

VCI Contribution to the Consultation on

## **SIMPLIFICATION: BPR IN THE FRAME OF OMNIBUS X**

The following VCI comments are exclusively related to the proposals COM(2025)1020 and COM(2025)1030 which contain amendments to the Regulation (EU) Nr. 528/2012 (BPR).

### **Comment**

VCI strongly welcomes the Commission's initiative to simplify and streamline legislation under the Food and Feed Safety Simplification Omnibus (Omnibus X). The current situation is placing an enormous burden on companies and threatens to result in the loss of important active substances, biocidal products and essential uses.

Simplification is urgently needed to reduce the accumulated complexity and lengthy procedures, in order to finally achieve the original objectives of the BPR – a harmonised single market and a high level of protection.

- ▶ With regard to the proposed amendments to the Biocidal Products Regulation (BPR), we consider the move away from the time-limited **validity of approvals** in cases where neither article 5 nor article 10 are concerned an important step focussing on the finalisation of the Review Programme. However, re-assessment remains possible when justified at any time. Against this background, in cases where approval remains limited because of intrinsic properties of the active substance, the approval period should be lengthened to reduce workload and to improve focussing the finalisation of the Review Programme, thus the initial evaluations.

To ensure coherence and effectiveness, we recommend aligning product authorisations with substance approvals. Biocidal products containing solely active substances with unlimited approval periods should not be subject to authorisation with time-limited validity periods. These simplifications would allow authorities and companies to focus on new scientific developments and relevant risks rather than on repetitive procedures.

- ▶ The proposal emphasizes a **renewal mechanism for substances with unlimited approval periods**, as already foreseen through the new Article 14a. It is very important that renewals are in any case clearly focus on new information. Requests for additional data must be scientifically justified and proportionate, and new studies should only be required where new insights are expected. Full re-evaluation of previously assessed data should not become the default. The same approach should apply to renewals of biocidal product authorisations.

- ▶ We strongly support the proposal to **replace the implementing act and its individual publication in the Official Journal** with a Commission implementing decision send to the applicant which would simplify Union authorisations in a relevant matter.
  
- ▶ Regarding **data protection**, we welcome the extension of protection periods for existing active substances. Data protection should be ensured for an adequate time in any case. This measure should ensure that additional data generated or to be generated in response to evolving regulatory requirements underlies adequate cost sharing.  
However, further clarification is needed concerning data submitted in the context of renewal procedures for existing active substances. A clear, fair and predictable data protection framework is essential to safeguard investments and encourage the provision of high-quality safety data.
  
- ▶ Finally, the Omnibus X offers the opportunity to **strengthen risk assessment and** to remove the direct link between classification and biocidal product authorisation. Therefore, we propose an amendment to Article 19(5) to ensure that important and essential active substances and their corresponding products can be made available on the market and at the same ensure hazard communication. Risk assessment should replace the current hazard-based approach.  
Recently the example of Ethanol has shown that the current approach of direct linkage between hazard and biocidal product authorisation can lead to significant challenges.

## **Conclusion**

The Omnibus X has the potential to make an important contribution to a more efficient, predictable and proportionate regulatory framework by simplification. It should create legal certainty and improve the competitiveness of the European industry. At the same time, it ensures the established high level of protection for European people and their environment.

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- ▶ Identification no. in the EU Transparency Register: 15423437054-40
- ▶ The VCI is registered with registration no. R000476 in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government.

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