(English version)

Question for written answer E-004160/25
to the Commission
Tomáš Zdechovský (PPE)
(22 October 2025)

Subject: Obsolescence of Regulation (EU) 528/2012 on biocidal products and restrictions on innovative filtration technologies

Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation — BPR) was adopted with the aim of protecting human health and the environment from the harmful effects of biocidal substances. However, its current wording often fails to reflect rapid technological developments in filtration materials and technologies that do not use chemical biocides, but are nevertheless effective in capturing and inactivating microorganisms.

As a result, innovative companies developing safe and scientifically proven technologies with a physical effect (e.g., permanent electrostatic charge or 'NanoFlashing') face severe restrictions in their ability to market and advertise. Although these products can be sold legally as harmless to health, any mention of their effectiveness against microorganisms is considered a violation of the BPR, even though it does not rely on a chemical reaction, but a physical process.

In light of the above:

1. Is the Commission considering revising Regulation (EU) 528/2012 to take account of new scientific findings and allow innovative technologies with physical effects to be placed on the market without unnecessary legal restrictions?

2. Does the Commission plan to expand or clarify the definition of 'biocidal effect' so that the physical inactivation of microorganisms is clearly distinguished from the chemical action of biocides?

Submitted: 22.10.2025

Answer given by Mr Várhelyi on behalf of the European Commission
(16 December 2025)

The Commission considers that mere filtration systems which do not use any active substance would not be covered by the scope of Regulation (EU) 528/2012 (BPR) ([1]), as the regulation excludes products acting by 'mere physical or mechanical action' (Article 3(1)(a)).

However, the Commission considers that the term 'mere' in the biocidal product definition implies that an action which is physical, but also biological/chemical, remains within the scope of the BPR.

The Commission does not intend to clarify the current definition of 'biocidal product' as the Court of Justice already provided a legally binding interpretation of the EU law.

The Court has adopted a broad interpretation on what constitutes a biocidal product under the biocides' legislation (e.g. Cases C-420/10 ([2]) and C-592/18 ([3])), with each case assessed on its own merits.

Member States have a primary responsibility to monitor the application of the relevant legal provisions and to take the necessary steps for enforcement. In its role as guardian of the Treaties, the Commission monitors the situation and may decide to take appropriate action.

In July 2025, the Commissioner for Health and Animal Welfare engaged in an implementation dialogue ([4]) with stakeholders to gather feedback on the challenges facing the biocidal products sector and potential solutions. The dialogue focused, among others, on simplifying the regulatory framework and encouraging innovation.

The issues raised will be considered during the upcoming evaluation of the BPR, which will assess the performance of the regulation in relation to its objectives and address both existing and emerging needs. The outcome will guide the Commission on whether further action or a revision is necessary.

([1]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).
([2]) Case C-420/10, Söll: https://curia.europa.eu/juris/document/document.jsf;jsessionid=E28DF9EC0C15745B2B9EADAF97E665DD?text=&docid=119906&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=1682570.
([3]) Case C-592/18, Darie https://curia.europa.eu/juris/document/document.jsf?text=&docid=221808&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=1682815.
([4]) https://health.ec.europa.eu/events/implementation-dialogue-biocides-2025-07-15_en.