EU Framework - Biocides

Sectoral Dialogues regarding the Control and Regulation of Pesticides and Biocides

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Outline

- Definition of biocides;
- Key actors;
- Approval process;
- Simplified authorisation procedure;
- National authorisation and mutual recognition;
- Union authorisation;
- Parallel trade;
- Regulation of the use phase of biocidal products.

Directive 98/8/EC

- Set out process of authorisation and placing on the market of biocidal products in the MSs, provided for mutual recognition and established list of active substances.

- MS to ‘ensure the authorisation, classification, labelling, packaging and proper use of biocidal products’.

- Review of active substances – examination of all existing active substances used in biocidal products by end 2024.

- Repealed by Regulation (EU) No 528/2012 on 22 May 2012 – with effect from 1 September 2013.

Biocidal products

- *any substance or mixture, […] 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*
- 4 main groups:

  1) Disinfectants – Product types 1 - 5;

  2) Preservatives – Product types 6 - 13;

  3) Pest control - Product types 14 - 20;

  4) Other biocidal products – Products types 21 & 22.

Biocidal products

Main Group 1 - Disinfectants

- PT 1 – Human hygiene
- PT 2 – Disinfectants & algaecides
- PT 3 – Veterinary hygiene
- PT 4 – Food and feed area
- PT 5 – Drinking water

Main Group 2 - Preservatives

- PT 6 – Preservatives for products during storage
- PT 7 – Film preservatives
- PT 8 – Wood preservatives
- PT 9 – Fibre, leather, rubber & polymerised materials preservatives
- PT 10 – Construction material preservatives
- PT 11 – Preservatives for liquid-cooling and processing systems
- PT 12 – Slimicides
- PT 13 – Working or cutting fluid preservatives

Main Group 3 – Pest control

- PT 14 – Rodenticides
- PT 15 – Avicides
- PT 16 – Molluscicides, vermicides & products to control other invertebrates
- PT 17 – Piscicides
- PT 18 – Insecticides, acaricides & products to control other arthropods
- PT 19 – Repellents and attractants
- PT 20 – Control of other vertebrates

Main Group 4 – Other biocidal products

- PT 21 – Antifouling products
- PT 22 – Embalming and taxidermist fluids

Key actors

National competent authorities:

Austria	Belgium	Bulgaria	Cyprus	Czech Republic
Denmark	Estonia	Finland	France	Germany
Greece	Hungary	Iceland	Ireland	Italy
Latvia	Liechtenstein	Lithuania	Luxembourg	Malta
Netherlands	Norway	Poland	Portugal	Romania
Slovakia	Slovenia	Spain	Sweden	United Kingdom

Active substance approval

ECHA

- Application to ECHA
- Validation check by ECHA

MS CA

- Completeness check by Evaluating Competent Authority
- Request for additional information
- Dossier evaluation (365 days)
- Draft assessment report & conclusions of evaluation
- Receipt of comments & finalisation of evaluation

ECHA

- Peer review by Biocidal Products Committee (270 days)
- Opinion on approval of active substance

COM

- Adopts implementing Regulation approving active substance, or
- Adopts implementing decision that an active substance is not approved.

Dossier evaluation

1) Exclusion criteria

- Aims to phase out most hazardous active substances;
- Derogations available.

2) Approval criteria

- Product must be sufficiently effective;
- Product must have no unacceptable effect

3) Principle of substitution

- Aims to phase out hazardous active substances over time;
- Comparative assessment during product authorisation process.

Simplified authorisation

- ‘Eligible biocidal product’:
  - Active substances listed in Annex 1 BPR;
  - No substances of concern;
  - No nanomaterials;
  - Sufficiently effective;
  - Handling of product does not require PPE.
- Application to ECHA
- Evaluating CA to assess application (90 days)
- If granted, authorisation for 10 years
- No requirement for mutual recognition
- Notification to MS only

National authorisation

MS CA

- Application to receiving Competent Authority
- Validation check by receiving Competent Authority (30 days)
- Request for additional information (up to 90 days)
- Validation or rejection of application (30 days)

ECHA

- Assessment of technical equivalence

MS CA

- Dossier evaluation (365 days)
- Comparative assessment (where candidate for substitution)
- Request for additional information (up to 180 days)
- Draft assessment report & conclusions of evaluation
- Receipt of comments & finalisation of evaluation
- Grant or reject national authorisation

Mutual recognition

- Harmonisation between MSs;
- Mutual recognition in sequence – require authorisation in one MS, then apply to others.
- Mutual recognition in parallel – apply in one MS and ask other MSs to recognise once granted.
- Coordination group to resolve disputes
- Derogations

Union authorisation

- Excluded products:
  - Those containing active substances that meet exclusion criteria;
  - PT 14, 15, 17, 20 and 21 which are either banned in MSs or where issues arose during mutual recognition procedure;
- Products have ‘similar conditions of use’ across EU;
- Application to ECHA
- Evaluating CA to assess application (365 days)
- If granted, authorisation for 10 years
- No requirement for mutual recognition
- Notification to MS only

Parallel trade permit

- Available where biocidal product identical to product already authorised in the territory of a MS
- 'Identical' means they are:
  - manufactured by the same company or an associated undertaking in accordance with same manufacturing process;
  - identical in specification and content in respect of the active substances and the type of formulation;
  - the same in respect of the non-active substances present; and
  - either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human health, animal health or the environment.

Sustainable Use of biocides

- Overview of the promotion of best practices as a means of reducing the use of biocidal products to a minimum ;
- Identify whether need for additional provisions regulating users;
- Investigate and make recommendations for the most effective approaches for monitoring the use of biocidal products ;
- Specify the risks posed by the use of biocidal products in specific areas and whether additional measures are required to address those risks; and
- Examine the relevance of integrated pest management principles for biocidal products;
- Investigate the possibility to attribute an eco-label to biocidal products;
- Provide an overview of voluntary schemes that are used to highlight those products and uses that have a better environmental and human health profile, and suggest other approaches or tools;
- Analyse whether it is appropriate to revise Article 72 of the BPR.

Questions?

Thank you

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