

Report on the IDEA (International Dialogue for the Evaluation of Allergens) 7th Annual Review

Advancing a collaborative and science-based methodology for risk assessment of fragrance skin sensitizers

*Thursday 29 January 2026 – In-person event (13.30 – 16.45)
Sofitel Bruxelles Europe, Place Jourdan 1, 1040 Brussels, Belgium*

Moderator: Dr. Matthias Vey, IFRA Vice-President for Scientific Affairs.

Report prepared by the IFRA team.

In-person: Nathalie Alepee (L'Oreal), Hind Assaf Vandecasteele (L'Oréal), Julia Baines (PETA UK), Caroline Bassoni (COSMED), Cristina Bentio Vioria (Spanish Agency of Medicines and Medical Devices (AEMPS)), Ofelia Bercaru (ECHA), Fanny Boislève (Chanel), Emanuela Corsini (University of Milan), Jennifer Dorts (IFRA), Matthias Vey (IFRA, moderator), Andy Forreryd (SenzaGen), Lorena Gonzalez (Eurofragrance), Kelly Goris (The Regulatory Company), Peter Griem (Symrise), Joseph Huggard (Huggard Consulting), Hans Ingels (European Commission) (partly), Amaia Irizar (IFRA), Tobias Koppitz (DVRH), Katia Lacasse (Cefic), Charles Laroche (EFEO), Andrea Maltagliati (EFFCI), Philippe Massé (PRODAROM), Alexander Mohr (IFRA), Giorgio Moreschetti (EFFCI), Loukas Papavasileiou (European Parliament) (partly), Aurelie Perrichet (IFRA), Gretchen Ritacco (RIFM), Vera Rogiers (SCCS Observer), Thomas Rustemeyer (University of Amsterdam, IDEA SG), Cesar Scrochi (Crème Global), Katherina Siewert (German Federal Institute for Risk Assessment – BfR, partly), Pamina Suzuki (Cosmetics Europe), Martin ter Bekke (P&G), Wolfgang Uter (University of Nuremberg), Erik Van Miert (dsm-firmenich), Lei Samekto (IFRA), Christos Vasilakos (European Parliament, partly), Johannes Weiss (IFRA), Nicolas Wolf (LVMH).

Apologies: Gergana Andreeva (BNAEOPC), Cristina Arregui (IFRA), Jim Bridges (IDEA Chairman), Silvia Casati (European Commission), Pieter-Jan Coenraads (SCCS Observer), Julie Janssis (AISE), Petra Kern (P&G), Ian Kimber (University of Manchester, IDEA SG), George Manikas (European Commission), Virginie Noret (LVMH),

Summary of discussions

Session 1: Advancing risk assessment through state-of-the-art science and data

Welcome and opening remarks

→ **Hans Ingels, Head of Unit Bioeconomy, Chemicals & Cosmetics (GROW.F.2), European Commission**

Mr Ingels set the scene by outlining the evolution of the EU chemicals framework and reaffirmed the critical role of science-based risk assessment, in particular approaches that do not rely on animal testing. He stressed that this remains essential for the safety assessment of fragrances, which requires robust, scientifically sound methodologies.

He underlined that the context for the IDEA project has evolved significantly since its launch. Recent geopolitical developments have shifted the EU's overarching focus from the European Green Deal towards the European Clean Industrial Deal. Nevertheless, he emphasised that safety, consumer

protection, and science will remain at the core of EU policies, and that work on skin sensitizers continues to be of high importance, given the inherent scientific complexity of skin sensitization.

Mr Ingels also referred to ongoing institutional and regulatory developments, including the Simplification Omnibus initiative and the future integration of the SCCS within ECHA. He noted that later this year, the European Commission will launch a call for applications for the renewed mandate of SCCS members, highlighting the importance of preserving the independence of the SCCS within ECHA.

Looking ahead, he explained that Omnibus VI is expected to increase the SCCS workload, notably due to a higher number of harmonized classification (CLH) dossiers and an increased number of derogation requests. In this context, he recognized the value of the work conducted under IDEA as a bridge between science and trust, contributing both to the protection of European consumers and to European industrial competitiveness.

→ Alexander Mohr, IFRA President

Mr Mohr reaffirmed IFRA's partner-based approach to its work and cooperation with stakeholders. He thanked all participants for their engagement and expressed particular appreciation to Matthias Vey for leading the organization of the meeting.

Session 1 Advancing risk assessment through state-of-the-art science and data

1.1 – Scientific advances in skin sensitization assessment

→ Dr. Amaia Irizar and Dr. Peter Griem (IDEA Management Team)

The presentation focused on providing a Progress report on integrating non-animal scientific tools (New Approach Methodologies (NAMs)) into the QRA methodology as well as perspectives on practical implementation. Dr. Amaia Irizar opened the session by revisiting the evolution of Quantitative Risk Assessment (QRA) for fragrance ingredients as embedded in the IFRA Standards. She outlined how the method, initially mainly relying on human and animal data, supports setting safe use levels for sensitizing ingredients. Dr. Irizar emphasized current efforts to advance regulatory acceptance of QRA methodology that relies solely on New Approach Methodologies (NAMs), enabling future assessments without the use of animal or human data.

A key element of this work is the Reference Chemical Potency List (RCPL), which ranks 110 chemicals using potency values derived from human and animal evidence. The RCPL now provides a benchmark for evaluating NAM performance and serves as a foundational point of departure (PoD) for integrating NAM-derived NESILs into QRA.

Dr. Peter Griem expanded on how NAM-based QRA can be applied to clinically relevant fragrance allergens. He showed that potency predictions from all three validated NAM approaches, Regression Defined Approach, SARA-ICE Defined Approach, and GSDR, correlate strongly with the RCPL potency values. This consistency confirms that NAM-derived PoDs can reliably support QRA, including for new fragrance materials where no traditional data exist. He also noted that NAM-derived NESILs tend to be conservative compared to existing RIFM NESILs, reinforcing confidence in their protective value.

Together, the speakers highlighted that NAM-only QRA is now scientifically robust and practically applicable. With defined adjustment factors to account for method-specific variability for when no other data are available, the fragrance sector is positioned to implement QRA for new materials based exclusively on NAM data. The next priority is gaining regulatory acceptance to enable full transition away from animal and human testing in skin sensitization safety assessment.

Session 1.2 – Exposure and use data: Addressing the gaps

→ Cesar Scrochi (Creme Global) and Gretchen Ritacco (RIFM)

Cesar Scrochi presented the Creme-RIFM Aggregate Exposure Model, a probabilistic, data-driven system developed to accurately estimate consumer exposure to fragrance ingredients across multiple product categories and routes of exposure. He introduced the model's broad scope, covering cosmetics, personal care, air care, and household products, and populations in the US, Europe, and Singapore. The presentation outlined how the Creme-RIFM model calculates exposure by drawing on robust data sources, applying structured model calculations, integrating exposure and optimization frameworks, and offering customization, flexibility, and forthcoming enhancements.

He highlighted how the model integrates detailed habits and practices data derived from large-scale, high-quality consumer usage surveys, notably the Kantar World Panel, which now includes updated 2023–2024 diaries, new product types, refined body-region application data, and expanded demographic coverage, including infants. These data address long-standing exposure information gaps and respond directly to questions raised by bodies such as the SCCS.

Gretchen Ritacco explained that traditional deterministic methods tend to overestimate exposure by assuming maximal use of all products. In contrast, the Creme-RIFM model uses distributions of actual consumption behaviors, including variability in frequency, amounts applied, retention factors, penetration factors, and ingredient concentrations, to generate realistic population-level and individual-level exposure estimates across dermal, oral, inhalation, and systemic routes.

She further demonstrated how these data strengthen safety assessments by supporting more accurate risk characterization, placing exposures to fragrance ingredients, which are considered very low, into context. Analyses show that exposure to fragrance ingredients across product categories remains orders of magnitude below levels of concern for the vast majority of consumers, including high-exposure “loyal consumers.” Reference to a respective publication was provided.

Overall, the presentation showed how robust, regularly updated exposure modelling, built on high-quality survey inputs and industry concentration data, plays a central role in closing information gaps and ensuring more realistic, human-health-relevant safety assessments across the fragrance value chain.

Session 2: Science in practice: Clinical surveillance, dialogue, and policy coherence

Opening remarks – Perspectives on ongoing EU legislative files shaping fragrance and cosmetic safety

→ Christos Vasilakos, Head of Office to MEP Dimitris Tsiodras (EPP, Greece), coordinator for Parliamentary work in ITRE, ENVI and IMCO Committees

Mr Vasilakos provided an overview of the current EU policy context, with a focus on the 2024–2029 EU mandate, which places strong emphasis on competitiveness, innovation and regulatory simplification. He highlighted several key legislative initiatives shaping the future of chemicals and cosmetics regulation, including Omnibus VI on Chemicals and the ECHA Basic Regulation, and their relevance for fragrances and cosmetic safety.

He underlined the importance of risk-based and proportionate regulatory approaches for consumer products such as cosmetics. In this regard, he stressed the need to consider exposure, conditions of use and safe use, in addition to hazard identification, in order to ensure balanced and proportionate rules that effectively protect consumers while supporting innovation.

Mr Vasilakos expressed strong support for collaborative, multipartite platforms such as IDEA, recognizing their value in informing policy debates with robust scientific evidence and strengthening the science-policy interface. He emphasized that preserving science in EU decision-making is essential for better regulation.

From a European Parliament perspective, he shared practical advice on how stakeholders can most effectively contribute to policy discussions:

1. Engage early in the legislative process.
2. Frame scientific evidence clearly, explaining concrete implications in accessible and straightforward terms.
3. Be transparent about uncertainties, noting that openness strengthens credibility rather than undermines it.

In conclusion, Mr Vasilakos highlighted why initiatives such as IDEA matter: by bridging perspectives, supporting science-based dialogue, and contributing to better regulation. He emphasized that the future of EU chemicals policy will depend on strong science and continued, open dialogue, making science-based engagement not just desirable, but a necessity.

Session 2.1 – Surveillance in practice: EFISS early insights

→ Prof. Thomas Rustemeyer and Dr. Matthias Vey

Prof. Thomas Rustemeyer introduced the EFISS (Extended Fragrance Ingredients Surveillance Study), outlining its objectives, scope, and early learnings. He reminded participants that EFISS is an industry-sponsored, multi-year clinical surveillance study designed to generate high-quality data on skin contact allergy to fragrance ingredients. As he explained, the project responds to a key expectation from the European Commission and other stakeholders, which is that QRA2 must be supported by a robust post-market stewardship program grounded in clinical surveillance.

Dr. Vey further detailed the two-phase structure of EFISS: an initial pilot phase followed by a large-scale extended study. The pilot, conducted in 2022 across four dermatology clinics and involving around 400 patients, focused on establishing appropriate patch test concentrations for additional fragrance materials, so far not routinely patch tested, and verifying the functionality of the study processes. This included deploying a new syringe auto-dosage system and strengthening quality-control measures such as training sessions and site visits. Results from the pilot, published in *Contact Dermatitis*, confirmed that the methodology is both feasible and reliable.

Moving to the full study rollout, he highlighted efforts to ensure harmonization and rigorous quality control, including a dedicated patch-test reading workshop held in 2024 at Malmö University Hospital. During this workshop, clinicians and nurses practiced standardized chamber-loading techniques and performed blinded readings to refine interpretation skills, particularly for distinguishing weak sensitization from irritation.

Dr. Vey shared that clinic recruitment is now complete, with 9 clinics across 8 European countries engaged, and ethics approvals nearly finalized. The extended study will operate over three testing cycles of approximately 15 months each, targeting more than 8,000 patients overall. The study protocol was published in 2025, and the first cycle is currently underway, expected to conclude in early 2026.

Finally, he noted early reflections from clinical and academic partners, emphasizing strong collaboration, the importance of standardized methodologies, and the value of EFISS as a future early-alert system capable of identifying trends in fragrance-related contact allergy. The insights generated will help evaluate actual exposure conditions, assess whether existing risk-management measures are sufficiently protective, and guide corrective actions where needed.

Panel discussion – Bridging science and policy

Panelists:

- Dr Julia Baines, Head of Science Policy at PETA UK and Science Advisor at PETA Science Consortium International
- Dr. Amaia Irizar, Senior Toxicology Associate, IFRA and IDEA Management Team
- Prof. Dr. Thomas Rustemeyer, member of the IDEA Supervisory Group and EFISS
- Dr. Katherina Siewert, Head of Dermatotoxicology Study Centre, The German Federal Institute for Risk Assessment (BfR) (*unable to attend the panel due to travel disruptions*)

The panel discussed how to strengthen the interface between scientific progress and regulatory decision-making, focusing on the interplay between risk assessment, surveillance, and policy.

A central theme was the importance of linking clinical surveillance with risk-assessment methodologies to support better-informed regulations. Panelists emphasized that science-driven, transparent, and collaborative approaches are essential for strengthening trust among regulators, clinicians, NGOs, and industry. As noted, IDEA provides a valuable consensus-building forum that has fostered trust over many years.

The discussion highlighted what makes a collaborative platform resilient: Dr. Irizar pointed to the need for shared ownership, openness, and sustained partnership, while Dr. Baines underscored the value of initiatives such as EPAA (European Partnership for Alternatives to Animal Testing), where regulators, NGOs, academia, and industry contribute collectively to advancing alternatives. Transparency and inclusion, “having all stakeholders in the same room”, were described as foundational.

Prof. Rustemeyer raised a practical regulatory challenge: although 81 fragrance allergens now require labelling under EU law, validated diagnostic test material for many of them is not yet available, making it difficult for clinicians to assess contact-allergy patients. This gap illustrates the tension between regulatory requirements “on paper” and implementation feasibility.

The panel also examined barriers to wider regulatory uptake of NAMs. Dr. Baines noted that aspects of the EU regulatory framework still limit NAM acceptance. Dr. Irizar added that NAMs require lengthy validation processes and that capacity building is crucial, not only in expanding CRO capabilities, but also in developing expertise within industry and regulatory agencies. She stressed that cocreating such capacity is an essential component of collaboration.

During the Q&A, a question from the audience addressed the role of education. Prof. Rustemeyer acknowledged that structured education is not currently part of IDEA's mandate but agreed that fragrance-specific training, particularly in patch testing and interpretation, could be highly valuable for clinical practice.

Dr. Baines concluded by reflecting on the significance of being the first NGO invited to the IDEA forum. She highlighted the strong alignment of interests, particularly on NAM development and acceptance, and encouraged continued efforts to “consider your partners,” noting that even well-established organizations often remain unaware of parallel work unless explicit bridges are built.

Closing remarks and way forward

→ Dr Ofelia Bercaru, Director of Prioritization and Integration, ECHA

Dr. Ofelia Bercaru began by expressing her appreciation for being invited to the meeting, noting that this was her first exposure to IDEA's collaborative platform and that she valued the opportunity to better understand its work.

She highlighted ECHA's ongoing efforts to advance NAMs, particularly through the development of test guidelines and their integration into REACH requirements. Linking this work to the European Commission's Roadmap for phasing out animal testing in chemical safety assessment, she underlined

ECHA's support for a stepwise, coherent transition. The forthcoming Roadmap, expected by summer, should acknowledge both the progress made and the significant remaining gaps, including:

- The gap between academic innovation and regulatory readiness.
- Insufficient validation pathways and criteria.
- Limited development in key scientific areas, such as toxicokinetics and computational approaches.

ECHA has submitted concrete recommendations to the Commission to address these shortcomings. In the long term, she emphasized, achieving full replacement of animal testing will require major scientific advances, sustained commitment, and willingness from all actors to adapt, and ECHA stands ready to contribute.

On collaboration, Dr. Bercaru stressed the need for strengthened dialogue between scientists and regulators to bridge the gap between scientific development and regulatory enforceability. ECHA is actively building collaborative platforms on NAMs, bringing together Member State representatives and scientific partners to support capacity building, which she identified as essential for ensuring understanding, trust, and consistency across Europe.

She also emphasized the importance of forums such as IDEA and EPAA, which help align scientific innovation with future regulatory needs and promote convergence between what science can deliver and what legislation will require.

A key takeaway from her intervention was the value of high-quality clinical data, such as those generated in IDEA's surveillance activities, for understanding population-level impacts and informing proportionate and protective regulatory outcomes.

Dr. Bercaru encouraged IDEA to continue facilitating close cooperation between scientific bodies, fostering methodological consistency, and maintaining strong bridges between ongoing scientific progress and other relevant initiatives. She also noted that ECHA has recently been entrusted with expanded responsibilities, including through the OSOA and the ECHA Basic Regulation, aimed at strengthening regulatory coherence. As part of this evolution, the SCCS will be transferred to ECHA, signaling recognition of the need for more integrated approaches, including NAM-based methods.

She closed by thanking the organizers for the opportunity to deliver the concluding remarks, expressing hope that continued collaboration will accelerate NAM development and build stronger bridges between all stakeholders.

Closure of the meeting

To conclude the meeting, Matthias Vey thanked all participants for their engagement and contributions throughout the day.
