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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Report on the implementation of Regulation (EU) No 528/2012 concerning biocidal products *- Information from the Commission*

Delegations will find an information note on the State of play on the implementation of Regulation (EU) No 528/2012 concerning biocidal products from the Commission in the Annex to this note.

This note is intended to be presented under "Any Other Business" at the meeting of the EPSCO Council (Health) on 7 December 2021.

ANNEX

Report from the Commission to the European Parliament and the Council on the implementation of Regulation (EU) No 528/2012

- Information from the Commission -

Background

According to Article 65(4) of Regulation (EU) No 528/2012 on Biocidal Products[1] (the BPR), the Commission has to submit every five years to the European Parliament and the Council a report on the implementation of the Regulation. The report has to be drawn up on the basis of reports provided by Member States and it is to be submitted to the European Parliament and the Council within 12 months from the deadline for submission of Member States' reports to the Commission. The deadline for the submission of the very first report was 30 June 2021 – covering the period from the entry into application of the BPR (1 September 2013) until 31 December 2019. The report[2] and the accompanying Commission Staff Working Document[3], which presents detailed evidence for the findings, were published on 7 June 2021.

Biocidal products are designed to control organisms that are harmful to human or animal health or materials. The BPR sets up a two-step approach: 1) approval of the active substances at Union level after a thorough scientific evaluation, followed by 2) the authorisation of products containing them at national or Union level with a view to ensuring that only products evaluated for safety and efficacy according to the harmonised rules of the BPR are made available on the Union market.

Main findings and conclusions of the report

The report finds that eight years after the adoption of the BPR all its provisions are fully operational. The importance of biocidal products, in particular disinfection products, has been particularly highlighted during the COVID-19 pandemic. The provisions in the BPR on emergency situations allowed Member States to address the shortages in the supply of disinfectants that followed the steep increase in demand in the initial phase of the pandemic.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0287
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021SC0128

The report however also identifies the alarmingly slow progress in the execution by Member States of the Review Programme of the so-called existing active substances (i.e. those that were already placed on the market in May 2000) and the resulting substantial delay in active substance approval. Although initially foreseen to be completed by 2010, the duration of the Review Programme had to be extended already twice (to 14 May 2014 and then to 31 December 2024, which is the current deadline). At the end of the period covered by the report (i.e. five years before the final deadline), only 35% of the Review Programme has been completed.

In addition, the report identifies that for the various procedures for product authorisation, Member States do not respect the legal deadlines foreseen in the BPR. Especially for mutual recognition, more than 60% of the procedures are delayed. Delays occur also in the Union authorisation procedures during the assessment by the evaluating Member State and, as a result, up to now, it was not possible for the Commission to complete any procedure for Union authorisation within the deadlines in the BPR.

Because of the delays in the Review Programme, the majority of the products on the market (several tens of thousands) still fall under transitional measures, which in many Member States do not require any evaluation for safety and efficacy of the product. The completion of the Review Programme is thus crucial for the achievement of the objectives of the BPR to ensure a high level of protection of human health and the environment.

The slow progress with the Review Programme is also a disincentive for the development of new active substances, since products containing active substances in the Review Programme can be made available on the market under national rules, which are less stringent than the rules in the BPR. The report points out that very limited innovation on new active substances occurred under the BPR.

The report finds that the main reason for the delays is a systemic lack of resources in the Member States. Already in 2015, the Commission sent letters to all Member States, highlighting the importance of completing the Review Programme and inviting them to ensure that competent authorities have the appropriate resources to fulfil their obligations under the BPR. In 2017, the Commission initiated discussions with all parties involved in the process (competent authorities, European Chemicals Agency (ECHA), industry associations) to better understand the main causes of the delays, identify possible actions to minimise such delays, and seek for the renewal of the commitment from Member States in completing their tasks. A list of actions to be undertaken by all parties involved was agreed in 2018. ECHA has also drawn up an action plan to accelerate the pace of the Review Programme.

In the report, the Commission concludes that the regulatory system set out in the BPR cannot function properly if Member States do not fulfil their legal obligation to ensure that their competent authorities have the appropriate resources.

The Commission also invites Member States to review the fees that they can collect from applicants to cover all costs related to the BPR procedures with regard to the appropriateness of their level and the need to ring-fence the revenue derived from them for activities related to the BPR.

Follow-up actions

In light of the findings of the report, on 25 June 2021, Commissioner Kyriakides sent letters to the relevant Ministers of Member States, calling on them to urgently review the situation in their country and to take the appropriate measures to ensure that the competent authorities tasked with the implementation of the BPR properly execute their roles. The 14 Member States that responded so far acknowledge the importance of concluding the Review Programme and appreciate the initiative of the Commission to contract technical experts to support competent authorities. In some of the responding Member States actions have already been taken to improve the resource situation of competent authorities, while in others the national fee system has been revised or is under revision.

The Commission calls on all Member States to take the necessary steps to improve the situation otherwise the objectives of the BPR cannot be achieved.

The Commission is willing to support Member States in this process. Under the Single Market Programme 2021-2027, the Commission services intend to establish a contract with technical experts who will be available to support directly Member States' competent authorities in specific areas where they do not have sufficient expertise available.

Environment Council on 6 October 2021

This topic was discussed at the Environment Council held on 6 October 2021. The Commission highlighted the importance of completing the Review Programme and called on Member States to ensure that their competent authorities have sufficient resources to complete their tasks. The Member States taking the floor expressed support for the Commission's call.