Workshop on Registration Best Practices

ABIM 2023

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First Part – some achievements to be reminded at EU and MS level

Second Part – some points to be clarified (SLIDO selection)

First Part – some achievements to be reminded

Efforts to improve regulatory practices at EU level :

- Regulatory environment: 4 new regulations, need-to-know approach, guidances, explanatory notes, ….
- Working forces: Biopesticides Working Group, BTSF training of regulators, Grants to recruiting staff in Member States dedicated to biocontrol assessment
- Studies: OECD for appropriate testing methods (involvement of researchers, EU agencies,…), DG SANTE studies on background levels and on biology/ecology of MO, RATION research project, EFSA plans for risk assessment

Efforts to improve regulatory practices at MS level :

- Ctgb reshufling of the teams (see slides next)

Anne Steenbergh, Ctgb NL

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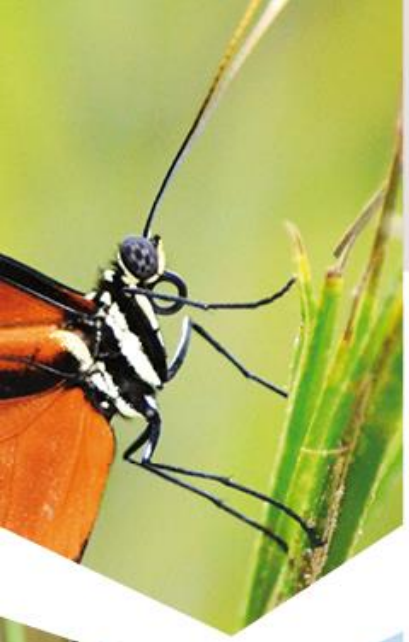

Non-chemical PPP: active substances

- Rapporteur for 70% of current new non-chemical substances in EU
- Multidisciplinary Green Team since October 2023: 11 fte specialised risk assessors - and growing
- However:
  - Number of requests higher than capacity
  - Currently not possible to comply with legal timelines
- Current efforts for faster EU approval (and authorisation) process:
  - Regulated growth of Ctgb Green Team
  - Help to increase EU capacity (BTSF training risk assessment microbial PPP)
  - Improving regulatory framework (e.g., Horizon EU project RATION)
  - For applicants: pre-submission meetings, evaluation manual (-> explanatory notes) and workshops

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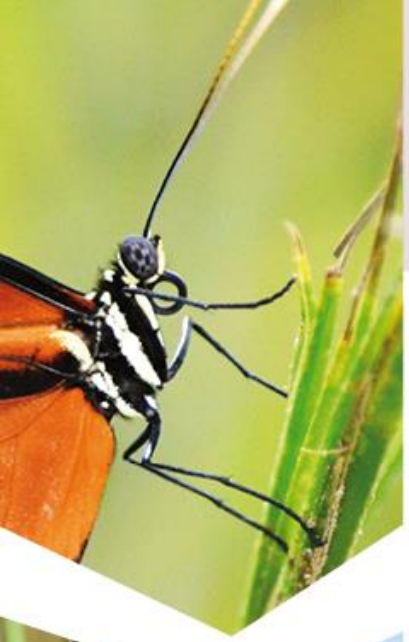
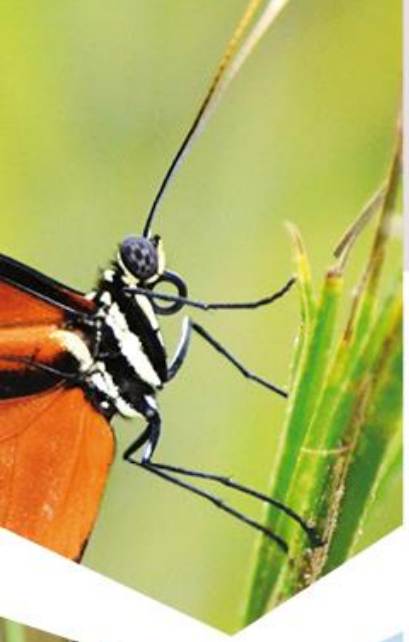


Non-chemical PPP: product authorisations

Dedicated national authorisation procedures for low-risk/ non-chemical PPP:

- Administrative procedure for minor uses of low-risk products (niche crops) (in place)
- Faster authorisation procedure for major uses of low-risk products based on ‘exceptional need’ (in place)
- Sustainability desk: priority procedure for applications for authorisations of non-chemical PPP meeting certain criteria (public consultation via Ctgb website until 22 November – implementation planned for 01/01/2024)



Administrative procedure for minor uses

- Extension with minor uses of low-risk products in principle via administrative procedure, if:
  - Low-risk product
  - Application rate/frequency same or lower
- In some cases partial assessment needed, e.g., if:
  - No exposure of humans or NTO assumed for representative use, but humans or NTO are exposure based on use applied for.
- More information: Ctgb website ‘NLKUG for low-risk products’

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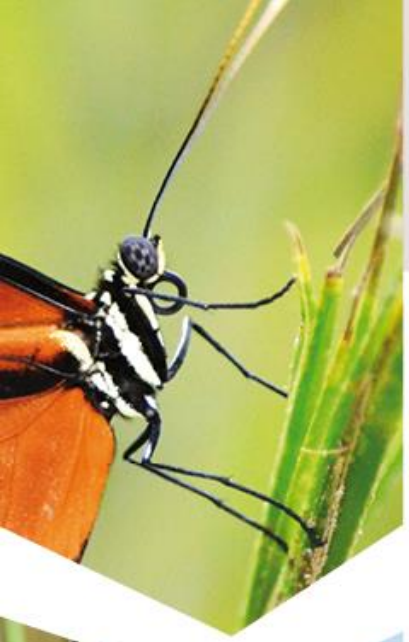

Major uses & exceptional need

- Extension of label of low-risk product with major uses via procedure for minor uses (e.g., risk envelope approach).
- As part of Dutch policy vision on the future of plant protection 2030 -> procedure in place until 2030
- See definitions in PPPR: *'minor use' means use of a PPP in a particular Member State on plants or plant products which are:*

  (a) not widely grown in that Member State; or

  (b) widely grown, to meet an exceptional plant protection need;
- More information: 'list of minor uses' on Ctgb website

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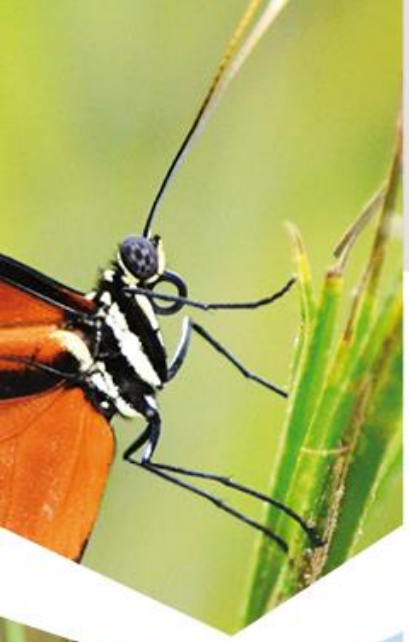


Sustainability desk

- Priority procedure for non-chemical PPP authorisations which contribute to resilient cropping systems
- NB: intake limit for zonal applications (still) in place
- For application meeting certain criteria:
  - At least one new use in Netherlands
  - All active substances are in at least one of the following categories:
    - Low risk substances (including preliminary LR based on COM list 2018)
    - Living microorganisms
    - Pheromones
    - Other non-chemical PPP excluding those with broadspectrum toxicity (e.g., could include dsRNA, peptides and non-toxic plant extracts or other non-toxic biological substances)
- More information: Ctgb website ‘verduurzamingsloket’

Road to 2030!

Micro-organisms (MO)

- **New Reg on MO** → EC Communications → Explanatory notes
- **OECD activities** → Test methods for MO → Consensus documents on MO
- **Other initiatives**

Biological control

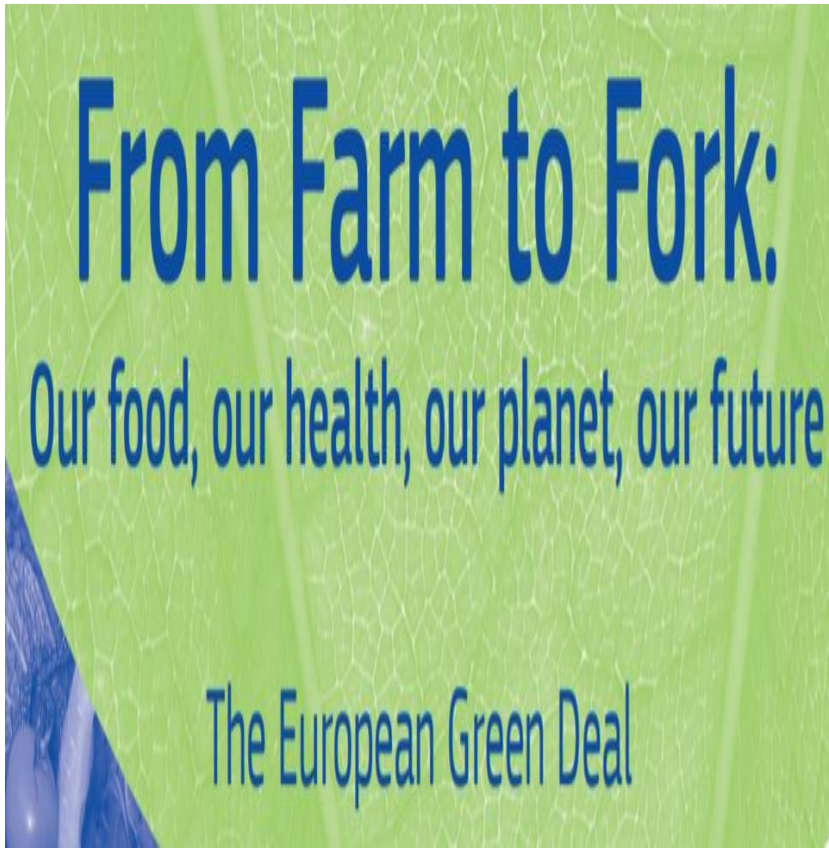
- **Semiochemicals etc.**
- **Other biological control agents**

→ Waiving (point 1.5 introduction data requirements)

Strengthen MS capacity

- **BTSF**
- **Relevant expertise (grants)**

2030



European Commission

Regulatory practices on micro-organisms: on track !

New Regulations on MO

- ❑ Four implementing Regulations
- ❑ Applicable as from Nov 2022

Two Communications from the European Commission

- ❑ List recommended test methods/ guidance documents
- ❑ Support dossier-preparation
- ❑ Not legally binding
- ❑ Endorsed in March 2023
- ❑ Additional database of useful guidance documents

Explanatory notes + dRR

- ❑ Support understanding of the new EU Reg
- ❑ Support dossier-preparation
- ❑ Harmonise risk assessment and risk management
- ❑ Not legally binding
- ❑ Endorsed at PAFF October
- ❑ dRR also endorsed
- ❑ Check our SANTE website

Tools

- ❑ IUCLID
- ❑ New test methods (OECD)
- ❑ Consensus documents
- ❑ ….

Completed/available

On-going

SECOND PART - TOPICS TO BE DISCUSSED

- EN: Sensitisation phrases
- EN: Microbial consortia
- EN: Biostimulant /biocontrol boundary
- EN: IBMA suggestions all on board ?
- WGS and GLP requirements?
- Low-risk for semiochemicals?
- IUCLID for MO ?
- Data protection : use of old studies – non-paper
- Low-risk PPP – article 47 ?
- Co-formulants?
- Barriers to marketing low-risk PPP?

slido

TOPICS TO BE DISCUSSED

ⓘ Start presenting to display the poll results on this slide.

Revision of Labelling Requirement Regulation 547/2013
Standard phrases for hazard communication of plant protection products containing micro-organisms

1. Standard phrases and attribution criteria for hazard communication (RSMo)

RSMo 1: MAY HAVE THE POTENTIAL TO CAUSE SKIN AND/OR RESPIRATORY SENSITISATION.

The phrase shall always be assigned to a plant protection product containing micro-organisms as precautionary statement.

RSMo 2: MAY CAUSE SKIN AND/OR RESPIRATORY SENSITISATION.

The phrase shall be assigned to a plant protection product containing micro-organisms where there is clear evidence from experimental systems, documented human exposure or available scientific literature that the plant protection product may show sensitising effects.

If the attribution criteria is fulfilled for RSMo 2, RSMo 1 shall not be considered.

Microbial consortia

Definition provided in the explanatory note:

- ‘Consortium’ means a qualitatively defined combinations of strains as they occur naturally or by manufacture.
- Acknowledges that combination is more efficient, due to their different modes of action, possible synergistic effect (helper) or antagonistic.
- All strains must be identified and registered, and have specific morphological characteristics to distinguish individual strains in a consortium

Biostimulant/biocontrol boundary

- Biocontrol (= PPP) : acting on the life processes of plants, such as substances influencing their growth other than as a nutrient or a plant biostimulant
- Biostimulant (= fertilising product): stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or plant rhizosphere a) nutrient use efficiency; b) tolerance to abiotic stress; c) quality traits; d) availability of confined nutrients in soil or rhizosphere.
- Ex. Seaweed extracts – Plant Growth Regulation effect is not due to stimulation plant nutrient processes (which would make it a biostimulant) but rather due to the high content of plant hormones (e.g. auxins) in the sea-algae extract
- We need harmonised interpretation across MS !

IBMA suggestions about EN: all on board ?

- All carefully considered if consistent with data requirements and uniform principles.
- Avoiding valuation of a reference: « highly effective to inform », « may be challenging »….more neutral wording !

WGS: no need for GLP

- Check of existing practices in other sectors
- Check with OECD and member countries
- Okay for the operational part but who is able to certify the interpretation part?
- In general part of the MO characterisation, so no need for GLP certification !

IUCLID for MO: how to reduce the burden?

- EFSA - in the lead, several MS strongly involved in IUCLID working party on microorganisms
- Key instrument: report generator
- Example: secondary metabolites summary table (Appendix I to SANCO/2020/12258):
  - Identify the places (documents/paths) in the dossier where the different information collected in this table is located
  - Creation by the report generator populating a table shaped on appendix I template.

Data protection : use of old studies – non-paper

- Under discussion with MS
- Article 3(21) Reg1107/2009, “data protection” means the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant.
- DR states: all data including old studies: *Any information including any known data on potentially unacceptable effects of the active substance, its metabolites and impurities on the environment, plants and plant products shall be included.*
- Repetition does not exclude the need to access old studies
- But: *In case certain studies cannot be submitted despite best attempts to locate and access them, this should not preclude admissibility of the renewal application. RMS should take the study (or if the study cannot be accessed despite all efforts by the applicant and the RMS - the study summaries available from previous evaluations) into account in its evaluation (Article 11(3) of Regulation 2020/1740).*

Low-risk PPP – article 47

- Under discussion with MS – lack of harmonised approach
- Low-risk substance: Article 22 and annex II + Art.4 – fulfilled !
- Low-risk product: One safe use without specific risk mitigation measures
- Specific risk mitigation measures: those identified by the risk assessment to validate a safe use
- Presence of substances of concern in the PPP: classification levels according to CLP - triggered

Co-formulants of concern

- Annex III – negative list of co-formulants
- EFSA technical report identified in the representative product (appendix IV – confidential composition) substance of concern.
- COM to identify substances of concern in the PPP
- Bio-control products: please check !

Barriers to marketing of low-risk/biocontrol

- Discussed by Council WP during SUR negotiations
- PPP are authorised by MS but not available on the market
- Market is too small?
- No distributor?
- Parallel import?
- Workshop on 26 October 2023 to discuss it.