Approval of Biocides in EU

ATV meeting 48,
18-09-2019, Århus

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Danish Technological Institute

DANISH
TECHNOLOGICAL
INSTITUTE

STATUS

An independent, non-profit institution.
Approved as a technological service institute by the
Danish Ministry of Science, Technology and Innovation.

OBJECTIVE

The objective of DTI is to address the needs of the industrial sector and society as a whole through the development and dissemination of technological innovation.

Presentation of DTI - Divisions and Centres

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BUILDING and CONSTRUCTION
Concrete
Building Processes
Indoor Climate and Building Inspection
Masonry
Sustainable Building and Construction
Swimming Pool Technology
Textiles
Wood Technology

BUSINESS DEVELOPMENT
Policy and Business Analysis
Human Resources Development
Creativity and Growth
Technology Partnership

PRODUCTIVITY AND LOGISTICS
Automobile Technology
Packaging and Logistics
Production
Robot Technology

DANISH MEAT RESEARCH INSTITUTE (DMRI)
Hygiene and Conservation
Measuring Systems and Data Integration
Processing Quality
Slaughtering Technology

LIFE SCIENCE
DTI Oil & Gas
Fisheries and Environmental Technology
Food Technology
Chemistry and Microbiology
Laboratory for Microbiology

TRAINING
IT Training
Conferences
Management

ENERGY AND CLIMATE
Energy Efficiency and Ventilation
FEM-Secretariat
Installation and Calibration
Refrigeration and Heat Pump Technology
Pipe Centre
Renewable Energy and Transport

MATERIALS AND PRODUCTION
Materials Testing
Microtechnology and Surface Analysis
Metrology and Quality
Plastics Technology
Product Development
Tribology

INTERNATIONAL CENTRE

Chemical Laboratory

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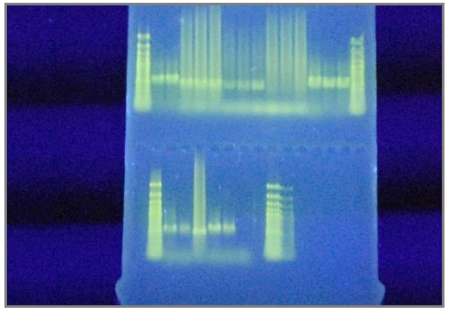
- 30+ employees located in Århus
- 50 years experience supplying commercial laboratory services to Danish industry
- Accredited test laboratory (DANAK, ISO 17025)
- Authorised by the Danish Medicines Agency to provide §39 approved analyses of medical products
- Comprehensive commercial programme of standardised tests and analysis of raw materials and products as well as error analysis
- Partner in a wide variety of research and development projects within analytical chemistry and microbiology

DANAK



Wood Technology

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- Wood protection (treated wood, modified wood, coatings and natural durability)
- Inspector for NWPC in Denmark and member of NWPC Technical committee
- Efficacy testing (Denmark, Malaysia and lab trials)
- Environmental impact testing
- Preparation of dossiers for documentation acc. to BPD/BPR
- R&D (basic wood science, adhesive/resin technology and coatings)
- Timber constructions
  Physical and mechanical testing of wood-based materials, panels, flooring etc.
  Adhesives
  On-site inspection
  CE labeling
  Life cycle analysis (LCA)
  Environmental Product Declaration (EPD)
- Microbiological test facilities: moulds, fungi, bacteria etc.
  Analysis of samples from damaged buildings

ilac-MRA

DANAK
TEST Reg.no. 2

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The Biocidal Products Regulation - BPR

- September 1, 2013 the BPR went into force, replacing the BPD of 1998
  BPD: 63 pp, 36 articles
  BPR: 128 pp, 97 articles

- To ensure that biocidal products on the market are suited for their purpose

- To protect human health and the environment when using biocides

Relationship to other European legislations

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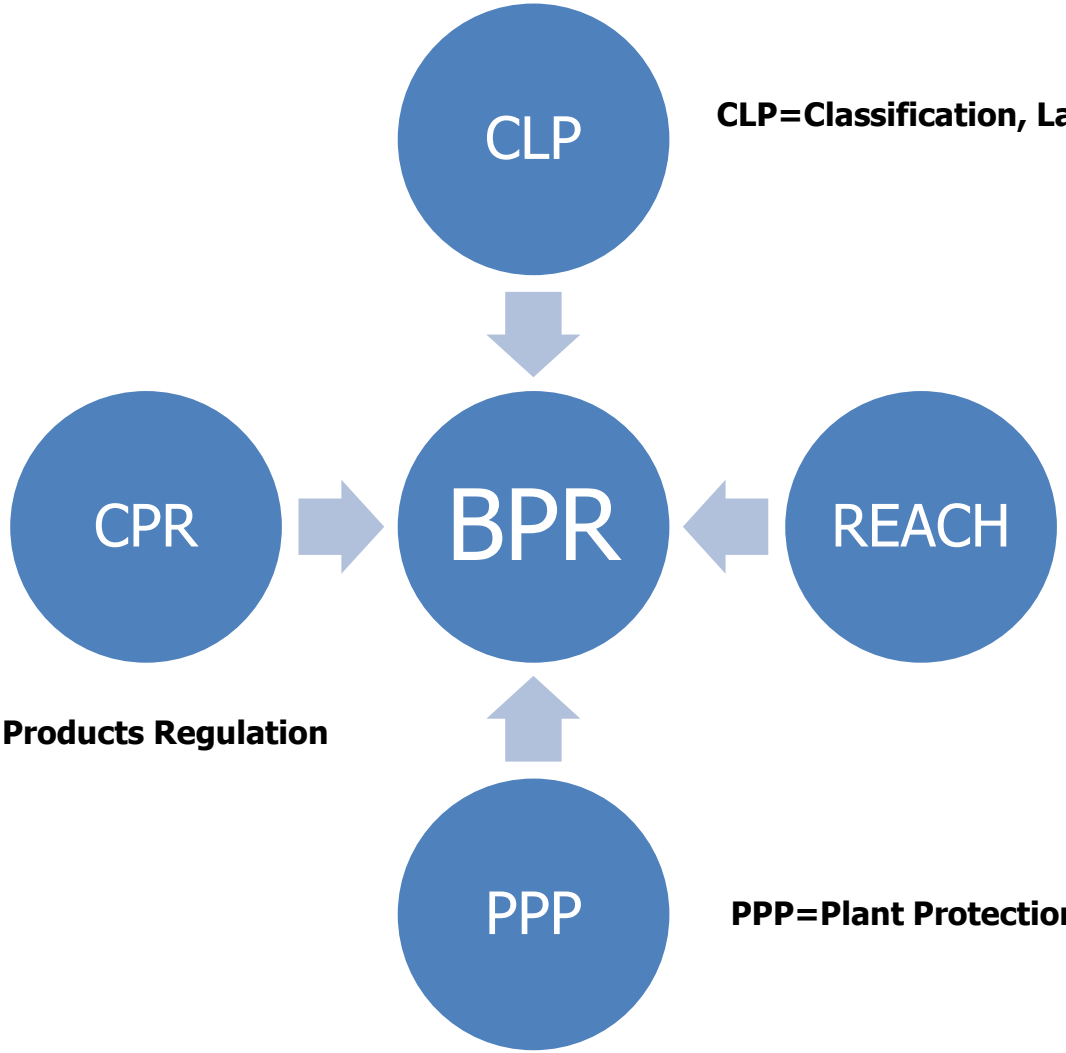

CLP=Classification, Labelling and Packaging

REACH= Registration, Evaluation, Authorisation and Restriction of Chemicals

CPR=Construction Products Regulation

PPP=Plant Protection Products

Structure of BPR

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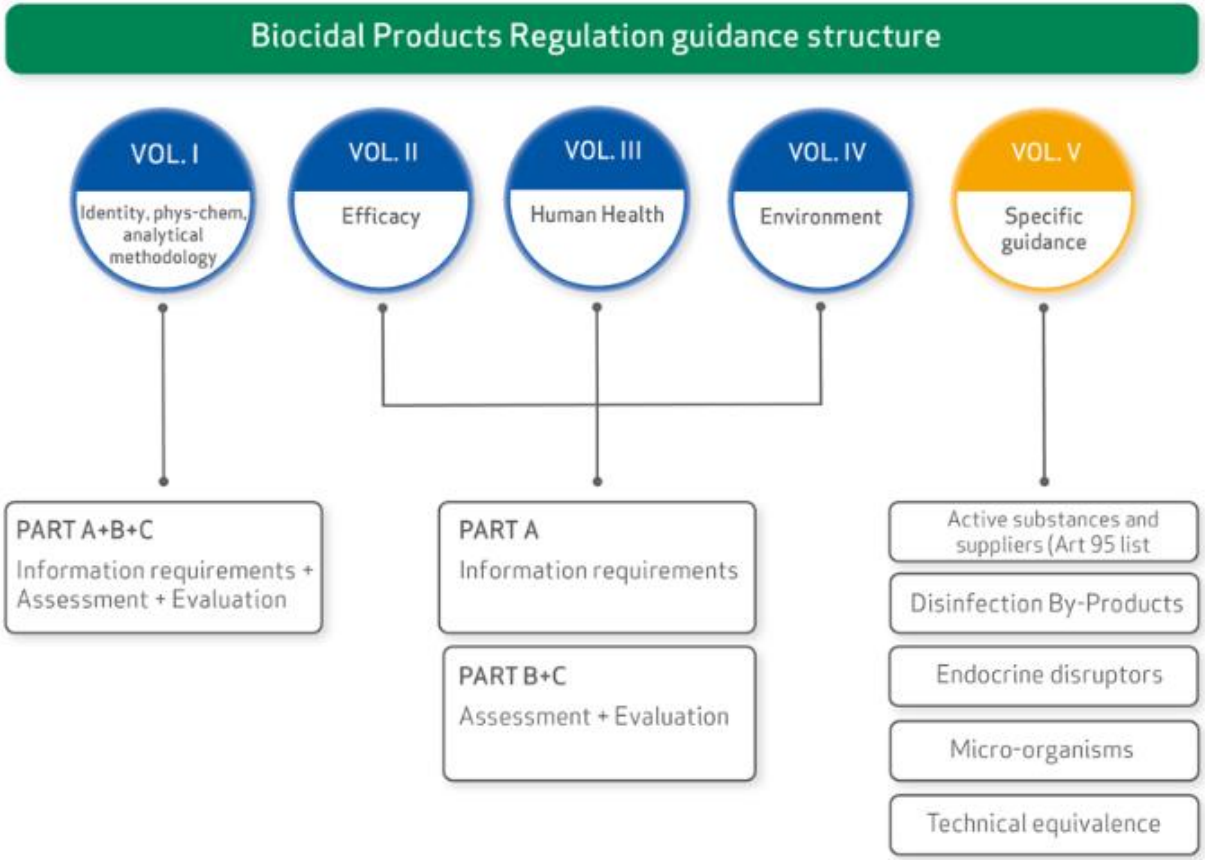

https://echa.europa.eu/da/guidance-documents/guidance-on-biocides-legislation

Main Group 1: Disinfectants		
1	Human hygiene	Biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp
2	Disinfectants and algaecides not intended for direct application to humans or animals.	Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools aquariums, bathing and other waters, air conditioning systems; w'alls and floors in private, public and industrial areas and in other areas for professional activities. Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
3	Veterinary hygiene	Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function. Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.
4	Food and feed area	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage, or consumption of food or feed (including drinking water) for humans and animals. Products used to impregnate materials that may enter into contact with food.
5	Drinking water	Products used for the disinfection of drinking water for both humans and animals.
Main Group 2: Preservatives		
6	Preservatives for products during storage	Products used for the preservation of manufactured products, other than foodstuffs, feeding stuffs cosmetics or medicinal products or medical devices by control of microbial deterioration to ensure their shelf life. Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.
7	Film preservatives	Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
8	Wood preservatives	Products used for the preservation of wood, from and including saw-mill stage, and wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventative and curative products.
9	Fibre, leather, rubber and polymerised materials preservatives	Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
10	Construction material preservatives	Products used for the preservation of masonry, composite materials or other construction materials other than wood by the control of microbiological and algal attack.
11	Preservatives for liquid cooling and processing systems	Products used for the preservation of water and other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product type.
12	Slimicides	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, and porous sand strata in oil extraction.
13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.
Main Group 3: Pest control		
14	Rodenticides	Products used for the control of mice, rats or other rodents by means other than repulsion or attraction.
15	Avicides	Products used for the control of birds, by means other than repulsion or attraction.
16	Molluscicides, vermicides and products to control other vertebrates	Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.
17	Piscicides	Products used for the control of fish, by means other than repulsion or attraction.
18	Insecticides, acaricides and products to control other arthropods	Products used for the control of arthropods (e.g. insects, arachnids and crustaceans) by means other than repulsion or attraction.
19	Repellents or attractants	Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
20	Control of other vertebrates	Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.
Main Group 4: Other biocidal products		
21	Antifouling products	Products used to control growth and settlement of fouling organisms (microbes and higher forms of plant and animal species) on vessels, aquaculture equipment or other structures used in water.
22	Embalming or taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts of thereof.

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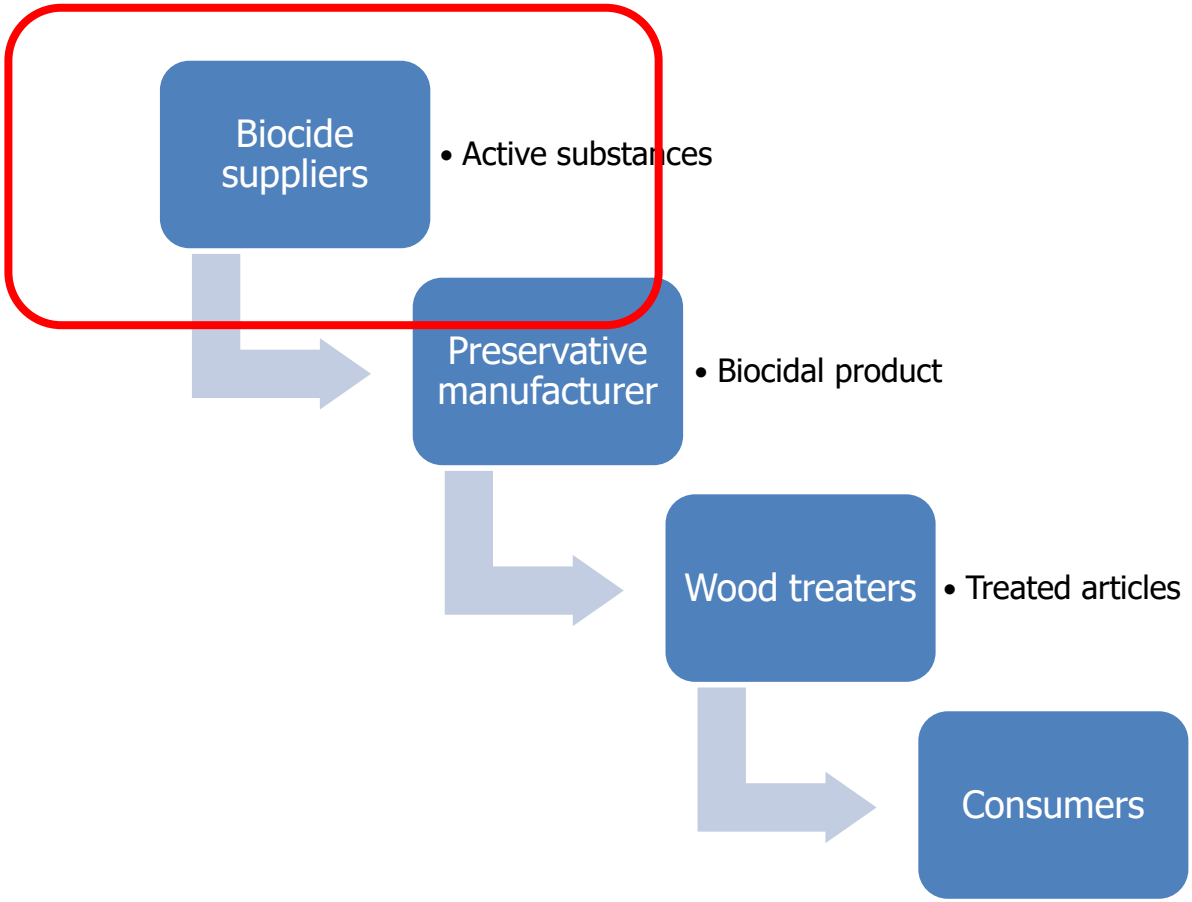
The Biocidal Products Regulation - stakeholders



Dossier for an Active Substance
– endpoints

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- Determine identity and properties of the substance – incl. analytical methods

- Demonstrate efficacy

- Determine **P**redicted **N**o-**E**ffect **C**oncentration values (PNEC) for all relevant recipients in the environment:
  - soil
  - surface water
  - sediment
  - ground water (Estimation based on e.g. FOCUS-PEARL)

- Determine safe levels for humans (No Observed Adverse Effect Level - NOAEL)

Label Claim!

Dossier for an Active Substance
– procedure

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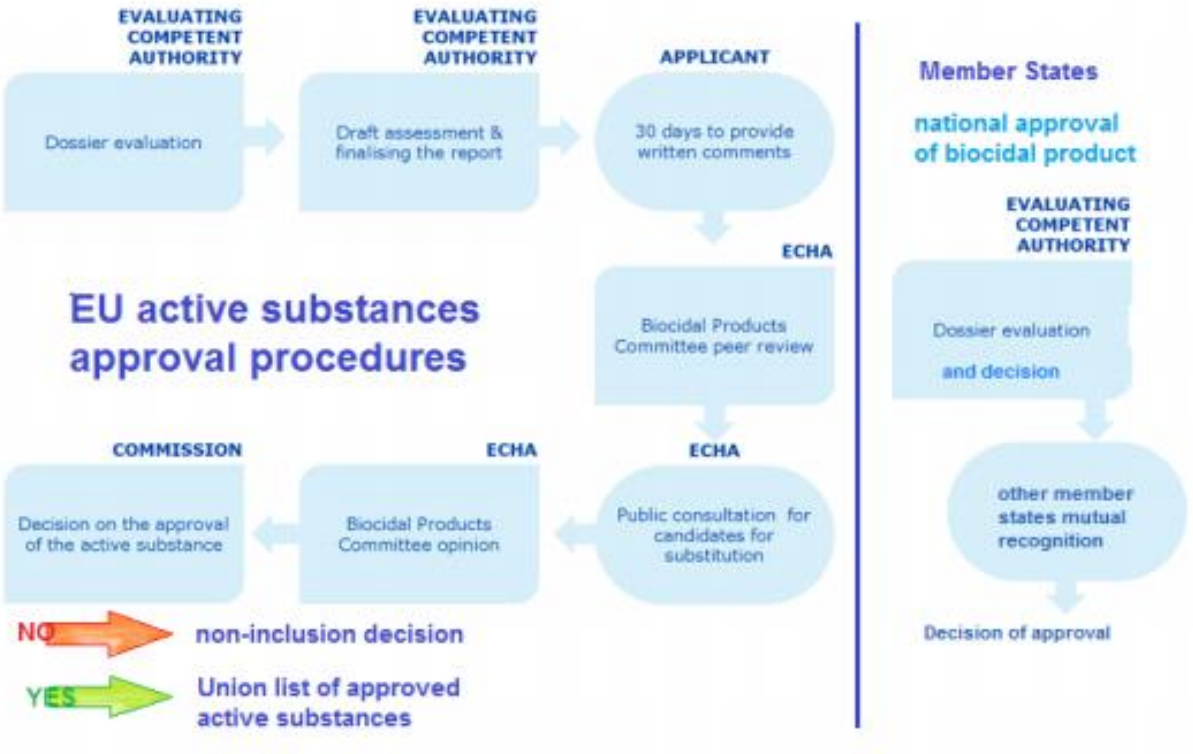

Figure 1 - General procedure for review of an active substance at EU-level and authorisation of a product at the national level. These procedures are repeated in 10 year cycles in order to take new scientific information into account. While the overall responsibility for decision making and providing the public with documentation rests with the European Commission, all the practical details about the review process are the responsibility of ECHA since 2014.

Active Substances
– status

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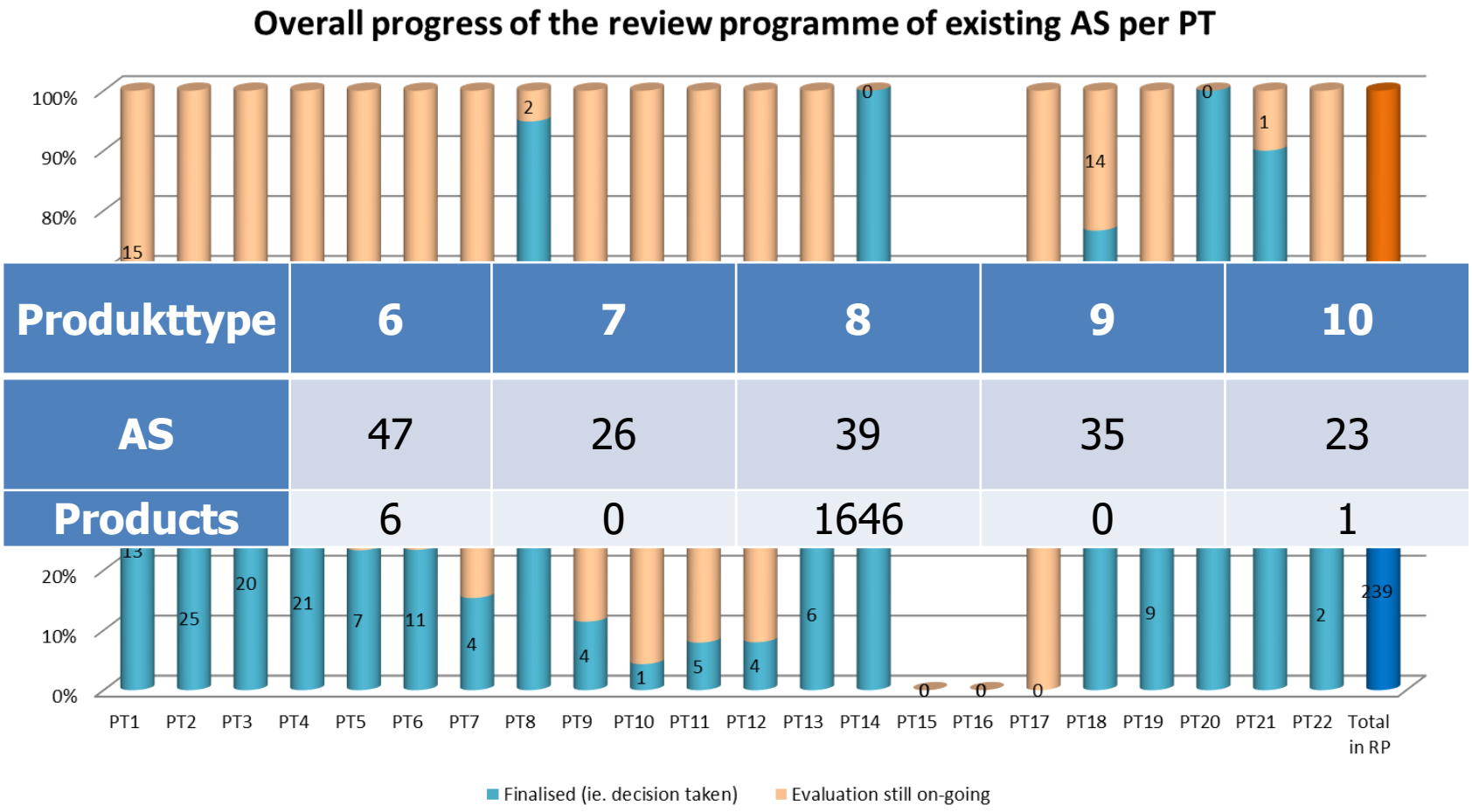

Produkttype	6	7	8	9	10
AS	47	26	39	35	23
Products	6	0	1646	0	1

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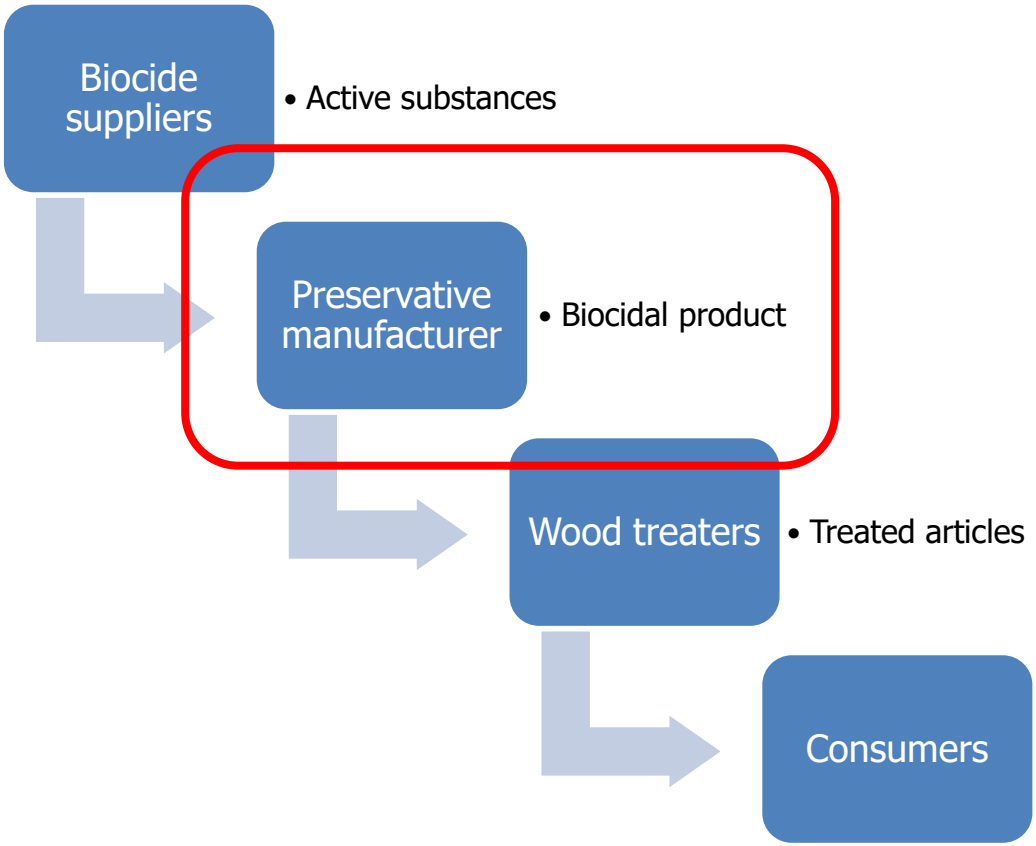
The Biocidal Products Regulation - stakeholders



Procedure for national approval of a product

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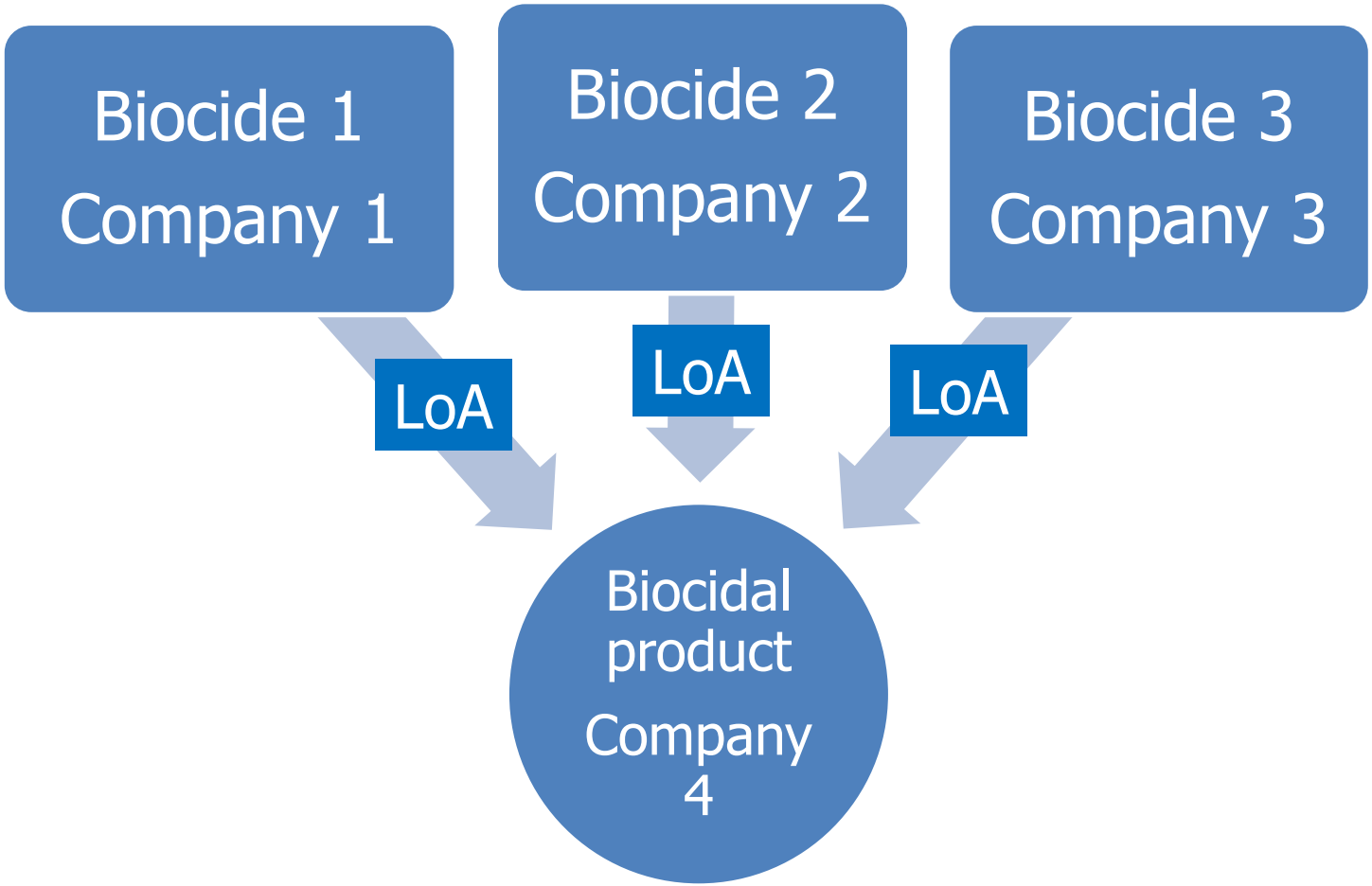

Procedure for national approval of a product

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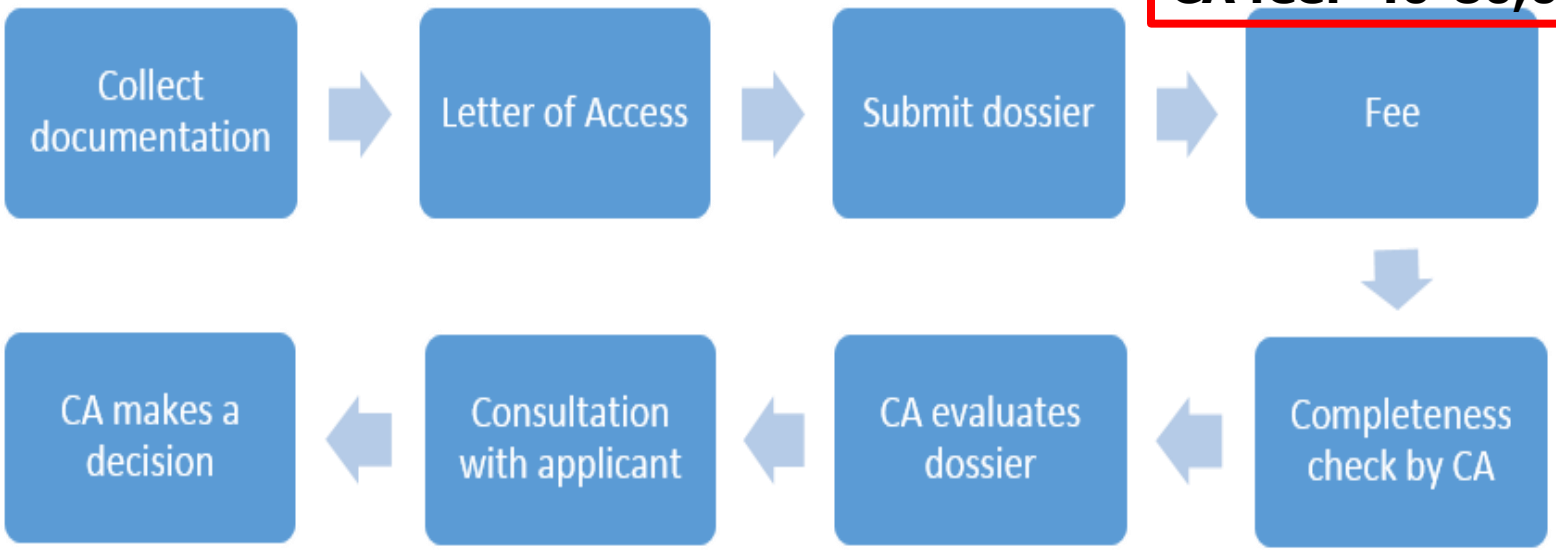
CA fee: 40-80,000 €



Approval in one country -> mutual recognition = more fees!

+ annual fee!

Approval of a PT 8 product
- efficacy

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Categories	Matrix wording	Code for product
User category	**Professional**	**A;20**
Wood category	softwood and hardwood	B.10 ; B.20
Wood product	solid wood	C.10
Application aim and Field of use	preventive treatment - use class 3.2	D.40; E.32
Method of application and rate	superficial application / dipping treatment application rate: 100 g/m² in the analytical zone a top coat must be applied.	F.14
	Pressure process / vacuum impregnation application rate: 50 kg/m³ in the analytical zone	F.31
Target organisms	wood boring beetles	G.30
	termites (genus *Reti…*)	G40
	brown rot fungi	G.10
	white rot fungi	G.11

EN 599-1

Approval of a PT 8 product
– release to the environment

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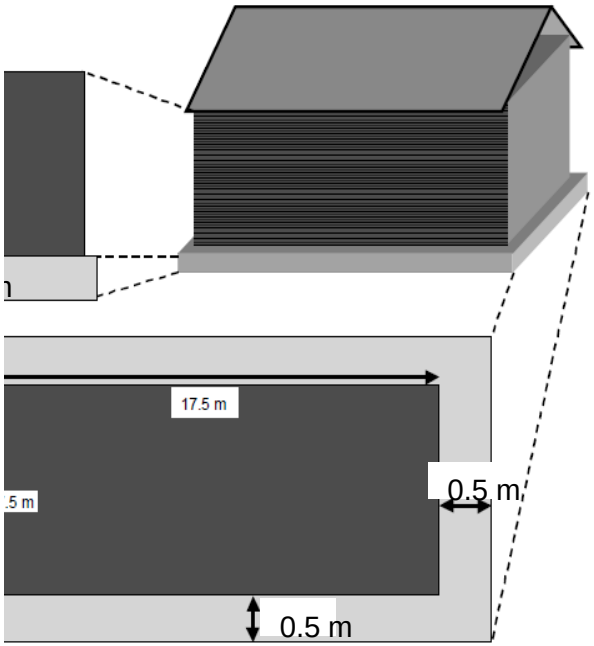
Label Claim: Cladding for a house; Use Class 3 (above ground not in contact with soil)

Parameters

Scenario: House (Use Class 3)	Nomenclature	Value	Unit	Origin
Inputs				
Leachable wood area	$AREA_{house}$	125	[m^2]	D
Duration of the initial assessment period	$TIME1$	30	[d]	D
Duration of the long-term assessment period	$TIME2$		[d]	D
Cumulative quantity of an active ingredient leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$		[$kg.m^{-2}$]	A
Cumulative quantity of an active ingredient leached out of 1 m^2 of treated wood over a longer assessment period	$Q^*_{leach,time2}$		[$kg.m^{-2}$]	A
(wet) Soil volume	V_{soil}	0,50	[m^3]	D
Bulk density of wet soil	RHO_{soil}	1700	[$kg_{wwt}.m^{-3}$]	D
Outputs				
Cumulative quantity of an active ingredient, leached over the initial assessment period	$Q_{leach,time1}$		[kg]	O
Cumulative quantity of an active ingredient, leached over a longer assessment period	$Q_{leach,time2}$		[kg]	O
Concentration in local soil at the end of the initial assessment period	$Clocal_{soil,leach,time1}$		[$kg.kg_{wwt}^{-1}$]	O
Concentration in local soil at the end of a longer assessment period	$Clocal_{soil,leach,time2}$		[$kg.kg_{wwt}^{-1}$]	O

D=default, A=based on information of applicant, O=output



OECD Emission Scenario Document for Wood Preservatives, PART 2

Approval of a PT 8 product
– release to the environment

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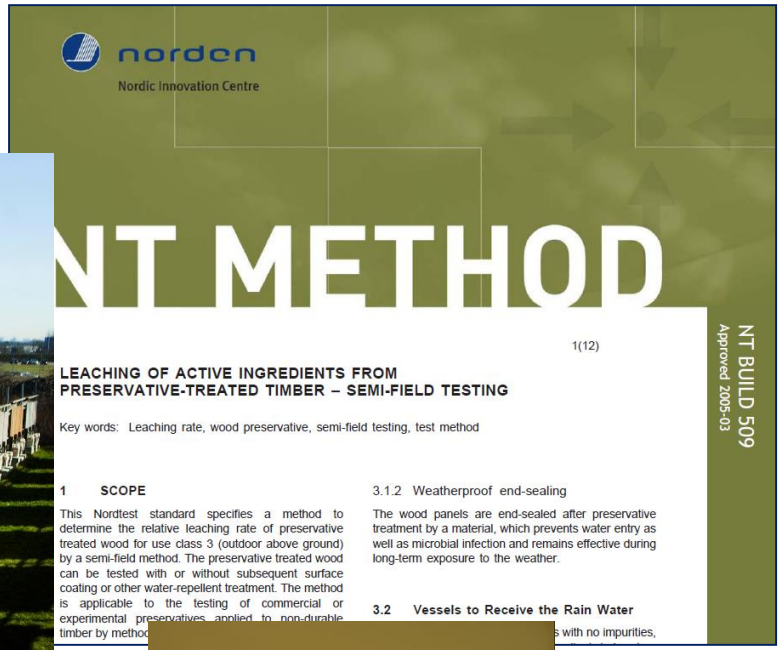
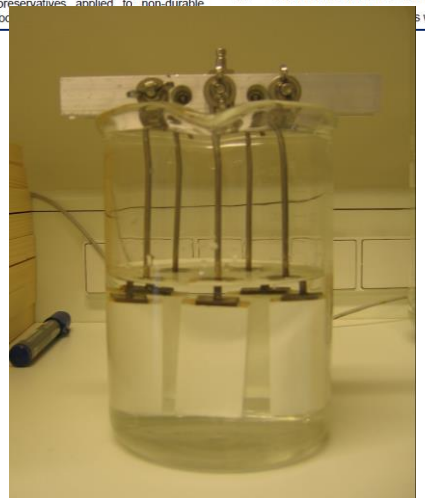
- Semi-field leaching (NT Build 509, now becoming an EN standard)



- Laboratory leaching (OECD guideline, CEN/TS 15199-1, EN 16105)



NT Build 509; Semi-field Leaching Test
- standard test set-up

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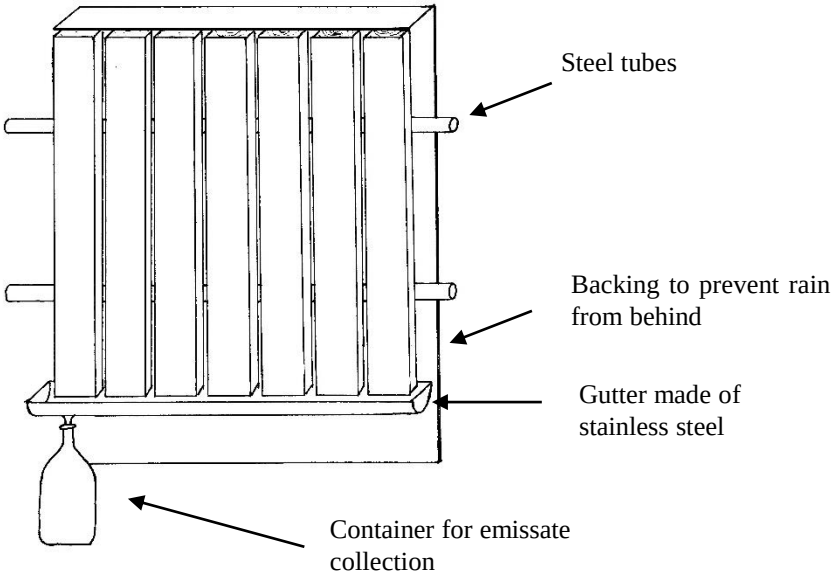
- NT Build 509:2005 (CEN/TC 38; WI 00038179)
- Oriented to the South
- Vertical or horizontal exposure
- Leachate collected after each major rain event
- Samples stored at -18° C
- Chemical analyses ~ 5 times during the first year of exposure
- ~ 2 times the following years



NT Build 509; Semi-field Leaching Test
- Accumulated leaching

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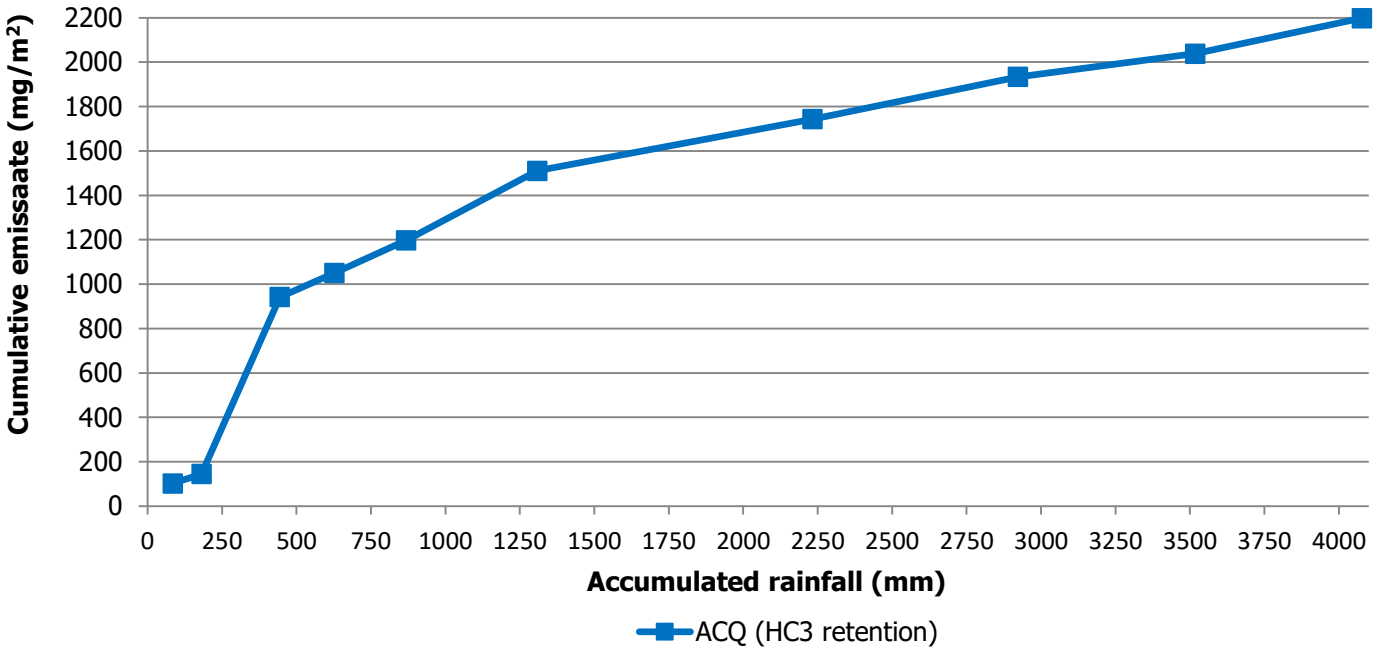
Cumulative quantity of Cu leached/m^2 as a function of accumulated rainfall



Influence of curve fitting
PT 8: Wood preservative

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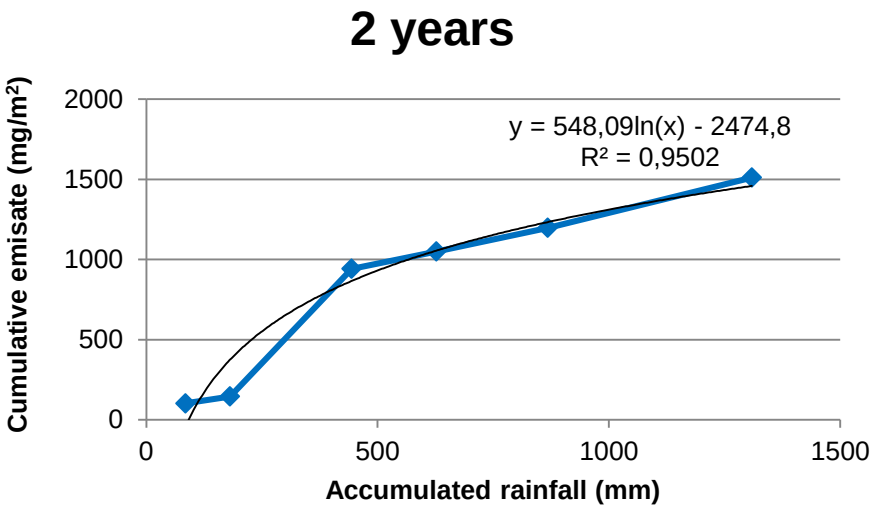

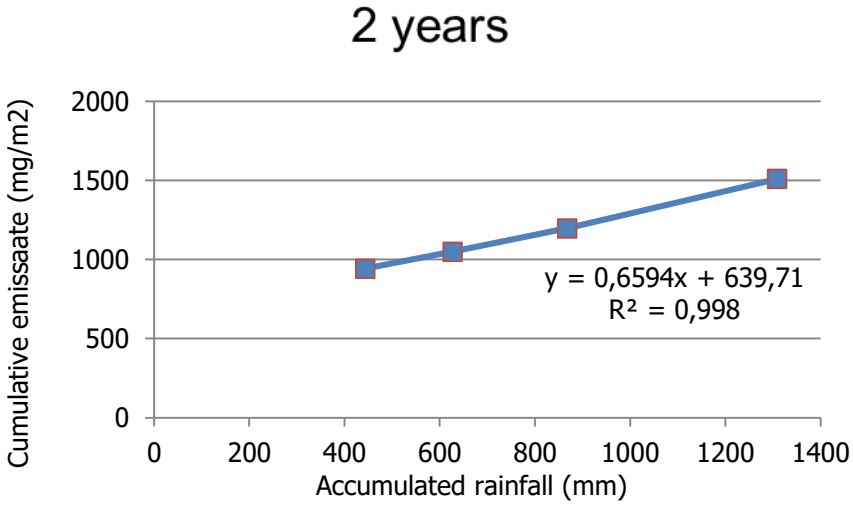

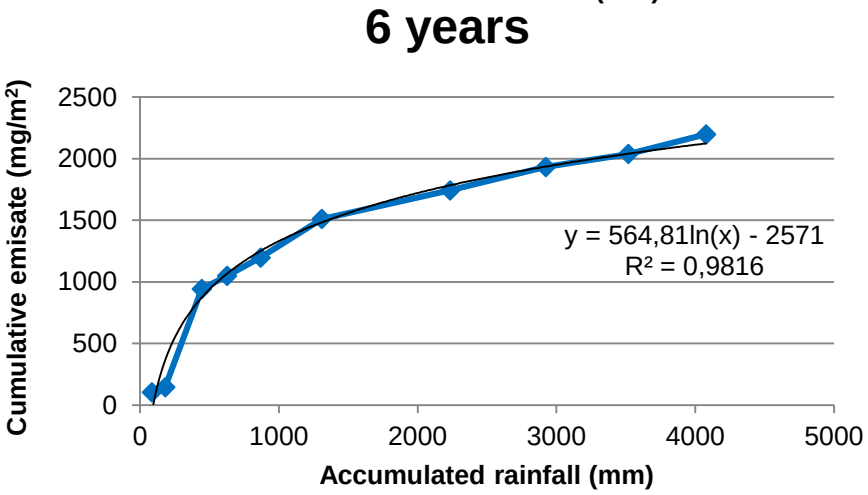

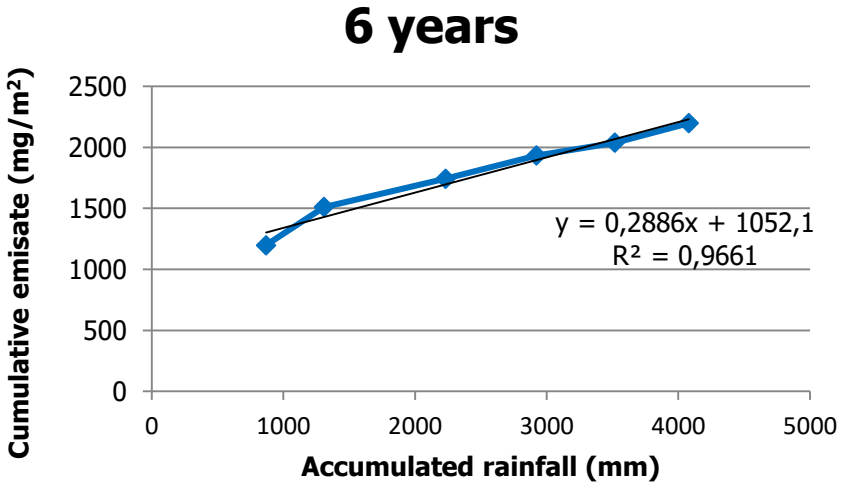

Influence of curve fitting
PT 8: Wood preservative

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	Curve fit	R^2	20 years (mg Cu/m²)	% of initial
2 years	Logarithmic	0.959	2724	10.0
6 years	Logarithmic	0.989	2837	10.4
2 years*	Linear	0.998	10135	37.1
6 years**	Linear	0.966	5208	19.1

*excluding the first 6 months
**excluding the first 12 months

A factor of 4 between highest and lowest estimate!

Approval of a PT 8 product
– release to the environment

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Label Claim: Cladding for a house; Use Class 3 (above ground not in contact with soil)

PEC: Predicted Environmental Concentration
PNEC: Predicted No-Effect Concentration

Example: product containing IPBC and propiconazole:
PNEC values to soil: determined at the A.S. level (LoA)

$PEC/PNEC < 1$

$PEC_{IPBC}/PNEC_{IPBC} + PEC_{propi}/PNEC_{propi} < 1$

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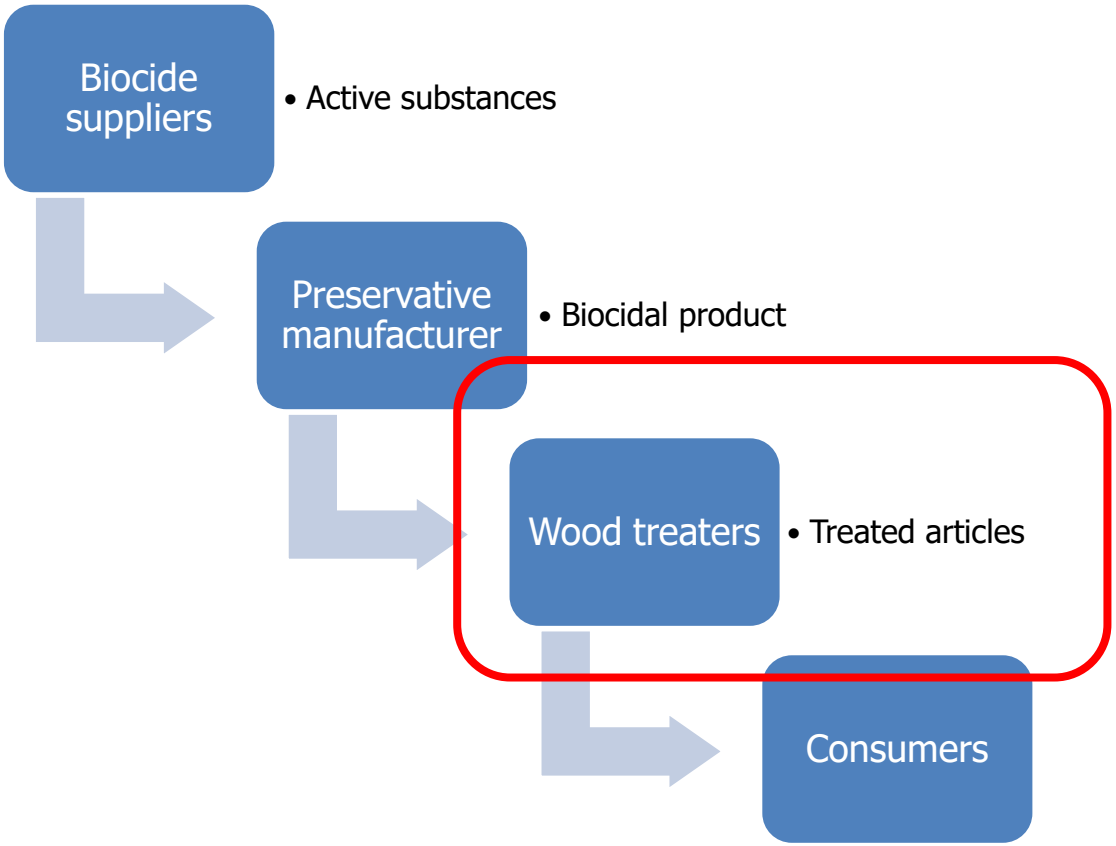
The Biocidal Products Regulation - stakeholders



Treated articles

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Articles that have been treated with a biocide do not need BPR authorisation, but they can only be placed on the EU market when the active substance in the biocide has been approved for the specific use. This also apply to imported articles from outside EU.

Examples of treated articles:
- a paint that contains an in-can preservative (mixture)
- a sock that contains silver fibre to prevent odour (article incorporating a biocide)
- a refrigerator that has been treated with substances to prevent mould and odour (article).

In any case, the active substance must have been approved or be under review.
The treated article must be labelled.

Conclusions

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Authorization of active substances and biocidal product is an on-going process. Within PT 6, 7, 8, 9 and 10 only wood preservatives are close to finalization.

ECHA estimates that the review of existing active substances should be finalized by 2024. Authorization of related products will take additional 2 years.

When implemented BPR should ensure that only efficaceus biocides with an acceptable risk to humans and environment are used. Also for products imported to EU.

IRG 04-20302: *Leaching of active components from preservative-treated timber. Stage 1: Semi-field testing*
IRG 04-20303: *Leaching of active components from preservative-treated timber. Stages 2 & 3: Laboratory testing and comparison with semi-field testing*
IRG 08-50258: *Comparison of laboratory and natural exposure leaching of copper from wood treated with three wood preservatives*
IRG 10-50274: *Comparison of laboratory and semi-field tests for the estimation of leaching rates from treated wood – part 1: above ground (UC 3)*
IRG 11-50278: *Characterizing long term leaching behavior of copper from preservative treated wood in a practical exposure scenario*
IRG 14-50303: Influence of Exposure Direction on Leaching of a Biocide from Painted Wood Surfaces

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Thank you for your attention!