Parlamento europeo
2024-2029

Commissione per l'ambiente, la sanità pubblica e la sicurezza alimentare

2023/0453(COD)

5.12.2024

EMENDAMENTO 547

Progetto di relazione
Dimitris Tsiodras
(PE763.255v01-00)

sulla proposta di regolamento del Parlamento europeo e del Consiglio che istituisce una piattaforma comune di dati sulle sostanze chimiche, stabilisce norme per garantire che i dati in essa contenuti siano reperibili, accessibili, interoperabili e riutilizzabili, e istituisce un quadro di monitoraggio e prospettive per le sostanze chimiche

Proposta di regolamento
(COM(2023)0779 – C9-0449/2023 – 2023/0453(COD))

Emendamento 547
Jutta Paulus

Proposta di regolamento
Allegato II – Parte 1 – Introduzione

Testo della Commissione	*Emendamento*
Dati specifici sulle sostanze attive ***pertinenti*** da identificare conformemente all'articolo 4, paragrafo 5, lettera b), che rientrano nell'ambito di applicazione del presente regolamento ai fini dell'articolo 3 per i medicinali per uso umano e veterinario:	Dati specifici sulle sostanze attive da identificare conformemente all'articolo 4, paragrafo 5, lettera b), che rientrano nell'ambito di applicazione del presente regolamento ai fini dell'articolo 3 per i medicinali per uso umano e veterinario:

Or. en

Motivazione

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