European Parliament
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Committee on the Environment, Public Health and Food Safety

2023/0453(COD)

5.12.2024

AMENDMENT 547

Draft report
Dimitris Tsiodras
(PE763.255v01-00)

on 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

Proposal for a regulation
(COM(2023)0779 – C9-0449/2023 – 2023/0453(COD))

Amendment 547
Jutta Paulus

Proposal for a regulation
Annex II – Part 1 – introduction

Text proposed by the Commission	*Amendment*
Specific data on ***relevant*** active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products	Specific data on active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products

Or. en

Justification

In order to have a true COMMON data platform, data for all active substances that are chemicals should be included in the platform, and not just for "relevant" ones. All data on pharmaceutical active substances are relevant for other policy areas and therefore, it is not appropriate to limit input to the data platform to dual use substances, PBT substances or active substances with known high level of residues. Data on medicines are rich, using many tests on animals as well as clinical studies. These data can contribute to the development and validation of predictive toxicological models, reducing the needs for animal tests in other policy areas (see references below to exchanges between EFPIA and ECHA as well as between the US FDA and ECHA. Data on all active substances are relevant for environmental legislation, because most if not all active substances or their metabolites will end up in the environment to a significant degree. Medicines may well have toxic properties and it is important to include such data in the platform, not only when they are also persistent and bioaccumulative. In addition, it is inappropriate to only include active substances with known high level of residues given combination effects and cumulative exposure, constant load into the environment and the need to be able to detect emerging risks in time.

The value of such data for developing predictive toxicology assessment - and thus for saving animal tests - has been officially recognised by ECHA.
https://echa.europa.eu/-/pharmaceutical-industry-provides-unpublished-data-on-chemical-substances

For latest situation of this data sharing , see https://iuclid6.echa.europa.eu/data-contribution

A similar exchange exists between the US FDA and ECHA: https://iuclid6.echa.europa.eu/us-fda-toxicity-data