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CONSEQUENCES OF THE BPR

2 Importance of biocides

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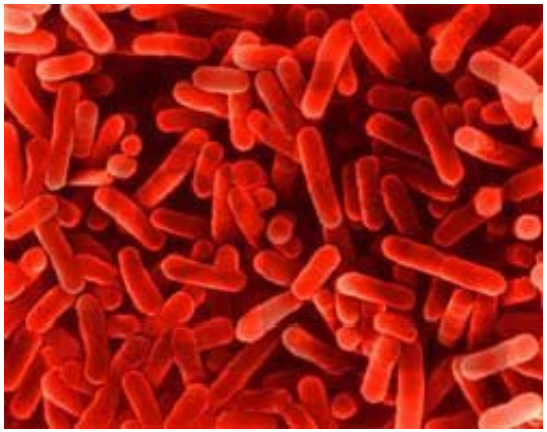
Microorganisms can be harmful

Pathogenic to other life forms

- direct infection
- toxin production



Spoilage and deterioration, e.g. of

- food
- water
- water based products
- construction materials

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Benefits of disinfection: Protecting Health

Prevention

- **diseases**

  Legionnaire's disease, swimming pools, etc

- **food poisoning**

  food processing and brewing, etc

- **cross-infection**

  hospitals, surgeries, public places, etc

→ **Longer Life (approx. 30 years compared with 150 years ago)**

5 European Biocidal Product Directive (BPD = EC 98/8)

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BPD – Main aims

Harmonization of the European Union market for biocidal products (incl. Norway, Swiss).

Provision of a high level of protection for humans and the environment.

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BPD definition of a biocide

Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy,

deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

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Operation method under BPD

Both Active Substances and Biocidal Products have to be registered

- Annex 1 List (Active Substances) - Community Decision
- Authorization of formulations - Member State Decision
- Mutual Recognition - Rule not exception

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Applications covered (23 product types; PT)

Disinfectants (5 types)	Human hygiene, Public health, Veterinary hygiene, Food and Feed, Drinking water
Preservatives (8 types)	In-can, Film, Wood, Fibre Leather etc., Masonry, Liquid cooling, Slimicides, Metal-working
Pest Control (6 types)	Rodenticides, Avicides, Moluscicides, Piscicides, Insecticides, Repellents & Attractants
Others (4 types)	Preservatives for food & feedstocks, anti-foulants, embalming fluids, vertebrate control

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Market consequences

- Reduction of actives
- Reduction of formulations
- Extensive reformulation work
- Number of active suppliers will decrease. Only big companies can afford to continue to support a.s.

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Timing under the BPD

May 13, 1998	Adoption of BPD by EU
May 14, 2000	BPD implemented in national laws and in force. Start of 10 year transition period
March, 2002	Identification/Notification
March, 2004	Full dossier to be sent for wood preservation and insecticides.
July, 2007	Full dossiers for disinfection areas
October, 2008	Full dossiers for preservatives
May 2010	End of transition period. All existing actives supported should be on Annex 1

3 The situation during the transition period 2000-2014

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The situation during the transition period 2000-2014 (probably extended till 2024)

The situation during the transition period differs per situation and per country:

For formulations based on a.s. under evaluation but not approved yet the national situation can remain in place:

- National registration scheme in place continues until Annex I inclusion
- A notification scheme is in place
- No official system in place

For formulations based on a.s. included in Annex I:

- A BPD registration scheme should be in place

5 European Biocidal Product Regulation (BPR = EC528/2012)

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Timelines new BPR

-1 September 2013

- Biocides Product Regulation will replace the Biocide Product Directive.

(A regulation is immediately in force and needs no local implementation in the national law)

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Main provisions BPR

-ECHA will be the main contact point

-Treated articles: „any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products“ will have to be registered. (Art.58)

-Biocidal product family replace framework formulation: more flexibility to include several formulations in one application. (Art.3)

- Union authorization of biocidal product: there will come a possibility to apply via ECHA for Union wide authorization for product that have the same use over the whole union. (Art. 41,42)

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Main provisions BPR

-"Free-rider issue" will be solved: Active substance suppliers not having own dossier or LOA will have to phase out by September 2015 (Art.95-3)

All participants in the review program have to do Art 95 notification before 1st of September 2015 indicating which a.s. are supported for which PT's.

Beginning September 2015 ECHA will publish a list of approved suppliers.

From 1st September 2015 only a.s. from this list may be used in biocidal formulations.

6 The consequences of BPR (EC 528/2012)

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Operation method under BPR

Both Active Substances and Biocidal Formulations have to be registered

- Union list (Active substances) - ECHA Decision
- Authorization of products (formulations) - Member State Decision / ECHA decision
- Mutual Recognition - Rule not exception

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How can you remain on the biocides market

To remain on the market with biocidal products one needs approval for the biocidal product.

- A full own biocidal product dossier incl. access to the a.s.

- A own biocidal product dossier including Letter of Access for the data on the a.s. but own biocidal product data

- A Letter of Access to a biocidal product dossier

“Letter of Access" means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of this Regulation

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Letter of Access

A letter of access shall at least contain the following information:

(a) the name and contact details of the data owner and the

beneficiary;

(b) the name of the active substance or biocidal product for which access to the data is granted;

(c) the date on which the letter of access takes effect;

(d) a list of the submitted data to which the letter of access grants citation rights

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Costs involved

Costs of an a.s. dossier on one simple a.s. is build up from:

- data development costs - approx: 2.000.000 Euro
- management costs - approx 1.000.000 Euro
- registration fees - approx 300.000 Euro

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Costs involved

Costs involved in the registration of a biocidal product based on one simple a.s.

-costs estimated for a biocidal product dossier preparation: 150.000 Euro

-fees for the countries of interest and perhaps the ECHA fees for a union authorization

-management costs to negotiate with authorities

Letters of Access will be bound to costs and will be subject to a contract between submitter and receiver

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Proposed ECHA fees

Proposed ECHA fees for Union Authorization of Biocidal Products:

Description	Euro
Single Product	80.000
(Single product identical with representative product in AS dossier 40.000)	
Family Product	150.000
Annual fee for single product	10.000
Annual fee for Family Product	20.000

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Union authorization

For the Union authorization:

ECHA will take care of management and times lines are kept.

ECHA will take care of IUCLID maintenance and development specific tools like SPC (summary Product Characteristics).

ECHA coordinates the check of the SPC translations and it is responsible for submitting the SPC to the Commission in all the official languages

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Authorization process

-only interested in one country:

Registration fees for local approval under BPR is applicable but fees for each member state are not always clear yet.

-Interest in a few countries:

1st authorisation in main country of interest and then ask for mutual recognition in the other countries of interest. Costs involved are fees for 1st authorisation + mutual recognition fees for the other countries of interest. (art 32,33,34 give details for mutual recognition process)

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Authorization process

-Interested in many countries for similar use:

Union authorisation: agreement with a local authority to perform the evaluation should be searched 6 months before submission. Costs will be ECHA fees + fees for local 1st authorisation + the mutual recognition fees of other MS.

Important to keep in mind:

-It should be more efficient process than country by country process due to limited contact points and limited dossiers to be submitted

-Only possible for biocidal products with the similar conditions of use for whole EU

-Country of 1st authorization can be of influence of the whole process and final costs.

-expensive process.

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Authorization process

-It cannot be guaranteed upfront that all MS will accept the approval

-Union authorization is not immediately possible for all PT's

(Article 42 step-wise approach for workability, capacity and experience building)

• From 1/9/2013, any products containing new active

substances and PTs 1, 3, 4, 5, 18 and 19;

• From 1/1/2017, PTs 2, 6 and 13;

• From 1/1/2020, PTs (7, 8, 9, 10, 11,12, 16, 22).

-Union authorization is not possible for PT 14,15,17,20,21

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Biocidal product dossier

-You have to submit via R4BP an English version of the SPC together with the product dossier (IUCLID 5.5 file). (IUCLID 5.5 is released in March 2013)

-summaries of all studies shall be compiled in IUCLID

-SPC (Summary Product Characteristics) has to be generated and attached to IUCLID.

-Evaluation documents DOC I and II(A-B-C) to be attached to the IUCLID file (.doc and/or.pdf).

• LoA can be submitted instead of the mentioned document at any level.

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Biocides-specific webpages:

http://echa.europa.eu/regulations/biocidal-productsregulation

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

https://circabc.europa.eu/

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THANK YOU!