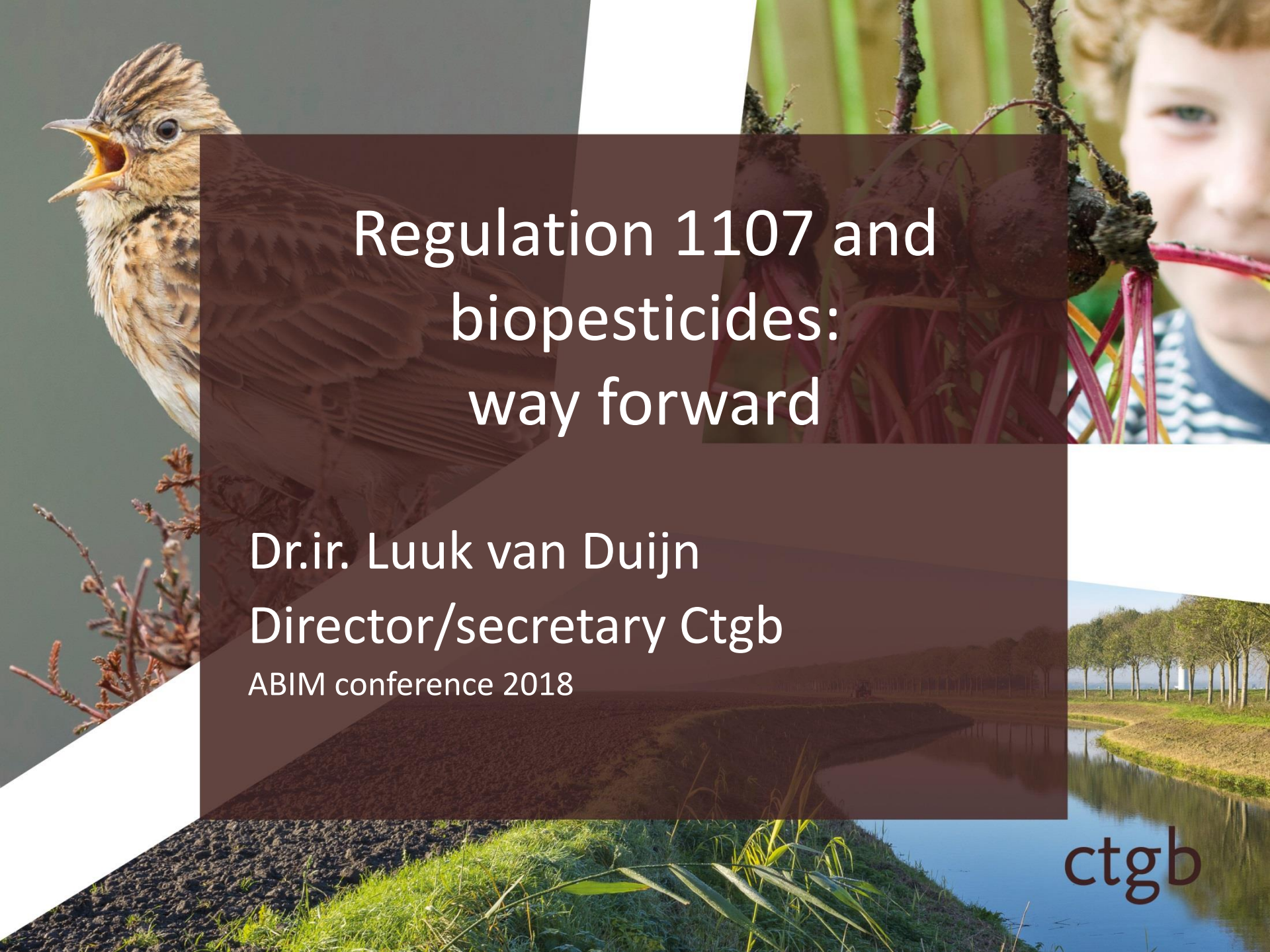

Regulation 1107 and biopesticides: way forward

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ABIM conference 2018

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Content

- Introduction
- Biopesticides authorisation: state of play
- Issues to be solved
- Perspective

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Ctgb, a short introduction

- Dutch competent authority for pesticides and biocides
- Autonomous governmental body
- All assessments are performed by secretariat “in house”
- Decision upon advice of the secretariat is taken by the Board
- Renowned independent experts in their field on 1 day per week basis

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Tasks

- Decide upon authorisation of PPP's and biocides
- Acts as Rapporteur Member State for active substances
- Advisory role to ministers of agriculture, environment and health (on demand and own initiative)

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Organisation

- Financed for 85% by fees
- Can adapt to demand for applications
- 150 fte (90 experts and project managers) and legal, policy, communication and business
- Embedded in Dutch agriculture (innovative, moving towards sustainable agriculture, high tech solutions)

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EU regulatory framework

- EU Regulation 1107/2009 on placing on the market of plant protection products (PPP).
- A PPP needs to be authorised before it can be placed on the market
- Authorisation is granted when a scientific risk assessment proves its efficacy and is safe for man, animal and environment
- Applicant is responsible to demonstrate safety (dossier with studies)

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EU regulatory framework

Regulation lays down procedure:

- Active substance: approval at EU-level (rapporteur MS, EFSA, European Commission)
- PPP: zonal level (zonal rapporteur MS)

Uniform principles and data requirements:

- What to assess and how to make decisions
- What data to provide in the dossier

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Biopesticides

Biopesticides are of natural origin:

- Microbials
- Botanicals
- Viruses/Bacteriophages
- Semio chemicals
- Isolated compounds from these

Note:

- In the regulation biopesticides are not mentioned as a group.
- The regulation differs between high risk (CfS), " regular" and low risk compounds and PPP's
- Only for micro-organisms there is a specific set of data-requirements
- For semio chemicals and botanicals there are guidances

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State of play

Biopesticides

- highly specific,
- small niche markets,
- generally no knock out profile,
- quite often low risk

In the same regulatory framework as chemicals

- less specific,
- big markets etc

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State of play 2

Examples

- Data requirements microorganisms chemical oriented
- Regulatory framework gives less room for innovation (consortia of micro's, RNAi, bacteriophages)
- EFSA sticks strictly to data requirements and precautionary principle; MS might have more pragmatic approach

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Result

Uncertainty about requirements combined with small markets:

- Business case is not easy to make

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Perspective

- Adaption of framework and change of the assessment approach to biopesticides takes quite some time
- From chemicals to biopesticides: a giant step

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Efforts towards change

- Developments of new guidances for microbials:
  - Human toxicology
  - Efficacy (low risk)
  - Secundary metabolites (under development)
- Strengthen regulatory knowledge on biopesticides (greenTEAM, specialisation of CA's)

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Issues Low risk

Regulation 1107:

- Burden of proof: an active is high risk unless proven otherwise
- Could be true for quite some actives, including biopesticides
- But there are exceptions eg. several often used bacterial species/strains, semio chemicals
- See provisional low risk list of COM
- For PPP authorization Ctgb will regard these as low risk

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Issues microbials

- Specific data requirements for microbials exist but are not to current scientific standards (still chem-oriented)
- Data requirements are used unnecessarily strict: the phrase "*where appropriate or relevant*" often is ignored

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Revision of requirements

- Uniform principles and data requirements in need of revision:
  - More proportionate to foreseeable risks
  - Requirements must be feasible in practice
  - Aware of other policy areas where microorganisms are regulated and risks accepted there (biostimulants, food safety)

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Issues microbials

Interpretation of data requirements:

Examples:

- '*Assessment should be made of any known relevant metabolite*' is (mis)interpreted by EFSA as '*demonstrate that no metabolites are produced under any relevant conditions*'
- '*Where appropriate, give information on genetic transfer*' is (mis)interpreted by EFSA as '*Exclude occurrence of transfer of genetic material*'
-

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- How to proceed

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Industry

- Share knowledge with regulatory agencies
- Invest in research on risk assessment of biopesticides
- Submit good quality dossiers: Identify risks of your own portfolio and how to assess this
- Submit proposals to improve the risk assessment and decision making process for biopesticides

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Member states

- Specialize and share knowledge
- Develop new guidances, better targeted to biopesticides
- Invest in risk assessment technologies for biopesticides
- Reach out towards industry to inform them about (current) requirements
- Ctgb is working on a position paper for data requirements for micro’s

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EFSA

- Take risk profile into account during weighing of evidence
- Expand in-house knowledge base on biopesticides (green team)
- Make more room for expert judgment in data requirements and assessments
- Work actively together with MS and COM to develop practical guidance on biopesticides

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European Union

Starting point: biopesticides are low risk unless….

This will give EFSA and member states room to change the attitude..

… but requires revision of regulation 1107/2009 (Refit)

Include a new chapter in the regulation on biopesticides or low risk?

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Conclusion

- 1107 is more “fit for purpose” than rumour will have
- Fastest way to change is work within the current frame work
- Make use of the possibilities
- Next step: make room in 1107 for a chapter aimed at biopesticides: Biopesticides are low risk, unless…

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Thank you for your attention
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