New initiatives in regulating biopesticides

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ABIM, Basel, 22 October 2019

1. Update data requirements for microorganisms

- Current DR
- Need
- Subject
- Process

2. New guidance documents

3. Improved risk assessment process and quality of dossiers

Current data requirements

- *Reg. 283/2013 active substances, part B*
- *Reg. 284/2013 plant protection products, part B*

Minor review conducted in 2013, but a major review is needed (e.g. avoid mimicking part A and developed legal text tailored for microorganisms)

- *Reg. 546/2011 uniform principle, part B*

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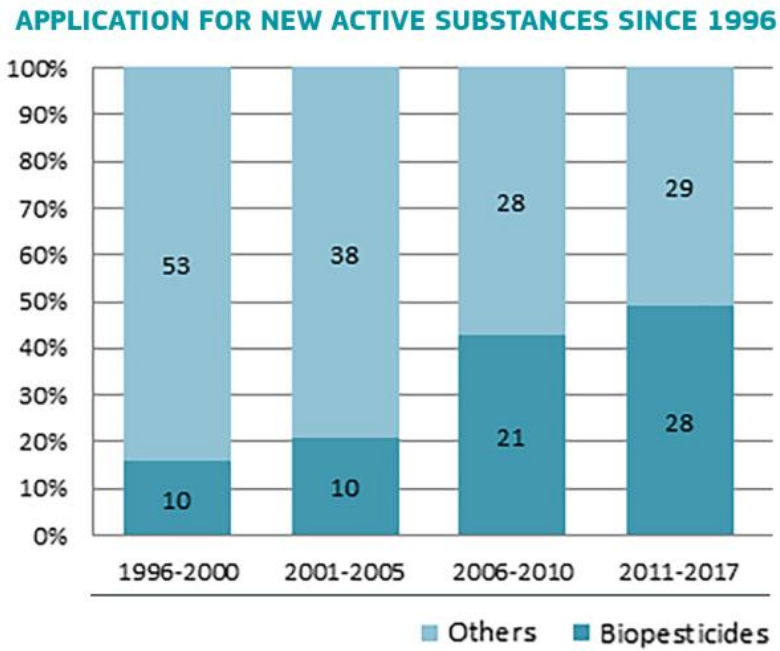
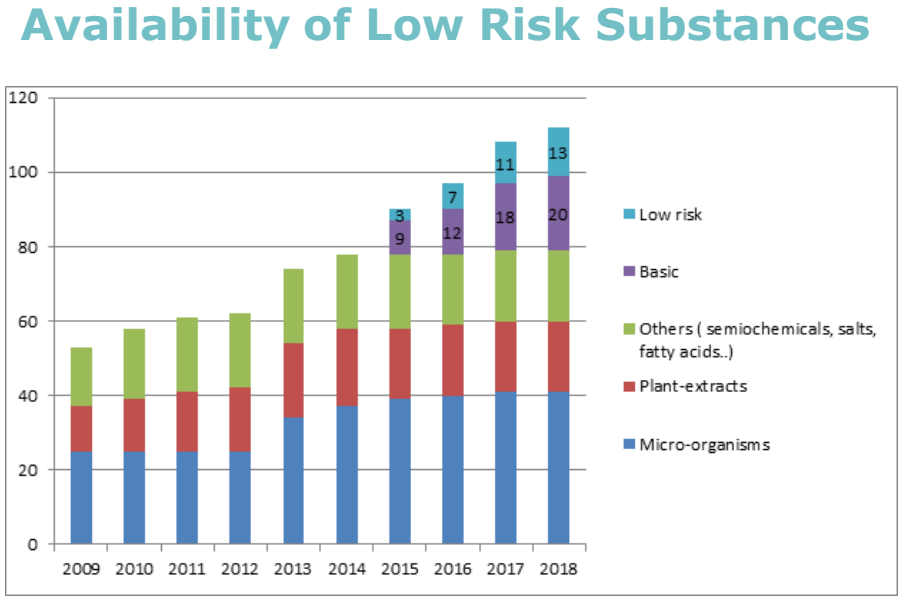
Need of more specific and flexible approach:

- *New challenges/ new PPP*
- *The evolution of science supporting risk assessment*
- *Increased number of applications for microbial PPP*





Subject of data requirements revision:

*Art 3(15) Reg.1107/2009 defines **microorganisms** as "any microbiological entity, including lower fungi and viruses, cellular or non cellular, capable of replication or of transferring genetic material"*

Definition of substances:

- *Art 3(2) Reg.1107/2009*

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Process – activities conducted *(1)*

- ***Q4 2018**: identification of issues of the 3 Regulations*

- ***Q1 2019**: categorization of issues of current DR*
  - Data requirement cannot be technically met
  - Meaningfulness of data requirement
  - Technical inconsistency between Reg. and UP
  - Appropriateness of txt (in light of technical evolution)
  - Clarification/ interpretation issue
  - Lack of guidance
  - Inconsistency with guidance

Process – activities conducted *(2)*

- ***Q2 2019**: review of issues and proposal on way forward*
- ***Q3 2019**: identification of "Biological Properties" of Reg. 283/2013 as the "cornerstone chapter"*
- ***Q4 2019**: initial drafting of revision of Reg. 283/2013*

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Process – agreed principles *(1)*

- *No need to start from scratch! Source of inspiration:*
  - Existing text
  - Other legislations involving MO
  - Experience on current applications

- *Be good at the first time!*
  - "Need-to-know" approach (i.e. which questions are we trying to answer?)
  - More details and explanatory points for applicants
  - More emphasis on request to justify missing data

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Process – agreed principles *(2)*

- *New scientific approaches:*
  - Evolution of science and technology reflected in the legal txt
  - More importance to literature review
  - Experience with current applications
- *Tiered-based approach (mandatory and conditional requirements)*
- *Stable and flexible data requirement*

Process – next steps

- *SCoPAFF*
- *Consultations (not necessarily in this order):*
  - EFSA panel
  - Stakeholders
- *Formal adoption process*

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Guidance on Antimicrobial Resistance

"Acquired AMR" acceptance negligible

Guidance on Secondary Metabolites of Concern

Tiered-based approach:

1. Determination of assessment type
2. Collection of basic info (Identification of "metabolites of potential concern")
3. Identification of "metabolites of concern"
4. Risk assessment

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3- Improve RA process and dossiers quality

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Points for improvement*:*

Risk assessors/ manager: expertise in microbiology to avoid misuse of chemical approach in risk assessment of microbial PPP (BTSF)

Applicant: understanding of risk assessment process to better comply with data requirements

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Thank you, and…

…stay tuned!!!!