this Bill from the Chief of Staff to the Argentinian congress as well as any future WTO notification of related resolutions by the ministries.

Brazil / Uncertainty over chemicals bill

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The new government environmental ministry administration decided to revise the text of the chemicals bill and make significant changes on its governance process (such as eliminating committees and public consultations). The new revised final text still unknown and it is expected to be sent back to the chief of staff. There is no information about when it could be sent to the Congress. The Brazilian government is very engaged in the OECD, and this could be a factor that may increase interest to support the chemicals Bill.

Colombia / **Draft regulation on chemicals substances for industrial use published**

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The Colombian Decree on Chemical Management of Substances is returning for revision by the new administration of the Environment Ministry. It is expected that discussions with industry will recommence in 2019. The decree requires registration of some categories of hazardous substances and mixtures. Another decree will further define requirements, phases and deadlines for the registration process. Risk assessment will be required only for new substances (no minimum threshold). However, a risk management program will be required for all registered substances with CMR or PBT characteristics.



Chile / **Draft regulation on chemicals substances for industrial use published**

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A Regulation on GHS (Globally Harmonized System of Classification and Labelling of Chemicals) and Chemical Management of Substances was approved by Chile's Council of Ministries for Sustainability in October 2018. The text will go through legal approval process in the following months before being published as a decree. It expected to be published in Q1 2020. The GHS Regulation is based on the CLP (Classification, Labelling and Packaging of substances and mixtures) Regulation, with some differences. Official GHS classification list will be provided.

United States / 9th Annual Federal Lobby Day

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Fragrance Creators' 2019 Lobby Day yielded significant advancements in the organization's advocacy goals focused on delivering results that protect and promote the fragrance industry's ability to innovate and grow. For the third consecutive year, Fragrance Creators set a record for number of meetings held (64). We connected with key decision-makers (Members of Congress and staff) on issues of key importance of the industry, including trade and tariffs, new chemical review, and cosmetics modernization.

Fragrance Creators strengthened existing relationships, gained new support in Congress, and expanded the Congressional Fragrance Caucus. As a result of Lobby Day, Fragrance Creators is poised to influence trade and tariff policy, drive legislative solutions regarding new chemicals, and shape a national cosmetics framework as related to fragrance.

United States / Fragrance Creators President & CEO Farah Ahmed Testifies Before USTR on E.U. Tariffs

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The international trade landscape is changing more rapidly than at any point in recent memory. Whether the Trump Administration is acting on trade agreements or tariffs or responding to retaliatory actions, the U.S. is the heart of activity.

On 15 May, Farah K. Ahmed, President and CEO of the Fragrance Creators Association, was selected to testify before the United States Trade Representative (USTR) requesting the removal of essential oils from potential tariffs levied against the EU. In June she will testify before USTR regarding List 4 tariffs against China, representing approximately \$300bn worth of goods. Fragrance Creators has also advised its members in managing existing Chinese tariffs (Lists 1-3) and increased rates (List 3). With India set to lose Generalized System of Preferences (GSP) status, Fragrance Creators has helped members navigate the consequences of tariffs increasing to 4% which is the standard most favored nation (MFN) rate.

Fragrance Creators has directly advocated on trade and tariff issues and has also leveraged the influence of the Congressional Fragrance Caucus and Fragrance Creators' relationships with the United States Trade Representative and the Department of Commerce. Fragrance Creators will continue to advance the industry's needs and provide its membership with the most up-to-date information and strategies.



United States / Fragrance Creators engages in cosmetics policy

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Fragrance Creators is actively engaged in cosmetics policy - as related to fragrance - at the federal and state level. Fragrance Creators is partnering with allied trades to have a coordinated state approach while taking ownership of fragrance policy. Negotiations with federal stakeholders in the House of Representatives is underway, and Fragrance Creators is prioritizing robust protection of intellectual property, regulatory predictability, and one nationwide system. A number of states considered cosmetic ingredient disclosure proposals in 2019.

While most state legislative sessions have adjourned, Fragrance Creators is still actively engaged in California and New York. In California, the passage of SB 574, a fragrance and flavor ingredient disclosure bill, appears imminent. Fragrance Creators is committed to limiting the impact of SB 574 and ensuring a workable solution in California.

United States / Chemicals Management: Modernization of TSCA, EPA New Chemical Approvals

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Fragrance Creators (FCA) met with Administrator Alexandra Dunn and key US Environmental Protection Agency (EPA) staff on 15 March 2019. Following a productive dialogue with representatives from the fragrance supply chain, FCA asks that EPA address issues impacting approvals of new fragrance chemicals, which has stalled innovation. Fragrance Creators knows that new fragrance molecules are often greener, safer, and more sustainable, and they are eager to support the advancement of these chemistries in the United States. Administrator Dunn acknowledged the value of new chemicals, noting that new chemicals are the closest thing EPA has to a product. She also appreciated the need to eliminate the existing backlog. Fragrance Creators applauded this commitment but cautioned that the overuse of SNURs (Significant New Use Notices) and COs (Consent Orders) has negative effects on our industry.

During this meeting, Fragrance Creators shared a report prepared based on the experiences of our members with the new chemical process under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). At Administrator Dunn's suggestion, Fragrance Creators has scheduled follow-up meetings with the agency leadership and career staff to continue our dialogue and share solutions.

United States / FDA proposal for a QRA model in determining safe use levels of fragrance materials on EU allergens list

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Following a request from the US Food & Drugs Administration (FDA), Fragrance Creators is leading the industry in dialogue with FDA on its upcoming efforts in quantifying the level of safe use of materials that have been identified by the European Union as being fragrance allergens.

In April 2019, Fragrance Creators, joined by its members and representatives of RIFM and the Personal Care Products Council (PCPC), met with Dr. Linda Katz, Director of the Food and Drug Administration's (FDA's) Office of Cosmetics and Colors, and senior staff. Fragrance Creators aimed to further develop its relationship with FDA, to obtain clarity about FDA's thinking and needs related to allergen communication; to share information about Fragrance Creators' initiative to educate the public about fragrance, The Fragrance Conservatory; and to facilitate further education about RIFM and QRA2.



FDA expressed a desire to learn more about how fragrance ingredients are assessed for safety. With respect to fragrance allergen safety, Fragrance Creators welcomes an ongoing dialogue and offers to facilitate a hands-on workshop with RIFM to support FDA as it learns how to best use the Creme RIFM aggregate exposure model. Fragrance Creators appreciates the agency's objectives and will work toward furthering our mutual public health goals as related to fragrance.

United States / Chemical Management: VOCs activity at the California Air Resource Board

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The California Air Resource Board (CARB) has broad statutory authority to adopt regulations to achieve the maximum feasible reduction in volatile organic compounds (VOCs) emitted by consumer products. In its 2016 Fragrance Survey and 2013-2015 Consumer Product Surveys, it is apparent that CARB made a number of inaccurate and incomplete assumptions about fragrance. While the Consumer Products Regulation includes an exemption for fragrances up to a combined level of two per cent by weight contained in a consumer product, CARB has indicated that "all options are on the table" during its next rulemaking. This includes reconsidering definitions, exemptions, VOC limits in various product categories, and reformulations.

In April 2019, CARB initiated rulemaking to meet 2023 and 2031 goals. This rulemaking could affect company costs due to increased regulatory burden and the bottom line and consumer choice as product reformulations could be needed. Fragrance Creators is participating in the rulemaking process. The goal is that - by being a resource to CARB and supplying more complete data and narratives - the industry will influence CARB as it drafts its recommendations for reducing VOC emissions from consumer products. CARB intends to have its rulemaking ready for review by its Board in late 2020.

International / Nagoya Protocol and access and benefit sharing (ABS)

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Find out more about the Nagoya Protocol

The IFRA-IOFI Nagoya Protocol Task Force continues to monitor the latest developments on the Nagoya Protocol on Access to Genetic Resources (GR) and the Fair and Equitable Sharing of Benefits (ABS)-related implementing policies and keep IFRA and IOFI members informed.

On advocacy, the Task Force, with the support of the IFRA national associations, is currently focusing on continuing advocacy activities in Europe, Brazil and South Africa, and exploring any potential outreach in countries such as India. Therefore, the Task Force is discussing on the best way to provide capacity building capabilities for national associations that are already actively engaged in advocacy activities with local authorities such as in Brazil, South Africa, Europe.

On India, IFRA informed members through IFRA Information Letter 1070 that India, a signed Party of the Convention on Biological Diversity, issued an Office Memorandum on 18 March to grant another 60-day amnesty until 17 May 2019 to register commercial use of Indian biological resources. This provides another opportunity to companies using Indian biological resources to retroactively ensure compliance with the Indian biodiversity regulations.

On Brazil, IFRA and our National Member Association ABIFRA, the Brazilian fragrance and flavor association, hosted a webinar with 240 participants on 4 February on the impact of the ABS Brazilian Legislation on the fragrance industry. IOFI and ABIFRA organized a similar webinar for the flavor industry on 30 April.

As part of IFRA's outreach activities, IFRA and IOFI are evaluating the possibility of collaboration with well-known ABS-related initiatives such as Union for Ethical BioTrade (UEBT) and German Association for International Cooperation (GIZ). They also attended the UEBT conference held on 20-21 May in Paris.

At an international level, as a follow up of the 14th United Nations Conference of Parties (COP) of the



Convention on Biological Diversity (CBD) that took place in Egypt in November 2018, a call for information from the CBD Secretariat on Digital Sequence Information (DSI) has been launched. The International Chamber of Commerce (ICC) has developed a position that has been submitted to the CBD, recommending the exclusion of DSI from the scope of the Nagoya Protocol. IFRA and IOFI have also submitted their comments supporting the position developed by ICC.

The final draft of the IFRA-IOFI Guidance on the Nagoya Protocol and ABS implementing regulations was discussed on the latest IFRA-IOFI Nagoya Protocol TF meeting held on 25 June 2019. The aim of this guidance is to position the industry as a responsible partner and solution provider rather than searching to escape the regulation. This Guidance document provides a summary of the principles of the Nagoya Protocol, a better insight of the activities of the fragrance and flavor industries, as well as a summary of the ABS regulations in countries relevant for the F&F industry. A list of examples is also provided to illustrate the complexity of the regulatory framework of the Nagoya Protocol and ABS.



Standards

IFRA Standards / 49th Amendment under consultation: new IFRA categories and classes

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IFRA has finalized its preparatory work on the 49th Amendment to the IFRA Standards. This amendment is one of the largest projects ever undertaken by IFRA and unique in terms of the number of Standards revised and their presentation, the use of new tools for setting the Standards, and product categorization. These changes encompass the inclusion of an updated Quantitative Risk Assessment methodology developed under the International Dialogue for the Evaluation of Allergens (IDEA) and the consideration of aggregate exposure for dermal sensitization and systemic toxicity endpoints. Consequently, the IFRA product categories have also been modified. This new IFRA Standard-setting process has been thoroughly documented and has undergone legal review.

IFRA recently started a series of consultations related to the 49th Amendment. On 14 February 2019 IFRA opened the consultation on the IFRA Standard-setting process and the Guidance for the use of IFRA Standards. On 21 March IFRA informed members about the launch of the consultation process of the Standards themselves. Both consultations end on 21 July.

The following elements of the IFRA 49th Amendment are covered under the four-month consultation:

- **≡** IFRA Standard-setting process;
- Guidance for the use of IFRA Standards, providing detailed information about the new IFRA product categories;
- ≡ IFRA Standards (new or revised Standards), including their respective Annex I (natural contributions) and Annex II (Schiff bases).

All IFRA members, partners associations and other interested parties are encouraged to provide their input to all the consultations by the 21 July deadline.

During the preparatory process, IFRA has kept members informed of the latest developments through a series of Information Letters (IL1028, IL1032, IL 1040, IL1047, IL 1048, IL1055) and several webinars in collaboration with RIFM, showing a high level of transparency with stakeholders and explaining the new tools for deriving the Standards.

IFRA wants to acknowledge the great work done by the IFRA Risk Management Task Force (RMTF) and the IFRA Natural Complex Substances (NCS) task Force during the preparatory process of the 49th Amendment.

The next steps will be to collect and review the feedback received during the consultation period to prepare for finalization and notification.

IFRA will also offer an IFRA Standards communication toolkit for IFRA member to help explaining internal and externally the latest amendment to the IFRA Standards. This toolkit will include a press release, slides and a Q&A; there will also be an updated IFRA website section, webinars and 'train the trainer' workshops (see below).

The notification of the IFRA 49th Amendment is set to happen at the end of Q3 or beginning of Q4 2019.



IFRA Standards / **Outreach and 'Train the trainer' workshops underway**

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As part of the internal communications work on the 49th Amendment to the IFRA Standards, IFRA has launched a 'train the trainer' program that seeks to provide information to members and others on the latest update to the Standards, allowing them to share the information within their companies and with other colleagues, thereby promoting and enhancing the implementation of the new Standards.

Such workshops have already been held in Asia-Pacific, Latin America and Europe. In Jakarta in April, the first 'Train the Trainer' session was held, seeking to develop regional leaders on IFRA Standards and key elements of 49th Amendment. In Latin America, this workshop took place alongside the IFRA Regional Committee meeting in Mexico City in June. Sessions have also been held in Europe, including a presentation to the SIPC, the International Society of Master Perfumers at their Annual Meeting.



Initiatives

IFRA Socio-economic analysis / 'Value of Fragrance' study launch

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Martina Bianchini, President of IFRA, officially launched IFRA's new socio-economic analysis, 'The Value of Fragrance', at a press conference on 13 June in Mexico City. Martina was joined by the Chair of the IFRA LATAM Regional Committee, Miles Sakal, and Leonel Chagoya, the President of IFRA's Mexican national association (ANFPA) to set out the key findings of the study and what it means at global, regional and national level. The audience included Mexican media organizations, IFRA members and clients.

The report, conducted by the professional services firm PriceWaterhouseCoopers (PwC) on behalf of IFRA, highlights the contribution of the fragrance industry throughout the fragrance value chain in terms of gross value added (GVA) and employment. It defines the fragrance value chain for the first time and examines how our industry supports upstream suppliers and downstream customers.

IFRA Chairman Michael Carlos noted that, "The fragrance industry may be relatively small, but it makes a big impression. This report shows how we add significant economic value to our suppliers and customers, as well as consumers, for whom fragrance is a major factor in purchasing decisions".

The report highlights ten key findings which showcase the relevant value of the fragrance industry in society. In figures, the report estimates at €7.2bn the total Value Added generated by the fragrance industry, based on operations of the industry and suppliers, and employees spending their wages. The fragrance industry also supports more than 415,000 jobs. Research and Innovation (R&D) is also a key asset, with 8% of the proportion of net sales invested in R&D by fragrance manufacturers.

The report, which covers Europe, Latin America and Asia-Pacific, will serve IFRA members in communications and advocacy activities by providing data on the value of fragrance.

The global study launch was broadly disseminated through a <u>press release</u> posted on 13 June, on the <u>IFRA website</u> and on <u>Instagram</u> and <u>LinkedIn</u>. A part of the overall outreach plan, IFRA has developed a communication toolkit so all IFRA members, in particular National Association Members, can share the main findings with key internal and external stakeholders. The figures will also be segmented by regions.

IFRA invites all members and partners associations to read the study and make use of it for their advocacy and communication activities. Regional Committees and National Member Associations are encouraged to use the study as they see fit. If you have any questions or feedback on the study, please contact David O'Leary (doleary@ifraorg.org).

IDEA / Annual Review and progress on QRA2, surveillance project and alternatives to animal testing

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One of the key elements under IDEA (the International Dialogue for the Evaluation of Allergens), has been to advance the enhanced Quantitative Risk Assessment methodology (QRA2) for fragrance materials. Led by the QRA Expert group established under RIFM, the industry is progressing on preparing a publication on the QRA2.

Lot of progress has been made regarding the surveillance project that, due to improved quality control elements, should provide reliable data on trends in contact allergy to fragrance allergens to inform on the risk assessment and management process. The IFRA Board has expressed its support, mainly looking at it as a product stewardship initiative.



A protocol including a Case Report Form has been developed and the partners who should manage the data collection and treatment as well as the quality control element have been identified. Five clinics across Europe have been invited and have agreed to be part of the pilot project. This pilot aims at determining the adequate patch test concentration for the seven fragrance ingredients, as recommended by an IDEA workshop, as well as testing procedures (such as online data reporting). All clinics have participated during Spring to collect detailed information to help refine and conclude the protocol.

Besides the work on the surveillance, another priority for 2019 is the integration of alternatives to animal testing (AAT) into the QRA. A major focus of this integration is to derive potency information as basis for a NESIL derivation that could be used as a point of departure in the QRA. Two workshops dedicated to the topic were already organized, the last one having been held on 12 December 2018.

The workshop did not solely focus on the incorporation of AAT in the QRA but on the role that AAT approaches can play in the characterization and categorization of allergens. A report is available on the IDEA website together with the workshop presentations and key conclusions.

The Supervisory Group (SG) is currently investigating with the IDEA Management those activities that can build on the recommendations from the December workshop.

Regarding pre- and pro-haptens, substantial progress has been made on the specific element of formation of hydroperoxides for linalool and limonene and the clinical issue around testing with oxidized forms of both materials. Following the development and validation of suitable analytical methods, analysis of more than hundred materials has been performed. The outcome of this analysis does not suggest that the investigated products (hydroalcoholic products such as fine fragrances, deodorants, body lotions, face creams and aromatherapy products, including some products provided by clinics in Spain) play a significant role in the elicitation and, even less, induction to hydroperoxides of linalool and limonene.

The results of the quantification of Linalool and Limonene hydroperoxides in the above-mentioned consumer products were published in <u>Food and Chemical Toxicology Journal</u>, <u>volume 127 (2019)</u> pages 156-162.

- The Chair of the IDEA Supervisory Group, Prof Jim Bridges, gave a presentation on predicting potency of skin allergens without animal testing at the ECHA-EPAA workshop on 7-8 February in Helsinki, Finland. More information can be found under the 'Alternatives to animal testing / EPAA' news later in this edition of Heads Up!
- The IDEA Annual Review took place on 25 February 2019 at the European Parliament in Brussels. Julie Girling MEP opened the session. She pointed out that the objective of IDEA is to facilitate the development of high-quality safety assessment tools. Prof Jim Bridges, chair of the IDEA Supervisory Group, outlined the progress made under IDEA after six years. Prof Bridges emphasized the strength of IDEA in providing a platform for multi-stakeholder exchange on issues around fragrance allergy in Europe. One of the key elements developed under IDEA in recent years has been a revised and improved version of the Dermal Sensitization QRA. Prof Thomas Rustemeyer from the University Hospital in Amsterdam then presented progress on establishing a surveillance project to follow trends in clinical reactions. The purpose is to provide a reliable basis for feedback into the risk assessment and management process.

Prof Bridges reported on progress on the identification of non-animal approaches to provide information on potency. Dr Matthias Vey, IFRA Scientific Director, updated participants on the status of the collection of exposure information on hydroperoxides of limonene and linalool to broaden understanding of exposure (see above for details of this project). The meeting concluded with a presentation of the vision for 2019. IFRA Chairman Michael Carlos reconfirmed the industry's commitment to IDEA and its projects. All presentation are available on the IDEA website.

Sustainability Initiative / IFRA-IOFI project moves to the final steps

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The IFRA-IOFI Sustainability Task Force continues its progress on finalizing the 'Charter in Action'. After approval of the final package by the taskforce, the core team is close to gathering and aggregating the first company report information into an industry snapshot.

The Sustainability Initiative, a joint project with IOFI, seeks to raise awareness within the sector; to give small



and medium enterprises a toolbox to help them rise the bar on sustainability; to report on progress at industry level; to build stakeholder trust; and to identify partners and collaborate along the value chain.

Its five main focus areas are securing sustainable sourcing throughout the value chain; reducing the fragrance and flavor industries' environmental footprint and addressing climate change; enhancing the well-being of employees and ensuring a rewarding labor environment; ensuring that we are at the leading edge of product safety; and making sure that we are seen as a transparent and a reliable partner for society.

The IFRA-IOFI Sustainability Charter is expected to be officially launched and rolled out in early 2020.

IFRA Communications / New IFRA website and social media channels

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The new IFRA website was launched in June at <u>ifrafragance.org</u>. With a fresher, more friendly and rejuvenated look, the website has six sections covering self-regulation, IFRA initiatives, policy and regulation, news, information about fragrance and information about IFRA. The new site is mobile-friendly and seeks to provide people with information about our industry in a clear and easy-to-understand way. We encourage members to visit and share their suggestions and comments with us.

In parallel, IFRA has begun to establish a limited presence on social media as a way of bringing information to new audiences and building a positive online voice for the industry. A 'social media playbook' has been developed and we have begun to post on <u>LinkedIn</u> and <u>Instagram</u>. Links to these and all our social media channels can be found on the IFRA website homepage or by searching for 'IFRAfragrance' on each channel. We welcome members and interested stakeholders to follow us on social media.

For internal communication and event management, IFRA has decided to phase out its Extranet as of June 2019. The Extranet has been largely replaced by Sharepoint and is currently used only to organize meetings. It will be replaced a simpler and more cost-effective online registration form that does not require log-in details.

Glossary / IFRA Fragrance Ingredient Glossary to be launched shortly

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IFRA's Fragrance Ingredient Glossary will be launched shortly, providing a list of harmonized positive olfactory descriptors for all fragrance materials on the IFRA Transparency List. It establishes a single harmonized vocabulary, offering consistent information to the industry, in particular to customers and suppliers. It also seeks to increase transparency and trust.

The Fragrance Ingredient Glossary – known as the 'FIG' – will be voluntary, for use with suppliers and customers. To ensure that it can be used throughout the value chain, it will be made available for download from the IFRA website using a simple form. It may be used later for wider public communications and will be available for use in projects by others (subject to attribution), including the Fragrance Creators Association's Fragrance Conservatory (see below).

Fragrance ingredients / Fragrance Creators Association continues work on the Fragrance Conservatory

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As fragrance and fragrance transparency continue to gain momentum with consumer audiences, Fragrance Creators is developing The Fragrance Conservatory – a consumer-facing website to house credible, relatable information about fragrance and fragrance ingredients. This effort is being steered by an Interested Party Group of Fragrance Creators members: Arylessence, Bell Flavors & Fragrances, Citrus and Allied, Chanel, The Clorox Company, Estee Lauder, Firmenich, IFF, Johnson & Johnson, P&G, SC Johnson, Revlon, Robertet, and



Takasago. RIFM and IFRA are providing support to ensure accuracy on science and on the IFRA Standards. The website will be launched in 2019.

The website does not include detailed odor descriptors at this time, but Fragrance Creators looks forward to the completion of the IFRA Fragrance Ingredient Glossary and incorporating information from the FIG in the Fragrance Conservatory.

India / IFRA delegation meets key stakeholders

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In March, an IFRA delegation headed by IFRA President Martina Bianchini and IFRA Chairman Michael Carlos met a range of stakeholders in India.

The meetings included discussions with a representation from FICCI - Federation of Indian Chambers of Commerce and Industry on 6 March. The IFRA delegation, along with the RIFM President Jim Romine and FAFAI (Fragrance & Flavour Association of India) met senior officials from the Ministry of Commerce and Industry of India.

The week of events concluded with IFRA participation in the National Seminar on Creating Awareness on Standardization & Regulation among Fragrance & Essential Oil Industry event on 7 March. The event was jointly organized by the Bureau of Indian Standards (BIS) and the Indian Institute of Integrative Medicine (CSIR IIIM).



IFRA and partners

IFRA Global Fragrance Summit / 2020 meeting to be held in Singapore

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After Barcelona and Paris, IFRA goes to Asia for the next edition of its annual meeting – the Global Fragrance Summit. This flagship event will take place in Singapore from 1-3 April 2020.

The summit will offer a platform for discussion, debate and networking with speakers from perfumery, consumer goods, science, business, government and beyond. IFRA will also present its latest initiatives to be launched during 2019.

Under the theme 'Small Scale, Big Impact', this event will showcase how the fragrance industry is a relatively small one with a big impact. At this Global Fragrance Summit, we'll be looking at a series of themes, including emerging policy, innovation, transparency, wellbeing and sustainability, to see how small changes can have global effects.

Further information on registration and hotel reservations will be communicated shortly. In the meantime, if you are interested in attending, or in participating in or sponsoring a session, or just have a suggestion, please click this <u>link</u>.

IFRA Europe / Active stakeholder engagement

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IFRA Europe continues to ensure advocacy and support to members in the region through active stakeholder engagement.

Charles Laroche attended the general assembly of SFFIA, IFRA's Swiss national association, on 21 May. In June IFRA Europe hosted its second Regional Committee meeting of the year and a meeting of the National Association Network.

Charles also participated, alongside IFRA President Martina Bianchini, in the AGM of our French national association member. Prodarom.

Externally, Charles spoke at the Agrimer 'Future of Naturals' event on 24 May in Grasse, France and attended the A.I.S.E. AGM on 19-20 June in Milan, Italy. Along with Nicole Vaini, IFRA Europe's Regional Issues Manager, Charles attended the Cosmed Aromadays event on 4–5 July in Avignon, France, where Charles gave a presentation on essential oils and allergies.

IFRA Europe will hold its next IFRA Europe Regional Committee meeting on 12 September 2019 in Brussels, followed by the 11th IFRA Europe Fragrance Party.

IFRA APAC / IFRA strengthens its outreach activities in Asia-Pacific

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As part of IFRA advocacy and stakeholder engagement in the Asia Pacific region, the IFRA APAC Regional Director, Rohaya Mamat, has put in place an extensive agenda of activities during Q2 2019.

In April, IFRA APAC held a series of events in **China** and **Indonesia**. On 9 April the IFRA APAC Technical



Committee met in China, followed by a meeting of the IFRA China Working Group the following day. Activities in China included a presentation on IFRA and the IFRA Standards given by Rohaya Mamat to students at the Shanghai Institute of Technology. Rohaya also had the opportunity to meet the President, Vice President and Dean of the School of Perfume and Aroma Technology. IFRA also met the CCIA (China Cleaning Industry Association) to discuss the aligned position of both associations on the China Dishwash Standard that was shared separately with authorities in January 2019.

In Indonesia, an IFRA delegation sought to raise awareness of the IFRA Standards and the upcoming 49th amendment to the Standards and discuss on the challenges faced by the industry in the country. This delegation, led by Martina Bianchini, met BPOM RI (the national drug and food control agency) on 23 April. The delegation also met with a group from PEKERTI (Household Products Industry Association). The following day, the delegation met the Halal Product Assurance Organizing Agency. The IFRA delegation also participated in an IFRA Standards workshop organized by AFFI, the IFRA National Association in Indonesia on 24 April. This seminar was well-attended by AFFI members, and representatives of PERKOSMI (Indonesia Cosmetics Association), BPOM, PEKERTI and Dewan Atsiri Indonesia.

Rohaya Mamat organized two IFRA workshops on IFRA Standards and the IFRA Code of Conduct on 26 April in Jakarta. As well as the first 'Train the Trainer' workshop on the IFRA Standards (see above), IFRA APAC hosted another session giving an overview of IFRA initiatives with a focus on the IFRA Standards and the forthcoming 49th Amendment. There were more than 70 participants from client companies, small and medium enterprise companies from Indonesia and Vietnam, as well as IFRA members and partners associations (CTFAS and ACA).

IFRA LATAM / Regional meetings held in Mexico

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The latest IFRA LATAM Technical Committee (TC) meeting took place on 11-12 June in Mexico City. It was followed by the IFRA LATAM Regional Committee (RC) meeting on 13 June. Representatives from IFRA member companies and national member associations from Argentina, Brazil, Chile, Colombia, and Mexico attended the meetings. Participants discussed and defined priorities and actions for the region that covered a series of topics related to the 49th Amendment to the IFRA Standards, chemical control legislation, sustainability (including Nagoya Protocol and ABS), and alternatives to animal testing and more.

IFRA President Martina Bianchini announced at the meetings that Eugenia Saldanha is the new IFRA LATAM Regional Director and Eduardo Valle the new LATAM Regional Issues Manager. Following the success of IFRA Europe and the recent launch of IFRA APAC, the new IFRA LATAM regional office will be inaugurated this year in São Paulo, Brazil. IFRA LATAM will share facilities with ABIFRA, the Brazilian fragrances and flavors industry association. The office and its staff will support IFRA members and the implementation of the IFRA strategy in the region.

At the Technical Committee Meeting of 11 June, representatives from each of the five LATAM member associations updated the participants on their respective country's local challenges and opportunities. From country-specific political and economic contexts to issues that may escalate to the regional or global levels, the country reports provided important input for the development of a more robust regional strategy for the fragrance industry in Latin America.

The discussions in Mexico also highlighted the relevant and transversal role of communications at global, regional and local levels. David O'Leary, IFRA Communications Director, presented the updated communications plan with a focus on clearer messaging and making more of IFRA's key initiatives, such as The Value of Fragrance report, the IFRA Fragrance Ingredient Glossary; the IFRA Standards and the IFRA-IOFI Sustainability Initiative.



IFRA / IFRA Environmental Task Force meeting

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The Environmental Task Force (ETF) held a meeting on 19 March 2019. This group is currently working on a series of topics.

On the issue of Poorly Biodegradable Organics (PBO) in the context of the A.I.S.E. Charter for Sustainable Cleaning, IFRA and the International Association for Soaps, Detergents and Maintenance Products have developed guidance on how to report those ingredients. Both associations agreed to change the key performance indicator and draft guidance is now available. With the revised approach, figures seem to bring down the in range of about 30 per cent.

The ETF is also working on an emissions project in the United States, which is linked to the defense of IsoE super at the US Environmental Protection Agency (EPA). This exercise, which is done on an ingredient-specific basis, will have relevance for all types of ingredients. A working group is being established to define a survey to capture accurate figures of amounts of fragrance mixtures remaining in drums where the EPA still assumes a number of three to four per cent. It should include collecting data from downstream users. It appears that facilities need to be in the US to ensure data are not challenged by the EPA.

Additionally, ETF is contributing to the development of the A.I.S.E. Environmental Safety check tool.

At EU level, ECHA (European Chemical Agency) is required to regularly prioritize the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorization. In the context of ECHA's eighth recommendation for the inclusion of substances in Annex XIV of REACH Regulation, the fragrance ingredient Karanal group, currently identified as a Substance of Very High Concern (SVHC), has been included in the Candidate List for authorization on 15 June 2015 (ECHA decision ED/39/2015). Based on the prioritization criteria applied, the Karanal group has received priority among the substances in the Candidate List and has been recommended for inclusion in Annex XIV.

However, it has been included to the Authorization List yet. Meanwhile, ongoing studies should help to decide on adequate risk management measures under the IFRA Standards.

Alternatives to Animal Testing / IFRA continues its commitments to CAAT and EPAA

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IFRA continues its commitment to both the global Center for Alternatives to Animal Testing (CAAT) and to EPAA, the European Partnership for Alternatives to Animal Testing.

EPAA grants to give support for alternatives to animal testing: the European Partnership for Alternatives to Animal Testing (EPAA) - of which The International Fragrance Association is an industry partner - has published calls for submissions for 3Rs Student Grants and the 2019 Refinement Prize. Every year, a number of high-profile international meetings bring together world-class scientists working on the development and acceptance of '3R' alternatives to animal testing (replacement, reduction or refinement). Costs linked to participation may prevent students with promising work from attending these events, so EPAA partners such as IFRA proudly sponsor the 3Rs Student grants to facilitate participation in such events. Find out more here.

EPAA has also launched its call for submissions for the Refinement Prize 2019. This prize of €6,000 will be granted to a laboratory technician, animal caretaker or technologist who has demonstrated outstanding achievements in new, novel approaches to advance implementation and/or awareness raising of refinement of animal testing. Find out more <u>here</u>.

IFRA joins EPAA and CEFIC-LRI in alternatives workshop: IFRA Europe joined with EPAA and Cefic-LRI to convene a meeting with relevant industry and EU member state regulatory agencies at the European Chemicals Agency (ECHA) in Helsinki on 7-8 February 2019. At this training workshop, participants discussed the progress made in applying non-animal testing strategies for assessing skin sensitization. Representatives also discussed



the challenges that remain, especially when dealing with difficult substances. You can find here a <u>link to the presentations</u>: and to a <u>video of the workshop</u>. Also, a manuscript for publication is under preparation.

SCCS workshop on Alternatives: The SCCS Working Group on Methodologies held a Scientific Workshop on Alternative Methods to Animal Testing in Human Health Risk Assessment of Cosmetic Ingredients on 27 February 2019 in Brussels. This was a closed invitation-only workshop which Matthias Vey, IFRA Scientific Director, and Amaia Irizar, IFRA Senior Toxicology Associate, attended. The minutes of the workshop can be found in this <u>link</u>.

New Approach Methods in Read-Across Workshop: On behalf of IFRA, Amaia Irizar attended the EU-ToxRisk workshop on 'New Approach Method (NAM)-supported read-across: from case studies to regulatory guidance in safety assessment' held on 21-22 May 2019 in Espoo, Finland. Altogether, a group of more than 60 international experts from industry, academia and regulatory authorities came to discuss a total of five scientifically advanced project case studies developed within EU-ToxRisk, the OECD/IATA program, and NIHS lapan. More information about the case studies examined can be found here.

IFRA Scientific Director meets CAAT: IFRA continues to work closely with the Center for Alternatives to Animal Testing. In Berlin in March, IFRA's Scientific Director, Dr Matthias Vey, held a meeting with CAAT representatives to discuss ongoing collaboration.

New Supporting Member / Imperial Fragrances & Flavours joins IFRA

Martina Bianchini mbianchini@ifraorg.org

Imperial Fragrances & Flavours Pvt Ltd, based in Kolkata, India, has become the latest Supporting Member of IFRA. Under the IFRA bylaws, supporting membership is open to companies based in countries where there is no IFRA National Association. The IFRA Board accepted Imperial's application on 21 February.

New staff / IFRA LATAM new team members

Martina Bianchini mbianchini@ifraorg.org

IFRA is pleased to announce a new set-up for IFRA LATAM, with Maria Eugenia Saldanha, Executive Director of Abifra, now working 50% for IFRA LATAM until December 2019. Maria Eugenia Saldanha is already well known to our industry through her role as Executive Director of ABIFRA. This new 50-50 time split between her work for ABIFRA and for IFRA LATAM will be in place for six months and reviewed in Q1 2020 to ensure it is feasible in the long term.

In addition, Eduardo Valle has joined IFRA in June as the new IFRA LATAM Regional Issues Manager. He previously worked in a public affairs consulting firm in São Paulo, covering sectors from agriculture and health to technology, energy, and the environment in Brazil and LATAM. He also served government and public research institutions in Brazil, such as the Brazilian Agency for Industrial Development (ABDI), in Brasília, and the State of São Paulo Institute for Technological Research (IPT), working mostly with innovation and sustainability-related projects and partnerships.

As a Fulbright Scholar, Eduardo has obtained an M.A. degree in International Relations with specializations in Latin American and Science, Technology & Environmental Policy from Syracuse University, NY. He has also been a visiting researcher or fellow with international organizations (United Nations, Organization of American States) and think tanks (National Academy of Sciences, VTT Technological Centre) in the United States and Finland.



Meetings and events

June

4-5 June / New York, USA IFRA and RIFM Board meetings

5 June / New York, USA

FiFi Awards

5 June / Paris, France

SIMPPAR-International Exhibition of Raw Materials for Perfumer

10-11 June / Helsinki, Finland

International Conference on Dermatology and Allergic Diseases (Allergic Diseases 2019)

11 June / Brussels, Belgium

Cosmetics Europe Annual Conference 2019

11-13 June / Mexico City, Mexico

IFRA LATAM Technical Committee (TC) and Regional Committee meetings

17 June / Brussels, Belgium

IFRA Europe National Associations Network meeting

18 June / Brussels, Belgium

IFRA Europe Regional Committee meeting

19-20 June / Milan, Italy

A.I.S.E. AGM

17-21 June / Seoul, South Korea

ChemCon Asia 2019

25 June / Brussels, Belgium

IFRA-IOFI Nagoya Protocol TF meeting

26 June / Paris, France

Prodarom AGM

26-28 June / Seoul, South Korea

In-Cosmetics Korea

July

4-5 July / Avignon, France

Cosmed Aromadays

15-18 July / Hawaii, USA

International Union of Toxicology (IUTOX)

19-28 July / Grasse, France

Festival du Parfum

August

16-28 August / Geneva, Switzerland **UN CITES COP-18**

25-28 August / San Diego, USA

American Chemical Society (ACS) Fall 2019



September

8-11 September / Helsinki, Finland **Eurotox 2019**

11 September / Brussels, Belgium

IFRA Europe National Associations Network meeting

12 September / Brussels, Belgium

IFRA Europe Regional Committee Meeting, plus IFRA Europe Fragrance Party

12 September / Weehawken, NJ, USA

RIFM Board Meeting

18-19 September / Sao Paolo, Brazil

In-Cosmetics LATAM

20 September / Sao Paolo, Brazil

CASIC Regulations Conference

19 September / Brussels, Belgium

EPAA Steering Committee and Strategy meeting

23-25 September / New Jersey, USA

RIFM Expert Panel Meeting

29-30 September / Bali, Indonesia

2019 IFEAT Conference

30 Sept-2 October / Milan, Italy

25th IFSCC Conference (ComsEthic)

October

1-4 October / Viña del Mar, Chili

The 3rd International Flavor and Fragrance Conference, IFFC2019

10-13 October / Linz, Austria

EUSAAT-European Congress on Alternatives to Animal Testing

10 October / Brussels, Belgium

IOFI 50th Anniversary

15 October 2019 / London, UK

IFRA UK Annual Meeting

16-17 October 2019 / Geneva, Switzerland

IFRA-IOFI GHS TF meeting

22 October 2019 / Geneva, Switzerland

IFRA Natural Complex Substances (NCS) TF meeting

23-24 October 2019 / Geneva, Switzerland

IFRA Environmental (ETF) TF meeting

29 October 2019 / Brussels, Belgium

EPAA Annual Meeting

April 2020

1-3 April 2020 / Singapore IFRA Global Fragrance Summit