Regulation (EC) No 1107/2009 – update and ongoing developments

PSN (EFSA)

29 October 2024

Karin Nienstedt - DG SANTE

Outline

- New / upcoming legal requirements
- New / upcoming GD
- Feedback from decision making on AS (feedback from PAFF)

Renewal Regulation and IUCLID

- **Implementing Regulation (EU) 2020/1740 of 20 November 2020**
- Applies to all AS in the 6th renewal programme (AIR6) onwards (and to some in AIR4 and AIR5)
  - Submission via IUCLID
  - Additional window to submit data for “new” issues during peer review
- Access to old studies for the purposes of renewal
  - a non-paper was endorsed by PAFF in January 2024 (published on SANTE website)
- **NAS & BS also submission via IUCLID**

Microorganisms

- Updated data requirements and uniform principles (Regulations 283/2013; 284/2013; 546/2011)
- Updated Annex II of Reg 1107/2009
- Commission Communications: List recommended test methods/ guidance documents

✓*Focus on biology/ecology - «need to know» approach*

✓*applicable as from Nov 2022*

Safeners and Synergists: Commission Regulation 2024/1487

Publication: 30 of May 2024 - Entry into force: 19 June 2024

New requirements:

- Setting data requirements (Art 25) – Annex III lists specific DR on efficacy, *otherwise like AS!*
- Establishing the work programme (Art 26)
  - List with 13 S&S on website
  - Notification 1 **by 19 Dec 2024** - add S&S to list via FMB specified in Regulation and stated on website
  - Notification 2 **by 19 Jun 2025** - intention to support S&S dossier
- Adoption of the work programme by amendment Annex I: 19 December 2025

Dates to keep in mind:

- for notified S&S (work programme): Dossier submissions latest 48 months from the date of entry into force - by 19 June 2028 - S&S not notified can no longer be on the market
- Transitional period for products already on the market: until 5 years of the adoption of that work programme – 19 Dec. 2030
- New S&S dossiers can be submitted at any time (free RMS choice)
- Submission via IUCLID (available by in April 2026). Shared submission to be preferred

https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists_en#safeners-and-synergists

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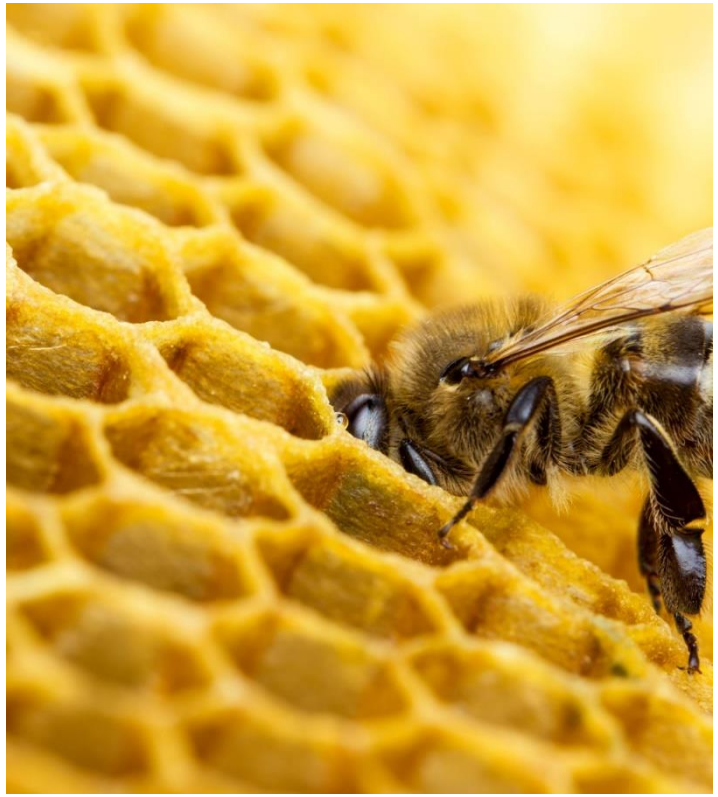
Update of the uniform principles and data requirements

- Which Regulations?
  - Regulations (EU) No 283 and 284/2013 setting data requirements for active substances and plant protection products respectively
  - Regulation (EU) No 546/2011 on the uniform principles
- Why?
  - To adapt to technical and scientific progress to take account of **updated guidance (bees and water treatment GD**)
  - Clarify some other important points - but not a full review
- Procedure?
  - Public consultation (feedback mechanism)
  - Regulatory procedure with scrutiny



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Co-formulants - requirements

- Negative listing (*different from AS positive listing*)
- DR for PPPs (Regulation 284/2013)
  - Introduction point 1.11 - *Information as provided for in Commission Regulation (EU) No 283/2013 may be required by the competent authorities on co-formulants. Before requiring additional studies to be performed, the competent authorities shall assess all available information provided in accordance with other Union legislation*.
  - Point 1.4.3 – link to CLP Regulation and REACH
  - Point 7.4 – link to REACH dossiers and safety data sheets

Co-formulants in PPP - progress

- List of unacceptable coformulants Reg. 2021/383 (Annex III of Reg 1107/2009)
  - 144 unacceptable substances listed
- Regulation 2023/574 sets criteria & procedure to amend Annex III
  - CLP Regulation CMR (Cat 1)
  - POP (Regulation (EU) 2019/1021)
  - REACH (PBT, vPvB, ED, or Annex XVII restriction as PPP-coformulant)
  - BPR (ED, non approved preservative, or restriction as PPPcoformulant)
  - Criterion 10 (safety net)
- On-going amendment of Annex III
  - 20 notifications received so far by 4 MS
  - 2 substances identified in the EFSA technical report

COMMISSION IMPLEMENTING REGULATION (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

ANNEX

Criteria for identification of an unacceptable co-formulant

(1) The co-formulant is classified as mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
(2) The co-formulant is classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
(3) The co-formulant is classified as toxic for reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
(4) The co-formulant is listed in Annexes I to V to Regulation (EU) 2019/1021 (POP).
(5) The co-formulant is included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006 (candidate list) due to its identification as:

(a) persistent, bioaccumulative and toxic (PBT) in accordance with Article 57, point (d), of that Regulation;
(b) very persistent and very bioaccumulative (vPvB)in accordance with Article 57, point (e), of that Regulation; or
(c) substance of very high concern in accordance with Article 57, point (f), of that Regulation due to endocrine disrupting properties (ED).

(6) The co-formulant is identified as having endocrine-disrupting properties in accordance with Regulation (EU) No 528/2012.(ED for BPR)
(7) A decision has been adopted not to approve the co-formulant as active substance for PT 6 under Regulation (EU) No 528/2012.(no BPR-PT6)
(8) A decision has been adopted to approve the co-formulant as an active substance under Regulation (EU) No 528/2012 with restrictions which are relevant for uses as co-formulant in plant protection products. (no BPR)
(9) The use of a substance as a co-formulant in plant protection products is included in Annex XVII to Regulation (EC) No 1907/2006, as restricted for the use in plant protection products.
(10) The co-formulant does not fall under any of the points 1 to 9, but, having regard to realistic conditions of use and good plant protection practice, it does not comply with one of the criteria for the approval of active substances as provided for in Annex II to Regulation (EC) No 1107/2009, when used as a co-formulant in a plant protection product.

Co-formulants in PPPs - progress

- EFSA technical report (based on products submitted for representative uses in the dossiers for active substances since 2019): https://www.efsa.europa.eu/en/supporting/pub/en-7547
- EFSA mandate to find additional unacceptable substances in their list of the technical report according to the criteria in Regulation 574/2023
- Workshops organized by COM & work in progress
  - Details on SANTE website https://food.ec.europa.eu/plants/pesticides/authorisationassessment-plant-protection-products

Regulation 2023/707: New CLP hazard classes

- New CLP hazard classes (ED, PBT, vPvB, PMT, vPvM), will classify more substances, including coformulants, fulfilling the unacceptability criteria (ED, PBT, vPvB), making easier the identification process.

Dates of application:

- **20/04/2023** MS may make proposals with new hazard classes
- **01/05/2025 for substances**; *DARs / ECHA alignment for applications received after this date need include the new hazard classes*
- 01/11/2026 for substances already supplied on the market on 01/05/2025 (need to update the label, or stop the supply of old stock after 01/11/2026);
- 01/05/2026 for mixtures;
- 01/05/2028 for mixtures already on the market on 01/05/2026 (need to update the label, or stop the supply of old stock after 01/11/2026).

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Implementing Regulation (EU) 2023/564 – electronic record keeping of PPP use

- Content of the records given in Art. 67 of Reg 1107/2009 is specified technically in an Annex
- Records as of 1st January 2026 have to be available in electronic format within 30 days of the use
- Interim arrangements: for uses before 1st January 2030 MS may provide longer periods

Draft amendment Regulation (EU) No 547/2011: Labelling requirements for Plant Protection Products (PPP)

Content of the proposal :

- Annex I: Information on the PPP identification and conditions of use
- Annex II: Standard phrases for safe disposal of the PPP
- Annex III: Standard phrase and pictogram for hazard communication of PPP containing chemicals: hazard for bees
- Annex IV: Standard phrase for hazard communication of PPP containing micro-organisms: sensitising effects
- Annex V: Standard phrases for risk mitigation measures: human health and environment
- Annex VI: Coloured scheme

- Regulatory procedure with scrutiny
- Public consultation (feedback mechanism)

Outline

- New / upcoming legal requirements
- New / upcoming GD
- Feedback from decision making on AS (feedback from PAFF)

Database of guidance and supporting documents

This database contains guidance documents, test methods and supporting documents relevant for the risk assessment processes for the (renewal) of approvals of chemical and microbiological active substances and for authorisations of chemical and microbiological plant protection products.

The database contains more documents than those currently contained in Commission Communications **2023/C 344/02** and **2023/C 344/01** (as regards chemical active substances and plant protection products), and the Commission Communications **2023/C 202/03** and **2023/C 202/02** (as regards microbiological active substances and plant protection products). These four Commission Communications are related to data requirements set out in Commission Regulation (EU) 283/2013 and 284/2013.

Procedural Guidance documents are also listed.

Documents other than those listed in the above Communications have been included in the database following suggestions by Member States or interested stakeholders during the consultations for the ongoing revision of the above Communications – **they are included for information purposes only**.

Click one of the following buttons to access the database content

List by Section ▾ | List by Documents

Pesticides Guidance Documents (europa.eu)

Version: 1.1.3

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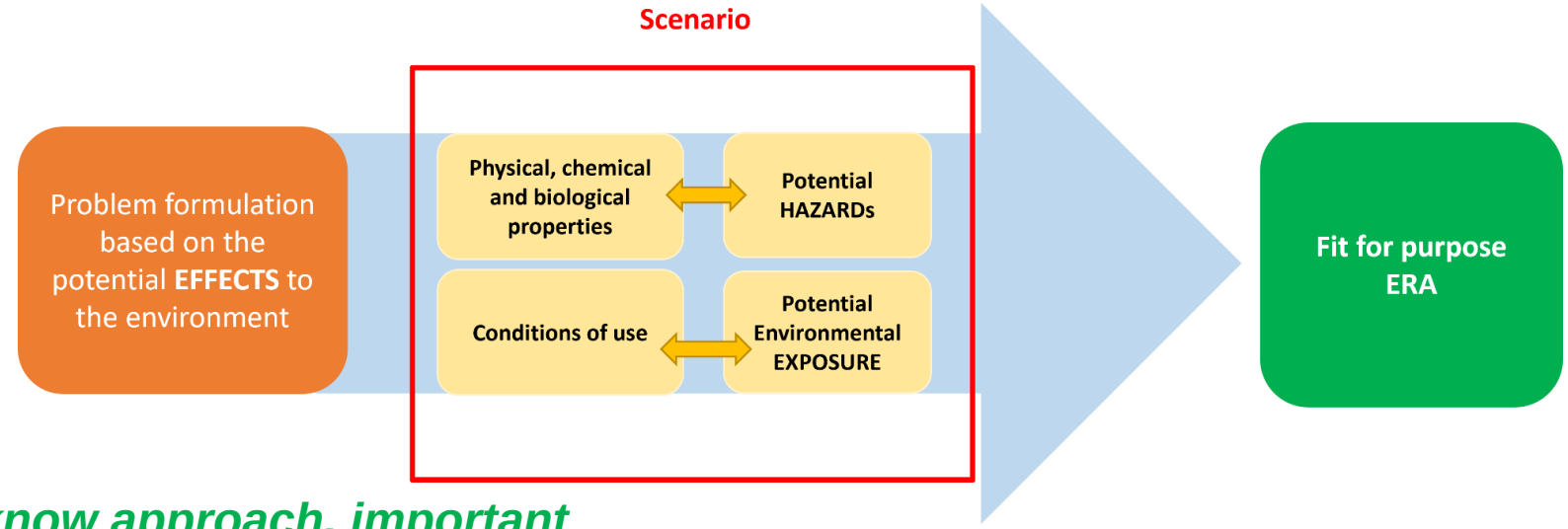
GD for microorganisms

- Guidance document on **Metabolites of Concern** (Oct 2020)
- Guidance document on **AMR** (May 2021)
- **Explanatory Notes** (Oct 2023)
- **Pheromones**: amended **GD on semiochemicals** extending the group of pheromones beyond the SCLP group – Adopted in January 2024
- **Baculovirus/bacteriophages**: ongoing revision of guidance document
- Consensus documents on MO species (on-going)
- Consensus document on background levels of MO (on-going)

Guidance: Problem Formulation for Environmental Risk Assessment



based on need-to-know approach, important for innovative modes of action (e.g. peptides)

To provide justifications as referred to 1.5 of the introduction of the Data Requirements: in cases where **experimental data would not be necessary owing to:**

1) the **nature** of the active substance
2) or the **representative uses** of the plant protection product containing it.

When comparing to a scenario in which a chemical pesticide is applied with a conventional sprayer in the open field, **lower environmental effects** may be expected for:

1) microorganisms, pheromones, botanicals, plant extracts, …
2) application methods such us indoor uses (permanent greenhouses or storage rooms), precision application techniques, localised applications (e.g., burrows, drip irrigation), …

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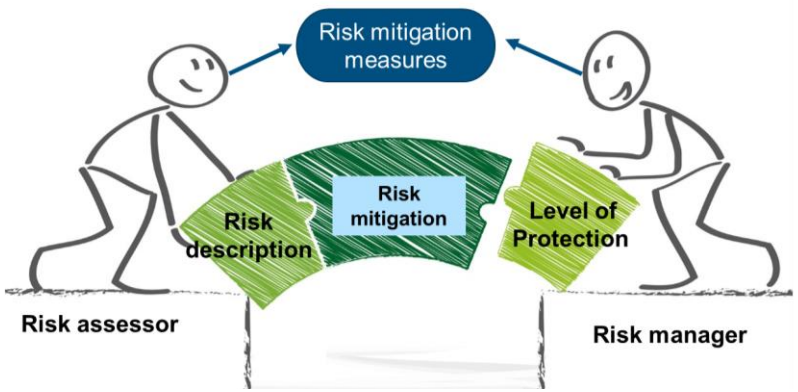
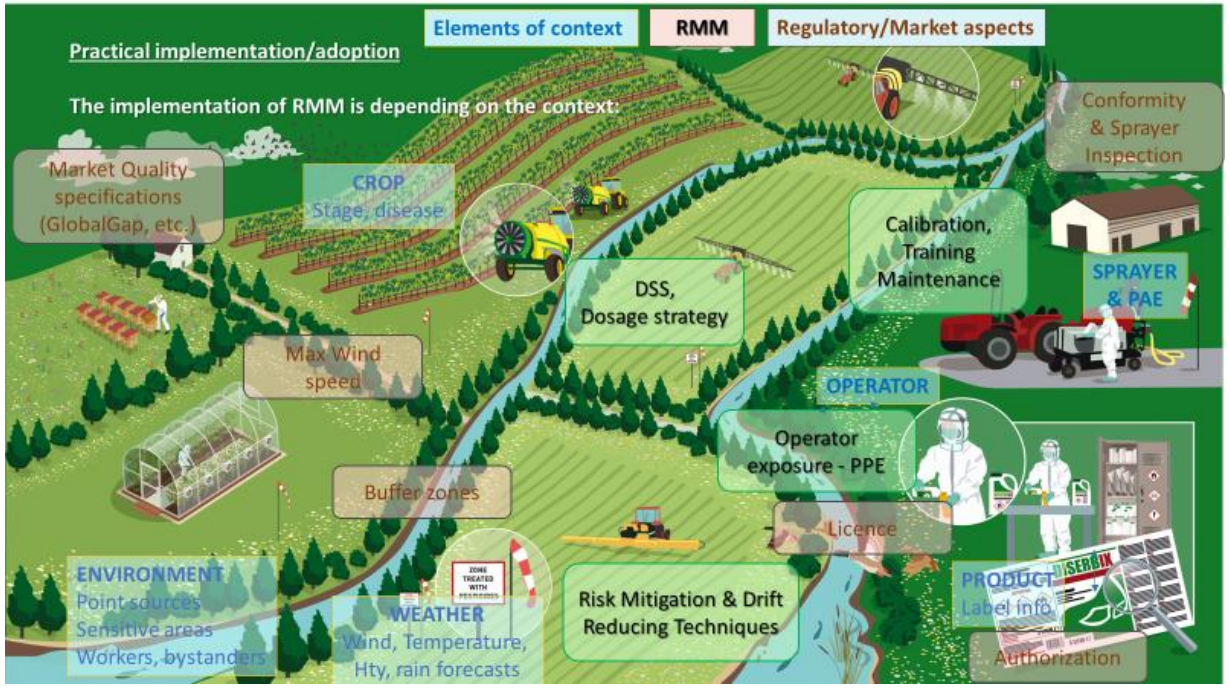
New / updated GD for chemical AS…

- Guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water – Endorsed March 2024
- GD on time dependent sorption of pesticides in soil (Aged sorption for groundwater leaching)
- Revised guidance for birds and mammals (October 2024)
- Compendium conditions of use to reduce exposure and risk from PPPs – Endorsed in March 2024

Horizontal Guidance: Compendium conditions of use to reduce exposure and risk from PPPs

- Could be relevant for your pesticide use scenario (GAP)





https://food.ec.europa.eu/document/download/cdd9b6c4-29dc-4077-a118-3e51c0abeb80_en?filename=pesticides_ppp_app-proc_guide_horiz_comp-cond.pdf

GD currently under preparation/revision or discussion in PAFF

Under preparation/revision:

- Updated guidance on emergency authorisations
- Negligible exposure – draft ready for stakeholder consultation (Q4 2024)
- Non target arthropods, soil organisms, non-target plants
- Indirect effects on biodiversity
- OPEX GD (closed transfer systems)
- Assessment of PPPs and co-formulants

Under discussion for endorsement in PAFF:

- Revised guidance on bees (after amendment of DR & UP)

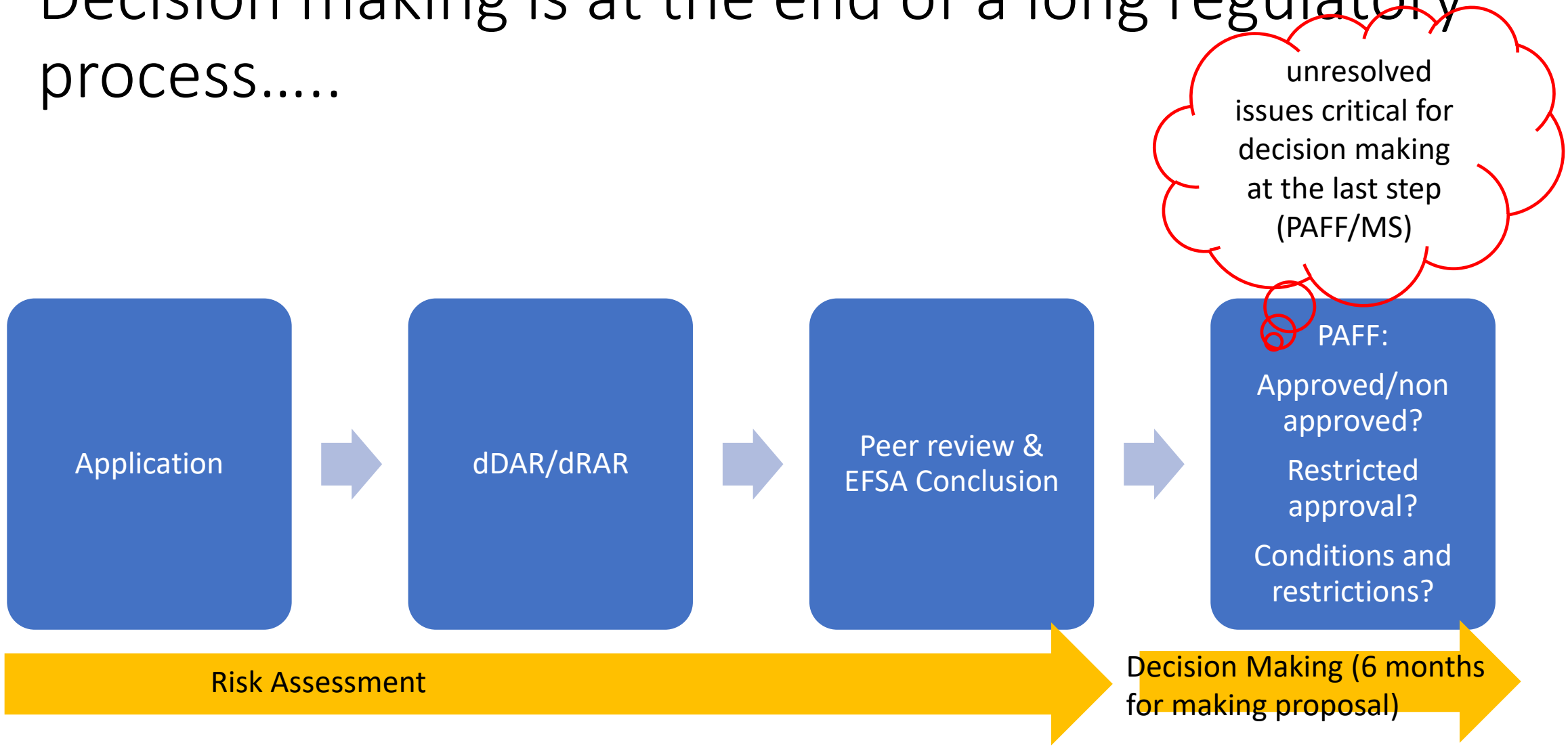
Outline

- New / upcoming legal requirements
- New / upcoming GD
- Feedback from decision making on AS (feedback from PAFF)

Standing Committee PAFF

- Meets 5 to 6 times per year, chaired by COM
- MS vote on drafts previously discussed as regards (non)approval or (non)renewal of AS – these drafts are based on the EFSA Conclusions (peer review)
- MS vote on drafts previously discussed on horizontal issues (e.g. data requirements) and endorse GD

Decision making is at the end of a long regulatory process…..



Standing Committee PAFF

- „difficult“ regulatory decision making is sometimes caused by:
  - No consideration of lower end of the GAP (if GAP a range)
  - No consideration of risk mitigation measures – follow up questions, now in light of the new Compendium
  - „natural“ AS assessed with a RA which might not be the most appropriate for this kind of AS (e.g. pelargonic acid, rape seed oil, sulfur)

This triggers follow up questions to EFSA and RMS (and peer review)!

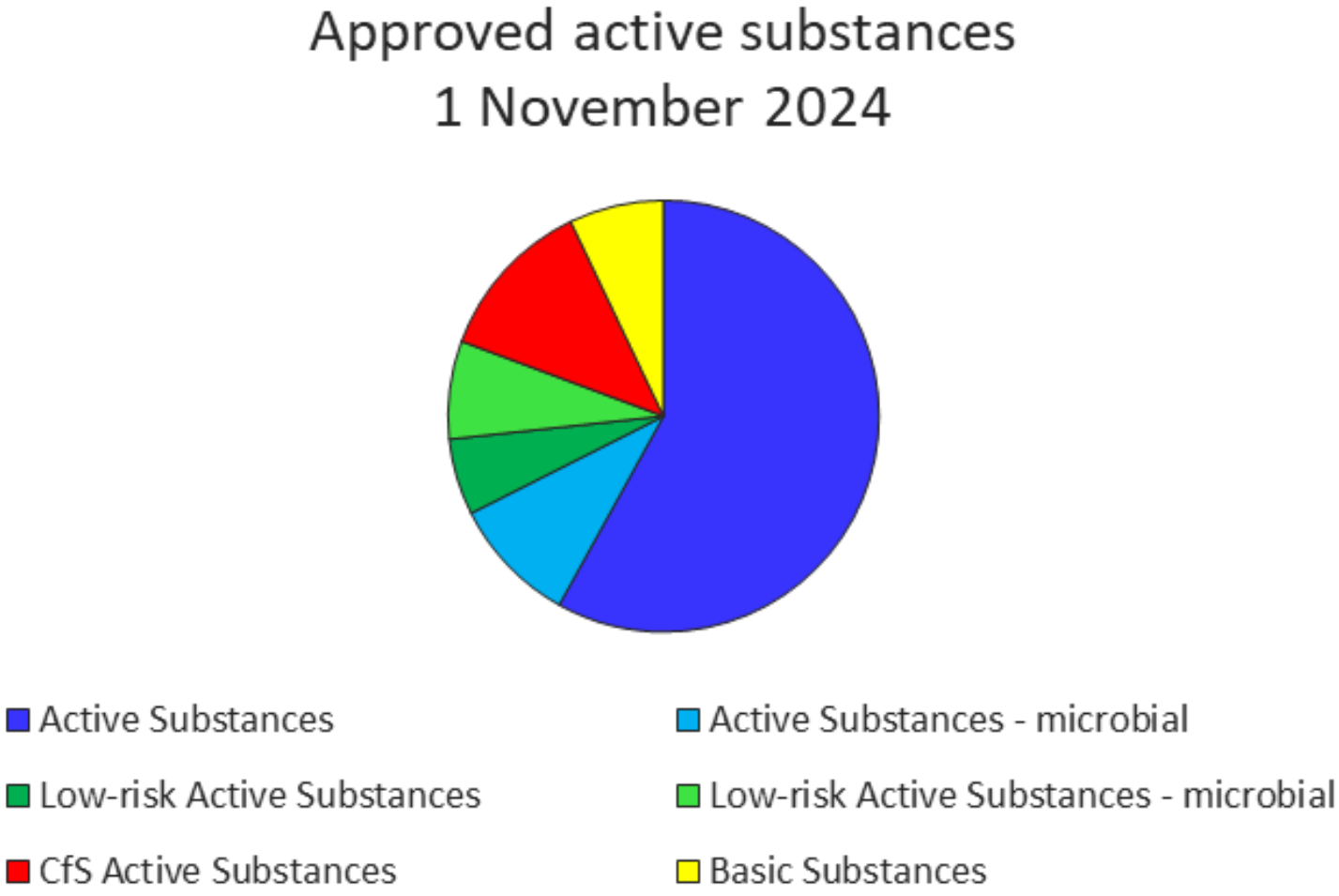
Assessment of alternative AS – be prepared

- Applications for AS with new modes of action „in the pipeline“
  - bacteriophages
  - peptides
  - RNAi
  - …

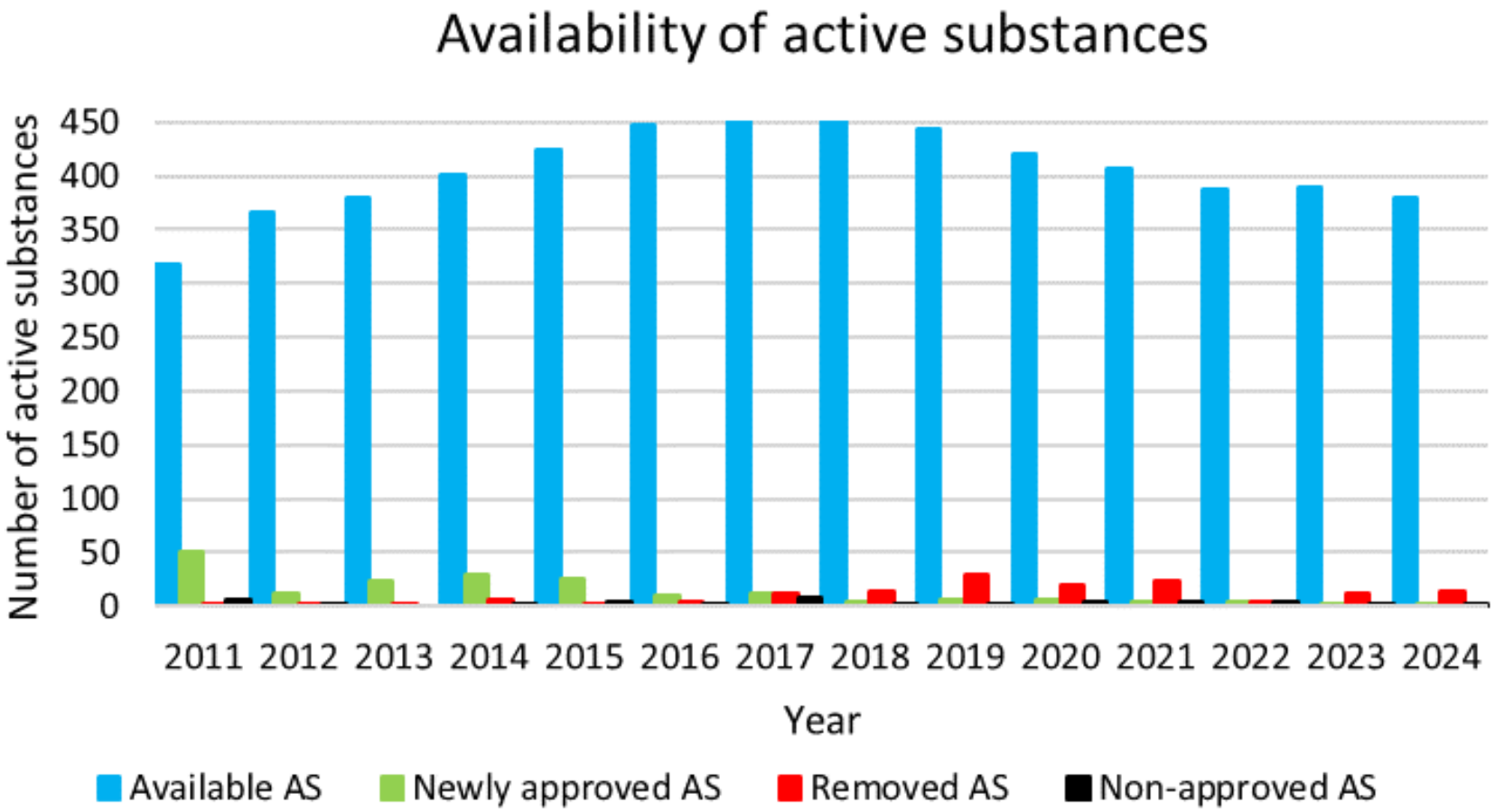
The current „schemes“ may not fit – ad-hoc & „need to know“ RA may be needed

Pre-submission meetings important!

Authorised Active Substances – Statistics



Authorised Active Substances – Timeline



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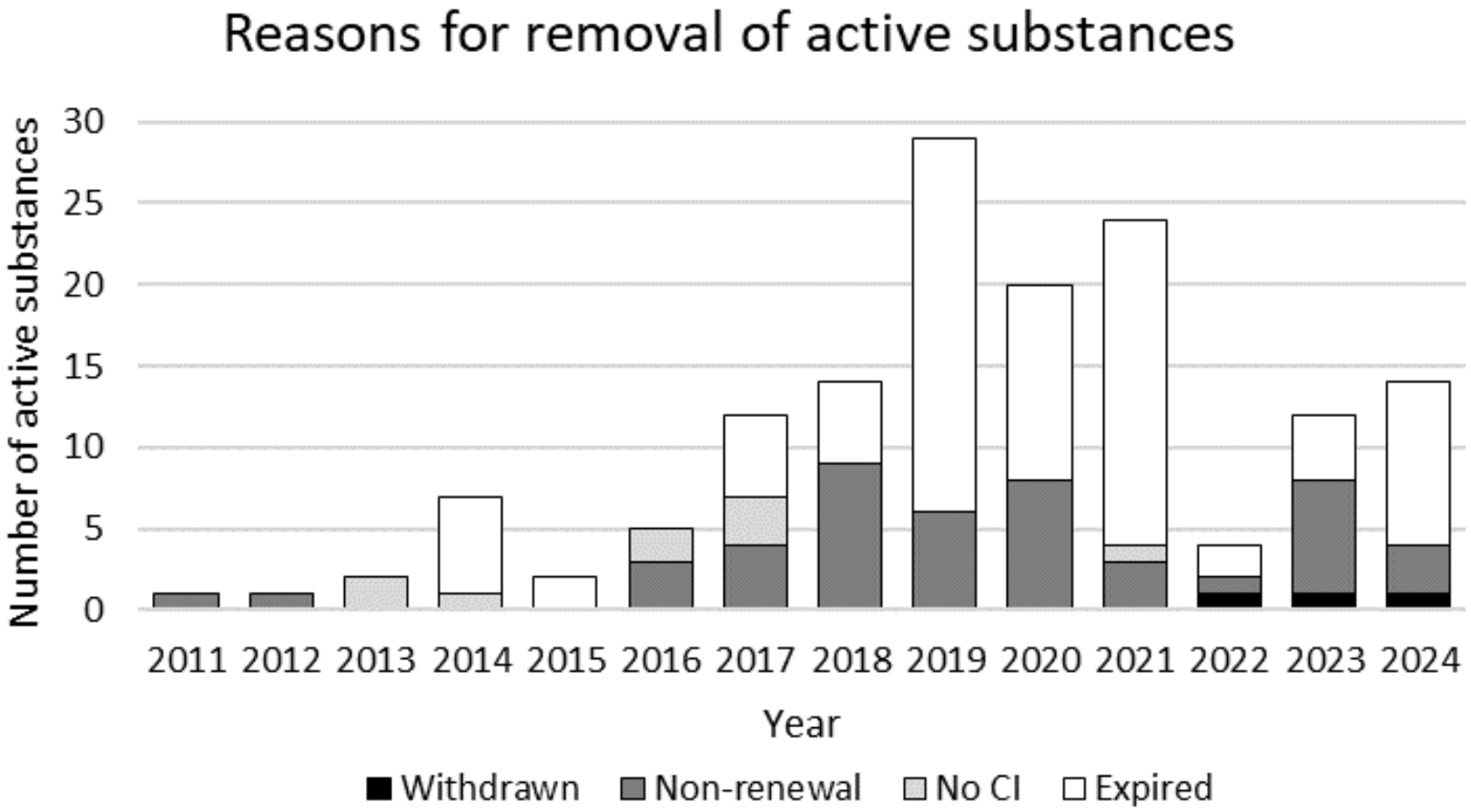
Unauthorised Active Substances – Timeline



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Actions to reduce delays and to increase availability of (low risk) PPPs

- Grants “SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA”
  - Priorities:
    - to reduce delays in approval and authorisations
    - to increase number of experts in microorganisms
    - to ring fence the fees for the authorities actually carrying out the work
  - Hiring additional staff
  - all grants signed, started as of 1 January 2024
  - €5 Million of total budget of 6 MS (AT, EE, ES, LT, LV, and SK)- € 3,4M EC contribution.
- Better Training for Safer Food – Risk Assessment on Micro-organisms
  - since July 2021
  - target: risk assessors
  - as of today, 11 sessions held and about 350 officers were trained
  - training session still ongoing until March 2025

Take home message from RM to peer reviewers

- Avoid delays (during peer review and considering the next steps - fit for purpose RA is essential!)
- Alternative PPPs are needed for the farmers toolbox : please give priority to new active substances
- Use PF and need to know approach – make good use of pre-submission meetings in particular for such innovative NAS and MO
- BEFORE finalising peer review
    - make sure all information is considered in the peer review (consider weight of evidence & expert knowledge),
    - consider RMM and lower range of GAP to see if there is a safe use

Thank you !

For further information:

https://ec.europa.eu/food/plant/pesticides

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