Status of the new Biocidal Products Regulation
Impact on formulators of disinfection products

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DHI Environmental Toxicology (EAT)

- International consulting and research organisation within water, [illegible]lth
- Support of industry and authorities in human and environmental risk assessment

  - Chemicals and consumer products
  - Biocides and pesticides
  - Food, feed, cosmetics
  - IT and chemical management
  - Pharmaceuticals and me
  - Water safety and cont
  - Marine waste and ba

Michael Fink

- Biologist, from 2008 at DHI-EAT
- Danish/German
- Risk assessment of biocidal actives and products
- Strategic advice of industry
- Researchprojects: Disinfection (Effi ety)
- Course leader: Authorisation ducts

DHI Environmental Toxicology courses

Chemicals Regulation IUCLID 5 course, QSAR workshop, classification and labelling of chemicals (CLP), approval of biocidal products, exposure scenarios	**Toxicology and Life Science** Human toxicology, toxicological risk assessments, environmental risk assessment of medicinal products and QSAR workshop
Industry and Environment Ecotoxicology, eco-labelling of detergents, and phytoplankton pigment analysis	**Food Regulation** Food contact materials, nutrition and health claims on food, food supplements, novel foods, and allergy

- www.tox.dhigrou

Agenda

1. The BPR and disinfectants
2. Status of the active substances of disinfectants
3. Procedures and costs within the BPR
4. Simplified procedure
5. Conclusions

1. The BPR and disinfectants

BPD 1998- aug. 2013 ⟶ BPR sep. 2013

Main purpose of BPR

- Biocidal products are safe for humans, animals and the environment
- Biocidal products are efficacious
- Harmonisation of rules concerning
  - Making available of biocidal products on the market
  - Use of biocidal products

1. The BPR and disinfectants

Approval process of biocidal products remains the same: The active substance (AS) sets the pace

1. Evaluation and approval of active substance(s)

2. Authorisation of biocidal product

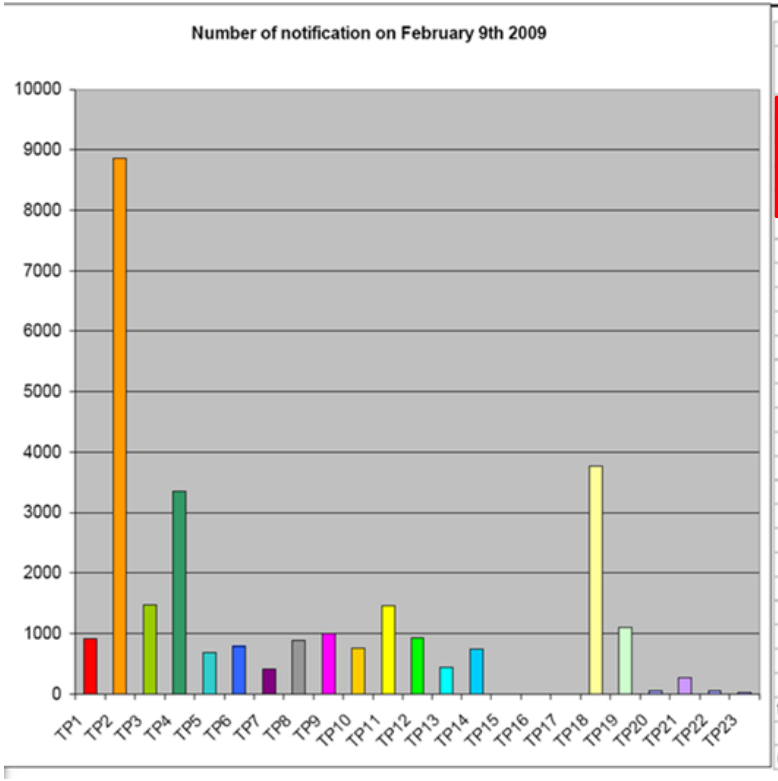
1. The BPR and disinfectants

Relevant product-types within the scope of the BPR

- Product-type 1: Human hygiene
- Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals
- Product-type 3: Veterinary hygiene
- Product-type 4: Food and feed area
- Product-type 5: Drinking water

- Product-type 6-13: Preservatives

1. The BPR and disinfectants



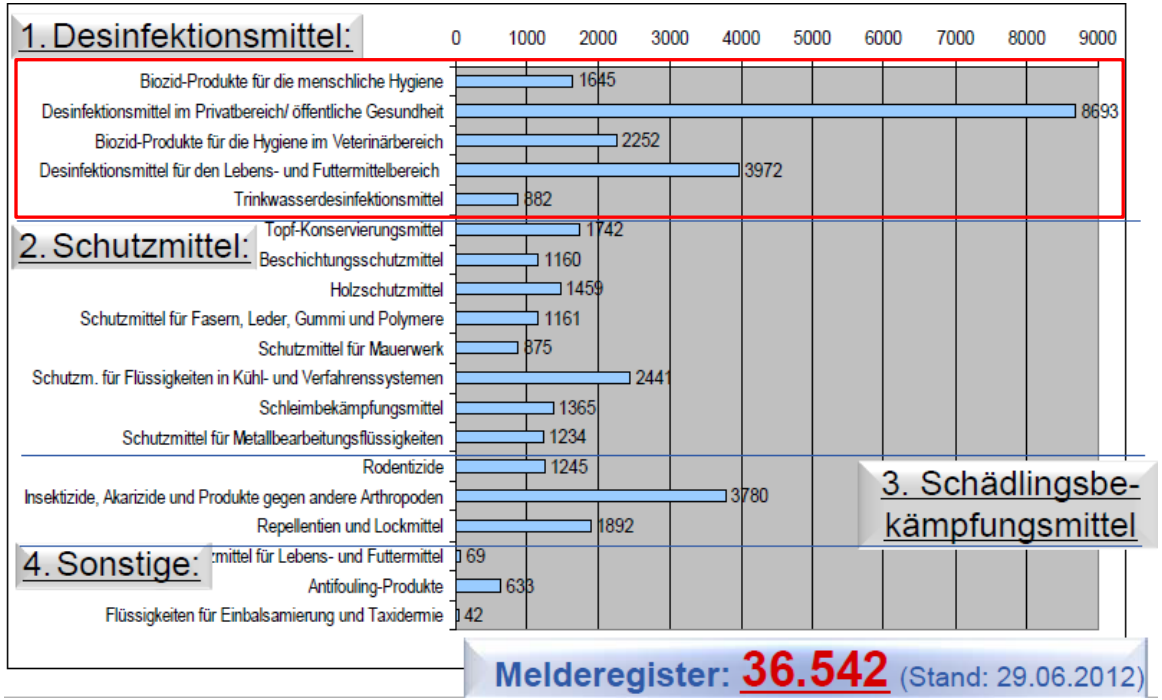
Notifications	
PT	Number of notifications
TP1	919
TP2	**8860**
TP3	**1470**
TP4	**3347**
TP5	687
TP6	787
TP7	404
TP8	881
TP9	993
TP10	756
TP11	**1458**
TP12	927
TP13	433
TP14	740
TP15	1
TP16	4
TP17	4
TP18	**3768**
TP19	1102
TP20	46
TP21	260
TP22	48
TP23	22
total :	27917
this corresponds to around **24099 different notifications** (products)	

How many disinfectants are on the market today?

France

Courtesy of MEEDDM, 2009

1. The BPR and disinfectants



How many disinfectants are on the market today?

Germany

Courtesy of BAuA, 2013

2. Status of the active substances of disinfectants

What's new with the BPR?

- European Chemicals Agency (ECHA)
- Review program extended to end of 2024
- **List of active substance suppliers deadline Sep. 2015**
- Inclusion of in-situ products
- Treated articles
- Mandatory data sharing extended
- Extended numbers of types of applications

2. Status of the active substances of disinfectants

From the final version of: REVIEW PROGRAMME OF ACTIVE SUBSTANCES: ESTABLISHMENT OF A WORK PROGRAMME TO MEET THE 2024 DEADLINE

- Provisional Work programme for the BPC in 2014, 2015, 2016

A detailed work programme should be established by the BPC with at least a rolling **2-year visibility**, and frequently reviewed by the BPC secretariat every 3-6 months in order to adjust it with regards to the priorities and new draft CARs that are submitted on a day-to-day basis.

Abbreviations: BPC= Biocidal Products Committee; CAR= Competent authority report

2. Status of the active substances of disinfectants

Priority	Existing active substances for product types	All draft CARs have to be submitted to ECHA by	The BPC have to submit all its opinions by
1st priority list	8, 14, 16, 18, 19, 21	31/12/2015	31/12/2016
2nd priority list	3, 4, 5	31/12/2016	31/12/2017
3rd priority list	1, 2	31/12/2018	31/12/2019
4th priority list	6, 13	31/12/2019	31/12/2020
5th priority list	7, 9, 10	31/12/2020	31/12/2021
6th priority list	11, 12,15,17, 22, 23 (new PT20 under BPR)	31/12/2022	31/06/2024

2. Status of the active substances of disinfectants

Still waiting for the final evaluation of some prominent PT1-5 AS

Ethanol	Sodium hypochlorite
Propan-2-ol	Calcium hypochlorite
Peracetic acid	Chlorine
Glutaraldehyde	Silver chloride
Quaternary ammonium compounds	PHMB
and many others	

3. Procedures for application and costs within the BPR

Expensive

- National authorisations
  - Biocidal products
  - Biocidal product family
  - mutual recognition
- Union authorisations

Less expensive

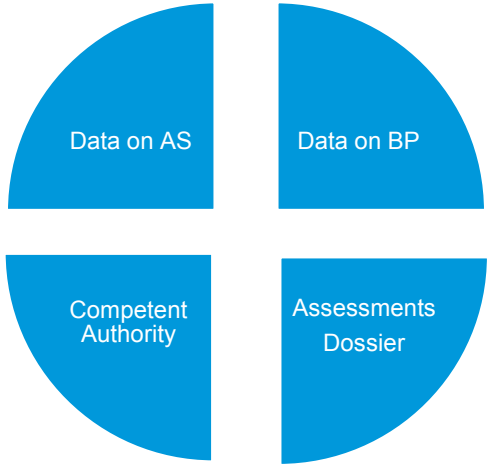
- Identical products
- Simplified procedure

3. Procedures for application and costs within the BPR

National authorisation of BP

Data on AS

- Letter of access- LoA
- Licens on data access- for authorities



- Data on BP
  - Phys chem, Physical hazards
  - Methods of detection and identification
  - Efficacy, Toxicology, Ecotoxicology

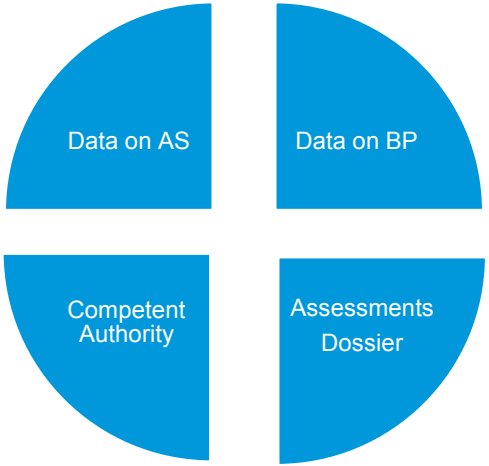
3. Procedures for application and costs within the BPR

Dossier

- Risk assessment
- R4BP, administrative tool
- IUCLID, data entries

Competent Authority

- Fee and communication



Abbreviations: IUCLID= International Uniform Chemical Information Database (software application to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances)

3. Procedures for application and costs within the BPR

National authorisation of identical product

Refers to already approved biocidal product

- Criteria for when products are identical
- No Letter of Access on the active substance
- Faster approval time: 120 days from submission to approval
- Less fee, 1.500 – 3.000 EUR pr. BP pr. PT

3. Procedures for application and costs within the BPR

National authorisation	Union authorisation	Identical BP
Full IPR	Full IPR	No IPR
1 year	1½ year	90 - 120 days
LoA on active(s)	LoA on active(s)	No LoA on active(s)
Full data package	Full data package	No data package
Fee to MS CA: 1. MS 5.000 - 45.000 EUR MR 1.000 - 16.000 EUR	Fee to MS CA: 80.000 EUR	Fee to MS CA: 1.500 – 3.000 EUR
Fee to ECHA for MR: 700 EUR pr. MS	Fee to ECHA: 80.000 EUR 10.000 EUR annually	No fee to ECHA

Abbreviations: BP= Biocidal product; IPR = Intellectual property rights; LoA= Letter of Access; MS= Member State; CA= Competent authority; MR= Mutual recognition

4. Simplified procedure

Conditions

- all the active substances contained in the biocidal product appear in **Annex I** and satisfy any restriction specified in that Annex;
- the biocidal product does not contain **any substance of concern**;
- the biocidal product does not contain any nanomaterials;
- the biocidal product is **sufficiently effective**; and
- the handling of the biocidal product and **its intended use do not require personal protective equipment**.

4. Simplified procedure

Approval process

- Application to ECHA
- Payment of fee to evaluating MS CA
- 90 days evaluation by MS CA
- Authorisation valid in all MS prior to notification,
- Lower fees to CA; 10,000 EUR + 800 EUR pr. notification

Abbreviations: MS= Member State; CA= Competent authority

4. Simplified procedure

The new Annex 1 of the BPR

Category 1
Lactic acid
Sodium acetate
Sodium benzoate
(+)-Tartaric acid
Acetic acid
Propionic acid
Category 2
Ascorbic acid
Linseed oil

Category 3 — Weak acids
No entries yet
Category 4
Lavender oil
Peppermint oil
Category 5 — Pheromones
Oct-1-en-3-ol
Webbing clothes moths pheromone

Category 6
Carbon dioxide
Nitrogen
(Z,E)-Tetradec- 9,12-dienyl acetate
Category 7 — Other
Baculovirus
Bentonit
Citronella
Iron sulphat

5. Conclusion

Present: Large costs for industry to defend biocidal actives

- ⟶ Less actives on the market
- ⟶ Less formulations
- ⟶ Little innovation? From chemical to mechanical products? Simplified procedure?

Future: Importers and formulators of disinfectants will face tough regulatory pressure the next 5 years.

- ⟶ Less formulations. From 50 to 1 product?
- ⟶ Less importers and formulators
- ⟶ Lesser formulations, large formulators will offer regulatory product package
- ⟶ Many SMEs will leave the market. Large AS suppliers and formulators will dominate (similar to what happened with the pesticides)

Thank you for the attention

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6th of May 2014
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