The Biocidal Products Regulation

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- Introduction
- Approval of active substances
- Review programme for active substances
- Autorisation of biocidal products
- Residues from biocide uses

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BPR regulates:

Active substances

- substance or micro-organism
- that has an action on or against harmful organisms

Biocidal Products

- substance or mixture,
- in the form in which it is supplied to the user
- consisting of, containing or generating one or more active substances
- with the intention of destroying, deterring, rendering harmless preventing the action of, or otherwise exerting a controlling effect on, any harmful organism
- by any means other than mere physical or mechanical action

Treated articles

- substance, mixture or article
- which has been treated with, or intentionally incorporates
- one or more biocidal products

Main principles

- Biocidal active substances: approval at EU level
- Biocidal products: authorisation prior to placing on the market
- National product authorisation with mutual recognition/Union authorisation
- National rules apply during the programme for review of existing active substances
- Industry responsible for submitting data allowing evaluation

Biocidal product types

Biocidal products fall into 22 Product Types (BPR, Annex V)

- **Disinfectants (PT 1 to 5)**
  disinfectants for human hygiene (e.g. hand disinfectants), general use disinfectants, **veterinary hygiene (PT3)**, **food and feed area (PT4)**, drinking water disinfectants
- **Preservatives (PT6 to 13)**
  in can preservatives, wood preservatives (against insects, fungi etc.), leather or textile preservatives, cutting fluids preservatives, cooling towers disinfectants etc.
- **Pest control products (PT14 to 20)**
  rodenticides, insecticides, repellants/attractants (e.g. spray against mosquitoes applied on skin) etc.
- **Other biocidal products (PT21 to 22)**
  antifouling products, embalming & taxidermist fluids

The European Chemicals Agency (ECHA)

- Provides scientific and technical support
- Coordinates substance approval, Union authorisation of biocidal products
- Secretariat for Biocidal Product Committee and the Coordination Group
- IT platform (R4BP)
  - Electronic submissions
  - Data dissemination

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Approval process

- Application submitted to ECHA
- Dossier evaluated by Member State
- Peer-review in the Biocidal Products Committee
- ECHA opinion
- COM implementing regulation approving the substance
- Standard approval 10y, renewal

Data requirements for active substance approval

- Dossier for active substance
  - Requirements in BPR, Annex II
  - Data on identity, physico-chemical properties/physical hazards, analytical methods, effectiveness against target organism, intended uses and exposures, toxicological profile for human, animals and the environment
- Dossier for at least one representative biocidal product
  - Requirements in BPR, Annex III
  - Similar data as for active substance, but more specific for properties/uses of the product (e.g. formulation-specific data, exposure from product, effectiveness of product)

Active substances – Exclusion

- Hazard based
- Objective: exclude active substances of very high concern
- CMR category 1A or 1B, PBT, vPvB, endocrine disruptors
- Principle: Such substances cannot be approved
- Derogation: Approval possible under certain conditions
  - negligible exposure/essential substance/non-approval with disproportionate negative impact
  - subject to risk mitigation measures
  - only for Member States where needed
  - approval for maximum 5 years
  - candidate for substitution

Active substances – Substitution

- Objective: Substitution of substances of high concern
- Criteria: Exclusion criteria + other properties of high concern (Art. 10)
- Approved for a maximum of 7 years
- Comparative assessment at product authorisation
- Alternatives must present significantly lower risk, be sufficiently effective, present no significant disadvantage, and ensure sufficient chemical diversity

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BPR – review programme and transitional phase for AS

- First Biocidal Products Directive (1998) initiated examination of biocidal active substances already on the market > "review programme"
- "inventory" of active substances
- Requirement to submit dossiers submitted by specified deadlines (2004-2008 depending on PT)
- AS not supported in the review programme cannot be used in BP anymore
- Most active substances still under assessment
- Projected end of review: 2024
- Transitional measures allow continued use of active substances included in review programme until decision has been taken

Relevant substances in review programme

	under review	approved	Deadline for ECHA opinion
PT3	**45 (14 not PT4)**	**1**	**31/12/2017**
PT4	**50 (19 not PT3)**	**2**	**31/12/2017**
PT5	17	-	31/12/2017
PT18	32	22	31/12/2016
PT19	10	5	31/12/2016

Also other PTs may contain AS with a potential for carry-over into food or feed production, e.g. PT6, PT12…

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Authorisation of biocidal products

- National authorisation/Mutual recognition
- Union authorisation
- Simplified autorisation

National authorisation/Mutual recognition

- Reference MS receives and evaluates dossier and authorises product
- Mutual recognition in sequence or in parallel
- 90 days for Member States to agree
- Procedure for resolution of MR disagreements
- Refusal or adjustment possible on grounds of
  - protection of, e.g., environment or health, or
  - absence of target organism

Union authorisation

- Authorisation valid for entire EU market
- For products with similar conditions of use
- Not for AS fulfilling the exclusion criteria, rodenticides or antifouling products
- Progressive phase-in until 1 January 2020 (depending on PT)
- Application submitted to ECHA
- Dossier evaluated by evaluating competent authority chosen by applicant
- Peer-review by Biocidal Products Committee, ECHA opinion
- COM decision authorising the product

Conditions for granting product authorisation (Art. 19)

- Active substance is approved for relevant PT, possible conditions are met
- Product fulfils criteria
  - Sufficiently effective
  - No unacceptable effects on target organism, human and animal health and environment
  - Analytical methods available
  - Physical and chemical properties acceptable
  - Nanomaterials have been assessed separately
  - Where appropriate, maximum residue levels for food and feed have been established for active substances

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Residues from biocides - MRLs

Art. 19(1)(e): Where appropriate, maximum residue limits for food and feed have to be established for active substances before products can be authorised, in accordance with existing relevant legislation:

- Regulation 315/93 laying down Community procedures for contaminants in food,
- Regulation 1935/2004 on materials and articles intended to come into contact with food,
- Regulation 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin,
- Regulation 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin,
- Directive 2002/32/EC on undesirable substances in animal feed

Residues from biocides – Procedures

- Art. 19(7) and Art.19(8) place the responsibility for applying for the establishment of maximum residue limits with respect to active substances contained in a biocidal product on the prospective authorisation holder (or its representative)

- 19(7) in general for all applicable legislation

- 19(8) clarifies specific situation for active substances in the review programme under Regulation 470/2009 on residue limits of pharmacologically active substances in foodstuffs of animal origin, (already covers biocides used in animal husbandry)

Residues from biocides – open questions

- Extent of carry-over of biocides into food and feed
- Critical areas with where biocide residues may have implications for consumer safety
- Best way to address safety concerns with limited resources available (Capacities of CAs, EMA, EFSA)
- Enforcement of limits
- Procedural aspects

Thank you for your attention!

For further information:

Commission website on biocides:

http://ec.europa.eu/environment/biocides/

CIRCABC public space on biocides:

https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942

ECHA website & Helpdesk on Biocides:

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