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Plant Protection Products Regulation 1107/2009 - an update

Advisory group on the food chain and animal and plant health plenary

November 2019

Food Safety

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Content

- Revision of Data Requirements (chemicals and microorganisms)
- GFL Amendement - Implementation
- updates on GD & related activities
- REFIT (no news)

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Revision of data requirements (micro-oganisms)

- Legal framework:
  - Reg. 283/2013, active substances Annex B
  - Reg. 284/2013, plant protection products Annex B
  - Reg. 546/2011, uniform principles
  - Commission Communications 2013/C 95/01 and 2013/C 95/02 (guidelines and tests)
- Scope:
  - Definition of microorganisms provided in Art. 3 (15) of Reg 1107/2009 (bacteria, fungi, viruses)
  - Semiochemicals and substances of natural origin NOT covered

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Revision of data requirements (micro-oganisms)

- Why?:
  - evolution of science
  - increased number of applications for approval
  - new scenarios
  - promotion of the use of non-chemical alternative & green deal
- How?
  - Work supported by experts of the BioPesticides WG of SCoPAFF
  - Additional expertise on an ad-hoc basis
  - Standard Commission procedure for adoption (stakeholders will be consulted, feedback mechanism will also apply)
  - Tentative timeline 1st draft texts: Q3 2020

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Revision of data requirements (micro-oganisms)

- Some principles so far…
  - Need to know basis (What are the questions we try to answer?)
  - Data requirements should be clearer for applicants
  - Risk should be treated alike with other legislations covering these substances
  - Reflect evolving technologies
  - tiered based approach: mandatory (baseline) vs. conditional requirements
  - Cannot cover all the specific cases/scenarios

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Revision on Communications on data requirements (chemicals)

- Adopted in 2013
- Updated list of studies and guidance documents was consulted with MS & stakeholders end of 2018
- Process currently on-hold, will be resumed in the next months…
- Regular updates foreseen (new scientific developments)

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GFL amendment
Improving the transparency and sustainability of the EU risk assessment in the food chain

- Publication in OJ 6 Sept 2019
- Entry into application: 18 months later (27 March 2021)

- Next step (SANTE coordinating):
  - Align existing COM guidance/implementing acts in sectoral legislation to the new rules
  - **Legislation on Pesticides**: Amendment of the Regulation (EU) No 844/2012
  - The amendment will be subject to the feedback mechanism

Guidance Documents

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Secondary metabolites produced by micro-organisms

- Based on an OECD Working Document (declassified)
- Discussed at WG on Biopesticides, since 2017.
- Reorganised according to **decision tree and scheme**.
  1. assessment type "PART A, PART B, NOTHING" (metabolite = active substance → part A; virus → no assessment needed)
  2. If part B:
     1. collect basic information (info on the species, literature and experimental data) to set up lists of identified metabolites, of toxic effects for specific metabolites, of toxic effects observed for the MO without link to a specific metabolite: "LIST of TOXIC METABOLITES OF POTENTIAL CONCERN".
     2. determine if metabolites of potential concern are produced and/or if exposure is negligible: "METABOLITE OF CONCERN IDENTIFIED"
     3. risk assessment
- Timelines: early 2020 stakeholder consultation (via Adv. Forum, by writing)

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Antimicrobial resistance in micro-organisms

- Based on the guidance on characterization of MO used as feed additives
  - adapted to the case of microbial PPP
  - resistance checks extended to full list of WHO medically important antimicrobials
- Focus is mainly on bacteria
- Stepwise approach based on genomic characterization and phenotypic testing
- No distinction between approvable and low-risk: focus shifted in relation with AMR
  - Approvable and low-risk if acquired transferable resistance to such WHO listed antimicrobials is absent
- Work almost finalized, to be integrated in the low-risk criteria guidance document for finalisation.

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Procedural GD on zonal assessments, mutual recognition

- Update of a 2014 guidance document
- Stakeholder consultation from 23 July to 20 Sept. 2019
- Clarifications and improvements:
  - Mutual recognition
  - Generic products (article 34)
  - Added chapter on low-risk products
  - Added specific points on authorisations granted in the interest of the general public

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Procedural GD on new active substance data post (renewal of) approval

- Update of a 2012 guidance document
- Stakeholder consultation from 23 July to 20 Sept. 2019
- Clarifications and improvements:
  - Clarification of the assessment process taking into account the kind of new active substance data
  - New active substance data submitted as part of an application for the authorisation/re-registration of a product
  - New active substance data resulting in a change of ADI, AOEL, AAOEL , ARfD, residue definition for commodities of plant and animal origin or in an evaluation of the toxicological relevance of metabolites

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Procedural GD on data matching

- First version revised by UK, following comments from PAI 06.03.2019
- Stakeholder consultation opened 29 October; will last until 26 November 2019
- Applicants must demonstrate access to, or match, the relevant protected active substance data relied on during approval or renewal of approval of the a.s.
- As the RMS for the original approval or renewal of the active substance is carrying out data matching on behalf of Member States, all study protocols/plans, letters of access and associated documents supporting product renewal must be submitted.

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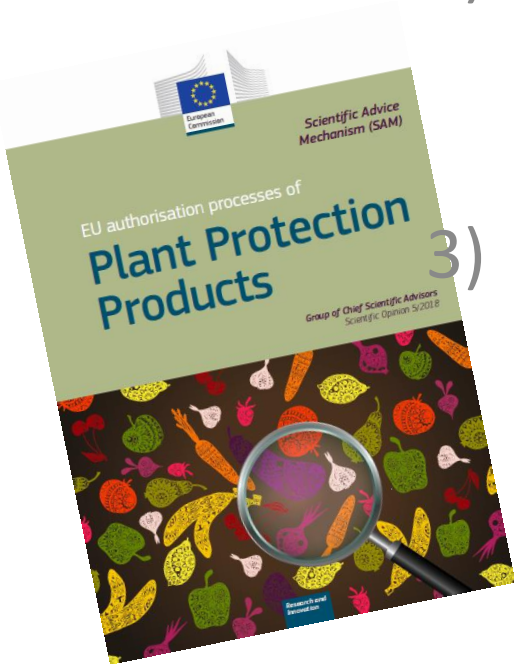
EFSA GD

- GD on isomers (adopted by EFSA)
- On-going mandates
  - update birds and mammals GD
  - update bee GD
- New mandates
  - impact of water treatment processes on residues of AS (EFSA / ECHA)
  - soil photodegradates
  - exposure to dust (treated seeds & granules, under discussion)

Specific Protection Goal Project

1) EFSA developed a method for defining SPGs using the ecosystem services approach (2010 , 2016).
2) cross check our current way of ERA & some concrete needs: EFSA mandates on GD Birds & Mammals, bee GD, …
3) Scientific Advisory Mechanism-SAM Opinion (2018): …*"Clarify the protection goals of the EU PPP approval and authorization system…*



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generic protection goals

"no unacceptable effects on biodiversity and ecosystem"

operationalise

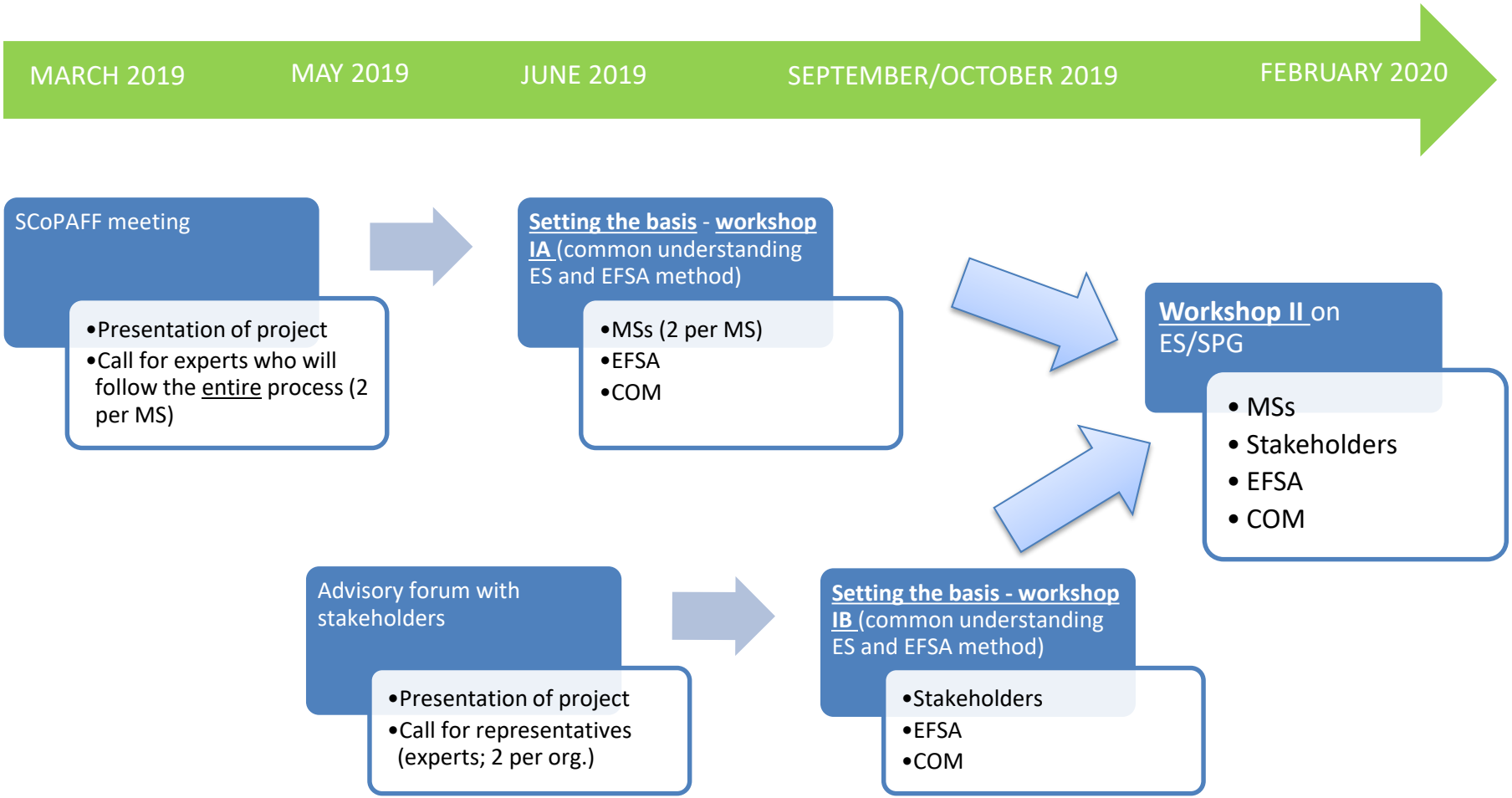
specific protection goals

what, where, and how long to protect?

… keeping in mind Art 4.3:

*"…consequent on application consistent with **good plant protection practice** and having regard to **realistic conditions of use**…"*

TENTATIVE PROCESS AND TIMELINE



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Participation

- June workshop:
  - 41 experts from 23 Member States and 1 expert from Norway
  - 16 COM (DG SANTE E4,F3; DG ENV; DG AGRI; JRC; DG HR)
  - 3 EFSA colleagues
  - 1 external expert

- September workshop:
  - 27 participants (4 industry, 3 retailers, 3 academia, 7 farmers, 6 applicants, 4 NGOs) from 24 stakeholder organisations
  - 2 Member States' representatives
  - 17 COM colleagues (DG SANTE E4, F3;DG ENV;DG AGRI)
  - 3 EFSA colleagues
  - 1 external expert

- workshop provided for interactive, open and serious discussions
- willingness to move with EFSA method
- highly complex and challenging topic
- identified several challenges and way for improvements
- Next step: joint workshop February 2020

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REFIT – Evaluation Steps

- Refit **Roadmap** published on 17 November 2016: purpose, content and scope of the evaluation + main evaluation criteria
- Evaluation study carried out by **external contractor** from July 2017 until June 2018
- **Workshops on specific topics** with a limited group of Member States and stakeholders in 9/2017 + 5/2018
- **Consultations:** general public, Member States, stakeholders and SMEs
- Other information sources: reports from the Commission on **audits** in Member States, 2 reports and studies from the European Parliament, Scientific advice mechanism, …
- Commission website on the evaluation: http://ec.europa.eu/food/plant/pesticides/refit_en