Use of biocidal products in aquaculture

Aquaculture Advisory Council

Working Group 1 “Finfish” Meeting

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Outline

- Main elements of the biocides regulatory framework
- Use of biocidal products in aquaculture

Main elements of the biocides regulatory framework

Regulation (EU) No 528/2012 – Biocidal Products Regulation, BPR

Various implementing and delegated acts

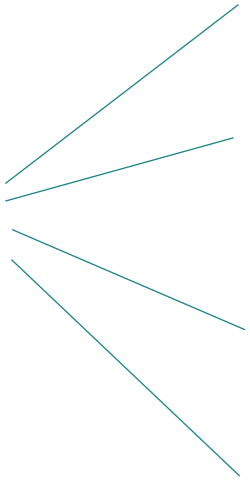
- Two-step system:
  - approval of active substances at EU level >> inclusion in Union list of approved active substances
  - authorisation of products containing those active substances at national level (in one or several Member States) or EU level (Union authorisation). Authorisation granted if their use does not present unacceptable risks and they are efficacious

- Review programme: work programme for the examination of existing active substances (active substances present on the market in biocidal products on 14 May 2000) started in 2004

- Transitional period (Article 89 of BPR): products containing active substances included in the review programme and still under evaluation remain subject to transitional national rules

Main elements of the biocides regulatory framework

- Biocidal products are categorised into
  - 22 product-types (PT)
  - 4 main groups



- disinfectants (PT 1-5): human hygiene, general disinfection (for home, for food processing area), veterinary hygiene, etc.
- preservatives (PT 6-13): in-can preservatives (e.g. in detergents or paints), wood preservatives, slimicides, cutting fluid preservatives, etc.
- pest control (PT 14-20): rodenticides, insecticides, repellents and attractants, etc.
- other biocidal products (PT 21 (antifouling), PT 22 (embalming and taxidermist fluids))

Tens of thousands of products are available on the EU market. A great part of them are made available under the transitional measures (national systems)

Main elements of the biocides regulatory framework

➢ **Exclusion criteria**

Set out in Article 5 of the BPR

Active substances with the worst hazard profile should not be approved, except in specific situations

Principle: non-approval for active 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

Derogation possibilities / conditions for derogation

Main elements of the biocides regulatory framework

➢ **Exclusion criteria**

Conditions for derogation (Article 5(2)):

- Risk from exposure to the active substance in the biocidal product is negligible (e.g. product used in closed systems)
- The substance is essential to prevent or control a serious danger to human health, animal health or the environment
- Non-approval of the substance would have disproportionate negative impact on the society compared to the risk from the use of the substance

The availability of suitable and sufficient *alternative substances or technologies* is a key consideration in the assessment of the conditions for derogation

Notable examples:

- Rodenticide active substances (anticoagulants): classified as toxic for Reproduction 1B or PBT, most of them are PBT or vPvB
- Iodine: identified as having endocrine disrupting properties for humans (and non-target organisms) (BPC opinion of 27 September 2022)

Main elements of the biocides regulatory framework

- **Exclusion criteria** – consequences for active substances and products

If the active substance is approved (one or more derogation conditions are met)

→ approval of active substance: subject to conditions, granted only for uses for which derogation conditions are met, maximum duration 5 years

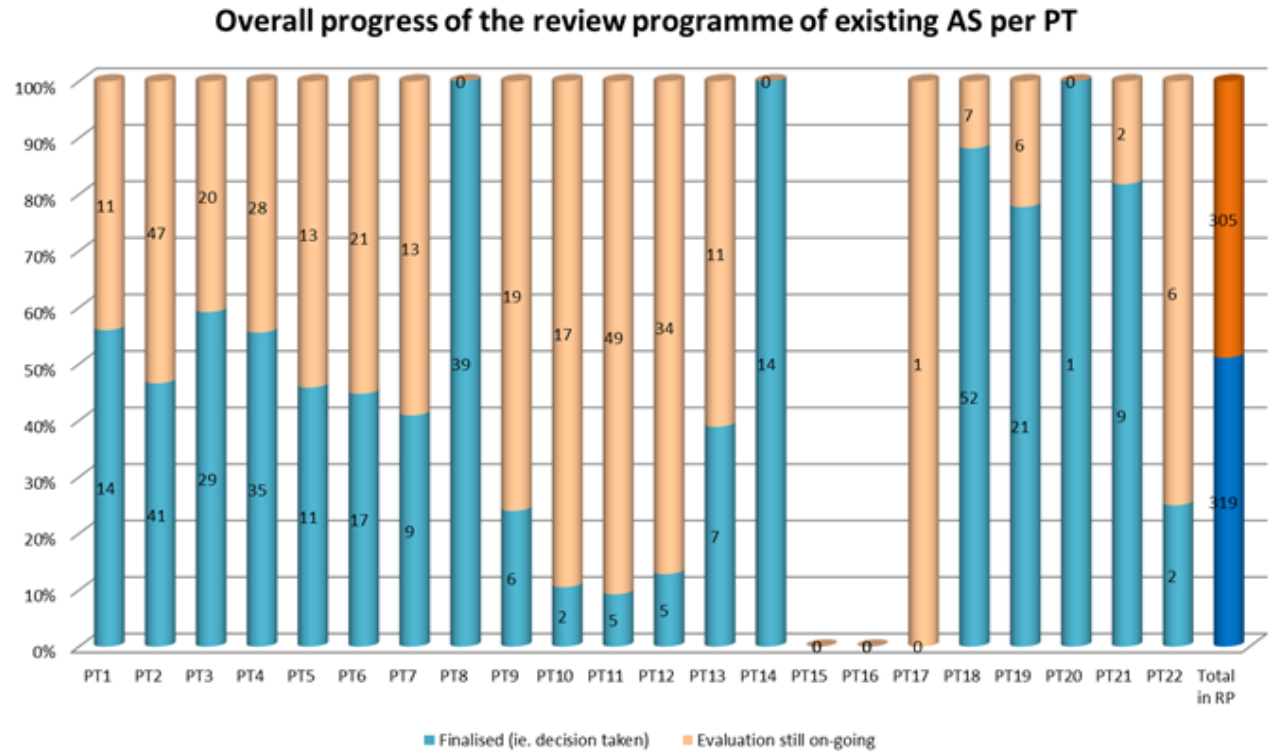
→ biocidal products containing those active substances: authorised only in those Member States where at least one derogation condition is met, are subject to substitution provisions (comparative assessment – assessment of alternatives and chemical diversity), are not eligible for Union authorisation, can be authorised for maximum 5 years

Main elements of the biocides regulatory framework

- Progress of the review programme

Substantial delays affect the review programme evaluations, mostly due to complexity of assessments, 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

- So far, 51% of the review programme has been achieved. Target deadline: 31 December 2030



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- Main elements of the biocides regulatory framework

- Use of biocidal products in aquaculture

Use of biocides in aquaculture

Biocidal products are needed in aquaculture for:

- Disinfection of tanks, nets and other material associated with the housing or transportation of animals, disinfection of fish eggs (PT 3)
- General disinfection of surfaces (PT 2)
- Disinfection of processing equipment (for surfaces in contact with food – PT 4)
- Antifouling products, applied to cages and nets to reduce the growth of algae and other organisms (PT 21)

From data available in R4BP, several active substances appear to be present in biocidal products used in aquaculture, among which: hydrogen peroxide, peracetic acid, tosylchloramide sodium (chloramin T), pentapotassium bis(peroxymonosulphate) bis(sulphate) (KMPS)

The status of an active substance (approved, not approved, under assessment) is available on the ECHA website: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

Use of biocides in aquaculture

There is no list of active substances specifically approved for use (also) in aquaculture

- the list of approved active substances for the different PTs (and related authorised products) is available on the ECHA website

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status		Related authorised biocidal products
Active chlorine generated from sodium chloride by electrolysis	-	-	PT03	01/07/2022	30/06/2032	Slovakia	**Approved**		
Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3	PT03	01/01/2019	31/12/2028	Italy	**Approved**		
Active chlorine released from hypochlorous acid	-	-	PT03	01/07/2022	30/06/2032	Slovakia	**Approved**		
Active chlorine released from sodium hypochlorite	-	7681-52-9	PT03	01/01/2019	31/12/2028	Italy	**Approved**		38
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	270-325-2	68424-85-1	PT03	01/11/2022	31/10/2032	Italy	**Approved**		1

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

Use of biocides in aquaculture

Detailed information on authorised products is available on the ECHA website

Trade name	Product-type	Active Substance	Market area	Authorisation type	
Buffodine	PT03	Iodine	Austria Czechia Denmark Finland Germany 9 more entries	National authorisation	

Product details | Authorisation details | History details and assessment | Print | [+] open all | [-] close all

[-] Biocidal Product details

Trade name	Buffodine
Product-type:	PT03

[-] Active Substance details

Substance name:	Iodine
IUPAC name:	
EC number:	231-442-4
CAS number:	7553-56-2

Product details | Authorisation details | History details and assessment | Print | [+] open all | [-] close

isation information

tion Type National authorisation

nent reports:

	Product-type	Market area	Authorisation holder	Authorisation number: R4BP 3 asset	Authorisation number: National	Authorisation start	Authorisation end	SPC	Decisions	Authorisation status
	PT03	United Kingdom	Evans Vanodine Europe	UK-0013486-0000	UK-2019-1172	29/01/2019	31/12/2020	SPC not available		Expired
Buffodine	PT03	Austria	Evans Vanodine Europe	AT-0021159-0000	AT-0021159-0000	08/08/2019	28/01/2029	Single SPC (de)	Bescheid.pdf (de) Buffodine_Anlage_1.pdf (de)	Authorised
Buffodine	PT03	Czechia	Evans Vanodine Europe	CZ-0025494-0000	CZ-0025494-0000	29/01/2019	28/01/2029	Single SPC (cs)	podminky-povoleni_PUBLIC.pdf (cs)	Authorised

https://echa.europa.eu/information-on-chemicals/biocidal-products

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Use of biocides in aquaculture

The ‘summary of product characteristics (SPC) provides specific information on use(s)

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Fish egg disinfection
Application method(s)	EYED EGGS: Disinfection by immersion - The concentrated product has to be diluted 1:100 by decanting or pumping. The eggs are immersed in solution for 10 minutes. After treatment, eggs must be washed gently four or five times in clean fresh water and placed in trays. All egg washings should be poured into drains and not into watercourses leading to fish farms or streams. NEWLY STRIPPED EGGS: Disinfection by immersion - The milt from the fertilized eggs is washed with a solution containg 90 g sodium chloride in 10 L water. The concentrated product is diluted 1:100 by decanting or pumping in 10L watter and 90 g sodium chlorid (edible quality salt) is added.The washed eggs are immersed in the prepared solution for a period of 10 minutes. Thereafter, the eggs must be washed gently four or five times in a solution containing 90 g sodium chloride in 10 L water, cleaned in freah water and placed in trays. All eggs washings should be poured into drains and not into watercourses leading ti fish farms or streams.

Use of biocides in aquaculture

- Borderline cases with other legislative frameworks – products out of the scope of the BPR since in the scope of other legislation: medicinal products (for humans or animals), detergents, plant protection products, medical devices, cosmetic products, food or feed additives, etc.

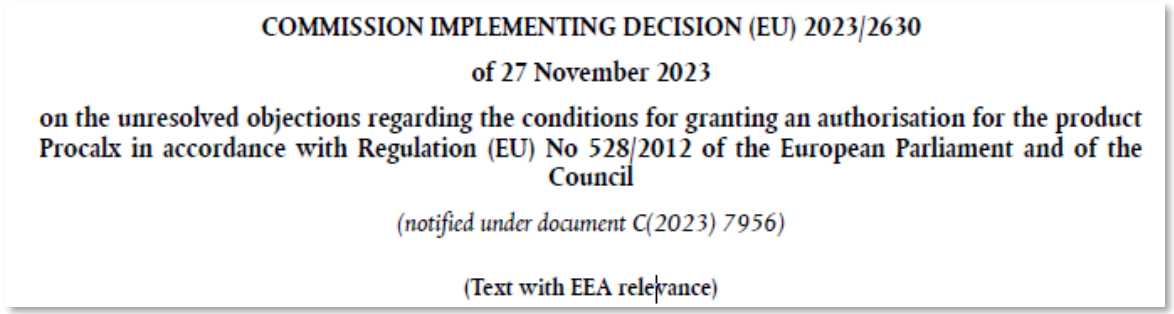
- Borderline between biocidal products and veterinary medicinal products usually as follows :
  - For general hygiene : biocidal product (ex: disinfectant for equipment)
  - For medical purpose, treatment of disease, therapeutical claims : veterinary medicinal product (ex: claims of treatment or prevention of specific fish diseases)

- Article 3 of Regulation (EU) 2019/6 on veterinary medicinal products:

  "Article 3 - Conflict of laws
  1. Where a veterinary medicinal product referred to in Article 2(1) of this Regulation also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council (20) or Regulation (EC) No 1831/2003, and there is a conflict between this Regulation and Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, this Regulation shall prevail. […]"

Use of biocides in aquaculture

- Borderline case – Commission Implementing Decision (EU) 2023/2630 concerning the product 'Procalx', http://data.europa.eu/eli/dec_impl/2023/2630/oj



COMMISSION IMPLEMENTING DECISION (EU) 2023/2630

of 27 November 2023

on the unresolved objections regarding the conditions for granting an authorisation for the product Procalx in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2023) 7956)

(Text with EEA relevance)

Product containing calcium oxide used as PT 3 (veterinary hygiene) in aquaculture to reduce the free-living stages of salmon lice (*Lepeophtheirus salmonis*)

- ✓ PT 3 not compatible with the use against salmon lice (control of crustaceans falls in the scope of PT 18)
- ✓ Calcium oxide is not approved for PT 18

The product does not meet the description of a biocidal product of PT 3 >> it does not meet the conditions for authorisation

Keep in touch

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

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Thank you

Slide xx: element concerned, source: e.g. Fotolia.com; Slide xx: element concerned, source: e.g. iStock.com

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