

CALL FOR EVIDENCE FOR THE BIOCIDAL PRODUCTS REGULATION EVALUATION

A.I.S.E. position paper

4 March 2026

Executive summary

A.I.S.E., the voice of the cleaning and hygiene products industry in Europe, welcomes the opportunity to provide comments to this call for evidence on the Biocidal Products Regulation evaluation.

- A.I.S.E. fully supports the objective of the BPR evaluation to simplify and reduce administrative burden for economic operators and competent authorities.
- A.I.S.E. calls for a revision of the BPR, that should aim at improving regulatory efficiency and agility, while maintaining high safety and efficacy standards, in order to better support innovation addressing current and future public health challenges.
- We are looking forward to contributing in an active and constructive way throughout the BPR evaluation process and consultations.

This evaluation is a timely initiative that can help make EU legislation more coherent, efficient and innovation-friendly - in line with the **Simplification and Better Regulation Agenda**, and consistent with the **Clean Industrial Deal** to ensure that public health's safety and innovation go hand in hand.

Biocidal products are a cornerstone of public health protection. They are used across a wide range of critical sectors such as healthcare, agriculture, food processing, hospitality sector and household applications. From hand and surface disinfectants, used to prevent the spread of infectious diseases, to rodenticides, or insect repellents used to control vector-borne diseases such as West Nile virus which are increasing public health concerns, biocidal products are indispensable to ensure Europe's resilience and preparedness to these new health challenges. The European biocides market is valued at approximately €10 billion annually, operated mainly by Small and Medium-sized Enterprises (SMEs), which account for nearly 90% of the economic operators within the biocides value chain.

Despite the central role biocides play in society's protection, the regulatory framework that governs them, **the Biocidal Product Regulation (BPR), remains one of the most complex and resource-intensive regulations for the chemical industry - especially for SMEs.** More than ten years after the entry into force of the BPR, we regret that little progress has been made in addressing the numerous challenges linked to the BPR and its implementation.

The major obstacle for bringing biocidal products to the market is the unpredictability in the authorisation process causing investment uncertainty for economic operators, triggered mainly by complex procedures, changing guidance, continuous substantial delays, and lack of consistency in Members States' approaches.

Such inefficiencies hinder the functioning of the internal market and the EU's ability to bring new, innovative and effective solutions to consumers and professional users. They also put Europe at a competitive disadvantage compared to other regions, where biocidal product approvals follow faster and more predictable timelines. Crucially, in the event of a public health crisis - such as the COVID-19 pandemic - such delays could seriously compromise the EU's level of preparedness.

The BPR evaluation is a crucial opportunity to reflect collectively and in a collaborative way on the current challenges that industry is facing linked to the BPR and its implementation, as well as identifying innovative solutions for major and sustainable improvements, that can be achieved only through a revision of the BPR. Further details are outlined in the following sections.

Key challenges for our sector

Persistent barriers to harmonisation and delays after a decade of implementation

When the BPR was adopted in 2012, A.I.S.E. supported its main objective of improving the functioning of the internal market through harmonisation of the rules, whilst ensuring a high level of protection of human and animal health, and the environment¹. A.I.S.E. especially welcomed several new processes, such as the Union Authorisation and the Biocidal Product Family concept, as promising opportunities to harmonise and streamline the authorisation of biocidal products.

More than 10 years after the entry in force of the BPR, we deplore that the core objective towards harmonisation is not met, mainly due to diverging approaches from Member States Competent Authorities, and that systematic delays affect all authorisation processes. In addition, the single market is jeopardised by an increasing number of national decrees that go beyond the BPR rules.

Lack of harmonisation in BPR implementation across Member States

Lack of harmonisation is mainly due to diverging Member States' interpretation of the BPR and its guidance, and different level of resource and expertise across Competent Authorities. The Mutual Recognition is one of the most affected processes, where some Member States do not rely on the work done by the reference Member States and re-evaluate dossiers - which is not in line with the concept of Mutual Recognition - and leads to lack of efficiency and delays. Similar challenges are encountered for Union Authorisation in the peer review process.

Delays and changing guidance

Continuous substantial delays is one of the main issues identified in the last Commission's report on the implementation of the BPR². More and more companies are reporting exceedance by Member States of the 3-year legal deadline to evaluate a product dossier by additional 3-4 years, followed in some cases by up to a further 4 years waiting for Mutual Recognition. In the meantime, Member States apply new or updated guidance to dossiers under evaluation (such as request for new efficacy data), further adding to the delays - such compounding delays are the most challenging for any applicant to deal with.

¹ BPR Article 1:

"The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment."

² Report from the Commission to the European Parliament and the Council on the implementation of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (COM (2021)287 final)

Fragmentation of the single market

In the past years, we saw an increasing number of national decrees adding specific rules for certain biocidal product types (PTs), that go above and beyond EU law, as such hampering EU market access. Examples include restricting in-store advertising of certain PTs (e.g. consumer insecticides), adding the requirements for specially trained staff and locked shelves for the products, leading to many stores delisting them due to an inability to accommodate the law. This in turn leads to a *de facto* ban of certain products from consumer shelves, with consumers in certain Member States having less access to registered products than others.

An unpredictable framework that hampers innovation

The challenges and shortcomings in implementing BPR create significant unpredictability for economic operators seeking to bring biocidal products to the market, at a time when companies require investment certainty more than ever. Such an unpredictable regulatory framework hinders innovation:

- Assessments for biocidal product dossiers can take over 7 years, tying up resources - especially for SMEs - which cannot be allocated toward innovation, such as developing new products with enhanced sustainability profiles.
- Lengthy authorisation timelines delay market access and return on investment, making it hard to cover R&D and regulatory costs.
- Finding an evaluating Competent Authority for simplified or Union authorisation is increasingly challenging, some authorities indicating capacity to evaluate dossiers in 3 years' time – such timelines prevent a fast access to market of innovative products.
- Biocidal products manufacturers are also facing a loss of active substances, with insufficient new actives being approved; availability of a variety of actives is critical for addressing in a timely manner future health crises, such as outbreaks caused by viruses like SARS-CoV-2 or the increasing spread of vector-borne diseases like West Nile virus or Chikungunya.

A.I.S.E. recommendations: The BPR evaluation is a unique opportunity and should lead to the revision of the BPR

Better recognition of the crucial role of biocides for public health

The BPR legislation should recognise the pivotal role biocides play in ensuring public health protection and should stress authorities' responsibility to ensure adequate and sufficient availability of biocidal products. Such recognition would be consistent with other legislative approaches such as the Plant Protection Products Regulation, which sets as one of its objectives the availability of plant protection products in Member States³.

³ REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market, recital (9): *"The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States"*

Prioritising Resources to deliver a ‘European baseline’

Resources – both from authorities and industry - should be directed towards securing initial approvals and authorisations to guarantee a minimum ‘EU baseline’, i.e. bringing all active substances and biocidal products under the BPR rules.

The European Commission acknowledged this priority in its recent “Food and Feed Safety Simplification Package⁴” which proposes establishing an unlimited approval duration for some biocidal active substances, so without the need to renew their approval. In this respect similar principle should also be applied to biocidal products that contain those actives.

More efficient and faster biocidal products authorisation process

As highlighted in the Commission’s report on the implementation of the BPR, the main reason for all delays observed is a “*systemic lack of resources in the Member States*”. We are doubtful that Member States’ capacity will increase sufficiently in the coming years, it is thus critical to optimise use of resources. To this aim, A.I.S.E. calls for **simplifying and streamlining of the biocidal product authorisation process, avoiding redundant assessments**, to allow gaining speed in the evaluation work. The BPR should take inspiration from best practices that are in place in some EU Member States and in other regions, such as:

- The Belgian and Dutch simplification schemes for authorisation of biocidal products that are under transitional rules - i.e. not yet under BPR rules - optimising the assessment procedure for a better use of competent authorities’ resources. Such approaches are delivering positive results, reducing delays and as such improving the time to market.
- The Canadian monograph authorisation procedure for well-characterised biocidal products (such as common disinfectants) that meet predefined efficacy and safety standards. This avoids duplicating assessments already completed for similar products, providing a prompt and effective authorisation route.

More consistent and harmonised decision-making process across EU

We recommend that **ECHA plays a greater coordination role** in product authorisation processes - especially Mutual Recognition - to ensure consistency in evaluations (for instance, pre-alignment on waivers and evaluation approaches), and as such improve their efficiency. Competent authorities’ expertise should be optimised at European level, by creating **pools of national competent authorities’ experts under ECHA’s coordination**, where some Member States would act as ‘reference experts’ for given Product Types, to support competent authorities that lack relevant expertise. This would improve efficiency in the use of resources.

“Freeze the guidance”

Guidance documents are regularly being updated or developed under the BPR framework. It is common practices that Member States apply new guidance to biocidal product applications that have already been submitted, sometimes two or three years earlier. Not only does this create additional work for all parties, but it can also often lead to confusion, disparity and extensive delays. Whilst we acknowledge the importance of taking into account recent scientific knowledge when evaluating dossiers, **we request that biocidal product dossiers are evaluated**

⁴ [Food and Feed Safety Simplification Package](#) – December 2025

according to the guidance available at the time of dossiers preparation - the standard being 2 years before the submission date. This ‘cut-off’ should be formally set in the BPR legislation.

Hazard classification should not exclude safe products from the market

The hazard-based approach under the BPR does not properly reflect the real risk and prevents valuable and safe biocides from being placed on the market.

A.I.S.E. believes that the BPR revision provides an opportunity to strengthen the risk management role of the European Commission in the process of approval of active substances. Regarding the exclusion and substitution criteria, a link must be established between the routes of exposure relevant for biocidal uses and the classification of a substance. In particular, a classification as CMR (Carcinogenic, Mutagenic or Reprotoxic) based on route of exposure which is not relevant for biocidal uses should not be taken into consideration under the BPR. In this context, the data used to support such classifications should relate specifically to the biocidal use of the active substance, in conditions where it can reasonably be expected to be used as a biocidal product.

To this end, **Article 5 paragraph 2 of the BPR should be amended to include a focus on contextual exposure and realistic use scenarios.** The objective should be to place biocidal products on the market where exposure scenarios show that they do not pose unacceptable risks under the conditions of use envisaged, aligning with a more risk-based, use-specific approach.

Legislative coherence

The BPR should be coherent with other legislation, for instance in the food area: some substances that are commonly ingested by humans, such as alcohol or essential micronutrients like vitamin D (cholecalciferol) or iodine, see their use as biocides restricted under the BPR rules – for instance a Dutch policy promotes iodine intake through bread, whilst iodine is restricted under the BPR due to its background value in Europe. Distinct management strategies for such substances are therefore critically needed.

In addition, the BPR shall not set requirements that would go beyond overarching chemicals legislation such as REACH or the CLP Regulation - for instance, using a child resistant closure for disinfectants classified Eye Dam. 1, as suggested in the ECHA BPR Human Health guidance⁵, whilst the CLP does not have such obligation.

Improved communication and transparency

Given the substantial delays observed across the BPR processes, it is critical to ensure regular and transparent communication between the evaluating Member States and the applicants. In the current challenging economic environment, companies need predictability to allow them to continue to place their biocidal products on the market. Applicants increasingly report lack of response from their biocidal product dossier evaluators as a major hurdle in bringing products to market – examples include companies receiving no feedback, up to 2 to 3 years after the start of the dossier evaluation. **A formal feedback loop during dossier evaluation should be put in place, ensuring that the evaluating body systematically gets back to the applicant at fixed intervals - set in the legislation - during the evaluation process.**

⁵ [Guidance](#) on the Biocidal Products Regulation, Volume III Human health, Parts B+C: Assessment & evaluation

A.I.S.E. is the voice of the cleaning and hygiene products industry

A.I.S.E. represents an industry that supplies essential detergents, cleaning and maintenance products, disinfectants and biocidal products for cleanliness and hygiene at home and in public spaces across Europe. Based in Brussels, the association has been the voice of the industry since 1952.

Membership includes 30 national associations across Europe, 19 corporate members, and 18 value chain partners, collectively representing a broad network of over 900 companies supplying household and professional cleaning and hygiene products and services. The A.I.S.E. network works with EU and national decision-makers to strengthen the Single Market through innovative, science-based solutions that ensure user safety, environmental protection, and regulatory compliance.

A.I.S.E. members active in the biocides supply chain are mainly formulators of biocidal products including a vast range of disinfectants (Product Types 1 to 5) for household and institutional uses in the healthcare sector and food, beverage and farming industries – as well as insect control products (Product Types 18 & 19). Most A.I.S.E. members are also downstream users of preservatives (Product Type 6) for liquid-based formulations such as laundry detergents, hand dishwashing liquids and all-purpose cleaners. The annual market value of biocidal products for healthcare facilities and food, beverage & farming industries is estimated at €2 billion each. Home insect control products represent approximately €1 billion per annum market value. www.aise.eu

Contact: Elodie Cazelle, Senior Scientific and Regulatory Affairs Manager, Elodie.cazelle@aise.eu

