CURRENT SITUATION FOR ACTIVE SUBSTANCES

- **Overview: NAS and renewals**
- **Update on guidance**

Mark Williams, DG Health and Food Safety, European Commission

Crop Life Europe Annual Conference, 5-6 March 2024

Active substances: where do we stand?

European Commission

Regulatory framework - approval and renewal

- **Regulation (EC) No 1107/2009**

REFIT Report (20 May 2020):

  - is effective in protecting human health and environment
  - its efficiency and implementation could be improved (delays!!!)
  - no re-opening of the Regulation, but improving implementation (all stakeholders of the same opinion!)

- **Implementing Regulation (EU) No 844/2012 (as amended: ED, CLH)**
- **Implementing Regulation (EU) No 2020/1740 – 'new renewal rules'**

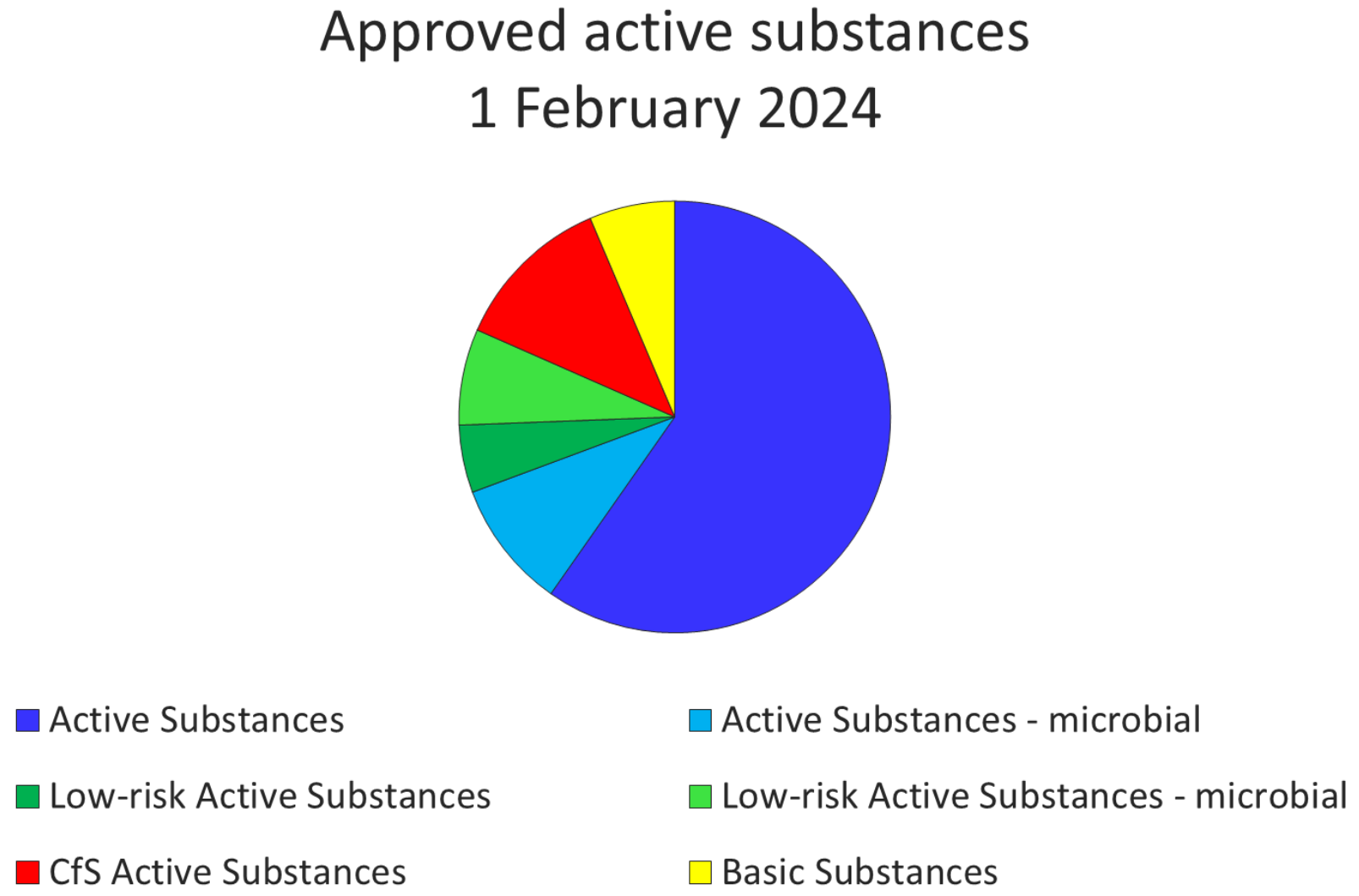
Approved active substances – the numbers

As of 1 Feb 2024: Annex to Implementing Regulation (EU) 540/2011 contains 5 parts, listing approved active substances + basic substances:

- **Parts A and B:** 260 active substances (excluding those in the Annex to Implementing Regulation (EU) 2015/408) – *including 36 microbial substances*
- **Part D:** 46 Low-risk active substances – *27 microbial substances*
- **Part E:** 13 Candidates for Substitution (further CfS are listed in the Annex to Commission Implementing Regulation (EU) 2015/408 – total 45)
- Part C: 24 basic substances

Note: Some listings contain more than one compound or microbial strain

Approved active substances - overview



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Not approved active substances

As of 1 February 2024, 136 active substances (incl. 7 microbial substances) that were approved under Regulation (EC) No 1107/2009 are no longer approved:

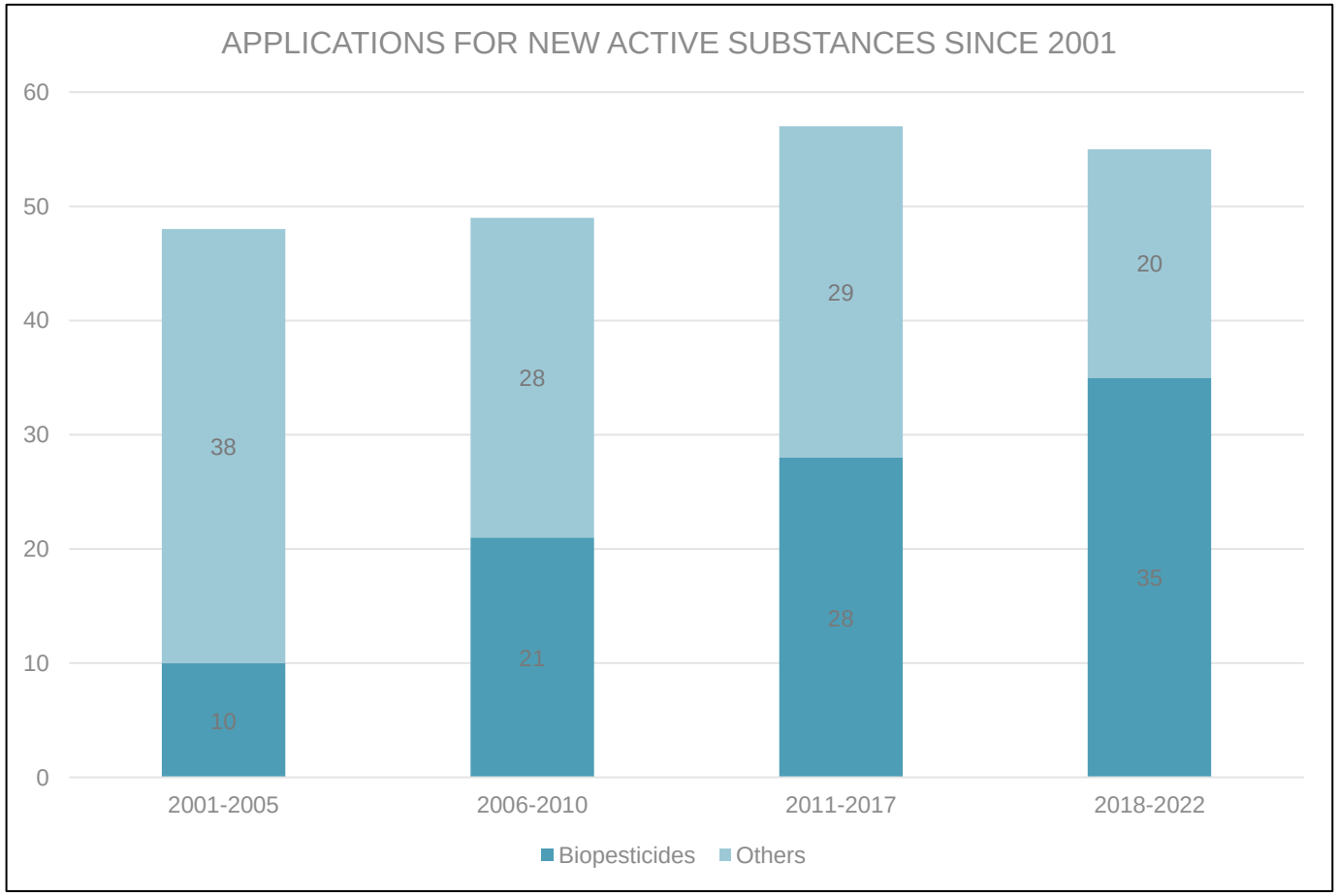
- 81 active substances expired due to lack of / withdrawn renewal application
- 44 active substances with a specific non-renewal decision (Art. 20(1)(b))
- 9 active substances withdrawn due to lack of / incomplete confirmatory information (Art. 21(1), second alternative)
- 2 active substance withdrawn in light of new data (Art. 21(3), first alternative)

No microbial active substance approval non-renewed or withdrawn

New active substances

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

- 112 applications between 2011 - 2022
- **Increasing number of biopesticides**
- As of 1 February 2024, there are 76 ‘pending’ applications for approval:
  - 32 are **microbial substances**
  - some **innovative NAS**: peptides, RNAi, bacteriophage
- 29 pending applications for approval as basic substance



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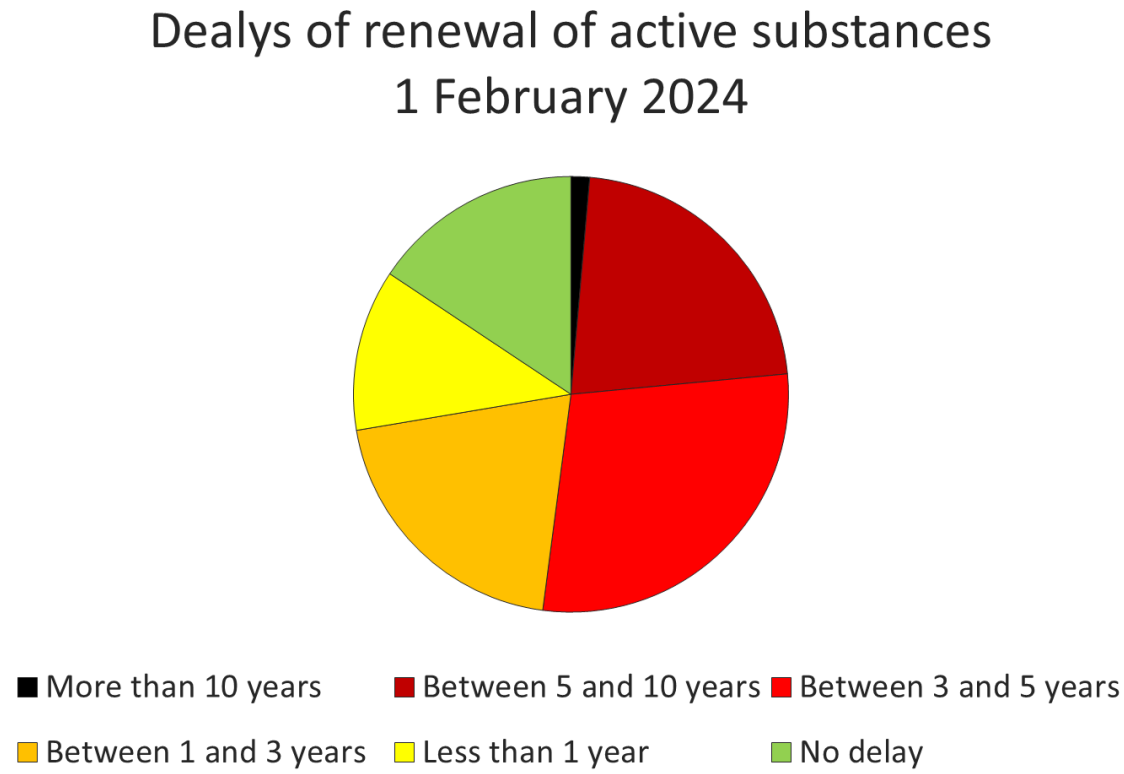
Renewal of approval

- As of 1 February 2024 → 217 active substances are in the process of renewal
- Renewals experience significant delays:
  - 34 no delay yet; 26 delay less than one year; 44 delay between one and three years; 62 delay between three and five years; 48 delay between five and ten years; 3 delay more than ten years
- In case the renewal process is delayed for reasons beyond the control of the applicant the approval is extended (Article 17)
- The extension period is based on the stage of the process and expected duration of remaining steps



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Implementation: important progress

- Scientific ED criteria - implemented for several years
- MO - new data requirements, uniform principles, approval criteria:
  - → Biology and ecology of the microorganisms at the centre
  - → Conditional data requirements / need to know approach (not nice to know!)
  - → https://ec.europa.eu/food/plants/pesticides/micro-organisms_en
- Transparency Regulation (IUCLID) & CLP alignment
- Unacceptable co-formulants list (Annex III) and rules and criteria for identifiying additional unacceptable co-formulants (Regulation 574/2023)
- Safeners and synergists – Regulation voted at PAFF in January 2024, scrutiny of EP and Council ongoing - EIF 20 days following publication. Work Programme to be adopted 18m after EIF

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Endocrine disruptors (ED)

- A number of active substances have been identified as ED according to the scientific criteria (Annex II 3.6.5 and 3.8.2 of Regulation (EC) No 1107/2009)
- No case (so far) of an ED only for non-target organisms
- Substances that are ED **can only be approved if exposure is demonstrated to be negligible**
- Draft GD (May 2015) is currently used. So far **no case of negligible exposure** has been identified (residues and/or non-dietray exposure). New guidance under preparation.
- **Article 4.7:** derogation from the approval criteria - **to be applied restrictively -** substances with hazards of high concern.
  - necessary to control a **serious danger to plant health** which cannot be contained by **other available means** including non-chemical methods
  - other approval criteria should be fulfilled
  - case by case – so far, no substance approved

Update on guidance

European Commission

Prioritisation exercise

- Guidance documents may be updated in view of technical and scientific progress or to reflect changes to the regulatory framework
- Jan 2023 - Standing Committee on Plants, Animals, Food and Feed (PAFF) has agreed on a prioritisation of guidance documents for which an update or a drafting is envisaged, as well as a process to keep this prioritisation up to date – priorities are based on a number of criteria including regulatory needs
- The documents have been included on the guidance section of the pesticides webpages: https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en

Guidance Documents: finalised or pending implementation

- Guidance to provide justifications as referred in point 1.5 of the Introduction of the Annexes of Regulations (EU) No 283/2013 and No 284/2013: Problem formulation for environmental risk assessment - endorsed January 2024
- Non-paper on obtaining old studies for renewal under Regulation (EU) 2020/1740 – endorsed January 2024
- GD on risk assessment for birds and mammals – published Feb 2023 - implementation discussions ongoing
- GD on risk assessment for bees - published May 2023

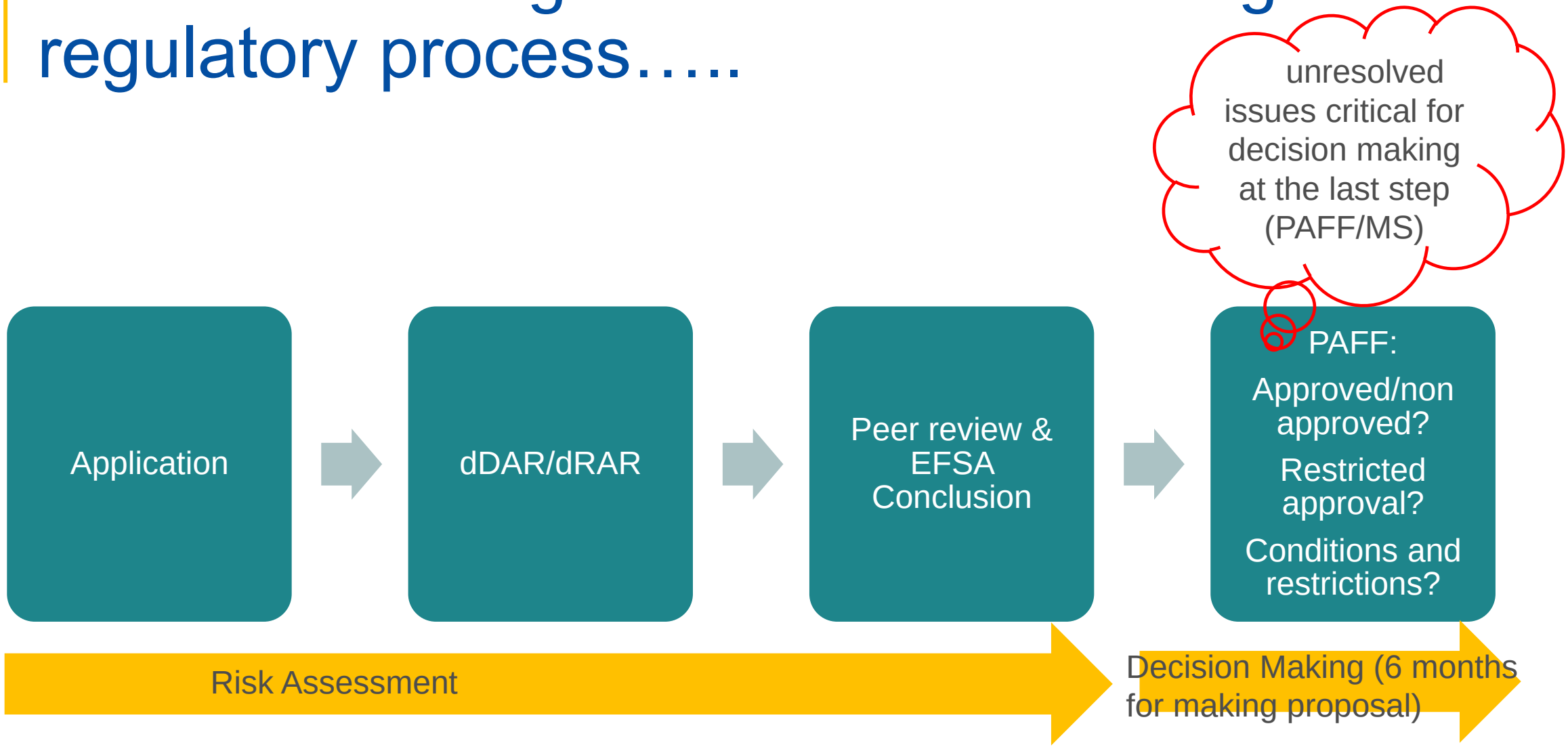
  - Update of Implementing Regulations (UPs, DRs) ongoing

- GD on the impact of water treament pocesses - published August 2023 – implementation discussions ongoing

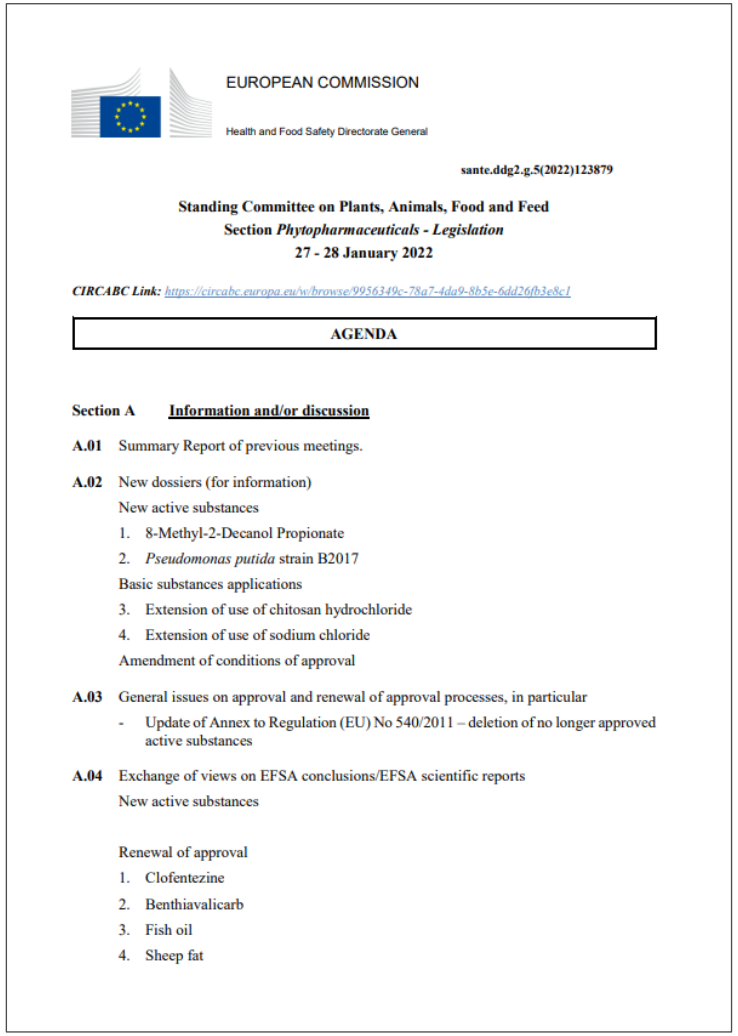
Guidance Documents: ongoing/upcoming

- Update of UPs (546/2011) and DRs (283 and 284/2013) – feedback mechanism will be launched before a vote is taken, then scrutiny by Council and EP
- Guidance on assessment of negligible exposure – WG preparing a new draft. Stakeholder consultation will be carried out following MS consultation
- Compendium of conditions of use to reduce exposure and risk from PPPs – *applicants should ensure GAPs are fully described including all conditions/ technical measures to reduce exposure*
- Guidance on emergency authorisations – discussions ongoing with Member States
- New active substance data post-approval – posssible review?
- Mandate on azoles (resistance in *Aspergillus spp*.): multi-agency task (+ JRC) – deadline for the Scientific Report extedned until 31 December 2024.

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



Anticipation and planning - how to predict decision making (procedurally)?



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2022)123879

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
27 - 28 January 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/9956349c-78a7-4da9-8b5e-6dd26fb3e8c1*

AGENDA

Section A **Information and/or discussion**

A.01 Summary Report of previous meetings.

A.02 New dossiers (for information)

New active substances

1. 8-Methyl-2-Decanol Propionate
2. *Pseudomonas putida* strain B2017

Basic substances applications

3. Extension of use of chitosan hydrochloride
4. Extension of use of sodium chloride

Amendment of conditions of approval

A.03 General issues on approval and renewal of approval processes, in particular

- Update of Annex to Regulation (EU) No 540/2011 – deletion of no longer approved active substances

A.04 Exchange of views on EFSA conclusions/EFSA scientific reports

New active substances

Renewal of approval

1. Clofentezine
2. Benthiavalicarb
3. Fish oil
4. Sheep fat

Section A

- Discussion on EFSA Conclusion (**A.04**)
- Discussion on draft Review/Renewal Report (**A.05**)

Section C

- Discussion on draft legal act and draft RR
- Legal act and RR published in the Comitology Register

Section B

- Discussion and possible vote on draft legal act and draft RR
- Legal act and RR published in the Comitology Register

Comitology Register - Committee Code: C20407
https://ec.europa.eu/transparency/comitology-register/screen/committees?lang=en

https://ec.europa.eu/food/horizontal-topics/committees/paff-committees/phytopharmaceuticals_en

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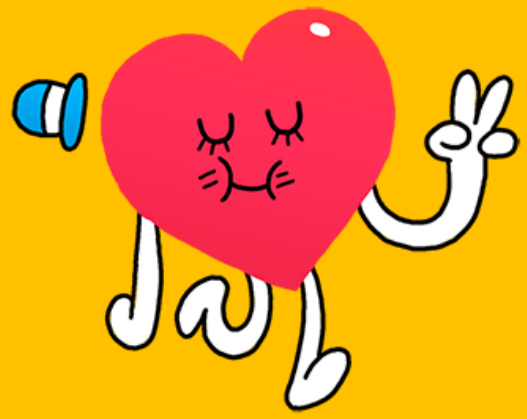
Thank you



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