The International Fragrance Association

CARACAL-54 meeting on 3 April 2025

IFRA comments on REACH Registration and Evaluation

The International Fragrance Association (IFRA) has submitted key recommendations to CARACAL in advance of the meeting on 3 April.

In our view, the changes proposed by the European Commission at the CARACAL meeting do not reflect a genuine simplification of REACH for either industry or authorities. We therefore wish to provide additional detailed comments on the proposed revision, particularly concerning Registration and Evaluation:

1. Flexibility in Case of Exceeding a Tonnage Band

We recommend introducing a transitional period when a company exceeds a tonnage band. This is especially important for SMEs and manufacturers of natural extracts. For all tonnage bands, registration dossiers should be allowed to reflect a three-year average volume, as was done for phase-in substances. This would provide greater investment predictability and prevent penalizing companies that only produce a batch every two to three years.

2. Registrations Expiring After 10 Years

We are concerned that this proposal would create significant administrative burdens without adding value. We also note that ECHA has not even completed their assessment of all existing registrations to enable registrants to complete the appropriate conclusion of data completeness and quality review. Further, as regulatory requirements continue to evolve, industry is already managing substantial workloads related to compliance checks, substance evaluations, and ongoing updates to registration dossiers. The practical implications of expiration are unclear:

- Would registrants be required to resubmit dossiers with outdated data—creating administrative burden with no benefit?
- Would they need to generate new data even if existing data remain valid?
- If registration numbers expire, would all related documentation need to be reissued and updated across both ECHA systems and industry's internal systems?
- How would existing registrations undergoing CCH and Evaluation be treated, as well as ongoing testing to fulfil each process, in the event of a 10 year expiry that may happen during the completion of such activities ?

Clarity on these points is critical.

3. Testing Proposals (TPEs) for All Registration Levels

Expanding the requirement for testing proposals to all registration levels would add unnecessary complexity. TPEs are already subject to considerable delays in processing. We recommend using the inquiry process instead, which is faster and more efficient.

Expanding data and testing requirements across all the registration bands leads to enormous cost, complexity and administrative burden that is unnecessary, as substances have already been

determined to be safe for use, and does not meet the commitments of simplification, nor reduction in animal testing.

Adding all low volume substances to the Annex VII registration data requirements places unnecessary burden on industry, that adds complexity, testing costs, and does not lead to simplification. Further it directly impacts SME's who are make natural products commonly used in very small volumes in the fragrance indusrty.

4. **Compliance Check (CCH) Efficiency**

We would welcome further clarification on the proposed statement to "increase efficiency and impact of compliance check" and, in particular, on the intended scope of ECHA's powers to address non-compliance. Greater transparency is needed on how these powers would be applied in practice.

The coherency between registration completeness and evaluation processes, and the CLP CLH process must be addressed, to prevent incoherent decisions on hazard classification. It is in appropriate for registrants to be subject to CLH decisions, when they are completing testing for CCH and Evaluation procedures. Furthermore, the ability of ECHA to delay decisions on testing proposals to enable a CLH decision before testing completion, is an unfair treatment of registrants who are completing required toxicity testing of their substances to establish safe use and hazard classification assessments.

5. **Improved Dialogue with Authorities**

A more structured and transparent communication process with Member State authorities and ECHA is essential during dossier and substance evaluation. We strongly support allowing industry stakeholders to participate in all discussions held by ECHA's scientific bodies and committees, ensuring meaningful and constructive engagement.

Additionally, IFRA would like to highlight the following implementation issues aiming at streamlining data submission and system efficiency

- IUCLID stability or adaptation is needed so that the latest features create quality checks but not submission checks.
- Simplify IUCLID dossiers: IUCLID requirements are becoming increasingly complex, often requiring the repetition of the same information in multiple sections. The speed of IUCLID needs to be improved, taking into account that more and more detailed information is requested by ECHA
- Testing proposals: simplify the submission procedure (not through the dossier update but through an inquiry/simple standard template). Currently, testing proposals must be submitted through a dossier update, which involves significant administrative effort. Testing proposals are required for Annex IX and Annex X dossiers, which are more extensive and complex compared to those for Annex VII or VIII.

  Additionally, with the current manual compliance checks during dossier submission, registrants must ensure that both the IUCLID dossier and the CSR are up to date when submitting a testing proposal request. Given that authorities allow up to 12 months to update a dossier in cases involving CSR revisions, this highlights how complex and time-consuming the process can be, even though the request is to perform a specific test. A simpler and more efficient process would be beneficial.

A simpler procedure, such as an inquiry-based approach (where you indicate the study you plan to conduct by selecting options), could streamline this process. While the evaluation of testing proposals is outlined in REACH, Article 40, and the requirement to include testing proposals is specified in Article 10, there is no explicit procedure in the legal text detailing how testing proposals should be submitted. This provides an opportunity for us to propose a simplified process, which could significantly improve the current system.

- Automatization of redundant information (avoid input duplication)

Brussels, 17 April 2025

About the International Fragrance Association (IFRA)

The International Fragrance Association, founded in 1973, represents the interests of the fragrance industry worldwide. IFRA comprises seven multinational Regular Members and 23 national associations in four global regions representing hundreds of small and medium-sized fragrance ingredient manufacturers, as well as supporting members. Its mission is to promote the safe use of fragrance for everyone's enjoyment.

Fragrances are a key platform technology used by consumer goods companies – for fine fragrances, personal care products, household care and more.

IFRA's flagship safe use program, the IFRA Standards, applies safety management measures based on scientific assessment and the evaluations of an independent Expert Panel. The program is at the heart of the IFRA Code of Practice, which applies to all IFRA members globally, including members of IFRA's national associations. The Code also requires members to abide by local, national and international regulation, and to apply good manufacturing practices.