

## VCI Position

# REGULATION ON ECHA

## Background

The European Chemicals Agency (ECHA) was originally established to implement the REACH Regulation, and its mandate has so far been part of the REACH Regulation.

Subsequently, further regular and ad hoc tasks were added (including under the CLP Regulation, Biocidal Products Regulation, Water Framework Directive, opinions on occupational exposure limits). And further tasks are planned, in particular the establishment of a common data platform under the “one substance, one evaluation” approach.

With its draft regulation of July 2025 ([COM/2025/386 final](#)), the EU Commission wants to shift the ECHA mandate to a separate regulation. In doing so, the Commission intends to take into account its common approach for EU agencies and aims to achieve more sustainable financing for the ECHA.

The Committees for Risk Assessment and Socio-economic Analysis are to get additional members, the Scientific Committee on Consumer Safety to be assigned to the ECHA, cooperation between EU services/agencies to be strengthened, substitution promoted, the previous separation of ECHA budgets abandoned, and a limited reserve from fees and charges to be created.

## VCI Position

The VCI supports an independent mandate for the work of the ECHA, its continuation, the planned strengthening of the RAC and SEAC committees, and sustainable financing for the agency.

For access to data the “originator” principle should be applied without exceptions, and fee income should be used exclusively for its original intended purpose.

The planned specification of details of the committees' working methods in their Rules of Procedure (rather than in the text of the regulation) allows for flexible adjustments to the workload and inclusion of experience gained, and should definitely consider appropriate involvement of the companies affected. Moreover, companies affected should also be able to object against committee opinions.

## **Uniformly apply the “originator” principle for access to data: amend Art. 37(2)**

Rules governing the handling of confidential information and public access to information, including access by third countries where applicable, form part of sectoral legislation (including the REACH Regulation, Biocidal Products Regulation). Therefore, consequently reference is made to this in Recital 29 and Article 42(6) of the text of the regulation. However, in deviation from this, Article 37(2) of the draft regulation is worded as follows:

*“For all other information and data not covered by paragraph 1 [open data platform], the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific and technical information concerning the safety of substances on their own, in mixtures or in articles where such information is not of a confidential nature as defined in sectoral Union legislation.”*

Companies must be able to rely on the fact that rules – according to which they prepare their dossiers in compliance with the law, check them relating to content and possible publication of data – are not undermined retrospectively. Items that are not intended for publication and for which, under the original legislation, there may be no possibility of requesting confidential treatment should be treated in accordance with the “originator” principle and therefore not made available to the public. Although the phrase “as defined by sectoral legislation” is included, the above wording would not be an appropriate application of the “originator” principle, as data that is not intended for publication under the original legislation could also be published if it has not been expressly identified as confidential.

**Therefore, Article 37(2) should be amended as follows, in line with the wording of Article 42(6):**

*“For all other information and data not covered by paragraph 1, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure **the availability to the public of regulatory, scientific and technical information concerning the safety of substances on their own, in mixtures or in articles “where such disclosure is provided for in the sectoral legislation, under which the information has been submitted and subject to the conditions therein, in line with the originator principle.”**”*

## **Use fees and charges exclusively for the intended purpose**

Fees and charges should only be used to cover the costs associated with the relevant service, and the relevant provisions of sectoral legislation must be taken into account.

For example, Article 74 of the REACH Regulation stipulates the following:

*„... the fees ... shall be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of the Agency's revenue pursuant to Article 96(1) [subsidy from the EU budget, voluntary financial contributions from member states] is sufficient to cover the cost of the services delivered.”*

This must continue even if, as planned, the strict separation of the previous separate budgets (REACH, Biocidal Products Regulation, etc.) is abandoned. Fee income from companies that register substances or apply for authorisations must not be spent on the

provision of services under other sectoral legislation or for (co-)financing other public tasks.

Therefore, a corresponding provision should be included in the text of the regulation, e.g., as an additional paragraph/subparagraph in Article 29:

*„Fees and charges under sectorial legislation shall continue to be set at a level such that the revenue generated from them, together with other sources of revenue of the Agency referred to in Article 29 (3), is sufficient to cover the costs of the services provided under the respective sectorial legislation as stipulated by this legislation.“*

While we support appropriate flexibility, the creation of the planned reserve must not lead to cross-subsidisation of certain services or (co-)financing of public tasks to be funded from the EU budget by fee income.

### **Qualification of SCCS members (Art. 14 para. 5)**

When the SCCS is transferred from the EU Commission to ECHA, its independence, scientific integrity, and fundamental working methods must be maintained, including the practice of appointing the chair from among the members of the SCCS.

In addition to the criteria for qualifying as a potential member of the SCCS already mentioned in Article 14 (5), members should also have expertise in the following areas:

- Grouping / clustering
- Safety assessment of nanomaterials
- Computational toxicology
- Exposure assessment

At least two of the members should meet the individual qualification criteria.

### **Better engage with and listen to industry – More informed committee outcomes by dialogue and involvement of companies affected in all ECHA committees**

To date, companies have only limited opportunities to present well-founded scientific arguments to the relevant ECHA staff and ECHA committees:

- They can comment on draft decisions addressed to them (e.g., evaluation under REACH) and participate in public consultations (e.g., REACH restriction procedure).
- Limited to the MSC, the relevant Rules of Procedure also define the role of a “case owner” (affected registrant or representative of a group of affected registrants in joint submissions), who may be invited to MSC meetings and may then comment within the narrow scope of the previously submitted opinion provided that the topic is discussed at the meeting - but may not comment on other opinions or information that may influence the committee's decision-making (see Decision ED/82/2022 by the ECHA Executive Director).
- For the RAC and SEAC committees, observers without the right to speak are currently provided for, but not case owners with limited speaking rights. This means that affected parties currently have no right to be heard in these committees.

This is not sufficient to take appropriate account of the complex issues that companies and committees have to deal with and to ensure that affected companies are adequately consulted on all facts relevant to the decision, giving consideration to the dynamics of incorporating information into the committee's work and the results of discussions.

**The consultation of affected parties should therefore be improved by the following measures**, which will also facilitate better-reasoned decisions and opinions by the authorities:

- **Dialogue option:** Affected companies should be given the opportunity to directly contact the competent authority with questions on all substance-related regulatory measures (Assessment of Regulatory Needs – ARN, Risk Management Option Analysis – RMOA, decisions in dossier or substance evaluation, identification of substances as SVHC, Annex XV dossier, registration, authorisation, CLH dossier, ...) and to receive feedback on planned company submissions. Where relevant documents are elaborated by authorities in the Member States, these should also be made available for such exchanges. If, in dialogue with the authority, it becomes apparent that the implementation of the planned measure would be technically/scientifically impossible or disproportionate, the measure must be adapted accordingly.
- **Implement the right to be heard for parties affected beyond the MSC and make it binding for RAC, SEAC and BPC as well:** To date, the role of a “case owner” is only included as an option in the MSC's Rules of Procedure. The role is essentially limited to explaining or clarifying the written comments submitted previously. Companies should be given the right to participate in all committee meetings that concern them or their dossiers or substances, and be able to contribute to informed discussions.
- **Full access to documents for parties affected:** All documents relevant to their case should be provided to those affected in good time before a meeting. This enables a comprehensive assessment of the current status and, if necessary, the involvement of the experts required, so that relevant points can be specifically addressed at the meeting.

**The ECHA Regulation should therefore take into account both the granting of a dialogue option (at the request of the registrant(s)) and the right of a case owner to be heard (case owner = registrant and/or representative of a group of registrants in a joint submission) as a binding element of the “Rules of Procedure” of the ECHA committees (MSC, RAC, SEAC, etc.). The same applies to the applicant for an authorisation.**

**Downstream users should be treated equally to registrants in the following cases: SVHC identification, ECHA recommendations for inclusion of substances in Annex XIV, restrictions, and harmonised classifications.**

**Examples** showing that more dialogue between companies and authorities can/would speed up procedures:

Modified AMA DPHP

- UBA/ECHA requested that an “Amphibian Metamorphosis Assay” be performed with numerous modifications for the substance bis(2-propylheptyl) phthalate

(DPHP). From the perspective of the company concerned, this method was not technically feasible.

- Since there was no opportunity for direct scientific exchange, the company decided to bring the case before the Board of Appeal (Case A-10-2022: Board of Appeal - ECHA). The Board confirmed the company's position.
- The lack of dialogue in this case led to additional time and resource expenditure for all parties involved – expenditure that could possibly have been avoided through early technical consultation.

#### Diisocyanate restriction

- The authorities had originally sought a blanket ban (authorisation requirement).
- However, close cooperation between industry and authorities made it possible to draw up a restriction dossier and thus implement a much more appropriate regime (see Commission Regulation (EU) 2020/1149 of August 3, 2020)

### **Ensure that stakeholders and affected parties are involved in ECHA committees**

The participation of stakeholder organisations with observer status in meetings should be a binding (rather than optional) requirement. The current **Rules of Procedure** of RAC and SEAC should therefore be revised to include the following amendments to the passages on stakeholder participation in Article 6.

*“6. Representatives of stakeholder organisations ~~may~~ **shall** be admitted as observers to the meeting of the Committee or its working groups ~~upon request of members of the committee or the management board~~. The list of regular observers shall be updated on an annual basis by the Committee, while the Chair **shall** in addition allow the participation of occasional stakeholders on an ad hoc basis from among the Agency's accredited stakeholder organisations, ~~taking due account of capacity limitations~~. These stakeholder observers shall conform to the ECHA “Code of conduct for observers from stakeholder organizations at ECHA meetings”.”*

As described above, involvement of affected parties should be bindingly included in the Rules of Procedure of RAC, SEAC, MSC and BPC. The existing passage in the MSC Rules of Procedure (paragraph 7 of Article 6) should be worded in a more binding manner and also included in the Rules for RAC and SEAC:

*“7. New: A case owner, i.e., a concerned registrant or applicant for authorisation or a representative of a group of concerned registrants in the case of joint submissions, **shall be admitted as a participant on request of the case owner** when their specific case or a case related to a substance registered by this party is addressed by the Committee. This includes but is not limited to the following: Decisions and opinions related to PPORD, dossier and substance evaluation, data sharing, SVHC identification, ECHA recommendations for inclusion of substances in Annex XIV, applications for authorization, restrictions and harmonized classifications.  
Downstream users should be treated as equivalent to registrants in the following cases: SVHC identification, ECHA recommendations for inclusion of substances in Annex XIV, restrictions and harmonized classifications.”*

The description of the rights of data owners could be based on the existing text in the MSC's Rules of Procedure:

*“The purpose of the **admission of case owners** is to:*

- a) **Provide a possibility to be heard orally and/or in writing about the views on scientific and technical points, including risk assessment, they have on any proposals, decisions, opinions or amendments before the final assessment/evaluation or decision or opinion making**
- b) **Provide a possibility to contribute to clarifying any discussion items, where necessary, directly to the Committee**
- c) **Ensure that all aspects related to relevant proposals are properly addressed and understood in the context of the case under discussion.”**

## **More transparency for committee work – “full” instead of “final minutes”**

ECHA regularly only publishes so-called “final minutes” after committee meetings. These documents show which topics were discussed, but in most cases do not allow to track the progress of the meeting and the meeting results in detail. For this reason, the approach is often perceived as non-transparent by those affected and also by the public.

In another context (the REACH Regulatory Committee), the EU Ombudsman recently criticised the EU Commission for providing overly general summaries of meetings and recommended that more comprehensive summaries be made available:

*„The Commission should publish more substantial summary records of the REACH Committee meetings, so as to allow the public to follow the progress of each authorisation file, understand outstanding issues and any reasons for delays. A good example could be the summary records of the SCoPAFF Committee.<sup>[47]</sup> These records should be published in a timely manner and in any case before the next meeting of the REACH Committee.”*  
 (Source: European Ombudsman, Case OI/2/2023/MIK)

Greater transparency has two effects: Stakeholders gain a better understanding of how ECHA works, enabling them to prepare better applications for authorisations or better comments for public consultations, for example. Thus, authorities can process applications, decisions, and opinions more efficiently.

**In future, ECHA should publish full minutes/comprehensive summaries rather than just general final minutes promptly after each committee meeting in order to make both the decision-making process and the decisions or opinions more transparent.**

**In addition, documents on overarching, non-substance-specific topics, e.g., the approach for prioritising SVHCs, the inclusion of substances in REACH Annex XIV, the evaluation of authorisation applications and restriction proposals, etc., should be published together with the “full minutes” of a meeting.**

## **Create an option for objections under REACH and CLP on committee opinions**

Under REACH and the Biocidal Products Regulation, certain decisions may be appealed. These cases are handled by the Board of Appeal (BoA) of ECHA. Decisions that can be appealed include the granting of a registration number or an ECHA decision on a PPORD notification, a dossier or substance evaluation, and data sharing under REACH.

However, no appeal is possible against ECHA opinions, e.g., in the context of restriction procedures under REACH or a harmonised classification of substances under CLP by the Committee for Risk Assessment. Furthermore, the procedure itself does not provide for any independent review of the opinions, even though the issues dealt with can be highly complex, require comprehensive and diverse expertise, and can have significant implications.

This means that complex proceedings must be brought before the European Court in order to lodge an appeal, and in some cases this is only possible at a later stage (e.g., not after an opinion has been issued, but after the legislation based on it has been published).

**A panel should therefore be set up with a composition similar to the BoA, which can be consulted on scientific or technical opinions issued by the ECHA committees. Any natural or legal person affected by such an opinion should be entitled to file an objection before this panel.**

**The outcome of the panel's review could include, among other results, the complete or partial revocation of the opinion and/or a referral back to the committee for further assessment with conditions.**

### **Set up a Data Owner Forum**

ECHA is responsible for defining various formats for submitting different types of data to the agency in accordance with sectoral regulations. While experience at the OECD level, for example, with the IUCLID User Forum shows how valuable practical expertise from industry is for further developments, no such advisory and/or monitoring forum is defined in the sectoral regulations. At the same time, companies have ownership rights to the data they submit, have first-hand knowledge of the processes for making the relevant data available, and need solutions that are optimally compatible with their standard company systems.

**A data owner forum should therefore be implemented by the ECHA Regulation to contribute to the quality and protection of data uploaded to the Agency's systems.** Members could be appointed by European stakeholders (associations) and, where appropriate, by Member States. Associations should be able to appoint not only their own staff, but also staff of companies.

The forum should have an advisory role:

- **Software and formats** should be developed in cooperation with data owners, and at least one written consultation based on a draft should take place before formats are changed.
- In addition, the agency should **report annually to the data owner forum on the implementation of relevant data protection and property rights requirements**, including any violations of such rights. Where necessary, the Agency should, after consulting the data owner forum, determine the necessary protective measures.

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