



Recommendation on access to biocidal products used in aquaculture

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I. Background

The use of safe and effective biocidal products as disinfectants and antifouling agents is essential for maintaining biosecurity, fish health and fish welfare in finfish aquaculture operations.

The use of biocidal products depends on many factors, but the need for these products is generally greater in recirculating aquaculture systems than in flow-through and 'open water' systems (nets, enclosures and pens).

The EU aquaculture sector is highly dependent on the development and uptake of alternative biocidal products that have been tested under monitored conditions in commercial settings.

The Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012)¹ concerns the placing on the market and the use of biocidal products. Annex V to the Regulation lists various biocidal product types. The following product types are commonly used in EU aquaculture:

- Product-type 2: Disinfectants (disinfection of embankments, basins, equipment, facilities, grids, etc.)
- Product-type 3: Veterinary hygiene (water treatment to control pathogens and/or improve water quality)
- Product-type 21: Antifouling products (to manage biofouling).

The AAC has identified the following core problems related to the use of biocidal products.

a) Borderline cases: Biocidal product or veterinary medicinal product?

Some biocidal products are used to control pathogens (parasites, bacteria, viruses, etc), while veterinary medicinal products are used to treat or prevent diseases. This may give rise to borderline cases concerning product classification. Article 3 of (EU) Regulation 2019/6 on veterinary medicinal products² stipulates that Regulation takes precedence when a veterinary medicinal product also falls within the scope of the BPR.

The absence of a clear distinction between the Biocidal Products Regulation and the Veterinary Medicinal Products Regulation leads to divergent interpretations across Member States. The Commission can issue a binding decision if a dispute arises between national competent authorities.

¹ <https://eur-lex.europa.eu/eli/reg/2012/528/oj/eng>

² <https://eur-lex.europa.eu/eli/reg/2019/6/oj/eng>

Example

Formalin-based treatments are authorised under specific conditions in certain Member States (e.g. Spain, where a veterinary medicinal product (VMP) is authorised), while they are restricted or not permitted in others (e.g. France or Italy).

b) Approval/authorisation: Status

The BPR requires that all active substances used in biocidal products to undergo a safety and efficacy assessment before they are approved for use across the EU. To manage the transition from the previous rules, the BPR maintained the existing review programme for assessing existing active substances that were already on the market in 2000.

The review programme aims to ensure that only substances meeting EU safety requirements remain available. Under the BPR, each application is assigned to an authority in a Member State acting as the evaluating competent authority, which prepares an assessment report. The European Chemicals Agency (ECHA) then coordinates a peer review among Member States and helps ensure consistency within the system. Final approval decisions are taken by the Commission in consultation with representatives of the Member States.

However, the review programme, launched in 2000, has been repeatedly extended and is now scheduled to be completed by 2030. As of September 2025, just over half of the substance dossiers had been assessed. These delays undermine the BPR's objective of ensuring, within predictable timelines, that only substances meeting EU safety requirements remain on the market.

The Commission has proposed more targeted and efficient renewal procedures for biocidal products (Simplification Omnibus Package, Commission Staff Working Document, SWD(2025) 1030 final)³.

This situation leaves the EU aquaculture industry facing uncertainty regarding the regulatory status of various biocidal products.

The AAC has compiled a list of the biocidal products most commonly used in EU aquaculture (Annex 1), and aquaculture operators are seeking information on the current legal status of the listed products:

- Which biocidal products are authorised or under review at Member State level or Union level for the relevant product types?

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025SC1030>

- Which biocidal products are, or are likely to be, regulated under Regulation (EU) 2019/6?

c) Approval/authorisation: Costs

The approval of active substances used in biocidal products takes place at Union level. The subsequent authorisation of the biocidal products takes place at Member State level, and the authorisation can be extended to other Member States through mutual recognition. The BPR also allows applicants to apply for Union authorisation.

Approval and authorisation procedures can be very costly and complex, and applicants are required to pay fees. For example, the Implementing Regulation (EU) 2025/1490⁴ increases the fees charged by the ECHA by 19,5%, bringing the fee for Union authorisation to approximately €180.000.

This creates challenges for the supply of biocidal products to the EU aquaculture industry, as markets for these products are very small and often consists of micro-segments.

Example

The use of copper-coated nets is permitted in Danish aquaculture, but the industrial coating process cannot be carried out in Denmark, as no biocidal products required for industrial net coating are currently authorised for use there under the BPR. Consequently, Danish aquaculture operators must therefore send their nets to specialised coating facilities in other in Member States, where the relevant biocidal products are authorised for industrial net coating. The product supplier had applied for authorisation in Denmark through mutual recognition, but withdrew the application because of the complexity and costs of the procedure, following subsequent request for additional information from the Danish competent authority.

AquanetUltra is authorised in Finland, Greece, Lithuania and Norway, while Netwax NI Gold is authorised in Iceland, Lithuania, Norway, Slovakia and Spain (ECHA database on biocidal products). This results in significant additional costs for the sector.

d) Alternative biocidal products

The EU market for biocidal products is limited and fragmented, and the development and uptake of alternative biocidal products remain constrained. Alternatives to traditional

⁴ https://eur-lex.europa.eu/eli/reg_impl/2025/1490/oj/eng



products may offer environmental benefits, greater effectiveness, improved ease of use and greater economic viability.

The AAC highlights the need for a legal pathway allowing emerging products to be tested under monitored conditions in commercial settings.

II. Justification

The new regulatory framework, together with significant delays in the review programme and divergent interpretations and implementation practices across Member States, creates uncertainty regarding the current and future use of biocidal products in aquaculture, unequal access to products and differences in authorised uses.

Complex and costly approval and authorisation procedures, combined with small and narrowly segmented markets, limit suppliers' willingness to invest in biocidal products for the EU aquaculture industry.

Seeking authorisation for certain products as veterinary medicinal products for specific uses would give rise to similar challenges relating to costs, regulatory hurdles and limited market size.

III. Recommendations

AAC Recommendations

To the European Commission:

1. Clarify the relationship between the Biocidal Products Regulation (regulation (EU) 528/2012) and the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) as regards their application to aquaculture.
2. Assist the AAC in clarifying the regulatory status and applicable legal pathway (biocidal product or veterinary medicinal product) for the most biocidal products most commonly used in EU aquaculture.
3. Inform the AAC of the status on the Simplification Omnibus Package covering biocidal products.
4. Streamline and simplify the procedures for Union authorisation and mutual recognition of biocidal products used in aquaculture.
5. Propose a legal framework allowing the controlled experimental use of alternative

biocidal products in EU aquaculture, including simplified approval and authorisation procedures.

IV. Annex: Commonly used biocidal products in EU aquaculture

Biocidal product	Objective
Acetic acid	Biofouling control and disinfection
Chloramine T	Disinfection
Copper oxide	Biofouling control
Copper pyrithione	Biofouling control
Copper sulphate	Disinfection/water quality
Formalin	Disinfection
Formic acid	Disinfection/water quality
Glutaraldehyde	Disinfection
Iodine	Disinfection
Hydrochloric acid	pH adjustment/biofouling control
Hydrogen peroxide	Disinfection/water quality
Lime	Disinfection/pH adjustment/water quality
Hydrated lime	Disinfection/pH adjustment/water quality
Ozone	Disinfection/water quality
Potassium peroxymonosulphate	Disinfection/water quality
Quaternary ammonium compounds (e.g. benzalkonium chloride (BAC) or didecyl dimethyl ammonium chloride (DDAC))	Disinfection
Salar Des	Disinfection
Sodium chloride	Disinfection/water quality
Sodium hydroxide	pH adjustment/water quality
Sodium percarbonate	Disinfection/water quality
Peracetic acid	Disinfection
Virkon Aquatic	Disinfection



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