

Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

2023/0455(COD) - 07/12/2023 - Legislative proposal

PURPOSE: to amend Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the Commission has, in its Communication ‘European Green Deal’, set an objective that chemical safety assessments should move towards a process of ‘one-substance, one-assessment’, calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions.

To achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.

CONTENT: this proposal proposes **targeted amendments** to attribute tasks in Regulation (EU) 2019/1021 on persistent organic pollutants, and Regulation (EU) 2017/745 on medical devices. The proposal also amends Regulation (EC) No 401/2009 establishing the European Environmental Agency and Regulation (EC) No 178/2002 laying down the general principles and requirements of food law and establishing the European Food Safety Authority. These amendments will ensure good cooperation among EU agencies on all aspects involving the consistency and efficiency of chemical assessments. These include the development of methodologies, data exchanges and reconciling divergence in scientific output.

The proposal:

- amends Regulation (EC) No 178/2002 (General Food Law Regulation). It includes provisions **enabling EFSA to better cooperate and coordinate with ECHA, EMA and EEA**. This cooperation would lead to **more consistent scientific assessments of chemicals** and encourage the agencies to develop consistent scientific opinions and methodologies, taking into account specific sectoral characteristics. The provisions on data and information exchange would bring the EU a step closer to the one substance, one assessment goals. These provisions make greater interoperability possible and scientific processes more robust;
- amends Regulation (EC) No 401/2009 (the EEA Founding Regulation). It includes streamlining obligations on the EEA to **promote and coordinate the development of assessment methodologies** and places cooperation obligations on the EEA;
- amends Annex I of Regulation (EU) 2017/745 (the Medical Devices Regulation) to task ECHA with **updating existing guidelines** on conducting the risk-benefit assessment of the presence of phthalates in

medical devices. The agency will also develop guidelines for other substances, which are classified as either carcinogenic, mutagenic or toxic to reproduction, of category 1A or 1B or have endocrine disrupting properties for human health of Category 1;

- amends Regulation (EU) No 2019/1021 by giving the Commission the possibility to request ECHA to develop a report **analysing the human health, environmental, social, and economic impact of introducing or modifying concentration limit values** specified in Annexes IV and V to Regulation (EU) No 2019/1021 (POPs Regulation).

Considering the highly technical nature of the amendments, this provision also introduces the adoption of amendments to Annexes IV and V by means of a delegated act. To promote the development of a comprehensive chemical exposure and toxicity knowledge base, as well as streamline data flows in line with the one substance, one assessment policy target, the provision also **diverts data flows** on the presence of persistent organic pollutant substances in the environment to EEA, which is the agency responsible for collecting occurrence data on chemicals in the environment.