



■ BASF

We create chemistry

Biologicals: Everybody seems to like them, just where are the regulatory actions?

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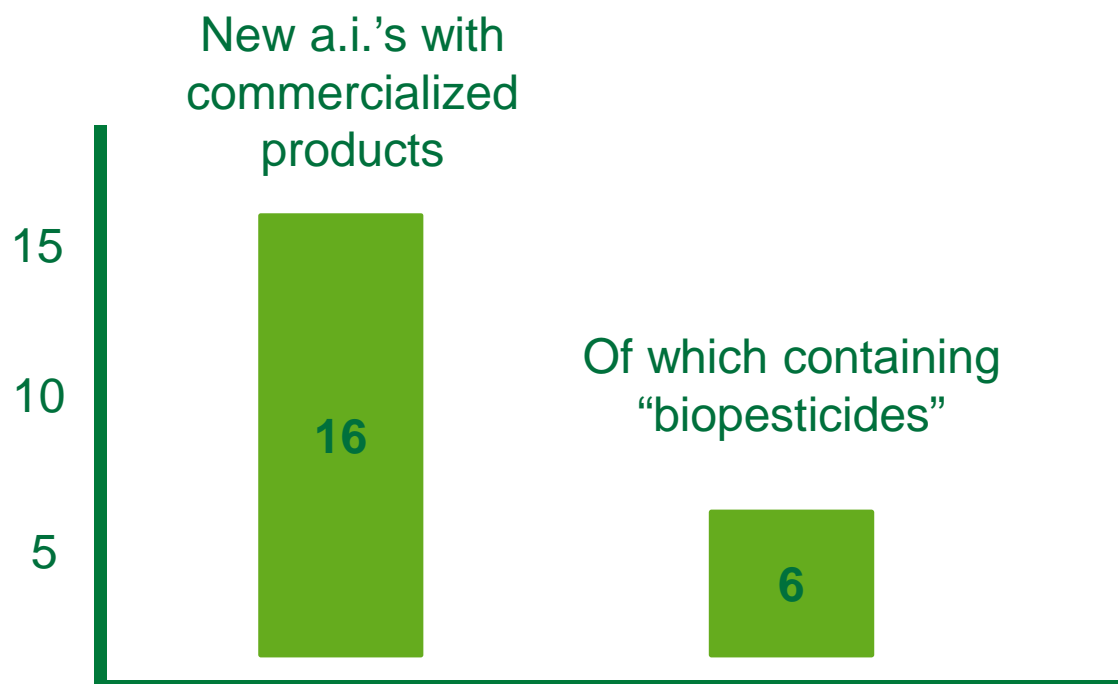
What are Biopesticides?

- It is complicated in the EU
 - Data requirements distinguish between chemical active substances and micro-organisms including viruses
 - In the data requirements on chemical active substances it is mentioned that for plant extracts and semiochemicals different approach might be needed
- EPA has a clearer definition
- For this presentation we assume micro-organisms and viruses are “biopesticides”

New registrations with the 1107

■ The good news

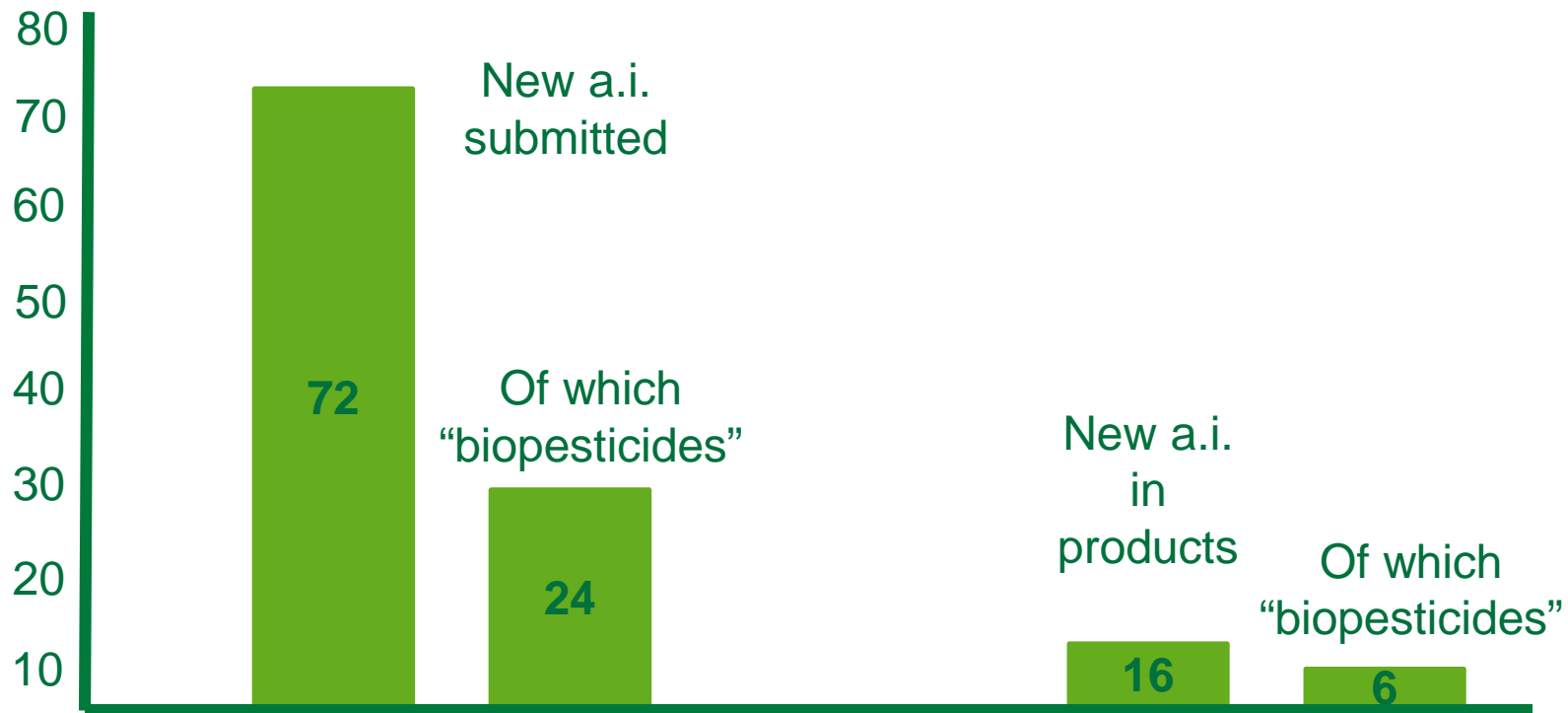
- Ca. 40% of all new actives that have products on the market since regulation 1107 are biopesticides



New registrations with the 1107

■ However...

- Only 16 a.i. got to products registered out of 72 a.i.'s submitted under 1107 of which we can consider 24 Biopesticides



Hindered innovation for both chemical and biopesticides

Why is innovation hindered in the EU?

▣ In general

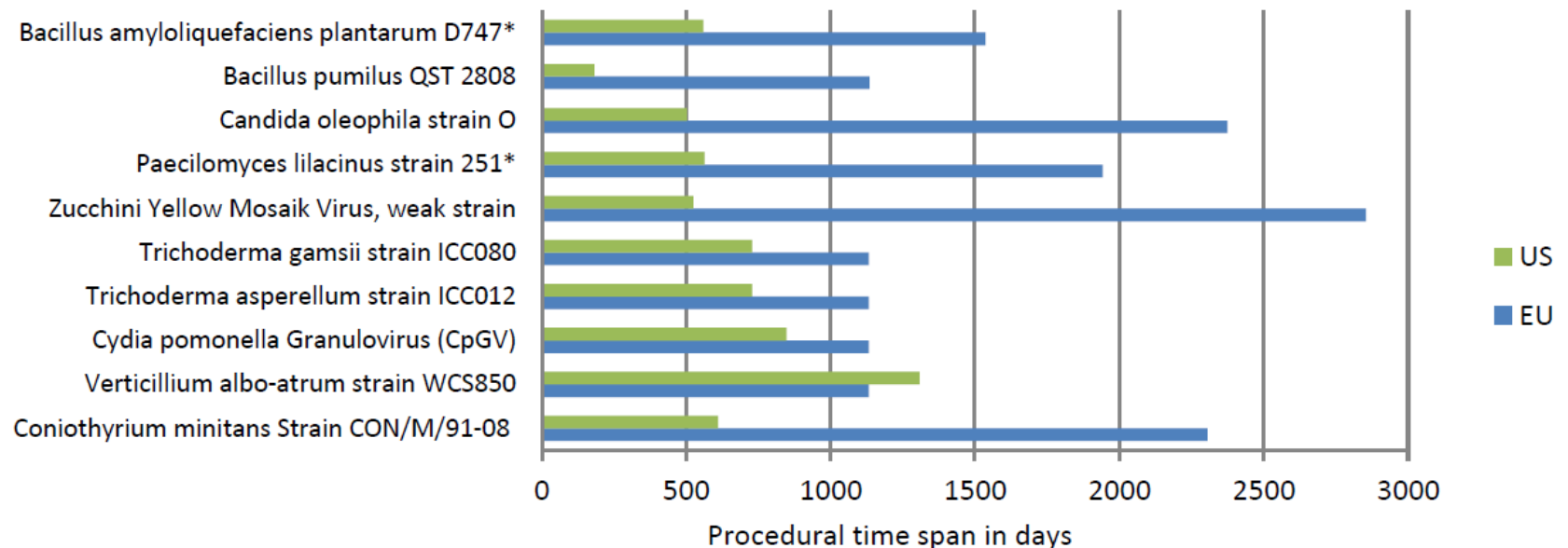
- Precautionary principle
- Poor execution of the 1107: Timelines

▣ Why specifically for biopesticides

- Unclear definitions?
- Open scientific challenges?
- Lack of guidance?

Timelines biopesticides

Individual time-lines per active

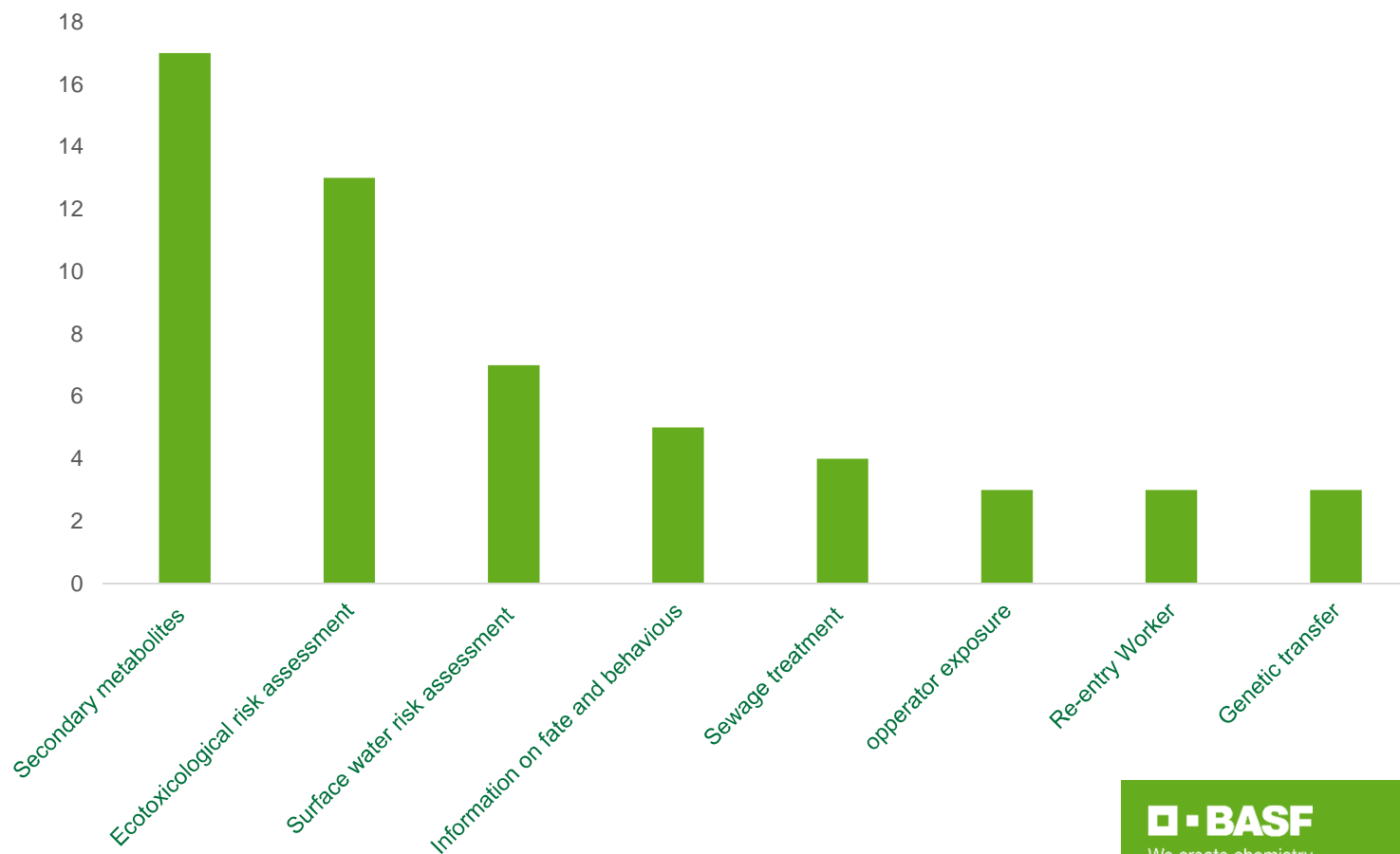


Timelines reduce incentive to submit innovation in the EU

Source: Master thesis Coen Frederiks

Open scientific challenges

- ▣ Reviewed 24 biopesticides on not finalized issues
 - Search on the EFSA website: conclusion & strain
 - Recorded all “not finalized” topics mentioned



Why are secondary metabolites an open issue?

- Micro-organisms are known to produce secondary metabolites
- Data requirements mention that secondary metabolites need to be addressed
- No or conflicting guidance

2.8. Information on the production of metabolites (especially toxins)

If other strains belonging to the same microbial species as the strain subject to the application are known to produce metabolites (especially toxins) with unacceptable effects on human health and/or the environment during or after application, the nature and structure of this substance, its presence inside or outside the cell and its stability, its mode of action (including external and internal factors of the micro-organism necessary to action) as well as its effect on humans, animals or other non-target species shall be provided.

The conditions under which the micro-organism produces the metabolite(s) (especially toxin(s)) must be described.

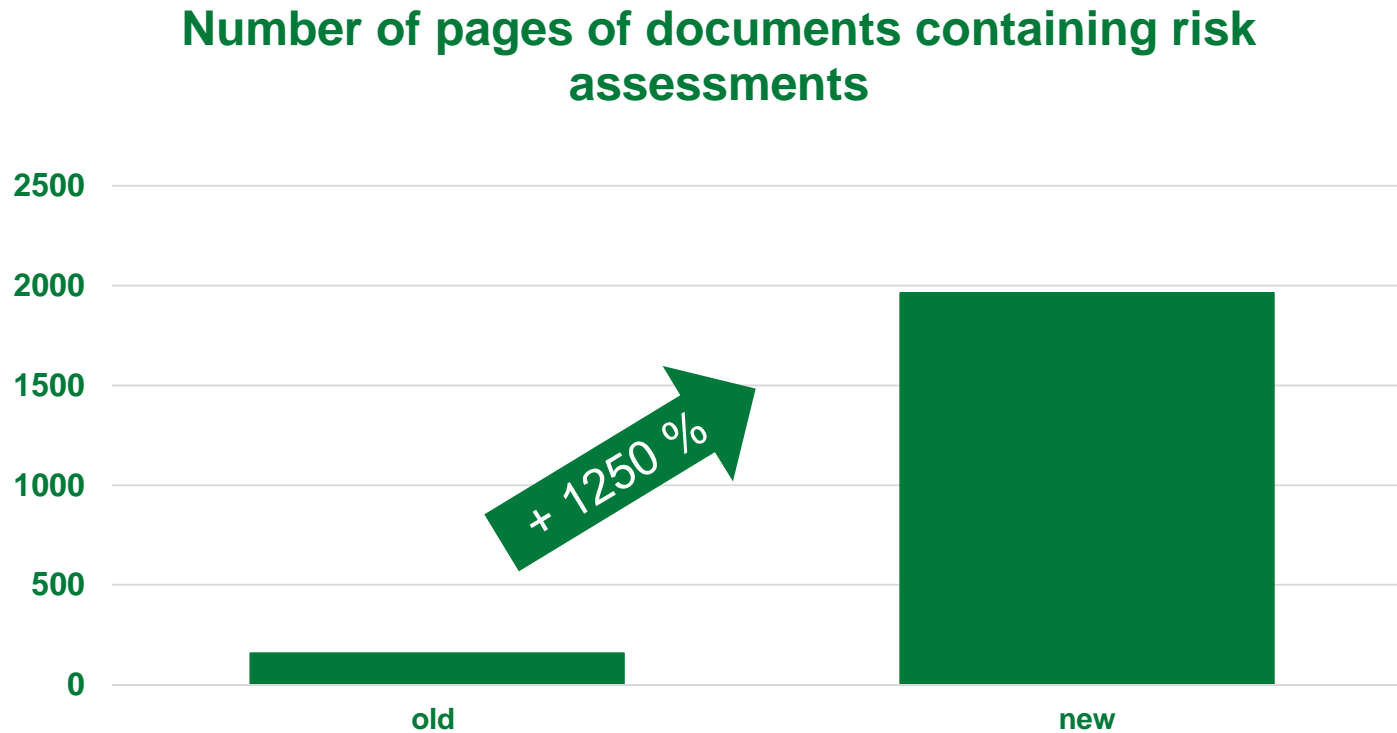
Any available information on the mechanism by which the micro-organisms regulate the production of the(se) metabolite(s) shall be provided.

Any available information on the influence of the produced metabolites on the micro-organism's mode of action shall be provided.

No regulatory accepted path forward on addressing metabolites

Why is ecotoxicology an open issue?

- EFSA is producing a massive number of outputs



Take home messages / conclusions

- Biopesticides and conventional regulations are not decoupled
- The regulation doesn't work for both of them
- Biopesticides also have their own scientific challenges
- Too much guidance doesn't help. We need to develop smart and aligned guidance
- Uncertainty from Regulators on how to handle biopesticides evaluation

Thank you





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