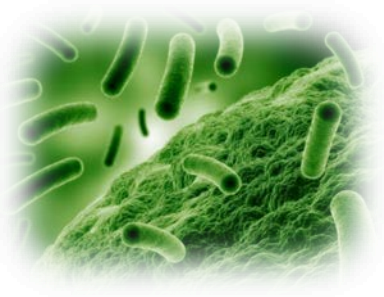


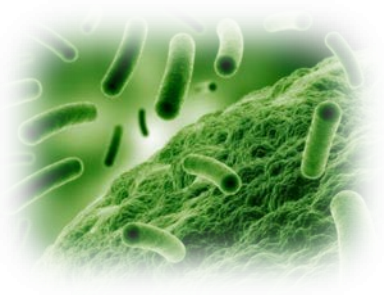
THE ENVIRONMENTAL RISK ASSESSMENT OF BIOCIDES

REGULATORY CHALLENGES AND SCIENTIFIC SOLUTIONS

Regulatory issues regarding the BPD, Product Authorisation and the new Regulation

Regulatory point of view

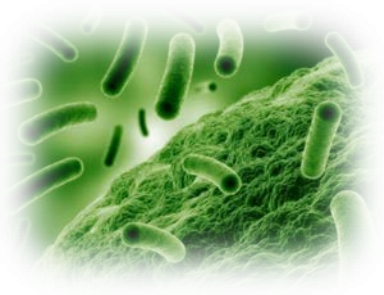
Erik van de Plassche ECHA, Unit B.2



Content

1. Biocidal Products Directive: regulatory basis and experience with environmental risk assessment in the Review Program
2. Biocidal Products Regulation
3. Conclusions on regulatory challenges

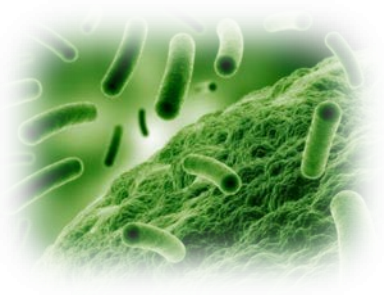
SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Regulatory basis

- “Ensure high and harmonised level of protection for the environment” → “no unacceptable effects” (Article 10) → PEC/PNEC < 1 for STP, aquatic compartment, soil compartment and secondary poisoning (Annex VI)
- “normal use” and “realistic worst-case scenario”
- “In the light of current scientific and technical knowledge “

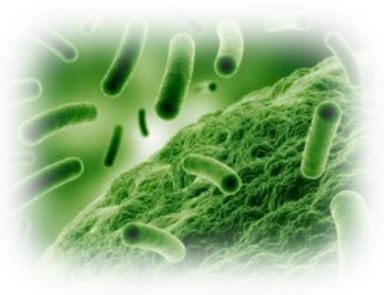
SETAC Europe ○ Avenue de la Toison d’Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Regulatory basis

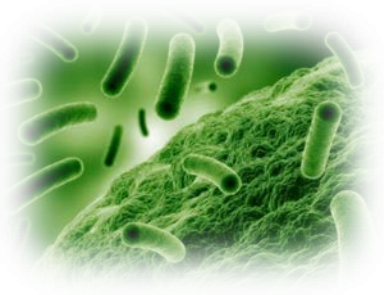
- Annex I inclusion of active substance followed by authorisation of the biocidal product
- Review Program on existing active substances (14 May 2000) and new active substances
- Review Program: 275 active substances with 700 active substance – Product Type combinations (total 23 PTs)
- Annex I inclusion is per active substance – Product Type combination

SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Biocides characteristics

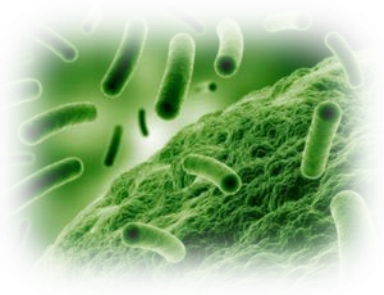
- Biocides is small
- Biocides is complex and it's all about environment and exposure assessment
- Biocides is relatively new EU regulatory framework but sometimes also national
- Member States are responsible for evaluations up to Annex I inclusion
- Limited role of Commission in peer review process



It seemed so easy

- Dossiers submitted in 2004 – 2008
- A Review Program of 10 years
- Extensive package of guidance developed
- Transitional phase over in 2014

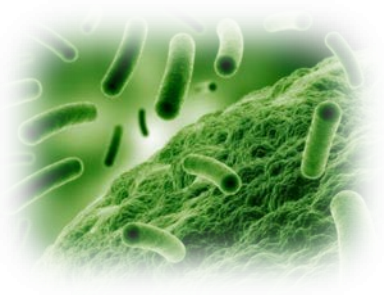
SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Rodenticides

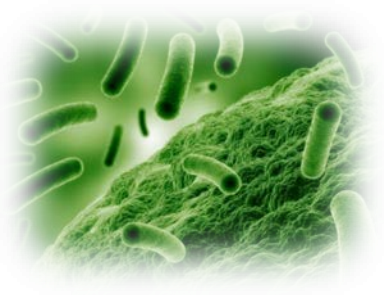
- 14 actives (fumigants, corn cob, anticoagulants)
- Primary and secondary poisoning
- Comparative assessment

SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



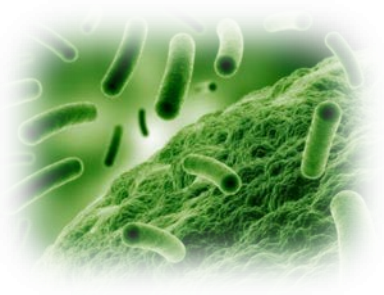
Wood preservatives

- 38 actives (fumigants, metal salts, quats, creosote, 'pesticides')
- Leaching distance and leaching rate determination
- Acceptance of risks in TIME 1
- New scenarios: house, railway sleepers, wooden pellets, termite control (foundation and trench)
- Product authorisation: efficacy of topcoat as risk mitigation measure



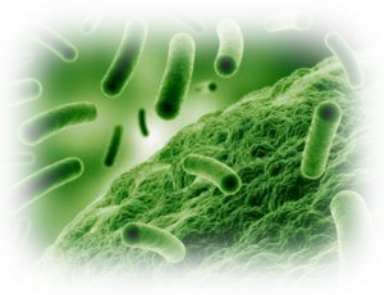
Insecticides

- 32 actives (fumigants, silicon dioxide, micro-organisms, Margosa extract, pyrethroids, neonicotinoids)
- ESD average consumption scenario revised: numbers of private houses, commercial buildings and hospitals for the 'standard STP', surface and treated area, cleaning efficiency, area susceptible to wet cleaning, simultaneity factor



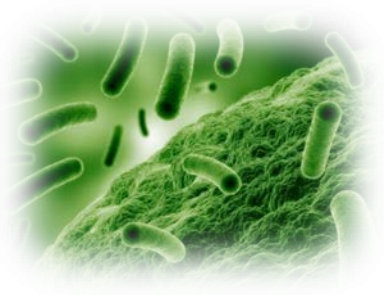
Repellents and attractants

- 8 actives (pheromone, CO_2, DEET, nonanoic acid, methyl nonyl ketone)
- Tonnage scenario
- Scenarios for cat and dog repellents in private gardens, swimming scenario



Antifoulings

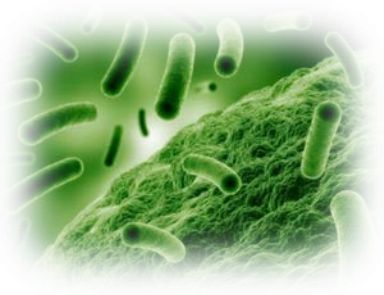
- 4 actives (all booster biocides)
- Sediment risk assessment
- Cumulative assessment for in-service, maintenance and repair and new build
- Parameter setting for MAMPEC



In-can preservatives

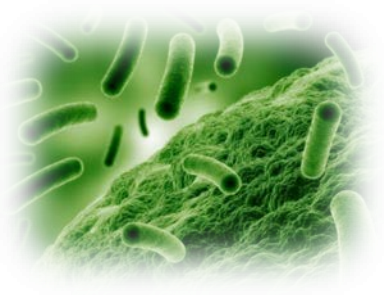
- Very limited experience
- Cumulative assessment

SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Control of other invertebrates

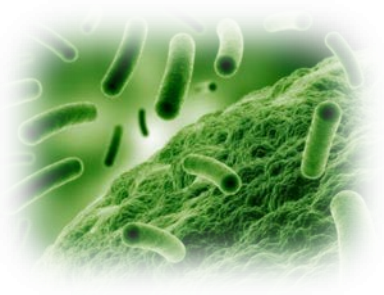
- Very limited experience
- Fumigant: recolonisation



To come …

- All or almost all actives for Product Types 01 to 05, 06, 07, 09, 10, 11, 12, 13, 22
- Around 160 Competent Authority Reports submitted to Commission for peer review for 114 active substances so 540 to come …

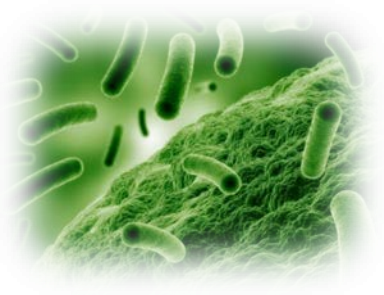
SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Regulatory science challenges

- Consensus building at Technical Meeting within the legal framework of the BPD according to the relevant guidance
- Harmonisation: similar substances, between Product Types, EU regulatory frameworks and … between Member States
- Transparency and consistency

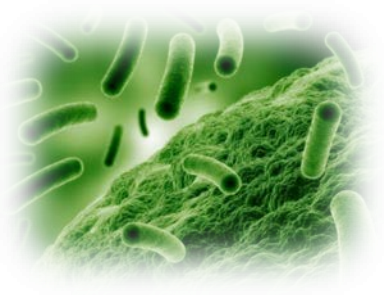
SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Observations Review Program

Progress of Review Program:

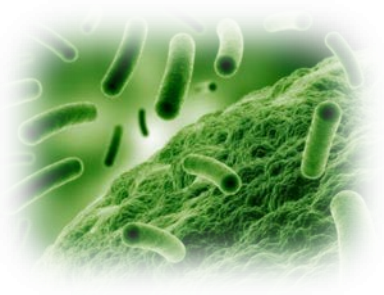
- Evaluation of the same active substance under different Product Types → new data or new guidance → impact on List of Endpoints relevant for product authorisation
- Consistency versus state-of-the-art scientific and technical knowledge versus legitimate expectations of applicants
- Refinement of risk assessment during peer review process



Observations Review Program

- Exposure assessment: considerable package of technical guidance but often revised or new scenario developed → for each 'new PT' there is a new start
- Realistic worst-case?
  - wood preservatives (10 → 50 cm); insecticides (revised defaults ESD) and antifoulings (wider environment scenario)
  - estimations versus monitoring
- Proportional?

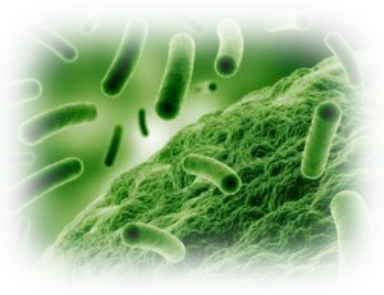
SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Biocidal Products Regulation

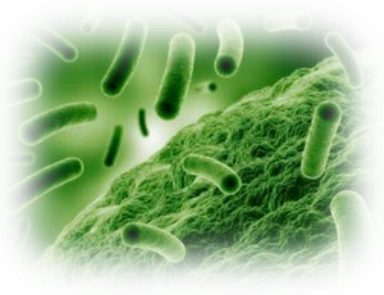
- Commission proposal 2009 → Second Reading → Foreseen application date September 2013
- ECHA takes over role of DG JRC
- Principle will not change: approval of active substance followed by product authorisation (national or Union)
- Member States will be responsible for evaluation

SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Other elements of new Regulation

- Scope
- Mandatory data sharing for testing with vertebrate animals
- Access to the active substance dossier
- Technical equivalence
- Improve legal basis for data waiving → exposure based waiving for active substances and biocidal products → delegated/implementing act

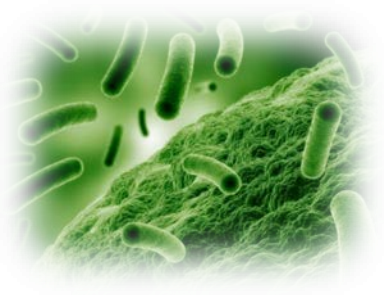


New elements compared to BPD

- Evaluation criteria
- Exclusion and substitution
- Comparative assessment

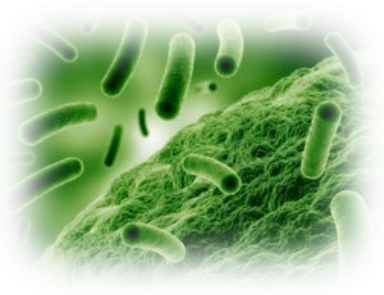
➢ Principles of environmental risk assessment as laid down in Annex VI will not change including data requirements

SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



Biocidal Products Regulation

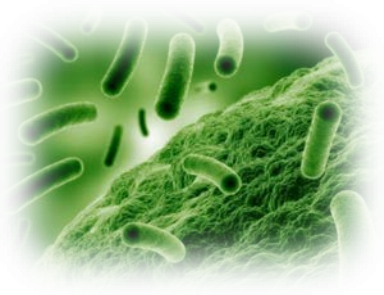
- Conditions for approval of active substance (Article 4 refers to 18(1)(b) taking into account 18(2) and 18(5)):
  - 'New' criterion: no unacceptable effects due to long range transport
  - 'New' factor to consider: cumulative and synergistic effects
  - 'New' factor to consider: authorisation possible when criteria are not fully met but disproportionate negative impacts for society



Biocidal Products Regulation

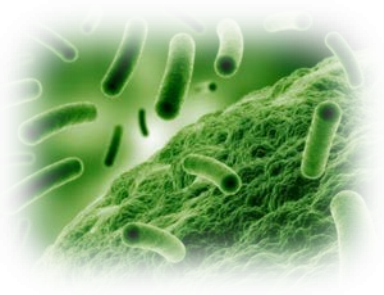
- Exclusion criteria: CMR Cat 1A or 1B, endocrine disruptor, vPvB and PBT (Article 5.1)
- Derogation (Article 5.2)

SETAC Europe ○ Avenue de la Toison d'Or 67 b 6 ○ B-1060 Brussels, BE
+32 2 772 72 81 ○ setaceu@setac.org



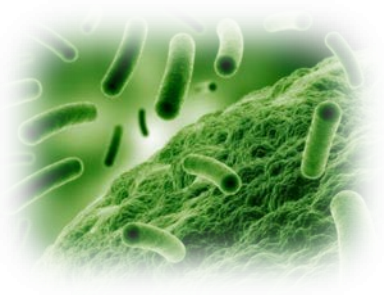
Biocidal Products Regulation

- Substitution criteria (Article 10):
  - One of the exclusion criteria
  - Significantly higher toxicity
  - Two out of three P, B and T
  - Concerns related to nature of critical effect which together with use pattern leads to cause for concern even with very restrictive risk mitigation measures
  - Significant amount of non-active isomers or impurities



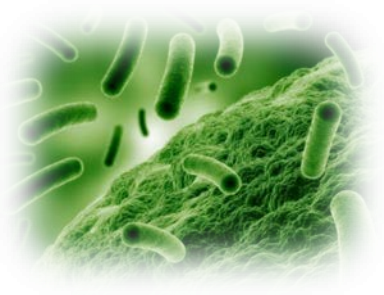
Comparative assessment

- If biocidal product contains an active substance that is a candidate for substitution a comparative assessment is required at product authorisation (Article 22)
- Prohibit or restrict if other biocidal product or non-chemical control with significantly lower risk under several conditions (same efficacy and no other economic or practical disadvantages and no resistance concerns)



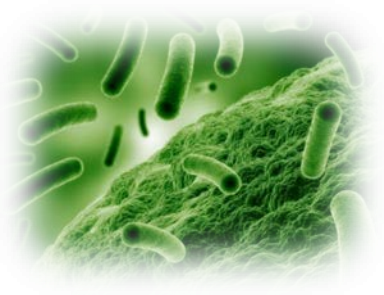
Future regulatory challenges

- Substitution criteria: how and when to apply? Technical guidance will be needed
- P and B assessment for biocides: temperature correction, photolysis, lab versus field studies, lipid normalised BCFs
- Cumulative and comparative assessment: need to develop suitable and pragmatic methods



Cumulative assessment

- Commission point of view under BPD: relevant for Annex I inclusion stage but not on a routine basis
- New regulation: no definition
- What to do if PEC/PNEC > 1 → WFD and REACH (draft CoRAP)
- Do all releases end up in the same STP?



Conclusions

- New Regulation: no major impact on environmental risk assessment
- Review Program: still a long road ahead …
- The new Regulation:
  - approval of actives is becoming more complex
  - necessary to have streamlined procedures
  - added value of a central organisation