Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals

2023/0453(COD) - 01/04/2025 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 481 votes to 170, with 22 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

The matter was referred back to the relevant committee for interinstitutional negotiations.

The main amendments adopted in plenary concern the following points:

Subject matter

By ensuring the effective delivery of coherent hazard and risk assessments of chemicals where such assessments are required by Union legal acts, the Regulation should (i) enable the development and use of **safe and sustainable chemicals**, (ii) enhance Union citizens' awareness of, and trust in, the scientific basis for decisions taken under Union legal acts in the field of chemicals, and (iii) contribute to the goal of **phasing out animal testing** wherever possible.

Common data platform on chemicals

Each chemical or material hosted on the common data platform should be identified by a **unique chemical identifier** and a chemical notation specifying its molecular structure without prejudice to any confidentiality requirements in the original act or related legal obligations.

The Authorities and the general public should have **easy access, free of charge**, to the data contained in the common data platform. **Security** measures should be adopted by the relevant agencies in cooperation with the European Chemicals Agency (ECHA) to ensure the secure transmission of chemicals-related data to the common data platform.

Stepwise approach

Taking due account of the administrative work for EMA coming from the adaptation of such data to an appropriate format for inclusion in the common data platform, Members suggested adopting a stepwise approach, and including during the first stage only chemical data for active substances which are submitted to the EMA in the context of the relevant procedures that are finalised after the entry into force of this Regulation. No later than **eight years** after the entry into force of this regulation, EMA should also include the chemical data on active substances from procedures concluded before the entry into force of this Regulation.

Data flows for the purposes of the common data platform

The Commission and the agencies should indicate whether data or information included in the common data platform can be made publicly available or whether it is considered confidential. Members specified that ECHA should host and administer data on the presence of chemicals relevant for workplace monitoring, including human biomonitoring data in the workplace.

Human biomonitoring data

The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitute a special category of personal data, namely, health data, the EEA, the Commission, the ECHA, the EFSA, the EU-OSHA and the EMA should process those data only where the processing is necessary for reasons of substantial public interest, and for scientific research. Members introduced amendments laying down the cases where there is such **substantial public interest** in processing human biomonitoring data constituting personal data.

Information on chemicals

To enhance visibility on the availability of data, and to promote research and development activities as regards safer alternatives, ECHA should establish and manage a **repository** of information on chemicals in articles generated or submitted under Union acts listed in Annex I. In addition, ECHA should also establish and manage a database collecting available information from Agencies, Member States and business operators on **safer alternatives to substances of concern**.

Study notification database

The ECHA should establish and operate a mechanism for cooperation and exchange of information with relevant **third countries' authorities** for the exchange of studies notified or submitted by business operators to those authorities to support an application, notification or regulatory dossier for a chemical no later than two years after the date of entry into force of the Regulation. Data in the study notification database should be considered **confidential** and should not be made public.

Notification of studies relating to chemicals

Scientific studies that are conducted only for research purposes, that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that are not part of a risk or safety assessment under Union acts listed in Annex I, do not need to be notified.

The obligation to notify studies should only start to apply **18 months** after the date of entry into force of this Regulation.

Where the Commission or any of the Agencies makes available to the ECHA, a registration, application, notification, it should indicate which elements of the study notifications are confidential when included in the common data platform.

Research data

Members stressed the need to **structure and make transparent** the assessment of research data in order to increase their use in the regulatory assessment of chemicals. No later than four years after the date of entry into force of the regulation, the Commission should assess the feasibility of harmonised reporting requirements and of enabling the integrating of relevant content from scientific journals and publications into the common data platform, in order to increase further the uptake of research data into the hazard and risk assessment of chemicals.