

The fragrance industry's recommendations for targeted REACH adjustments

The Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the EU's cornerstone legislation regulating chemicals. Since its adoption, REACH has significantly improved knowledge on chemical substances through registration and evaluation and has enabled the management of risks through authorisation and restriction processes. The framework has contributed to ensuring a high level of protection of human health and the environment while supporting the functioning of the EU single market.

At the same time, experience gained over nearly two decades of implementation shows that certain REACH processes have become increasingly complex, burdensome and time-consuming for both authorities and companies, in particular small and medium-sized enterprises (SMEs). Streamlining procedures, improving regulatory predictability and reducing unnecessary administrative burdens are therefore essential to maintain Europe's industrial competitiveness while preserving the high safety standards that REACH delivers.

In this context, **IFRA supports the European Commission's intention to not open the core legislative text of REACH** as this would create significant legal uncertainty and regulatory instability at a time when Europe must prioritise investment, innovation and industrial resilience. Instead, and in the spirit of the European Commission's agenda to simplify existing legislation while at the same time strengthening European competitiveness, the focus should lie on **improving the efficiency and implementation of REACH through secondary legislation, targeted updates to annexes, guidance, and better regulatory coordination**. Such an approach would allow the EU to address practical shortcomings identified during the implementation of REACH while preserving the stability of the existing legal framework.

With a sector composed of more than 750 SMEs alongside global companies and supplying ingredients used in over 500,000 consumer products, regulatory clarity and proportionality are essential to sustain innovation, competitiveness and Europe's leadership in fragrance creation and manufacturing.

IFRA stands ready to support EU policymakers in achieving adjustments to REACH that ensure safety, foster innovation, and enhance Europe's industrial competitiveness.

IFRA's recommendations at a glance:

1. **Enhance clarity and simplification of regulatory processes under REACH in alignment with CLP, strengthening dialogue with ECHA and Member States**
2. **Maintain proportionate rules for low tonnage substances to support competitiveness**
3. **Establish an exposure-based prioritisation roadmap before taking regulatory actions to improve predictability and prevent disproportionate restrictions**
4. **Avoid introducing a blanket Mixture Assessment Factor (MAF)**
5. **Accelerate the regulatory acceptance and use of reliable animal-free approaches**
6. **Streamline REACH implementation to reduce compliance costs, improve digital systems and ensure effective enforcement**

1. Enhance clarity and simplification of regulatory processes under REACH in alignment with CLP, strengthening dialogue with ECHA and Member States

A well-structured regulatory framework is essential for fostering innovation, ensuring compliance, and maintaining Europe's competitiveness. However, the current complexity under REACH creates unnecessary burden for businesses. Furthermore, misalignment between REACH and the Classification, Labelling and Packaging (CLP) regulation, coupled with fragmented decision-making, reduces regulatory effectiveness and weakens industry stability.

To address these challenges, a more structured and transparent regulatory approach is needed. Strengthening collaboration and communication channels will support a balanced approach to achieving health, environmental, and economic objectives while reducing inconsistencies that create unnecessary burdens. Enhancing dialogue with ECHA and Member States will help in clarifying the sequence of actions under REACH and CLP improving regulatory coherence, predictability, and enable faster generation of safety data.

What's at stake?

- **The absence of a clear sequencing in REACH** leads to overlapping and **parallel evaluations**, causing confusion, making compliance more complex and hindering long-term investment planning.
- CLH decisions under CLP are based on **insufficient data, without considering parallel data being generated under REACH** (e.g., compliance checks, substance evaluations), leading to restrictions or bans on certain substances.
- **Without continuous dialogue between Member States and ECHA, the REACH regulatory processes risk becoming inconsistent**, unpredictable, and inefficient, undermining legal certainty and innovation in Europe.

IFRA recommendations:

- ✓ **Improve coordination between CLH proposals and ongoing REACH testing proposals**, to ensure scientifically robust and well-informed regulatory decisions as well as establishing a dialogue with industry starting before the submission of a CLH intention.
- ✓ **Structure communication channels with ECHA and Member State authorities**, to improve transparency and consistency in dossier and substance evaluations.
- ✓ **Improve industry participation in all discussions of ECHA's scientific groups and committees**, to ensure that regulatory decisions are informed by comprehensive data and sector-specific industry expertise.

2. Maintain proportionate rules for low tonnage substances to support competitiveness

Upcoming adjustments to REACH should foster innovation, strengthen industrial resilience, and enhance economic competitiveness while preserving current high safety standards. To achieve this, they must be designed to prevent unnecessary administrative burdens that increase costs, discourage investment, and diminish Europe's attractiveness for manufacturing and R&D.

Therefore, it is important to stress that any new information requirements under REACH should be clear, justified and bring added value compared to the current situation. The current REACH framework maintains proportionality in information requirements and is supported by the low probability of significant exposures from low tonnage substances.

What's at stake?

- **Introducing new non-proportional information requirements increases administrative burdens and compliance costs, especially for SMEs** which could further impact competitiveness, innovation, and raw material availability.

- This is particularly relevant for the fragrance industry which comprises a diverse range of operators, from multinational companies to hundreds of SMEs. Moreover, **the sector relies substantially on substances produced in “low tonnage” and “very low tonnage” volumes**, many of which are natural complex substances (NCS).
- **More than half of the registered fragrance substances fall within the 1-10 registration tonnage band**, and in the case of REACH-registered natural complex substances (NCS) as essential oils, this **figure rises to 80%.** Introducing new information requirements for low-tonnage substances could thus have **adverse effects** on competitiveness, innovation, and the availability of key raw materials.
- It is therefore crucial to **approach any such changes with caution** when adjusting REACH annexes and ensure they are subject to a thorough **impact assessment** to avoid disproportionate consequences.

IFRA recommendations:

- ✓ **Maintain the current proportionality of information requirements**, recognising the low probability of high exposures from low-tonnage substances.
- ✓ Conduct a **comprehensive SME and competitiveness impact assessment** before imposing **new stringent requirements** to ensure proportionality and feasibility.

3. Establish an exposure-based prioritisation roadmap before taking regulatory actions to improve predictability and prevent disproportionate restrictions

The foundation of Europe’s chemicals legislation should be proportionate and balanced considering both hazard properties and actual exposure. Examining all the available information on chemicals ahead of initiating regulatory measures will allow for an informed decision on which substances and uses should be prioritised and which regulatory action should be applied.

What’s at stake?

- **Broad, wide-ranging restrictions** combined with temporary exemptions have become increasingly common in recent years. To make these untargeted rules workable, exemptions must be introduced leading to uncertainty, enforcement gaps, and inefficiencies. These challenges are illustrated by the ongoing skin sensitisers in consumer mixtures restrictions.
- Moreover, by strictly applying current rules without adequately assessing exposure, many **existing ingredients could be automatically and unnecessarily removed despite safe use** (e.g. ethanol).
- This point is especially relevant for the fragrance industry as fragrance ingredients are used in low concentrations, leading to **minimal consumer exposure** while delivering essential **olfactory and functional benefits**.
- The **absence of clear prioritisation in the regulatory actions** conducted under REACH additionally hampers the predictability of upcoming requirements and restrictions. This limits the ability of the industry to generate relevant data sufficiently in advance, engage in regulatory procedures, and offering the data and expertise necessary for authorities to make science-based decisions.

IFRA recommendations:

- ✓ **Enable the up-front collection and assessment of information of use and exposure data**, before determining further regulatory action.
- ✓ **Establish a structured prioritisation roadmap bringing clarity to the upcoming risk management measures and regulatory assessments, including restrictions under REACH** to ensure regulatory actions focus on substances where scientific risk assessments confirm genuine concerns. This would **prevent disproportionate restrictions on low-exposure and safely managed substances**, streamline decision-making across Member States and support long-term investment.

4. Avoid introducing a blanket Mixture Assessment Factor (MAF)

The assessment of combined exposure to multiple chemical substances should be guided by scientific rigor rather than a one-size-fits-all Mixture Assessment Factor (MAF).

What's at stake?

- Current REACH and sector-specific legislation already have **well-established methods to assess the safety of substances**, whether they are used alone or in mixtures. **These assessments are designed to be cautious** and take into account the **entire life cycle of a substance** - from its use to its waste. They also consider **potential combined exposures** (i.e. the exposure to multiple substances by a single or multiple use(s)).
- IFRA is therefore concerned about the **introduction of an additional blanket risk factor** (as a generic one-size-fits-all MAF) for fragrance substances. Combined exposure is a complex matter and cannot be addressed via this 'simple' solution.
- **A case-study conducted by Ricardo for IFRA**, based on a **factor of 10** shows that a generic MAF would create significant administrative burdens without effectively addressing combined exposures. The Ricardo economic analysis further estimates **a 33% loss in turnover** compared to the baseline scenario. **Separate examples from downstream users, including the fragrance sector**, further illustrate the **practical implications and operational challenges** associated with applying a generic MAF.
- Scientific assessments, including by experts from the **German Federal Institute for Risk Assessment (BfR)**¹, have found **no general evidence** that **combined exposure** to multiple substances inherently **increases toxicity** compared to individual exposures.

IFRA recommendation:

- ✓ **Oppose** the introduction of a **general MAF** and instead focus on **case-specific, science-based assessments of exposure to multiple substances**.

5. Accelerate regulatory acceptance and use of reliable animal-free approaches

New Approach Methodologies (NAMs) and Next Generation Risk Assessment (NGRA) can reduce animal testing while achieving high degree of safety. Targeted adjustments to REACH should reduce the hazard focus wherever possible allowing the use of NAMs and exposure considerations.

What's at stake?

- **Animal testing is still heavily required** under REACH, and often possibilities to use exposure-based approaches are limited².
- **New CLP hazard classes**³ risk **increasing demand for animal testing while** NAMs are still under development.

IFRA recommendations:

- ✓ **Support validation and adoption of NAMs**, aligning with EU ethical and political goals and global scientific progress.
- ✓ **Allow more flexibility when applying the exposure exemptions or read-across which would avoid animal tests** while ensuring that regulatory requirements remain proportionate and scientifically justified.
- ✓ **Ensure that future data requirements under REACH reflect a pragmatic combination of NAMs, NGRA approaches, and traditional methods**, where no alternatives currently exist while removing the default requirements for animal testing wherever possible.

IFRA supports **animal-free safety assessments** and engages in initiatives such as **EPAA** (European Partnership for Alternative Approaches to Animal Testing), **ICCS** (International Collaboration on Cosmetics Safety), and **IDEA** (The International Dialogue on the Evaluation of Allergens) to **advance**

regulatory acceptance of NAMs. Targeted adjustments to REACH should **embrace modern methodologies**, ensuring scientifically sound, ethical, and future-proof safety assessments.

6. Streamline REACH implementation to reduce compliance costs, improve digital systems and ensure effective enforcement

REACH can be streamlined to become both practical and meaningful, ensuring that compliance costs do not hinder SMEs and innovation. It should focus on reducing administrative burdens, as outlined in the EU Competitiveness Compass (which sets a target to cut administrative burdens by at least 25% for firms and 35% for SMEs) while ensuring that rules are both enforced and enforceable.

Effective implementation of REACH, especially the registration and evaluation processes, is also crucial for regulatory efficiency and business predictability. Optimising digital systems and regulatory coordination can prevent unnecessary administrative complexity and improve compliance processes.

What's at stake?

- **Fragmented enforcement across Member States creates regulatory inconsistencies**, making compliance unpredictable for businesses.
- **Failure to consider operational realities**, such as digital system usability and registration processes, can lead to excessive administrative burdens, making REACH compliance costly and impractical.
- **Overly complex registration processes and unstable or overly complex IT systems (e.g., IUCLID)** create market barriers, increase compliance challenges and hinder innovation.
- **Redundant data submission requirements** across different formats add inefficiencies and administrative burdens without improving regulatory outcomes.

IFRA recommendations:

- ✓ **Ensure clear and consistent REACH enforcement across all Member States** by improving regulatory coherence and structured stakeholder engagement, ensuring that new requirements are practical, proportionate, and enforceable in practice.
- ✓ **Allow registration dossiers to be based on a three-year average volume**, as applied for phase-in substances, providing businesses with flexibility to adapt before new compliance obligations take effect.
- ✓ **Streamline IT systems and IUCLID dossier requirements**, to eliminate redundant data entries, enhance user-friendliness, and improve efficiency.
- ✓ **Automate redundant information in REACH IT systems** to reduce duplication, simplify registration, and ease administrative burden.

¹ Herzler, M., Marx-Stoelting, P., Pirow, R. *et al.* The “EU chemicals strategy for sustainability” questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?. *Arch Toxicol* 95, 2589–2601 (2021). <https://doi.org/10.1007/s00204-021-03091-3>: “the impression that people exposed to mixtures of chemicals will always experience higher toxicity than when exposed to the same chemicals alone is not reflected in the current state of science or that of previous regulatory assessments.”

² Exposure driven waivers

³ Introduced in the CLP Regulation in 2023