



# The fragrance industry key recommendations for the REACH revision: enhancing economic resilience while safeguarding high safety standards

### Ensuring competitiveness, innovation, and proportional regulations in the EU 2024-2029 agenda

On 11 January 2025, the European Commission published its <u>Commission work programme 2025</u> outlining key priorities, including "*A new plan for Europe's sustainable prosperity and competitiveness*". At its core is the <u>Clean Industrial Deal</u>, designed to advance sustainability while reducing compliance burdens to strengthen industrial competitiveness.

As part of this initiative, the **Chemicals Industry Package** will introduce a **targeted revision of REACH**, aiming to improve regulatory efficiency while maintaining high safety and environmental standards. This presents a crucial opportunity to **enhance Europe's economic resilience by fostering innovation**, ensuring regulatory predictability, and supporting internationally competitive industries. However, for regulations to be effective, they must also be **practical**, **enforceable**, **and consistently applied across the EU**. A regulatory framework that lacks clarity or is difficult to implement creates legal uncertainty, hinders investment, and weakens enforcement at the national level.

The fragrance industry, represented by the International Fragrance Association (IFRA), plays a key role in Europe's economy, operating at the intersection of **agriculture**, **chemistry**, **and consumer goods**. With 750 SMEs – representing 50% of the industry's economic output – alongside large multinational players, the sector supplies over **500,000 everyday products** while preserving stringent safety standards. **A clear and proportionate regulatory framework** is essential for sustaining **Europe's leadership** in advanced ingredient development, cultural heritage and high-value-added manufacturing.

For Europe to remain a hub for fragrance innovation, manufacturing and sustainable growth, the REACH revision must strike the right balance – ensuring safety while eliminating unnecessary regulatory burdens, preventing excessive compliance costs, and fostering competitiveness. This requires continued and structured dialogue between industry, policymakers, and stakeholders to ensure regulations are both practical and enforceable, safeguarding safety while strengthening industrial competitiveness.

To achieve this, the International Fragrance Association (IFRA) outlines **key recommendations for a well-balanced REACH revision** that should:

- ✓ Reduce regulatory complexity, easing compliance burdens, specifically for SMEs and lowering compliance costs, fostering a more resilient industrial ecosystem.
- ✓ **Preserve a balanced risk management system**, ensuring that regulatory measures are proportionate **to the actual exposure** to humans and the environment.
- ✓ **Strengthen scientific integrity**, ensuring that regulatory decisions are based on robust scientific assessments that consider safe use and actual exposure levels, avoiding unjustified blanket restrictions.
- ✓ **Support innovation**, fostering the regulatory acceptance of New Approach Methodologies (NAMs) to reduce reliance on animal testing.
- ✓ Enhance regulatory predictability through clear, enforceable, and well-implemented rules, in alignment with the EU's broader economic and sustainability goals.

IFRA stands ready to support EU policymakers in achieving a balanced REACH revision that ensures safety, fosters innovation, and enhances Europe's industrial competitiveness



## IFRA recommendations for the REACH revision:

	Enhance clarity and simplification of regulatory processes under REACH in alignment with strengthening dialogue with ECHA and Member States2
2.	Ensure proportionate rules to support competitiveness
3.	Balance exposure data and regulatory actions for chemical safety3
	Ensure scientific rigor in assessing the combined exposure to multiple chemical substances, iding a blanket Mixture Assessment Factor (MAF)
	Accelerate the regulatory acceptance and use of New Approach Methodologies (NAMs) and t Generation Risk Assessments (NGRAs) to reduce animal testing
	Streamline REACH implementation to reduce compliance costs, improve digital systems and ure 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 and predictable regulatory framework is essential for fostering innovation, ensuring compliance, and maintaining Europe's competitiveness. However, the current **complexity and lack of clear sequencing in regulatory processes under REACH create uncertainty for businesses** and hinder efficient decision-making. Furthermore, **misalignment between REACH with CLP**, 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. Establishing a clear sequence of actions under REACH, ensuring that harmonised classification and labelling (CLH) decisions consider all available data, and enhancing dialogue with ECHA and Member States will improve regulatory coherence and predictability. Strengthening collaboration and communication channels will support a balanced approach to achieving health, environmental, and economic objectives while reducing inconsistencies that create unnecessary burdens.

#### What's at stake?

- The absence of a clear sequencing in REACH leads to overlapping and parallel evaluations, causing confusion, and 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.

- → Establish a clear and predictable sequence of regulatory processes under REACH to prevent conflicting or redundant evaluations and enhance regulatory coherence.
- → Ensure CLH proposals consider ongoing REACH evaluations and pending testing proposals, to ensure scientifically robust and well-informed regulatory decisions.
- → Simplify and structure communication channels with ECHA and Member State authorities, to improve transparency and consistency in dossier and substance evaluations.
- → Enable 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. Ensure proportionate rules to support competitiveness

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

It is important to stress that any new information requirements should be clear, justified and bring added value compared to the current situation. The current system maintains proportionality of information requirements and this concept is supported by the low probability of high exposures from low tonnage substances.

#### What's at stake?

- Regulatory complexity and administrative burdens increase compliance costs, especially for SMEs. For instance, stricter requirements for low-tonnage substances (1–10T) 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 micro and small enterprises (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 registered fragrance substances fall within the 1-10T registration band, and in the case of essential oils, this figure rises to 80%. Introducing new information requirements for low-tonnage substances (1-10T) could therefore have adverse effects on competitiveness, innovation, and the availability of key raw materials.
- It is therefore crucial to **approach any such changes with caution** 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 check before imposing new stringent requirements to ensure proportionality and feasibility.

## 3. Balance exposure data and regulatory actions for chemical safety

The foundation of Europe's chemicals legislation should be proportionate and balanced considering both hazard properties and actual exposure in final consumer products. Fragrance ingredients are used in low concentrations, leading to minimal consumer exposure while delivering essential olfactory and functional benefits.

#### What's at stake?

- **Generic restrictions only based on hazard trigger automatic bans** of fragrance ingredients, despite its safe use and ignoring the real exposure to consumers.
- This would force **widespread reformulations**, requiring alternative ingredients that may not provide the same performance, stability, or sustainability profile.
- Automatic bans and disproportionate restrictions do not necessarily foster long-term, meaningful innovation that improves product sustainability, performance, or consumer experience. Instead, they divert R&D investments away from forward-looking scientific advancements such as bio-based materials or enhanced safety assessment methods toward reactive, short-term substitutions that may not provide meaningful safety or environmental benefits.



- → Enable the up front collection and assessment of information of use and exposure data, before determining further regulatory action.
- → Establish a structured prioritisation workplan 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. Ensure scientific rigor in assessing the combined exposure to multiple chemical substances, avoiding 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 a new, blanket risk factor** (as a generic one-size-fits-all **Mixture Assessment Factor (MAF)**) for fragrance substances. Combined exposure is a complex matter and cannot be addressed via this 'simple' solution.
- Scientific assessments, including by experts from the **German Federal Institute for Risk Assessment (BfR)**<sup>1</sup>, have found **no general evidence** that **combined exposure** to multiple substances inherently **increases toxicity** compared to individual exposures.

## IFRA recommendation:

→ The REACH revision should **avoid a general MAF** and instead focus on **case-specific, science-based assessments of exposure to multiple substances**.

## 5. Accelerate the regulatory acceptance and use of New Approach Methodologies (NAMs) and Next Generation Risk Assessments (NGRAs) to reduce animal testing

The upcoming REACH revision should reflect the latest advancements in NAMs and accelerate their regulatory acceptance in hazard identification and risk assessment. NAMs can reduce animal testing while improving predictability and relevance in human safety assessments.

### What's at stake?

- **Animal testing is still required** under REACH, with only limited possibilities to avoid it based on real-life exposure data<sup>2</sup>.
- New CLP hazard classes<sup>3</sup> risk increasing demand for animal testing, unless NAMs are fully adopted.

<sup>&</sup>lt;sup>1</sup> 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). <a href="https://doi.org/10.1007/s00204-021-03091-3">https://doi.org/10.1007/s00204-021-03091-3</a>: ""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.""

<sup>&</sup>lt;sup>2</sup> Exposure driven waivers

<sup>&</sup>lt;sup>3</sup> Introduced in the CLP Regulation in 2023



- → Support validation and adoption of NAMs, aligning with EU ethical 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 new data requirements can be met with NAMs and NGRAs.

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. The REACH revision must 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

Regulatory simplification should be **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**.

Beyond the legislative revision, the **effective implementation of REACH** 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.

- → 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 phasein 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.