

ECHA and Biocides

Visit Ministry of Environment (MMA) and
Institute of Environment and Renewable
Natural Resources (IBAMA) of Brazil

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Committee



What are biocides under the Biocidal Products Regulation (BPR) EU 528/2012?

Control of organisms

that would

- be harmful to human or animal health
- cause damage to natural or manufactured products



when not covered by another legislation: pesticides,
veterinary medicines, cosmetics

chemicals or micro-organisms

Main groups and product types (PT)

Disinfectants

- ⇒ human hygiene (1), public health (2), veterinary (3), food and feed areas (4), drinking water (5)



Preservatives

- ⇒ in-can (6), film (7), wood (8), fibre (9), construction material (10), liquid cooling (11), slimicides (12), metal working fluids (13)



Pest control

- ⇒ rodenticides (14), avicides (15), molluscicides (16), piscicides (17), insecticides (18), repellents (19), other invertebrates (20)



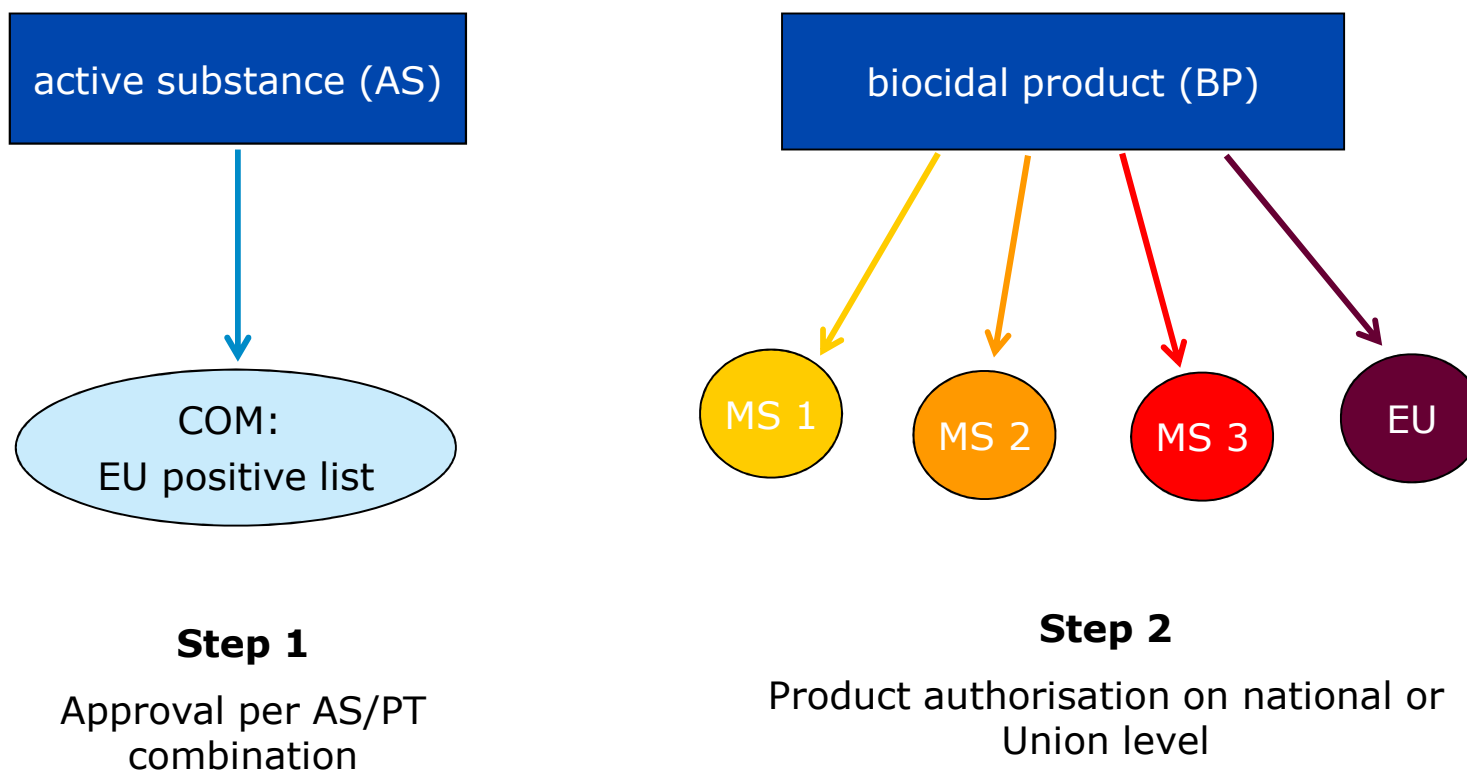
Other

- ⇒ antifouling products (21), embalming/taxidermist fluids (22)

Brazil and biocides

- MMA / IBAMA: Involved in environmental assessment of pesticides?
- Brazil big exporter of beef and poultry: use of disinfectants and insecticides
- Wood preservation
- Vector borne diseases (mainly malaria and dengue): temephos, organophosphates, pyrethroids, Bti and insect growth regulators (pyriproxyfen and diflubenzuron) – decline of options as no new development of new active substances and resistance

BPR process – Two-step approach



Biocides in EU

- BPR replace Biocidal Products Directive 98/8/EC
- Main actors:
 - Commission: DG Environment
 - Member States Competent Authorities
 - Industry: CEFIC (European Biocidal Products Forum) and sector associations
 - NGOs
 - And since BPR: ECHA
- Active substance market: dominated by multinationals while market biocidal products is dominated by small and medium sized enterprises (SME)

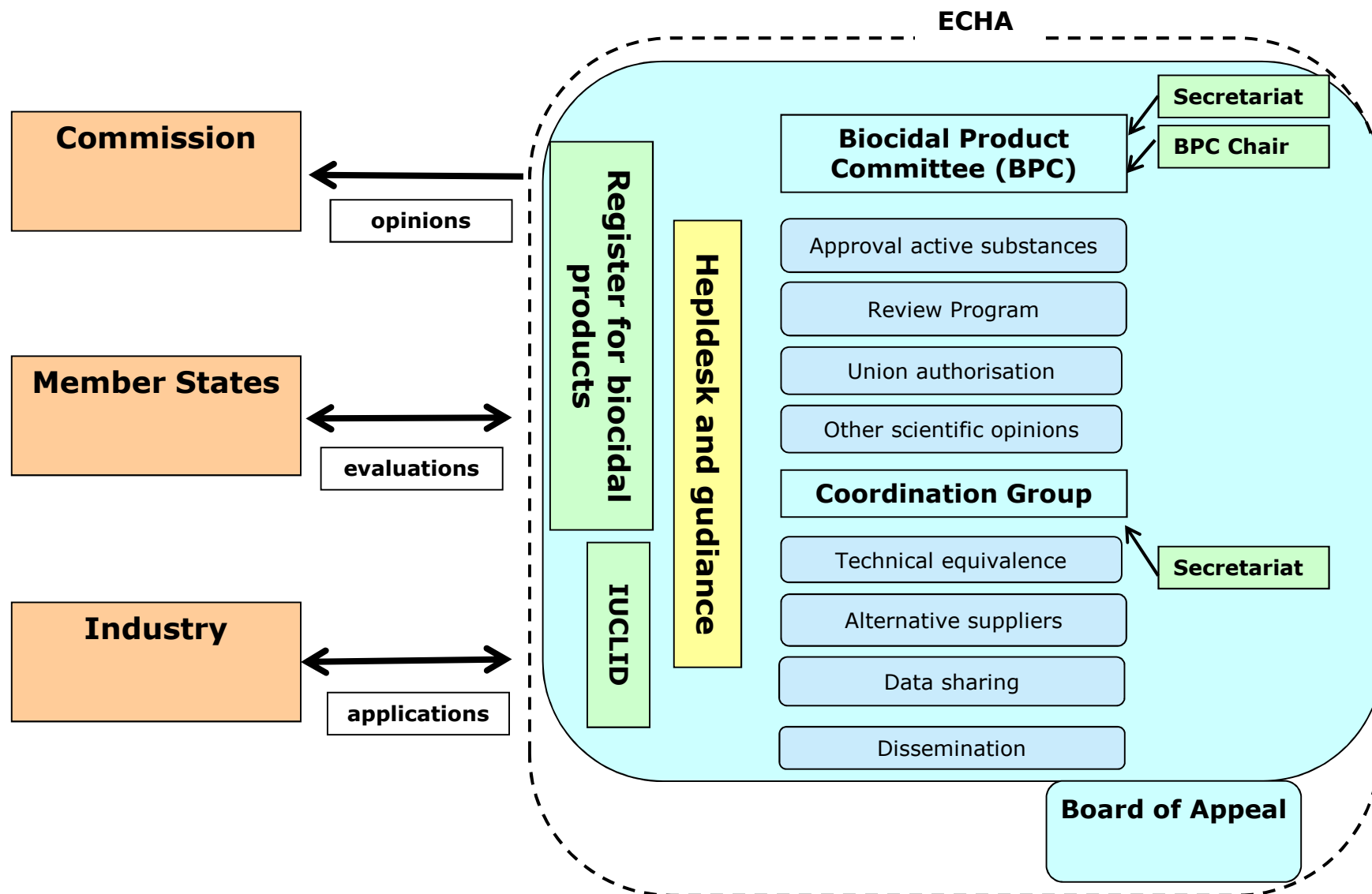
Biocides in the EU (BPD and BPR)

- Active substances:
 - Review Programme with a foreseen ending date of 2024
 - Around 75 active substance Product Type combinations approved
 - Around 600 active substance Product Type combinations under review
- Biocidal products:
 - After approval of active substance product authorisation is required
 - Around 1500 authorisation under EU scheme
 - Around 20,000 biocidal products on the EU market
- The EU market is in a transitional phase: national authorisations apply until BPR requires authorisation
- New active substances and new biocidal products

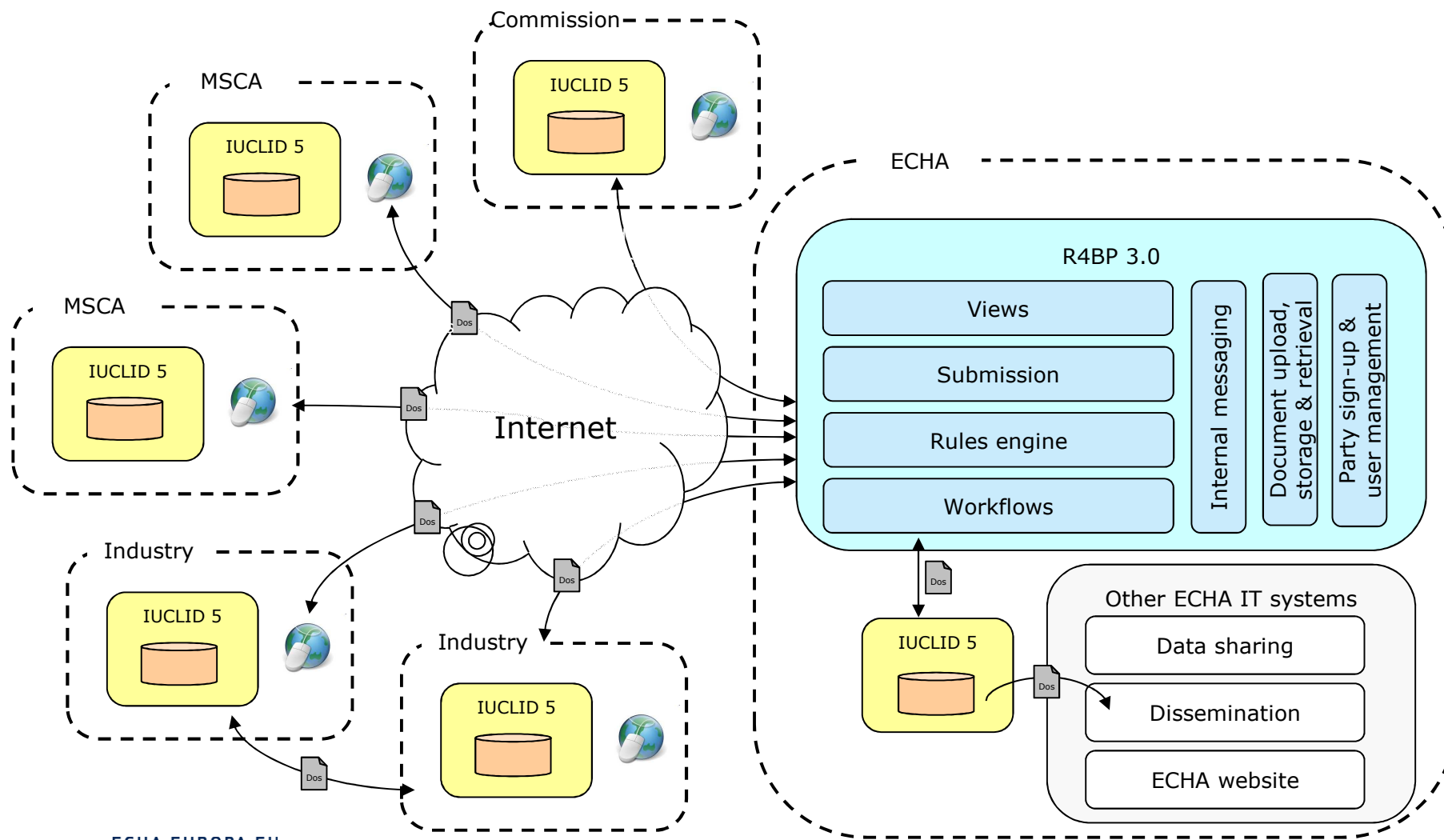
Process under BPR

- Dossier prepared by industry
- Submission to ECHA via Register for Biocidal Products
- Evaluation by a Member State
- For approval of active substance and Union authorisation: opinion in Biocidal Products Committee followed by decision by Commission
- For national authorisation: decision by Member State
- Possibility of mutual recognition (in sequence or in parallel) for national authorisations

The Agency and biocides



Register for Biocidal Products



Other relevant elements

- Dissemination for active substances and biocidal products
- Treated articles:
 - Active substance in biocidal product with which the article is treated needs to be approved in the EU
 - Labelling of treated article if there is a biocidal claim
- Technical guidance development
- OECD Biocides Task Force

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http://echa.europa.eu/regulations/biocidal-products-regulation

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Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection to humans and the environment.

- Understanding BPR
- Legislation

Processes

 <p>Companies can apply for the approval of an active substance by submitting a dossier to ECHA.</p> <p>Approval of active substances</p>	 <p>After the approval of an active substance, companies wishing to place biocidal products on the market have to apply for product authorisation at national or Union level.</p> <p>Authorisation of biocidal products</p>
 <p>Companies can ask ECHA to establish the technical equivalence of their active substance.</p> <p>Technical equivalence</p>	 <p>Manufacturers and importers not involved with the review programme of the previous legislation have to submit certain information to ECHA.</p> <p>Alternative suppliers</p>

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