Parlament Ewropew
2024-2029

Kumitat għall-Ambjent, is-Saħħa Pubblika u s-Sikurezza tal-Ikel

2023/0453(COD)

5.12.2024

EMENDA 547

Abbozz ta' rapport
Dimitris Tsiodras
(PE763.255v01-00)

dwar il-proposta għal regolament tal-Parlament Ewropew u tal-Kunsill li jistabbilixxi pjattaforma komuni tad-data dwar is-sustanzi kimiċi, li jistabbilixxi regoli biex jiġi żgurat li d-data li tinsab fiha tkun traċċabbli, aċċessibbli, interoperabbli u riutilizzabbli u li jistabbilixxi qafas ta' monitoraġġ u prospettiva għas-sustanzi kimiċi

Proposta għal regolament
(COM(2023)0779 – C9-0449/2023 – 2023/0453(COD))

Emenda 547
Jutta Paulus

Proposta għal regolament
Anness II – Parti 1 – introduzzjoni

Test propost mill-Kummissjoni	*Emenda*
Data speċifika dwar sustanzi attivi ***rilevanti*** li għandhom jiġu identifikati f'konformità mal-Artikolu 4(5)(b) li jaqgħu fil-kamp ta' applikazzjoni ta' dan ir-Regolament għall-finijiet tal-Artikolu 3 għal prodotti mediċinali għall-użu mill-bniedem u għall-użu veterinarju	Data speċifika dwar sustanzi attivi li għandhom jiġu identifikati f'konformità mal-Artikolu 4(5)(b) li jaqgħu fil-kamp ta' applikazzjoni ta' dan ir-Regolament għall-finijiet tal-Artikolu 3 għal prodotti mediċinali għall-użu mill-bniedem u għall-użu veterinarju

Or. en

Ġustifikazzjoni

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