

Experiences of EC, as risk manager for active substances deemed to be of low-concern

EFSA Workshop on the development of a fit-for-purpose approach for assessing the risk of low-concern active substances

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Content

- Trends in NAS applications and low-concern substances
- Definition of “bio-control agents” and “alike”
- What makes a substance, a ‘low-concern’ one?
- The problem formulation replying to the ‘need-to-know’ approach
- Some real case-studies deserving a ‘fit-for-purpose’ risk assessment
- Some reflections

Low hazard active substances and low exposure uses contributing to the objectives of the Green Deal and Farm to Fork.

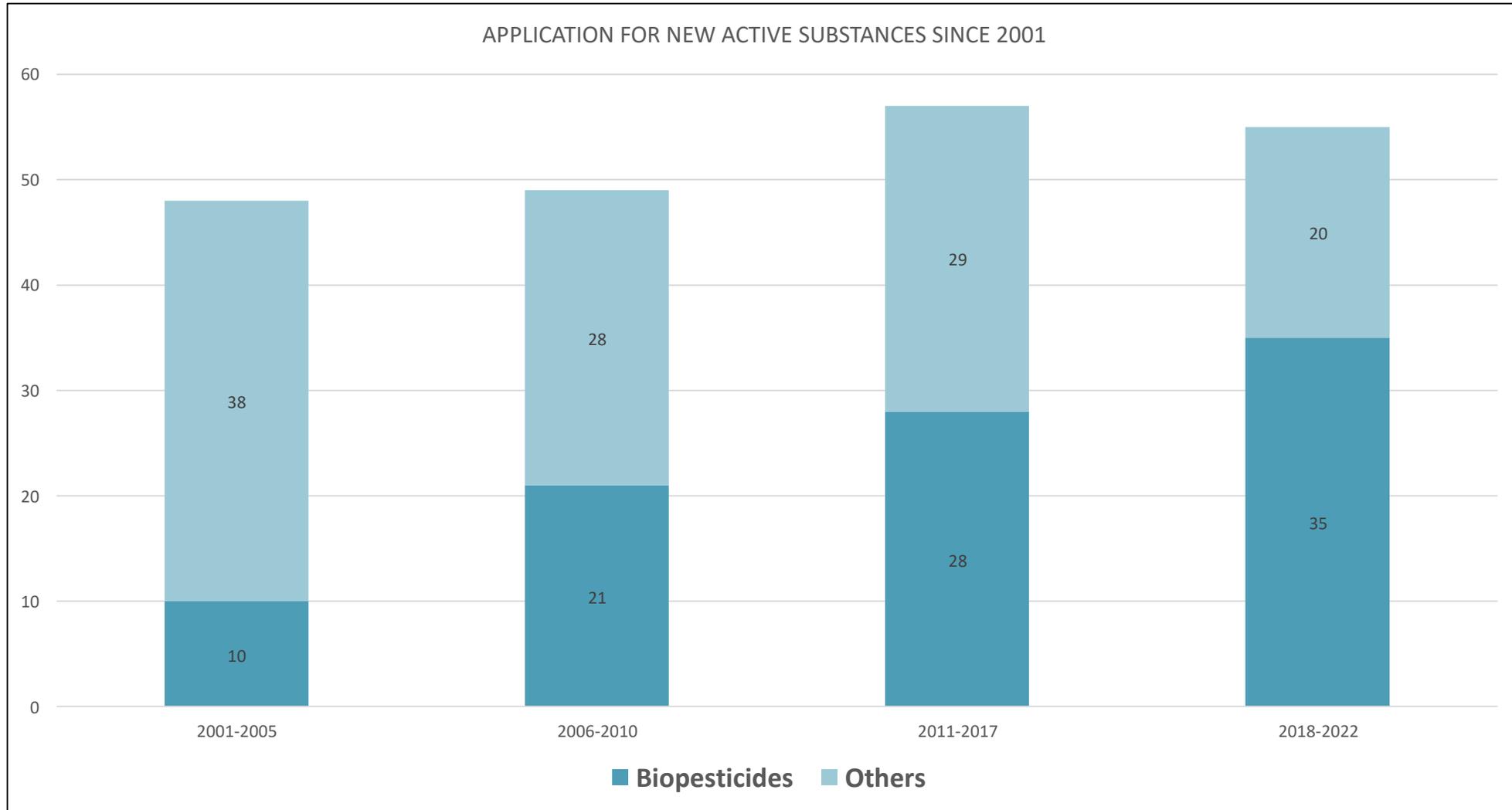


By 2030, the Commission needs to take actions to:

- **Reduce by 50%** the use and **risk of chemical pesticides.**
- **Reduce by 50%** the use of **more hazardous pesticides.**
- Achieve at **least 25%** of the EU's agricultural land under **organic farming.**



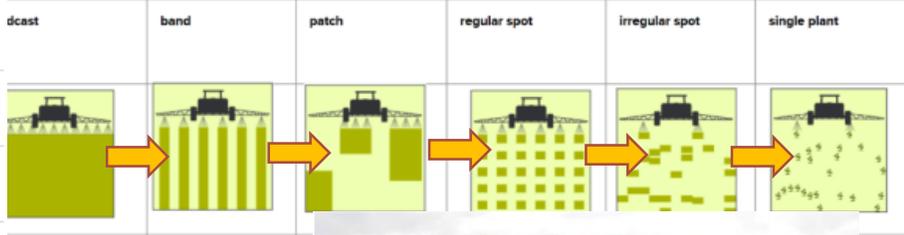
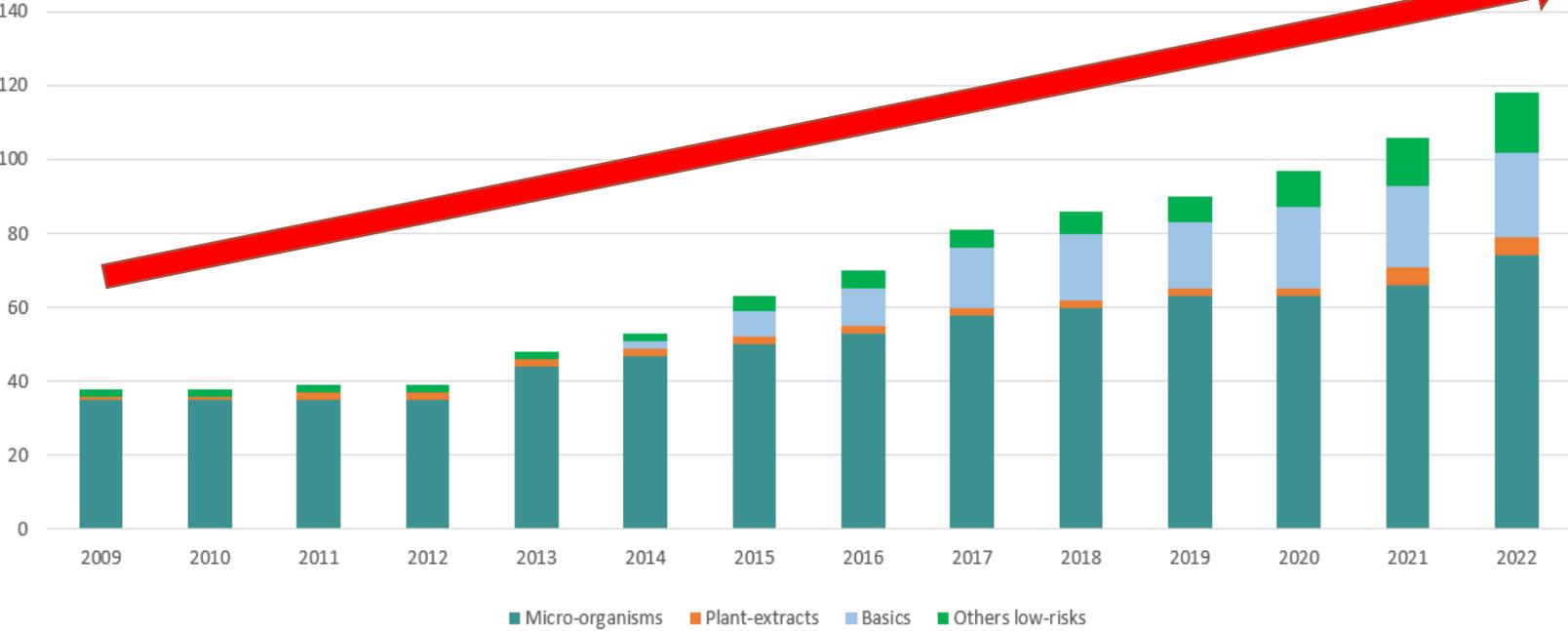
Trends in applications for new active substances



The increase of low hazard active substances (microorganisms, pheromones, basics and plant extracts) approved in the EU is expected to continue.

Precision applications to be included in the application dossiers (GAP table).

Low hazard active substances approved in EU



Low-risk, low-concern, biopesticides, bio-control agents: need for clarifications

- **Low-risk active substance:**
 - Art.22 of Reg 1107/2009, approved substances complying with criteria of Annex II, point 5, contained in PPP compliant with Art.47
- **Low-risk plant protection product:** compliant with Article 47
 - Low-risk active substances, safeners and synergist only
 - No substance of concern (no co-formulant of annex III)
 - No need for specific risk mitigation measures required by the RA

N.B.: draft GD on low-risk substances and PPP to be continued.

- **Biopesticides:** undefined until now but generally agreed as PPP containing micro-organisms, semiochemicals, plant extracts

Low-risk, low-concern, biopesticides, bio-control agents: need for definitions

- **Bio-control agents**: proposed definition under development in the draft amendment of Part A of DR (point 1.5 of the introduction to the Annex), aiming at justifying to “*dismiss some data requirements required for chemical active substances*”:

“A substance of biological origin (or a substance which is structurally similar and functionally identical to such a substance), such as

- a semiochemical,
- or a substance or mixture of substances originated from living organisms,
- or produced by living organisms and/or by biological processes, including extracts from a plant product,
- a metabolite produced by a micro-organism (purified from the micro-organism and if micro-organism no longer capable of replication or of transferring genetic material). ”

And what about 'low-concern' substances?

- By nature?
- By their origin (hence their 'reputed' safety)?
- By their mode of action? Their specificity?
- By their existing occurrence in agro-ecosystems?
- By their degradability, transitory effects?
- By the conditions of use? Mode of application? Timing?

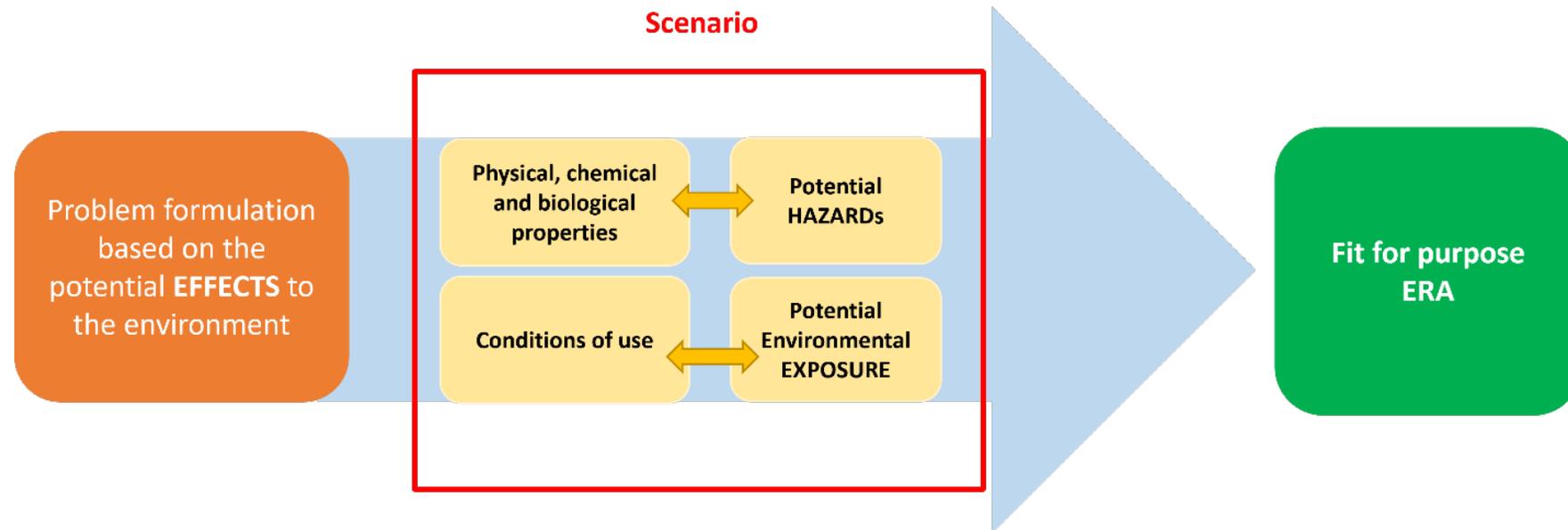
- Could that be defined?

- Do they deserve differentiated treatment in RA?

- Can this be addressed by setting criteria, rules, guidances, decision trees?

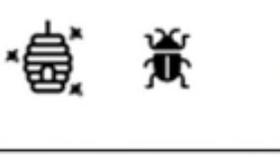
For this group of substances of low-concern, a 'NEED TO KNOW' approach to be recommended

A fit for purpose risk assessment driven by a problem formulation step!



https://food.ec.europa.eu/document/download/c4d6b7df-b7f9-4b3b-8ce5-b823ccd98c_en?filename=pesticides_ppp_app-proc_guide_horiz_problem-formulation-era.pdf

How to conduct problem formulation in practice?

Section 3- POTENTIAL EFFECTS ON NON-TARGET ORGANISMS			
Relevant Ecosystem Services	Service Providing Unit for the relevant Ecosystem Services ¹³	Are the properties of the active substance/ representative use of the formulated plant protection product and/or its exposure (considering all possible routes deriving from the representative use) expected to lead to unacceptable effects on...	If no, please justify. If yes, list the species to be tested. Current test species are listed in Annex I of this document. Additional ad-hoc test may also be proposed.
Fresh water		...this ES and in particular, algae, non-target aquatic plants and aquatic invertebrates? Yes/No.	
Erosion prevention and maintenance of soil fertility		...this ES and in particular, terrestrial invertebrates, earthworms, and soil micro-organisms? Yes/No.	
Pollination		...this ES and in particular, bees and other terrestrial invertebrates? Yes/No.	
Biological control		...this ES and in particular the biological control agents such as certain terrestrial invertebrates, soil micro-organisms and aquatic invertebrates? Yes/No.	
Habitats for species ¹		... on food, water or shelter needed to maintain soil micro-organisms micro, aquatic invertebrates, algae, non-target aquatic plants, non-target arthropods, earthworms, bees, non-target terrestrial plants, birds, fish, mammals and on any of these species? Yes/No.	

List of case studies used to test and complement the document

1. Permanent greenhouse by drenching or spraying / chemical fungicide
2. Permanent greenhouse soil application via the drip irrigation system / botanical active substance – nematocide
3. Greenhouse by foliar spraying / botanical active substance
4. In door - gas-tight storage structures/ chemical fumigant insecticide & rodenticide
5. In door by drenching or dipping / botanical active substance -fungicide / bactericide
6. In door by drenching or spraying / chemical fungicide
7. In door by dipping or drenching / lipopeptide - fungicide
8. Seed treatment in an ESTA certified site / chemical fungicide
9. Seed treatment in a non-ESTA certified site / micro-organism
10. Outdoor by foliar spraying/ botanical active substance
11. Outdoor spraying / glucose
12. Outdoor in a container-insect trap / chemical insecticide
13. Outdoor by burrow application / chemical fumigant insecticide & rodenticide
14. Outdoor by localised application -plant detection/chemical herbicide
15. Outdoor by broadcast application on established grassland / chemical – antibody based
16. Outdoor by broadcast application / chemical herbicide
17. Outdoor by localised application - precision technique/chemical insecticide
18. Outdoor by localised application – precision sprayer / chemical – selective herbicide
19. Outdoor by spraying/ micro-organism (entomopathogenic)
20. Outdoor by spraying / formulation that reduces drift
21. Outdoor by spray application / lipopeptide fungicide
22. Outdoor by spraying / RNA insecticide
23. Outdoor pre-emergence application after drilling /chemical herbicide

Some real cases where 'fit-for-purpose' approach in RA might help

- « **Oils** » (e.g. pelargonic acid, rape seed oil,...):
 - Naturally occurring: ✓, but application rate?
 - Mode of action: more “physical” than “toxic” interaction with target and non-target: ✓
 - Recovery of NTA at population level: ✓
 - Degradability/persistence: readily biodegradable ✓
 - Fit-for-purpose: “Kills what it reaches/covers and then degrades”
- « **Minerals** » (e.g. kaolin, sulphur,...):
 - Naturally occurring: ✓
 - Mode of action: more physical than chemical interaction with target and non-target: ✓
 - Degradability/persistence: transformed, vaporised ✓
 - Recovery of NTA at population level: from “nature to nature” substance – transitory effect ✓

Some real cases where 'fit-for-purpose' approach in RA might help

- « **Inherent plant compounds** » (e.g. gibberellins,...):
 - Naturally occurring “in plants”: ✓, low application rates?
 - Mode of action: specific action on plant physiology: ✓
 - Effect on NTA ? : ✓
 - Degradability/persistence: readily biodegradable ✓
 - Fit-for-purpose: “Regulates plant growth, physiological development – “No Kill”
- « **Substances extracted from** » (e.g. plant extracts, micro-organisms compounds)
 - Naturally present in the ecosystem: ✓
 - History of use (other than PPP)?
 - Mode of action? Toxic ? Specific ? Repellent?
 - Degradability/persistence: Transformed? Metabolised? Despite from “nature to nature”
 - NTA ‘know them’, so effect might be reported in literature

Challenge: the current ERA is not sufficiently flexible to accommodate environmental scenarios different than spraying a conventional chemical PPP with a conventional equipment in the field.

Conventional chemicals sprayed in the field



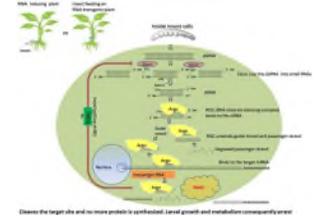
Science evolves



New actives, new uses



Semio



RNAi

And regulatory science needs to follow the new developments...

e.g. new Regulations on MoS!

Regulation 1107/2009

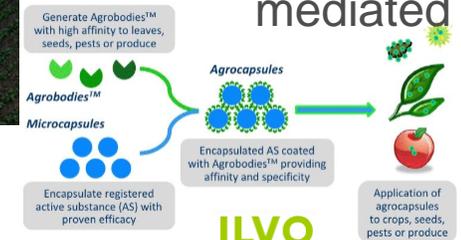
Data requirements

Uniform principles



Precision

Agrobodies-mediated



ILVO

Risk Assessment guidance documents & test guidelines

Some reflections to share...

- Problem Formulation (and risk assessment) for PPPs in the EU will always be a **prospective exercise**. This means that there will always be **uncertainties** when conducting problem formulation.
- **Research, experience using the Guidance and the template, training and trust in the whole regulatory system and its experts** are needed to obtain tangible results. Example of the case studies.
- Some Member States argued that the Guidance **lacks of specific criteria to exclude studies**.
 - Do not forget that a **Guidance will not cover all the cases** in particular for new and innovative active substances or uses. Science keeps evolving and regulatory science needs to “catch up” with those updates.
 - If we wait to have harmonised criteria for all the pesticides scenarios, will it be very **late** to place all these solutions on the market and achieve a reduction on the use and risk of pesticides?
 - **Research is on-going** to complement this Guidance. EFSA is working a project to develop a harmonised tiered approach for appropriate risk assessment of pesticides of potential low concerns.
- When it comes to the **protection of the environment from the use of pesticides, many fundamental or ethical questions and discussions arise for which the answers are unknown, or the views are very divergent**:
 - It is important that all the experts and stakeholders are **aware** about this and ready to leave them aside to have **constructive discussions and tangible outcomes**.
 - **Clear and simple communication** can help, e.g.: discussions to further define the protection goals set out in Regulation (EC) No 1107/2009. The current protection goals remain and apply when conducting problem formulation.