



Information on the EU Biocidal Products Regulation

Aquaculture Advisory Council

WORKING GROUP 1 “Finfish” Meeting

18 February 2025

DG SANTE, Unit E4

- I. Reminders on the Biocides Regulatory framework
- II. Biocidal products in aquaculture
- III. Case of iodine/PVP iodine active substances and biocidal products

I. Reminders on the Biocides Regulatory framework

What is a biocidal product?

- Biocidal Products Regulation : Regulation (EU) N° 528/2012 of 22 May 2012, the BPR
- Tens of thousands of products on the EU market
- Biocidal products are split into 22 product-types (Annex V of BPR):
 - Disinfectants (Product type PT 1 to 5): disinfectants for human hygiene (ex: hand disinfectants), general disinfectants (ex: for home, for food processing area etc.), veterinary hygiene (ex: stables, teat dips etc.), drinking water disinfectants etc.
 - Preservatives (PT6 to 13): in can preservatives (ex: in paints, detergents etc... to avoid the degradation of the product by bacteria, fungi...), wood preservatives (against insects, fungi etc...), leather preservatives, cutting fluids preservatives, cooling towers disinfectants etc.
 - Pest control products (PT14 to 20): rodenticides, insecticides, repellants/attractants (ex: spray against mosquitoes applied on skin) etc.
 - Other biocidal products (PT21 to 22): antifouling paints on boats, embalming & taxidermist fluids

Biocidal products in aquaculture

- Various products may be used in aquaculture settings (see Annex V to the BPR):
 - Hand disinfectants (PT1)
 - General disinfectant of surfaces not in contact with food (PT2)
 - Disinfectants of materials associated with the housing or transportation of animals (PT3)
 - Disinfectants of food processing equipment, surfaces in contact with food (PT4)
 - Disinfectants of drinking water (PT5)
 - Antifouling paints/coatings on boats or aquaculture equipment (PT21)
 - Other?

Borderlines with various legislative frameworks

- Borderlines / Products out of the scope of the biocides framework since already in the scope or regulated under other legislation, for instance :
 - Medicinal products for humans or animals
 - Detergents
 - Plant protection products
 - Food or feed additives, processing aids
 - Medical devices
 - Cosmetic products
 - etc.
- E.g.: a product for general disinfection/hygiene is usually a biocidal product (e. g.: a disinfectant for equipment); while a disinfectant used for medical purpose is considered as a medicinal product (e.g.: depending on claims, disinfectant/product against parasites to treat or prevent specific diseases on fishes)

Main objectives of BPR

- Improve the functioning of the internal market by the harmonisation of the rules in placing on the market and using products
- Ensure a high level of safety for health and environment
- Encourage innovation of products with a better profile
- Ensure safety of articles/mixtures treated with biocides
- Ensure effective and harmonised implementation and enforcement in the EU

Key elements of the regulatory framework

- Biocidal products can only be placed on the market and used if they have an authorisation, given only if their use does not present unacceptable risks and they are efficient
- Two step system:
 - First : establishment of a *list of active substances approved at EU level*, that can be used in biocidal products
 - Secondly : *authorisation of biocidal products* containing these active substances

Authorisations can be given either at national level by Member States (national authorisations that can be subject to mutual recognition process, where requested by the applicant) or at the Union level by the EU Commission

- Regular re-examination of the approval of active substances (5 to 15 years, but may exceptionally be less), and product authorisations (4 to 10 years)
- Review programme started in 2004: pending the decision on the first approval, products remain subject to transitional national rules (Article 89 of the BPR); if approval, products subject to BPR authorisation system

Exclusion criteria in the BPR (Article 5)

Objective : *exclude substances of very high concern*

- Substances that :
 - are Carcinogens, Mutagens, or toxic for Reproduction category 1A or 1B, or
 - are Persistent, Bioaccumulative and Toxic (PBT), or very Persistent and very Bioaccumulative (vPvB), or
 - have endocrine-disrupting properties for humans
- **The principle: The active substance shall not be approved**

Exclusion criteria in the BPR (Article 5)

Substances may nevertheless be approved if :

- Risk is negligible, or
- The substance is essential to control a serious danger to human or animal health or to the environment, or
- Non-approval will have disproportionate negative impact for society compared to the risks.

The availability of suitable and sufficient alternative substances or technologies is a key consideration.

Consequences of exclusion

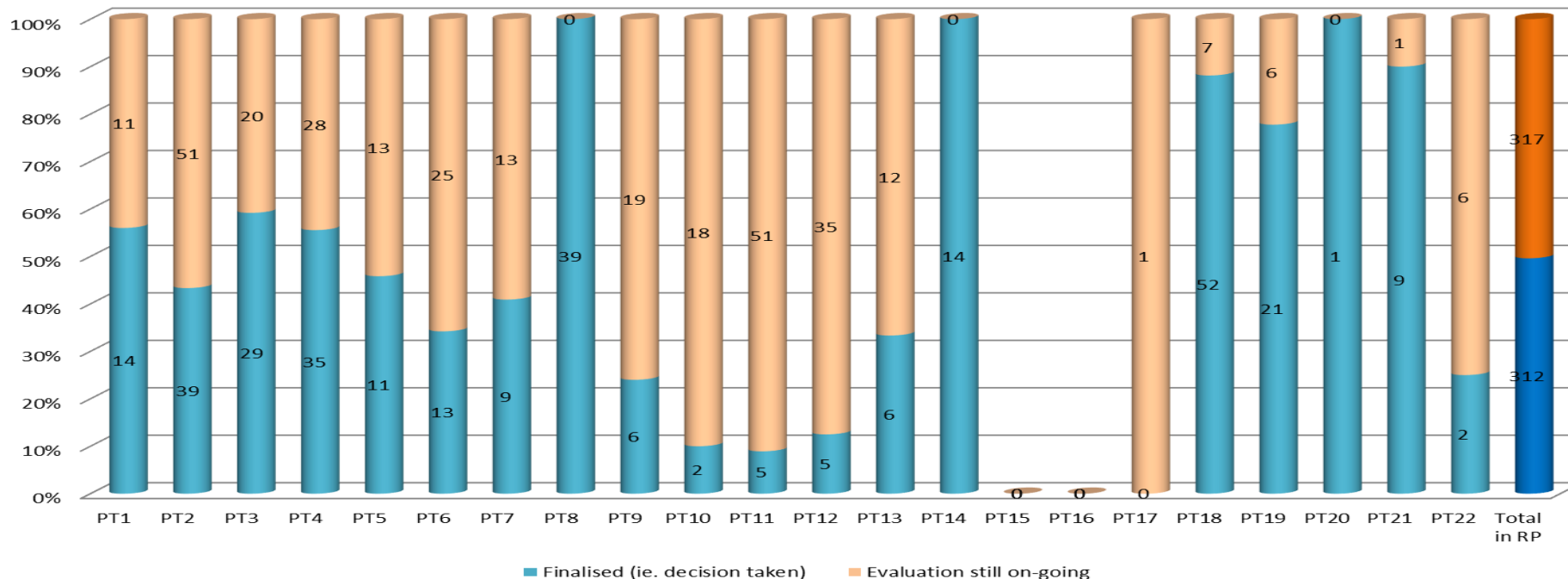
- Burden of proof is on the applicant to justify that at least one of the conditions for derogation is met, for active substance (renewal of) approval and for the product authorisation
- If the substance is approved / approval renewed:
 - For the Active Substance (AS):
 - Approval subject to strict conditions, only for uses for which the condition for derogation is demonstrated
 - Approved for a maximum of 5 years, and renewal possible for a maximum of 7 years (it can be less)
 - For the Biocidal Product (BP):
 - Authorisation only possible in Member States where at least one the condition for derogation is met
 - Targeted by the substitution provisions
 - Authorisation only for a maximum period of 5 years (it could be less)
 - Not eligible to apply for Union authorisation

II. Biocidal products in aquaculture

Progressive implementation of the Biocides legislation in the EU since 1998

- Substantial delays in the evaluation in whole review programme of active substances which started in 2004 (around 630 different evaluations) : complexity, delays in submission of missing data from applicants, lack of resources in Member States, need for applicants to submit additional data to assess endocrine disrupting criteria adopted in 2017
- Overall, 50% evaluations completed ; completion target : 31/12/2030

Overall progress of the review programme of existing AS per PT



Progressive implementation of the biocides legislation since 1998 in the EU

- Depending on the status of the active substances contained in the biocidal products, products subject to transitional national requirements, or to a product authorisation under the BPR
- Status of active substances can be checked on the European Chemicals Agency (ECHA website) :

<https://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

- Product authorisations are generally requested by companies placing them on the market
- Only compliant biocidal products can be made available on the market and used in the EU; same for treated articles with biocides (ex: treated fishnets?)
- Evolution of the market depending on whether or not active substances approved/non-approved, products authorised/not authorised; or renewed/not-renewed
- Status of products :
 - Products subject to transitional national requirements : check if any requirement on Member States competent authorities' website
 - Products subject to BPR authorisation : ECHA website <https://echa.europa.eu/information-on-chemicals/biocidal-products>

III. Case of iodine/PVP iodine active substances and biocidal products

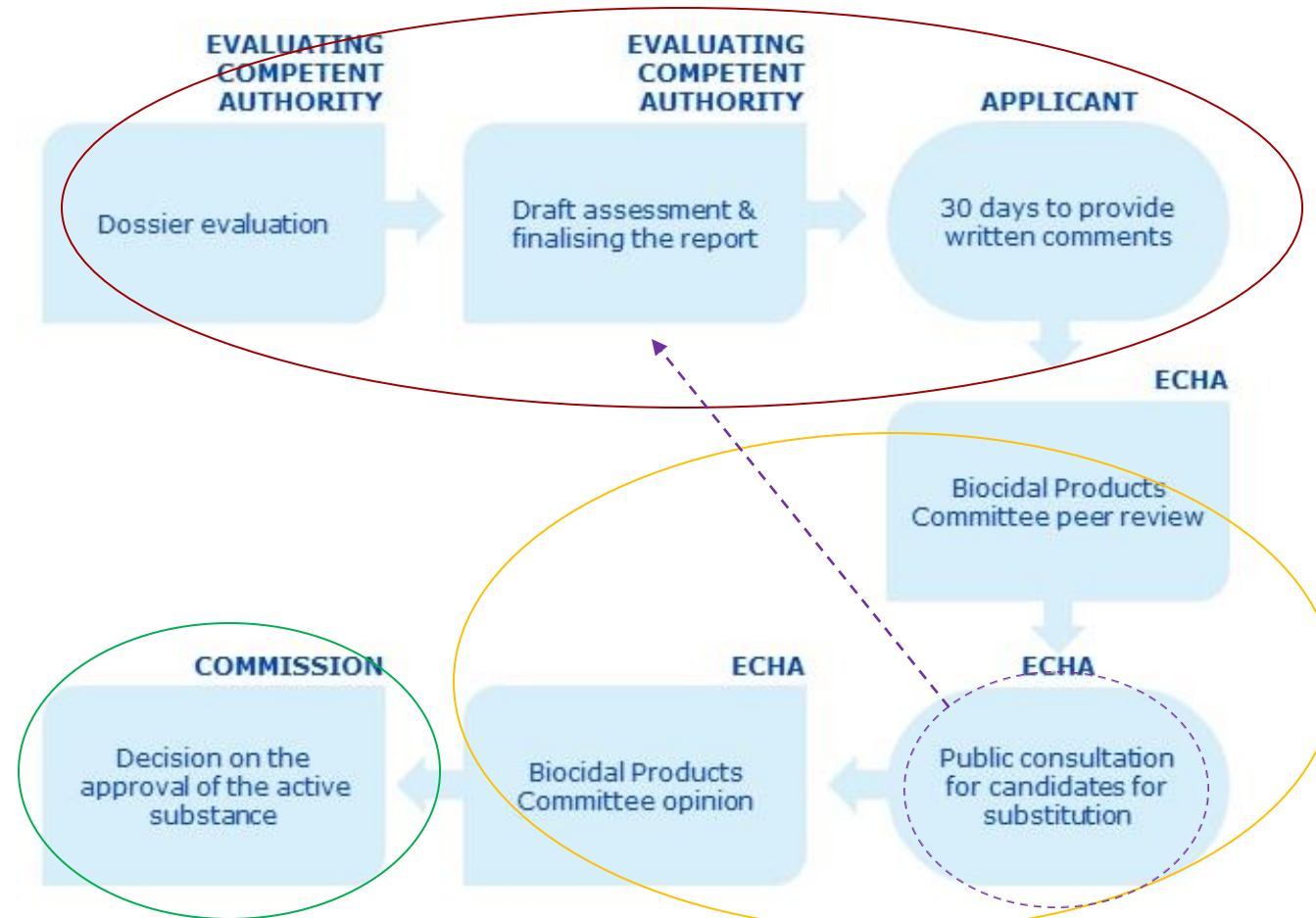
Iodine/PVP iodine

- Iodine and PVP iodine are approved for PT 1, 3, 4 and 22, until 31 August 2025 (Commission Implementing Regulation (EU) No 94/2014);
 - Applications for renewal of approval have been submitted (deadline was 28/02/2024) for :
 - Iodine only for PT3 (veterinary hygiene)
 - PVP iodine only for PT1 (human hygiene) and PT3
- possible extension beyond 31/08/25 only for these PTs
- Iodine and PVP iodine are considered since 2022 as endocrine disruptor for humans and the environment (non-target organisms) : ECHA BPC opinion of 27/09/2022

https://echa.europa.eu/documents/10162/1167923/article15_pvp-iodine_bpc_opinion_en.pdf/da55c1bd-a3c4-766d-7849-22b644fe1cfa?t=1668507867563

→ meet exclusion criteria : ED for human health

Process of evaluation for AS



Public consultation may be done earlier during the evaluation phase if the substance is already known as meeting exclusion criteria, like iodine/PVP-iodine

(Source : ECHA website)

This graphic shows an overview of the dossier evaluation process

Evaluation of the AS renewal application for iodine PVP iodine

- Process for analysis of the derogation to exclusion under Article 5(2): [CA-March24-Doc.5.4 - Exclusion substances final.docx](#)
 - Responsibility of the applicant to submit relevant information demonstrating that the conditions for derogation are met, in particular on the absence of sufficient and suitable alternatives
 - Public consultation organised by ECHA, mainly for third parties (from 24/05 to 23/07/2024): [Previous consultations on potential candidates for substitution and on derogations conditions – ECHA](#)
 - To help gathering information on the availability of alternatives; and on whether or not the substance may meet at least one of the condition for derogation (and which condition(s)?), for which use(s) within each product-type etc....)
- Currently under evaluation by the eCA (Sweden, Kemi), and then peer review and opinion by the ECHA's BPC
- Final decision on the renewal adopted by COM after consultation of Member States representatives (Standing Committee on Biocidal Products) : 2025-2026?

Current situation for BPs containing iodine or PVP iodine

- Products currently authorised under BPR : [Information on biocides - ECHA \(europa.eu\)](https://echa.europa.eu/information-on-biocides)
 - 31 August 2025: expiry/cancellation of PT1, PT4 iodine products; PT4 PVP iodine products (no BP currently authorised for PT22), as no renewal of approval has been applied for.
 - Biocidal products for PT3 containing iodine, and for PT1and 3 containing PVP iodine :
 - No renewal possible for Union authorisations; UA for PT3 iodine, PT1and 3 PVP iodine granted in the past remain valid until expiry. No new Union authorisation possible (or same BP).
 - Submission of applications for product authorisation / renewal of authorisation at Member State level only.
 - Before granting or renewing authorisations, Member States must in particular :
 - ✓ assess the risks of the products, including linked to ED properties
 - ✓ assess whether the conditions for derogation to exclusion are met or not on their territory for each product
- CA document CA-June22-Doc.4.2 “Consequences for biocidal products authorisations procedures of relevant information becoming available”:

<https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/aa098b99-9f78-4606-b9e0-9275764168d2/details>

→ This work takes place in parallel to the renewal of approval of the active substances, up to each Member State

Current situation for BPs containing iodine or PVP iodine

- Once a decision on the renewal of approval on iodine for PT3, and PVP iodine for PT1 and 3 is adopted : existing authorisations of products need to be aligned
 - Non-renewal of AS approval = cancellation of authorisations, phasing-out periods of Article 52 of BPR (6 months making available + 6 months use maximum)
 - Renewal of AS approval = adaptation of the existing authorisations with the renewed approval conditions, (re)assessment of Article 5(2) at Member State level on their territory

Actions for attendees

- Authorities/Members States : keep informed and coordinated with your national Biocides Competent Authority(ies) <https://echa.europa.eu/fr/contacts-of-the-member-state-competent-authorities>
- Users of biocidal products
 - ✓ Ensure compliance with BPR (buy/use compliant biocidal products/treated articles with biocides)
 - ✓ On iodine/PVP iodine :
 - ✓ Substitute iodine/PVP iodine in your uses when suitable and sufficient alternatives are available (exclusion objective from BPR)
 - ✓ Keep contacts with your suppliers, follow the progress of the iodine/PVP iodine review (ECHA website, ECHA newsletter, ECHA/national helpdesks)

Information on the BPR



https://ec.europa.eu/health/biocides/overview_en (DG SANTE Biocides website)

Email: SANTE-BIOCIDES@ec.europa.eu



CIRCABC

<https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b>

ECHA website <https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr>

Helpdesks :

<https://echa.europa.eu/de/contact/bpr>

<http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks>

<https://echa.europa.eu/fr/contacts-of-the-member-state-competent-authorities>

Thank you



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