Regulatory Challenges in EU for Biocidal Products

- Considerations wrt efficacy testing, focus on baits –

Skadedyrdagene 2025

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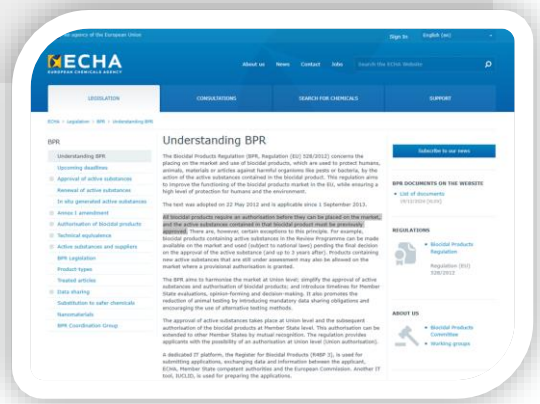
Mega trends that shape the biocidal markets

License to Operate

License to sell + Societal Acceptance

The EU Biocidal Product Regulation (BPR, Regulation (EU) 528/2012)

All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved.*



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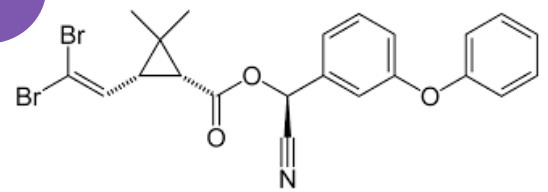


Active substance by product type

Up to 300 Mil €

Costs for new active ingredient

2

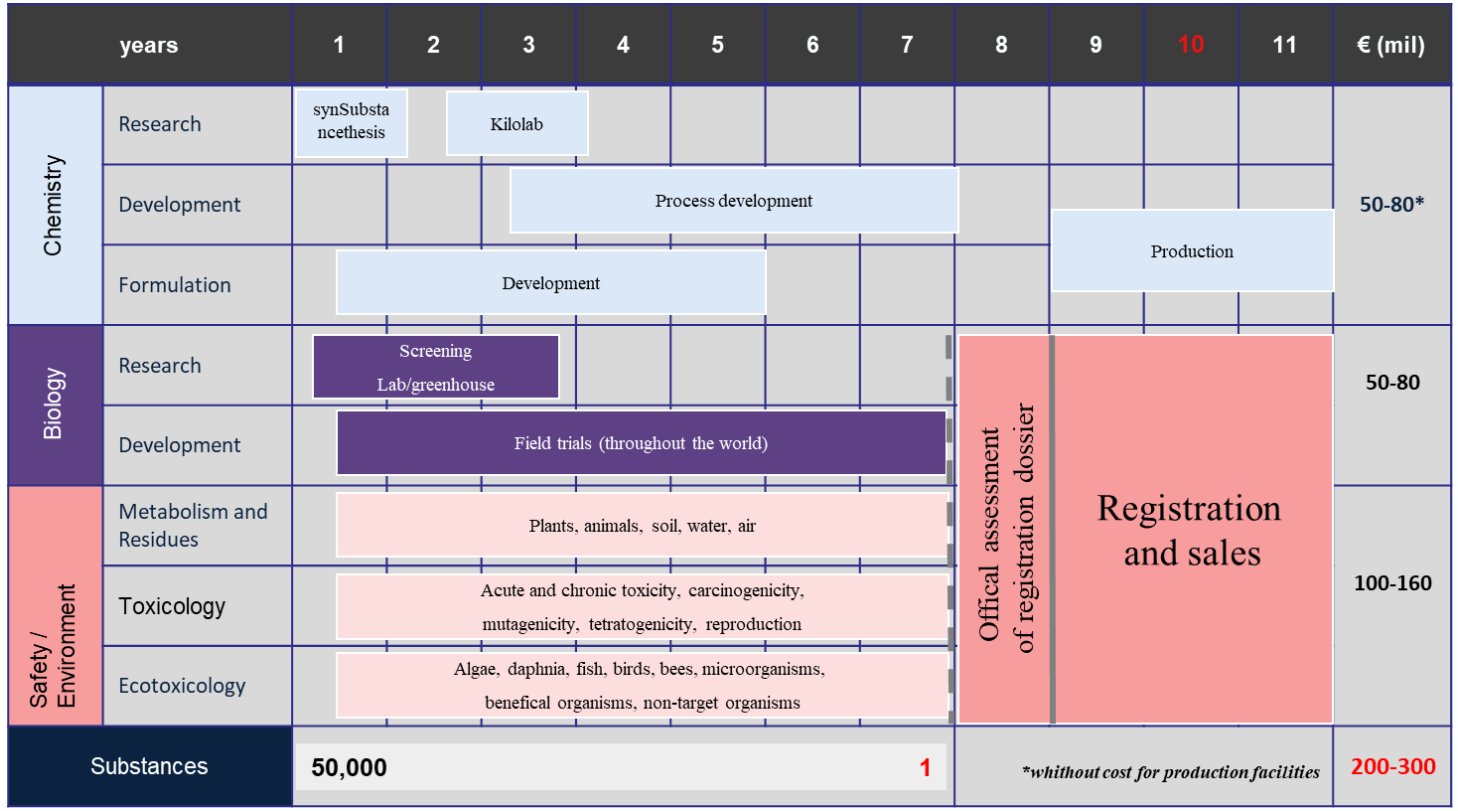
Biocidal product by product type

Up to 800k€

Costs for new dossier (incl data generation, consultancy, fees etc)

* Except product based on existing a.i. (notification on country level) – even in mixtures – until decision on approval

Development of Crop Protection products



+ Active Ingredients used in biocides are almost exclusively **spin-offs from crop protection streams**
+ Loss of a.i.s such as hydramethylnon, triflumuron, temephos, more recently bendiocarb, fipronil, clothianidin (09/2026)
+ Don‘t expect new active substances on a “daily basis“

Can we register?

Matching regulatory guidelines

1

envu

2

Can we sell?

Label claims serve customer needs

Can we manufacture?

3

What we are looking at?

The needy greedy detail

EU regulatory landscape under Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)

Zooming on PT18 (Insecticides, acaricides and products to control other arthropods); Product-types - ECHA (europa.eu): Description: Used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.

- Guidance on the Biocidal Products Regulation Volume II: Efficacy Parts B+C: Assessment and Evaluation Version 6.0, August 2023 (ae2e9a18-82ee-2340-9354-d82913543fb9)
- Technical Agreements for Biocides Efficacy (EFF), latest published in June 2025 (crack & crevice trial design, unicolonial ants) (EFF-TAB_2025_06_09.pdf

Dossier requirements

- "The following guidance is designed to be flexible and does not specify rigid protocols to which tests must be conducted."
- Consequently: Pre-submission meeting with RMS / eCA needed, all to define specific requirements / study designs in order to support intended label claims

By the way:
No need for testing labs to be certified against GLP or any other certification scheme when generating efficacy data for regulatory purposes.

PT18 Efficacy Assessment

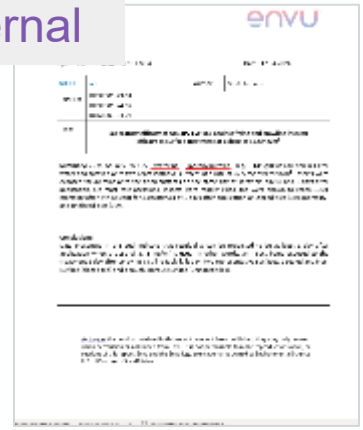
- The aim is to assess the efficacy of biocidal products, to ensure that **only effective products** enter the market
- A **combination of laboratory studies, rigorous simulated-use laboratory studies, or field studies** can be used to evaluate whether the product is effective for the requested use(s) at the specified doses.
- **Assessment** will be made mainly in **relation to the claims** for the effectiveness of the product made on the product label.

PT18 Product standards

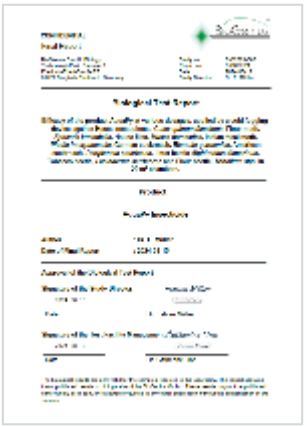
General rule:
Label claims require supporting data (incl. waiving)

- **Products used by professionals must have a high level of efficacy** since the objective is to eradicate the infestation.
- For professional use a field trial is always required.

Internal

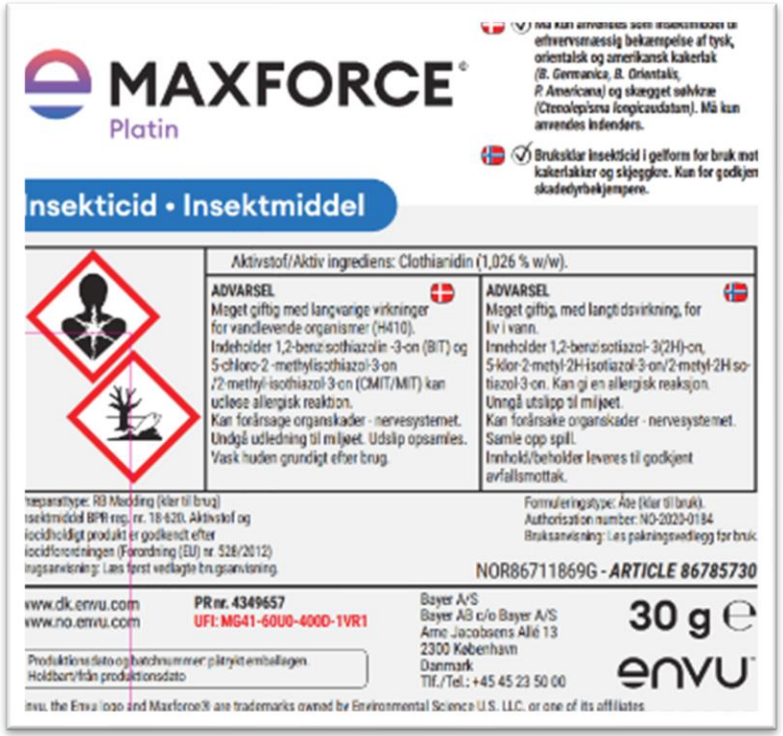


CROs



5.6.4.2

PT18 General Claims: Crawling Insects, Flying Insects



- **General claims** (e.g. insecticide, crawling insects) **cannot be used for bait products**, since the bait differs per insect species.

Data needed by species
If not on the label, the product is not approved for that use.
Risk of promoting an off-label use! = compliance issue!

PT18 Laboratory tests and field trials

- The aim of the **bait choice feeding trials** is to determine the palatability of the product for the test insect.
- In this test design, nymphs and adults of … cockroaches have the choice between a non-toxic food source (challenge diet, either the non-toxic bait or a non-toxic food source known to be a strong feeding source for the test species) and the bait containing the active substance.

PT18 Norms and Criteria

5.6.4.3.3.1 Norms and Criteria (cockroaches) | 5.6.4.4.3.1 Norms and criteria (ants)

Deviations from these norms is possible but should be justified in the application

Type of claim	Test design	Mortality (%)
Intended for use as baits	Laboratory palatability choice test	≥ 95% … at a given time point
	Simulated-use tests	≥ 90% reduction of the population within a few weeks
	Field trials	After a period of 2-10 weeks, the population reduction exceeds 80% relative to either untreated sites or pre-treatment levels

5.6.4.3.2.1 Test species (cockroaches): For bait products, the label can only claim efficacy against species that have been treated under field conditions.

- If conducted on **both fresh and aged product it may provide information on the storage stability** of the product.
- Residual treatments may also involve the use of palatable baits. When a bait product is claimed to be effective after a long period of storage, it is necessary to demonstrate that the product will still be effective and attractive after the stated storage period. (5.6.4.1.3.11)

The inevitable marketing slide

Our global R&D team is organized to best address our customers' needs

~6%	Around **6 percent** of our topline is invested in innovation
~18%	Around **18 percent** of our global Envu team works within our Innovation function
~30%	Around **30 percent** of our Innovation team is made up of top-level scientists
4	Our **4 innovation hubs** around the world ensure focus on customers in each region
2,000+	Envu has more than **2,000 product registrations** in over **100 countries**
5-10	We publish between 5-10 scientific papers each year

Take-away messages

- Don‘t miss to gain understanding around societal acceptance = listen to / consult your stakeholders, such as politicians, opinion leaders, registrar, customers
- Check registerability of intended label claim (define your label claims and support them with data)
- **For baits:**
  - In principle: field data compulsory for professional uses (except e.g. silver / paper fish)
  - No broad claims (like for other formulation types) = species specific data needed
  - Shelflife claim on aged product (shelflife: a.i. degradation over time + palatibility confirmation over time)

Thanks for listening
and
happy to discuss!