FEDERAL INSTITUTE FOR RISK ASSESSMENT

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Risiken erkennen – Gesundheit schützen

Assessment and Regulation of Nanomaterials under the European Biocides Regulation

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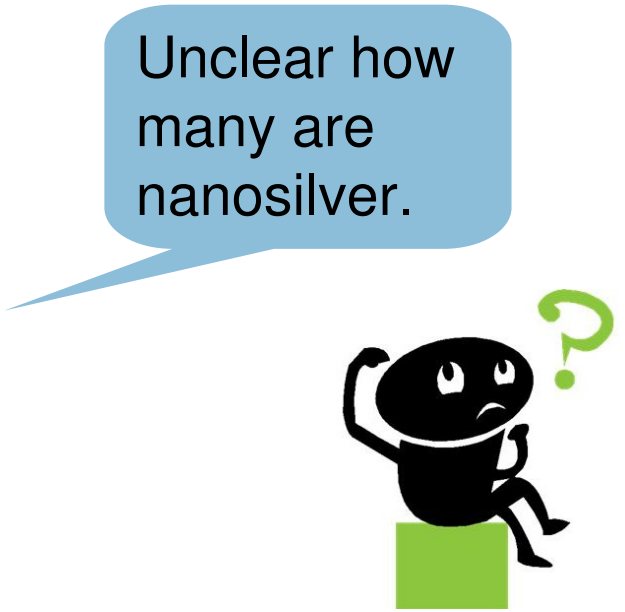
Silver-containing active substances notified under 98/8/EC

Biocidal Product Directive 98/8/EC

Silver + 8 silver compounds under evaluation:

Silver, silver zeolite A, silver chloride adsorbed to titanium dioxide, silver nitrate, silver chloride, disilver oxide, silver sodium hydrogen zirconium phosphate, silver phosphate glass, silver-zinc-zeolite



New Biocidal Product Regulation (BPR) brings changes for nanomaterials!!!

Definitions under the BPD and BPR

Active Substance a substance or a micro-organisms that has an action on or against harmful organsims

Biocidal Product a substance or mixture
- consists of, contains or generates one or more active substances
- intention of controlling a harmful organism
- exists in the form in which it is supplied to the user

Treated Article **BPR:** any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products. TA with a primary biocidal function is considered a BP.

Nanomaterial **BPD: none**

Principles of biocide risk assessment under 98/8/EC and the BPR

2 STAGE PROCESS

Assessment of the active substance at the EU level

- Hazard characterisation of the active substance
- Exposure assessment for example product
- Risk assessment for example product

<u>results in:</u>

- inclusion into Annex I / approval

through a peer review process ensuring stakeholder involvement

Product authorisation at the national level

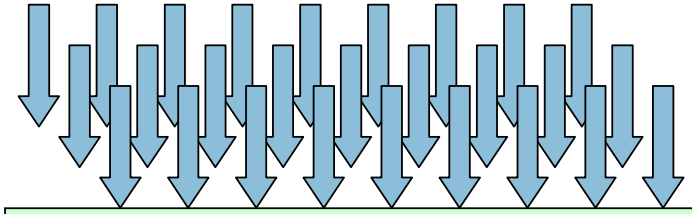
- Product specific hazard characterisation
- Exposure assessment for the actual product
- Risk assessment for the actual product

<u>results in:</u>

- product authorisation
- mutual recognition
- Union authorisation *(new under BPR)*

Principles of biocide risk assessment under 98/8/EC and the BPR

Directive 98/8/EC: Silver + 8 silver compounds under evaluation



Assessment of the active substance at the EU level

- For each compound, a separate risk assessment dossier has to be submitted.
- Applications for several product types require a separate dossier for each product type.
- Where there is more than one Applicant, each Applicant has to submit a separate dossier.

→

Product authorisation at the national level

- A separate application and dossier for each biocidal product.

Toxicological data requirements for biocidal active substances: core and additional data set acc. to Annex II BPR

1. Skin / eye irritation / corrosion
2. Skin and respiratory sensitisation
3. Mutagenicity and in vivo genotoxicity
4. Acute toxicity (oral / dermal / inhalation)
5. Toxicokinetics and metabolism
6. Repeated dose toxicity, at least short term, subchronic and chronic
7. Reproductive toxicity: pre-natal (at least one species) / two-generation
8. Combined carcinogenicity and long-term repeated dose toxicity
9. Medical (human) data; incl. surveillance, epidemiology, poisoning etc.
10. Additional studies may be necessary, e.g. neurotoxicity, endocrine disruption, immunotoxicity, mechanistic data

Data requirements related to human exposure: core and additional data set acc. to Annex II/III BPR

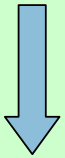
1. Estimation of human exposure through use of BP
2. Estimation of human exposure through use of treated articles
3. Estimation of exposure of humans through diet (ADS):
   - Behaviour of the residue on the contaminated food (e.g. degradation)
   - Information on contamination of food /feeding stuffs
   - Residue data on food and feeding stuffs
   - Information on exposure of food-producing animals
   - Feeding and metabolism studies in livestock
   - Effects of industrial processing / domestic preparation

4. Additional data requirements relating to analytical methods, phys-chem properties, environmental risk assessment, etc.

Regulatory basis for nanomaterials in biocidal products

No specific requirements for nanomaterials

Scientific uncertainty about safety of nanomaterials



Specific provisions for nanomaterials, which are to be reviewed regularly by the EU-Commission (Recital 66)

2013

Directive 98/8/EC (BPD)

Biocidal Products Regulation (BPR)

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0010+0+DOC+XML+V0//EN

Definition

In line with
Commission Recommendation
2011/ 696/ EU
of 18 October 2011

Definition for “nanomaterial” under the BPR:

a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range of 1nm-100nm. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1nm shall be considered as nanomaterials.

(a)‘particle’ means a minute piece of matter with defined physical boundaries;

(b)‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(c)‘aggregate’ means a particle comprising of strongly bound or fused particles;

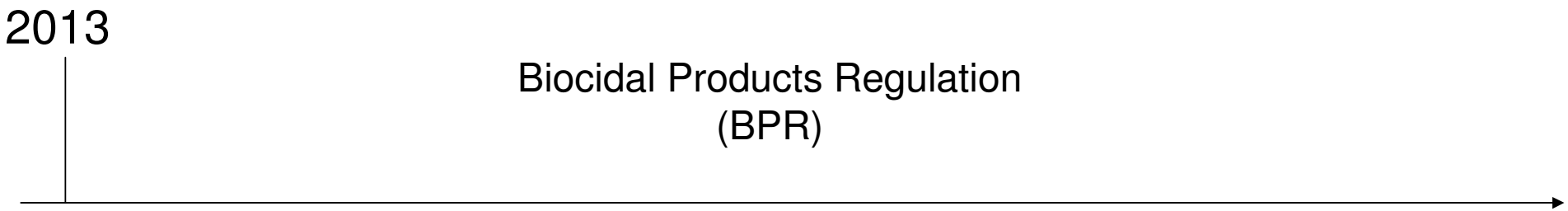
Commission may – on request of a MS – decide whether a substance is a nanomaterial.

Active Substance Approval

Approval of active substance DOES NOT automatically cover nanoform!
(Article 4(4))

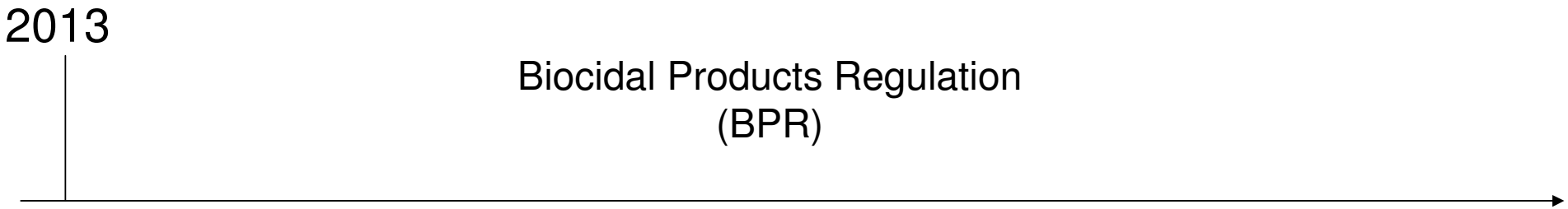
→ A separate dossier must usually be prepared for nanoforms of active substances.

- All data requirements equally apply to nanomaterials!
- Test methods already established for non-nanoforms may be used or adapted (justification!) – Annex II/III (5)
- New test methods specific for nanomaterials will have to be developed.
- Technical guidance on the evaluation of nanomaterials must be developed (Annex IV)



Biocidal product assessment and authorisation

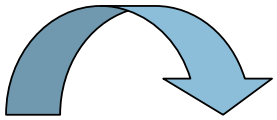
- Separate risk assessment for nanomaterials (active substances, formulants) in BP (Article 19(1)(f))
- Label of BPs and treated articles must indicate the name of each nanomaterial followed by the word “nano” in parentheses (Article 58(3)(d); 69(2)(b)).
- BPs that contain nanomaterials are NOT eligible for authorisation via the simplified authorisation procedure (Article 25(c)).
- Technical guidance on the evaluation of nanomaterials must be developed.



Regulatory basis for nanomaterials in biocidal products

- The Biocidal Product Regulation will enter into force in September 2013.
- The first draft CA reports for silver active substances are scheduled to be submitted by March 2012.

Taking into account the time required to finalise the active substance evaluation, …



… it can be expected that (nano)silver biocidal product authorisation will be performed under BPR rules!

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Thank you for your attention

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