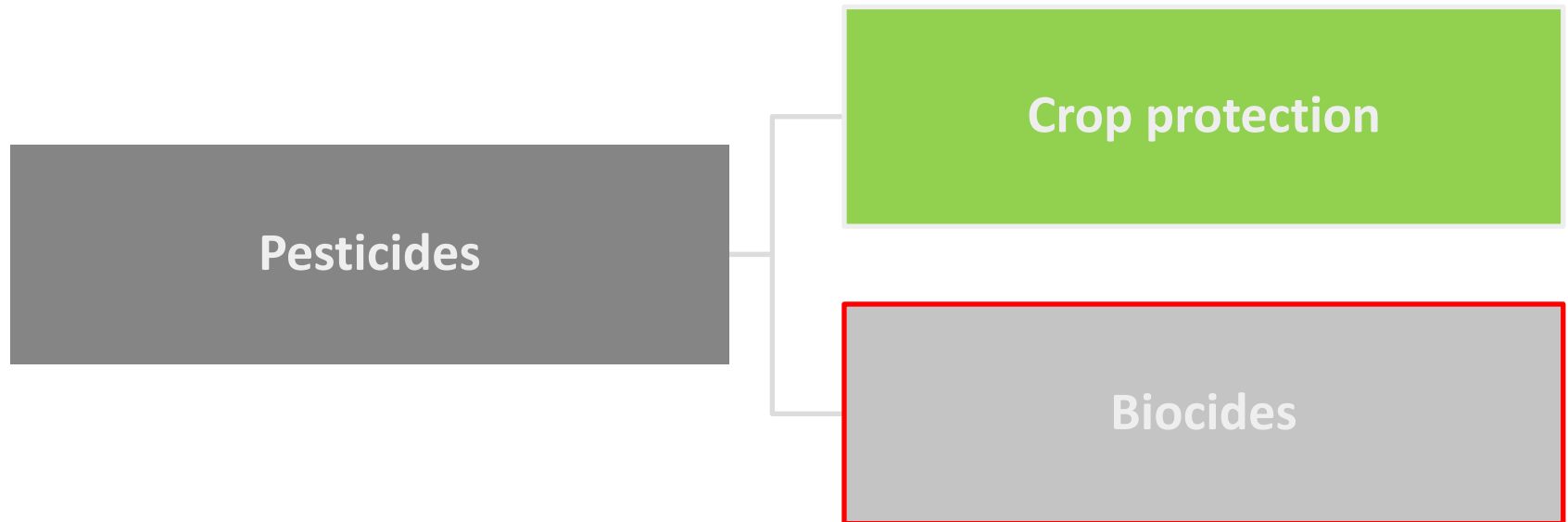


Legal provisions regarding the marketing of biocidal products

Duratex closing event – 22/09/20

Legislative Framework



Biocidal Product = any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Incl. Viruses

Legislatory Framework

Biocidal Product regulation – BPR

- The purpose of this Regulation is to improve the functioning of the internal market through the harmonization of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment.
- In contrast to REACH, the BPR is only applicable when a biocidal claim is made.

Legislatory framework

Europe

Biocidal Product Regulation (528/2012)

Concerning the
marketing & use of
biocidal products

Review program of
existing substances

Directive 98/8

Concerning
biocidal products

Belgium

R.D. of 8 may 2014,
conc.
marketing & use of
biocidal products.

Modified by R.D of
17/06/2018.

R.D. of 22 may 2003

Concerning
biocidal products

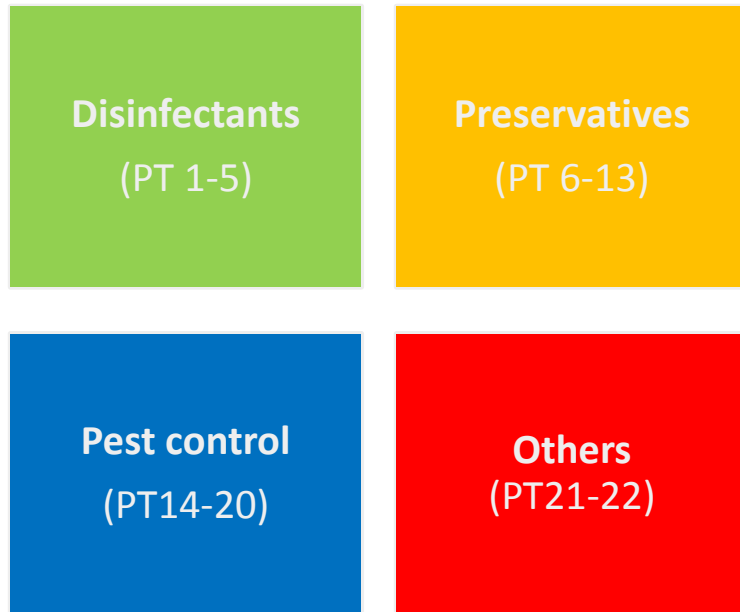
Swiss

Biocidal ordonnance

National "translation"
of BPR

Product-Types

The BPR distinguishes **22 product-types**, classified in **4 major families**, in conformity with the intended purpose:



- PT1 biocidal products used for **human hygiene** purposes, applied on or in contact with human skin or scalps
- PT9 preservation of fibrous or **polymerised materials, such as leather, rubber or paper or textile** products by the control of microbiological deterioration.
- PT18 **Used for the control of arthropods** (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.

Approval of an active substance / biocidal product is done per product type

<https://echa.europa.eu/regulations/biocidal-products-regulation/product-types>

ECHA – European Chemicals Agency

- Approval of active substances (European Level)
 - The Review Program
 - Silver

Approval of active substances (European level)

- "New" active substances
 - Request for approval of an active substance by submitting a dossier to ECHA. The competent authority shall perform a completeness check and an assessment within the one-year period. An opinion is then issued by ECHA's Committee on Biocidal Products within 270 days
 - The advice forms the basis for the decision-making of the European Commission and the Member States. The approval of an active substance is granted for a specified number of years, with **a maximum of 10 years**.
- Renewal of active substances
 - Similar procedure (complete <-> limited assesment)
 - The application must be submitted to ECHA 550 days before the previous approval expires.

<https://echa.europa.eu/nl/regulations/biocidal-products-regulation/approval-of-active-substances/new-active-substances>

Approval of active substances (European level)

» List of approved active substances:

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status	Related authorised biocidal products
(benzothiazol-2-ylthio)methyl thiocyanate (TCMTB)	244-445-0	21564-17-0	 PT09			Norway	Initial application for approval in progress Competent authority evaluation	
1,2-benzisothiazol-3(2H)-one (BIT)	220-120-9	2634-33-5	 PT09			Spain	Initial application for approval in progress Competent authority evaluation	
1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)	262-104-4	60207-90-1	 PT09	01/06/2015	31/05/2025	Finland	Approved	
2-butyl-benzo[d]isothiazol-3-one (BBIT)	420-590-7	4299-07-4	 PT09			Czech Republic	Initial application for approval in progress Competent authority evaluation	
2-octyl-2H-isothiazol-3-one (OIT)	247-761-7	26530-20-1	 PT09			France	Initial application for approval in progress Competent authority evaluation	
2-thiazol-4-yl-1H-benzimidazole (Thiabendazole)	205-725-8	148-79-8	 PT09			Spain	Initial application for approval in progress Competent authority evaluation	

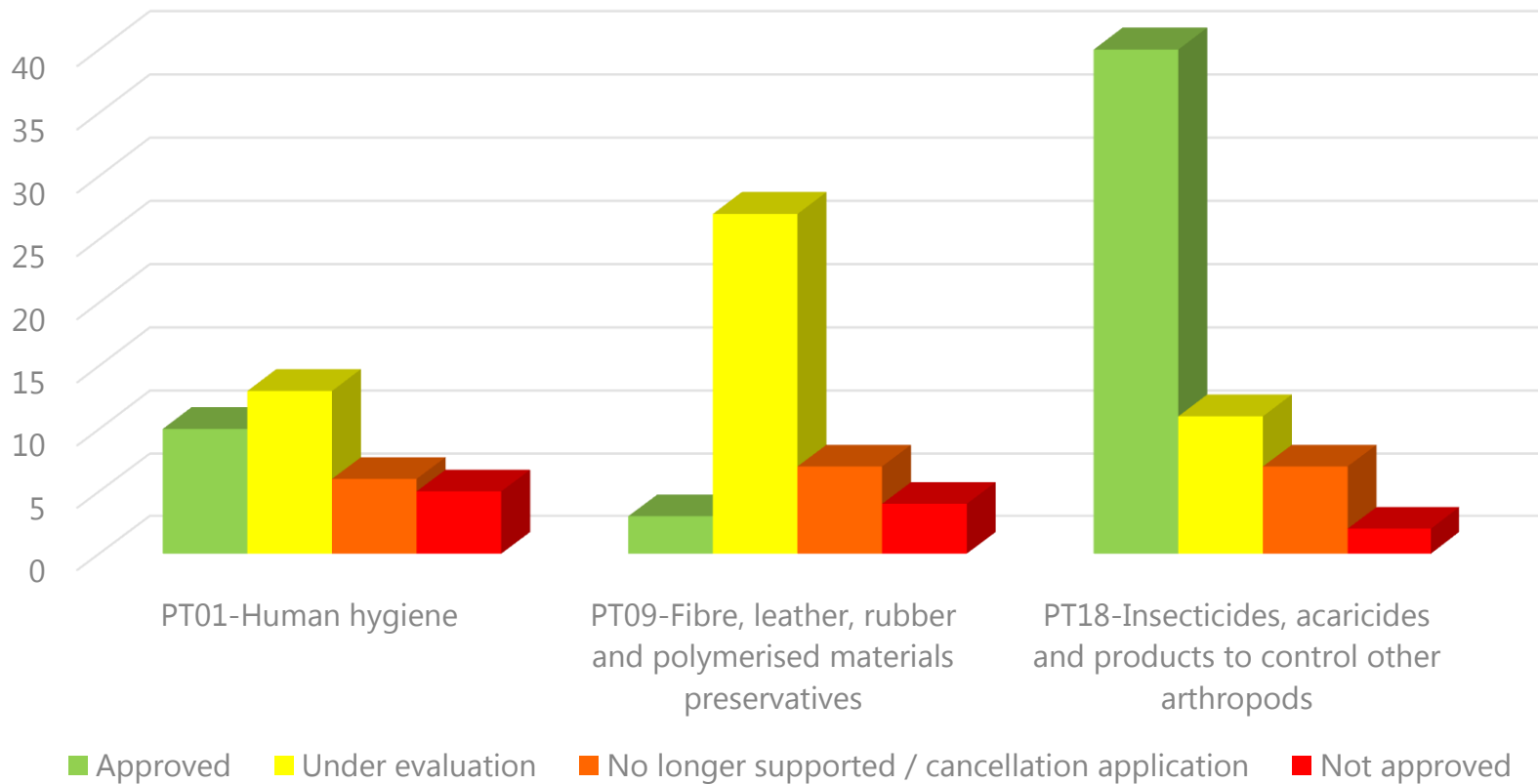
Reviewprogram

- **Assessment program** for existing **active substances**
- Prior to assessment, a notification needs to be performed by the supplier.
- Foreseen Finish: 2014?

Existing active substance:
Active substance, placed on the market on 14th may 2000

Reviewprogram

Review program



Reviewprogram

... no longer allowed!

PT 1	Citric acid	77-92-9
	2-Butanone / Methyl ethyl ketone peroxide	1338-23-4
	<u>Triclosan</u>	3380-34-5
PT 9	<u>Silver</u>	7440-22-4
	Carbendazim	234-232-0
	Cu-HDO	312600-89-8
	Triclosan	222-182-2
PT 18	Esfenvalerate	66230-04-4
	Triflumuron	64628-44-0
	Empenthrin	54406-48-3

Silver compounds

	PT1: Human Hygiene	PT2: Disinfectants	PT9: preservatives for textiles
Silver	Not allowed	Allowed (Review program substance)	Not allowed
Silver Chloride	Allowed (Review program substance)	Allowed (Review program substance)	Allowed (Review program substance)
Silver nitrate	Allowed (Review program substance)	Not allowed (under assesment)	Allowed (under assesment)
Silver (NM)	Not allowed	Allowed (Review program substance)	Allowed (Review program substance)

Attention: When using silver on treated articles: Check the exact substance & authorised PT's.

National level

Authorisation of biocidal products

Authorisation of biocidal products (national level)

- National authorisation:

Product to be placed on a **single market**, authorisation from that country is sufficient.

- mutual recognition:

Product on the **market in several countries**; application for mutual recognition for the product authorisation.

- Union authorisation:

An **EU-wide authorisation** of a biocidal product.

<https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products>

Authorisation of biocidal products (national level)

“quaternary ammonium”
based product (PT8)

Permethrin based product
(PT18)



Check national authorisations:

<https://echa.europa.eu/information-on-chemicals/biocidal-products>

Treated articles

Treated articles

Art. 58 of the BPR

Biocidal property

quality/property attributed to an object by treatment with or addition of a biocidal product

Ex: Mold resistance



Authorization!

Primary biocidal function

the article is intended for biocidal purposes

Ex: "kills 99,99% of the bacteria"



= Biocidal product

Guidance document:

[https://circabc.europa.eu/sd/a/d7363efd-d8fb-43e6-8036-5bcc5e87bf22/CA-Sept13-Doc%205.1.e%20\(Rov1\)%20-%20treated%20articles%20guidance.doc](https://circabc.europa.eu/sd/a/d7363efd-d8fb-43e6-8036-5bcc5e87bf22/CA-Sept13-Doc%205.1.e%20(Rov1)%20-%20treated%20articles%20guidance.doc)




Treated Articles

- Treat articles only with biocidal product / active substance that is approved or included in the review program for the relevant use
- “Claim triggers labelling”

Label

- a statement that biocides have been processed in the object;
- the attributed biocidal property
- Name of the active substance
- If nanomaterials present “nano” followed by the nano compound
- Users instructions & precautionary measures (if relevant)

TA- case 1: COVID

Community masks	Surgical masks	FFP masks
		
	legislation for medical applications	Legislation for personal protective equipment
Subjected to BPR		Subjected to BPR

TA- case 1: COVID

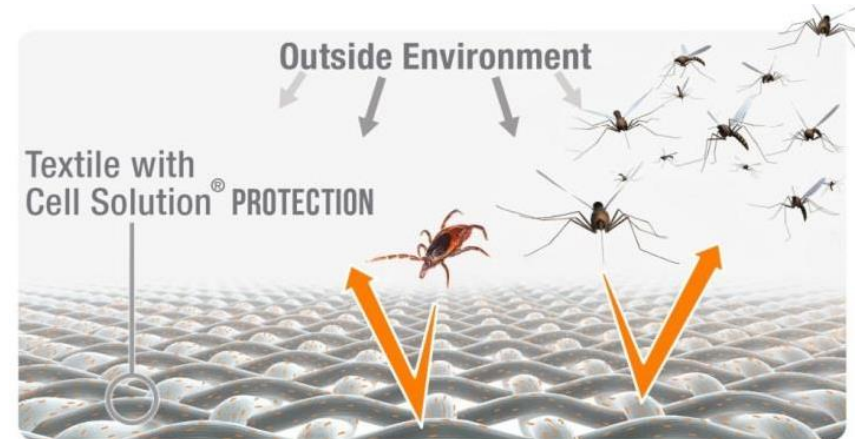
- Approval of the active component:
 - PT1: Human hygiene???
 - PT2: Desinfectants ???
 - PT9: Conservation of textiles ???

- Biocidal property? \leftrightarrow Primary biocidal function ?

TA- case 2: Insects

Yarns incorporating
Permethrin (PT18)

- Increased washing stability compared to permethrin coated fabrics
- Applications:
 - Socks & Garments (forest workers)
 - Military products
 - Tents



TA- case 3: Antimicrobial textiles

Textiles incorporating Silver ions (PT1)

- Silver treatment providing a hygienic advantage & preventing odour development.
- Applications:
 - Hospital textiles
 - Sports clothing
 - Tents



More information

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