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COMMON DATA PLATFORM AND RULES FOR RE-USE OF DATA – COM(2023) 779FINAL

VCI's feedback on the draft data platform regulation

Background

The European Commission intends to establish a common data platform on chemicals and to lay down rules to ensure that data contained are findable, accessible, interoperable and reuseable. In addition, a monitoring and outlook framework shall be built-up (Link to the draft regulation COM(2023) 779final).

The draft includes four main building blocks:

- Re-use of data: Establishment of a common data platform - content, data flows, rules for reuse of data on chemicals and environmental sustainability related data
- Monitoring and outlook framework: Indicator framework to monitor progress made with implementation of chemicals policy and an early warning and action system for emerging chemical risks.
- Data generation mechanism: Option for ECHA to commission scientific studies to support the implementation of Union acts on chemicals when such results cannot be obtained through existing law.
- Notification of studies: Business operators shall notify any study on chemicals they commission for regulatory purpose or as part of a risk assessment prior to placing on the market.

The provisions shall apply to data from about 100 EU acts (i.e., chemicals, environmental, worker protection, sustainability legislation) as specified in three annexes.

VCI's feedback on the draft regulation

Basically, VCI and its member companies welcome the establishment of a common data platform to support sound scientific hazard and risk assessments as well as best informed regulatory decisions while respecting efforts, ownership rights and confidential business information of companies. Recognition of specific competences of agencies involved and rules on data as established by the originating law are decisive as intentions, scopes, levels of detail and regulatory consequences vary between legislations providing data and other information for the common platform.

Some aspects require further elaboration:

Definition of platform elements: Make best use of industries expertise.

The establishment of the data platform is a complex undertaking, and as mentioned meta data are decisive to point out specific conditions, relevance and reliability of any information provided to allow proper re-use. Thus, also industry should be consulted before decisions on implementation plans, data collection or dissemination formats, vocabulary etc are taken.

Data generation mechanism: Consult industry and provide rationales.

We appreciate that this mechanism should not bypass existing specific data generation provisions and should focus on implementation issues of EU law. However, a cross-check with industry expertise is missing. Stakeholders could be consulted based on a draft testing proposal, including a rationale why such testing is needed.

Study notification: Clarify and design a fit-for-purpose scope.

We deplore that authorities want to introduce additional bureaucratic notification obligations due to lack of confidence. Moreover, this article lacks specificity and practicability.

- The term “study” is not defined. Enforcement authorities and industry require a suitable focus on data/endpoints where notification really would make a difference related to risk or regulatory management of a chemical.
  It might be acceptable to notify animal testing or migration studies for regulatory purpose. However, where a notification or approval is required under specific law, e.g. REACH testing proposals, no duplicate notification should be required. In case of an iterative testing approach, it might not be practicable to notify any amendments. Characterisation of the chemical tested is key but might be under development when commissioning e.g. toxicity testing.
- A concrete list of studies for each EU legislation of Annex I would clarify the scope and should be limited to the decisive data.
- Information flows in companies and authorities should be recognized.
- “Without undue delay” is an undefined term. Based on implementing regulation (EU) 2020/1435 defining this term inter alia for updates related to testing proposals under REACH, a 6 months’ timeframe might be an obvious choice.
- The impact assessment is not fully comprehensible: How many notifications for which kind of studies have been considered related to each of the relevant EU acts? Has this been checked via ex-post evaluation?
  The hourly rate considered in the cost calculation of 29.1 € seems to be quite low in view of expertise required for sound data collection and elaboration of a notification.

- How to handle data from testing for research or product development purposes or obtained in asset transfers and which only later-on is decided to be used for regulatory purpose? Would a subsequent notification be deemed required?
- Where cut-off limits applicable for the notification obligation are not provided by the original act, cut-offs should be defined.
- More clarification is required which obligations would be applicable in detail related to medical devices.

Overall, study notification as a non-core target "omnibus" intervention in 70 legal acts would introduce new bureaucratic burdens and competitive disadvantages compared to companies outside the EU, lack proportionality and thus should be abandoned.

Remark: The VCI feedback has been submitted under the "Have-your-say" feedback option related to COM (2023) 779final: Chemical safety – better access to chemicals data for safety assessments (europa.eu)

Contact: Dr. Angelika Hanschmidt

Division Wissenschaft, Technik und Umwelt
Department Produktsicherheit
P +49 (69) 2556-1440 **E** hanschmidt@vci.de

German Chemical Industry Association
Mainzer Landstrasse 55
60329 Frankfurt, Germany

www.vci.de | www.ihre-chemie.de | www.chemiehoch3.de

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- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered with registration no. R000476 in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government.

The VCI and its sector associations represent the interests of around 1,900 companies from the chemical-pharmaceutical industry and related sectors vis-à-vis politicians, public authorities, other industries, science and media. In 2022, the VCI member companies realized sales of ca. 260 billion euros and employed nearly 550,000 staff.