

Ministry of Infrastructure  
and Water Management

> Return address Postbus 30947 2500 GX Den Haag

**Bestuurskern**  
Dir Omgevingsveiligheid &  
Milieurisico's  
Cluster D  
  
's-Gravenhage  
Postbus 30947  
2500 GX Den Haag

Date 18 November 2021  
Subject Response to EC letter on the implementation of the  
Biocidal Product Regulation

Dear Commissioner Kyriakides,

Thank you for your letter on the report regarding the implementation of the Biocidal Product Regulation (BPR) (EU) 528/2012, as sent on June 25th 2021. Like the Commission, the Netherlands attaches great importance to an effective implementation of the BPR, including the completion of the Review Programme.

In the letter, you request to review the implementation of the BPR in the Netherlands and take appropriate measures to ensure that the competent authorities tasked with the implementation of the BPR properly execute their roles. Furthermore, you ask to consider to review whether there is a need to improve our national system for setting the fees that our authorities collect from applicants to cover the costs related to the procedures in the BPR and consider the possibility to ring-fence the revenue derived from these fees to ensure sustainable financing of the competent authorities. Finally, you request to be informed about the measures taken in response to this letter.

I strongly agree that the completion of the Review Programme is crucial for the achievement of the objectives of the BPR. For the Netherlands, the assessment under transitional law is very similar to that under the BPR. In other Member States, however, biocides can be marketed based on transitional rules that meet less stringent requirements. This poses several challenges, including those regarding a level playing field and products that arrive on the Dutch market but lack authorisation. These challenges will remain until the EU harmonized authorisation procedures apply in all Member States.

The competent authority of the Netherlands, the Board for the Authorization of Plant Protection Products and Biocides (Ctgb), is an independent administrative body. The Ctgb determines the fees required for the assessment for specific applications based on their experience of the cost required on previous cases. In doing so, we have ensured sustainable financing of the competent authority. The Ctgb strives to accommodate the demand of the industry to assess their dossiers,

and to further increase their capacity as necessary, as it has been doing continuously over the last ten years. As an independent administrative body with fees that fully cover the costs of the assessment, the Ctgb can adapt its assessment capacity to accommodate the demand within the limits of growing in a controlled manner. However, there are certain costs related to the applications of biocides, for which there is no (practical) option to charge the fee from the applicant. Our main concern are the costs related to the work on Union Authorisations in cases where The Netherlands (Ctgb) is not the evaluating Member State. Due to the rise in the number of Union Authorisations, this is becoming a significant financial and burden. In that regard, it would be very helpful if the Commission could work towards a solution together with ECHA and the Ctgb.

As also reported during the fact finding mission of the European Commission, the workload in the Netherlands has increased exponentially since 2017. An example thereof can be found in the fact that the Netherlands received almost half of the total number of Union Authorisations. While the number of applications received was in line with forecasts, these applications were far more complex than expected and therefore required more assessment capacity than anticipated. With regard to the overall European assessment capacity, the Netherlands makes a relatively large contribution, and will continue to make its efforts.

For reaching a harmonized approach and efficiency in the assessment, it is important that more European guidance is available for assessing the wide variety of applications covered by the BPR. The Netherlands will continue its involvement in developing and harmonizing European guidelines. To further support this process, the Commission could facilitate the exchange of expertise and development of guidance.

Concerning the delays and backlogs identified in the report, I would like to stress that these arise partly due to the increasingly intensive and complex procedures, caused by e.g. changes in the legal framework or scientific insights that act retrospectively. In my opinion, these changes need to be as limited as possible, to prevent further delays. I hope for the Commissions support on this position. We will continue our contribution to find ways to speed up the process, in line with the efforts already made by ECHA, the Commission and other Member States.

We would like to stress the importance of the necessary resources at the competent authorities and therefore welcomed your initiative to support directly Member States' competent authorities in specific areas where they do not have sufficient expertise available. This will certainly help to accelerate the work. It should also enable a more evenly distribution of the work as well as safeguard sufficient experience at the competent authorities and a high level of quality in the European review process and decision making process. The help of the Commission to reach further agreement on a more even distribution would be appreciated.

Finally, in line with the recognized importance of the completion of the Review programme, the Ctgb puts all efforts on finalizing its share. If needed I will look with Ctgb for ways to support them in this.

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I look forward to cooperate with you on this important topic.

Yours sincerely,

the State Secretary for Infrastructure and Water Management,

S.P.R.A. van Weyenberg