



# Plant protection products – update and ongoing developments

*PLENARY MEETING  
ADVISORY GROUP ON THE FOOD CHAIN AND  
ANIMAL AND PLANT HEALTH  
23 NOVEMBER 2020, VIRTUAL MEETING*

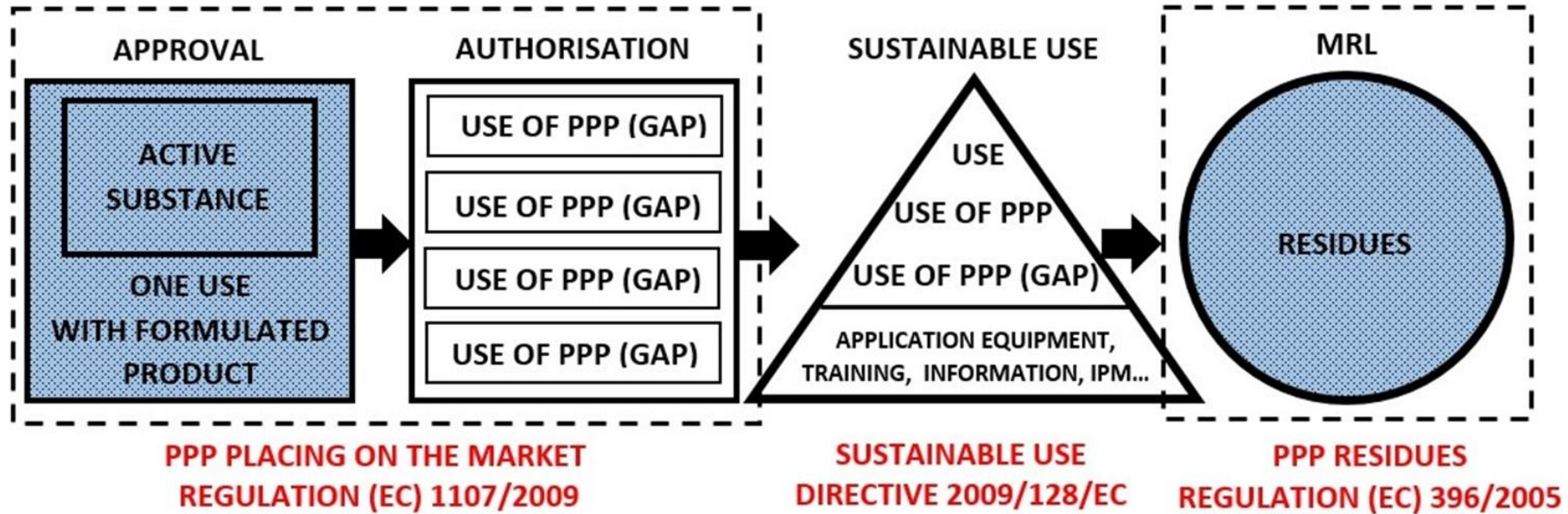
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# Outline

- REFIT and follow up actions
- Current developments on guidance documents

# REFIT and follow up actions

# Legal framework for Pesticides



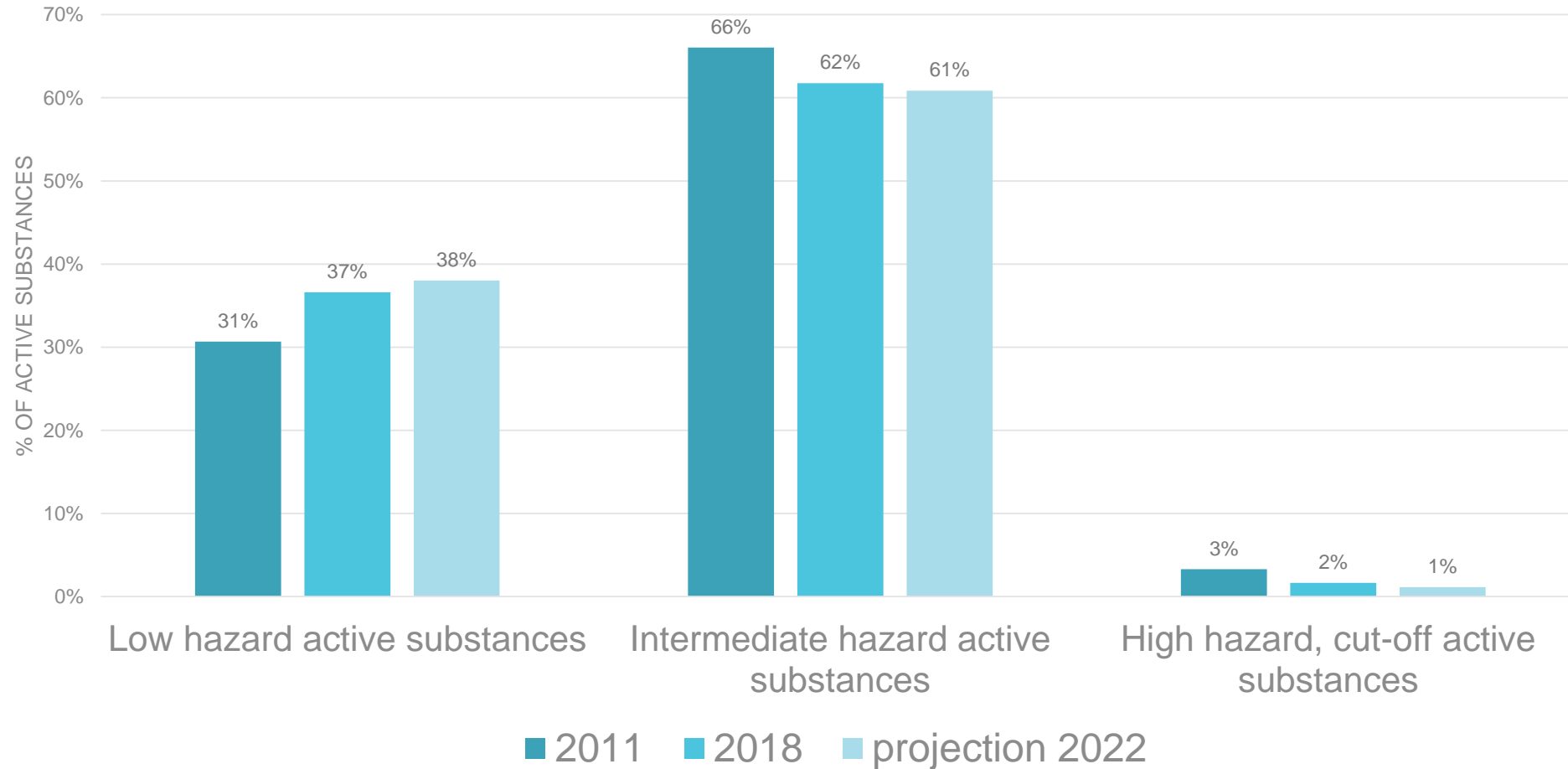
# REFIT report (PPP & MRL)

- Adopted 20 May 2020
- Adopted together with the Farm to Fork Strategy, the Biodiversity Strategy and the 2<sup>nd</sup> report on the implementation of the Sustainable Use Directive.
- Report to the European Parliament and the Council, outlining the main findings of the evaluation. Detailed findings presented in an accompanying Staff Working Document.
- Evaluation took into account European Parliament resolutions of September 2018 (ENVI Committee) and January 2019 (PEST Committee) and AGRIFISH and Environment Council discussions in November 2018 and in December 2018 – in addition to extensive consultations and external study for gathering evidence.

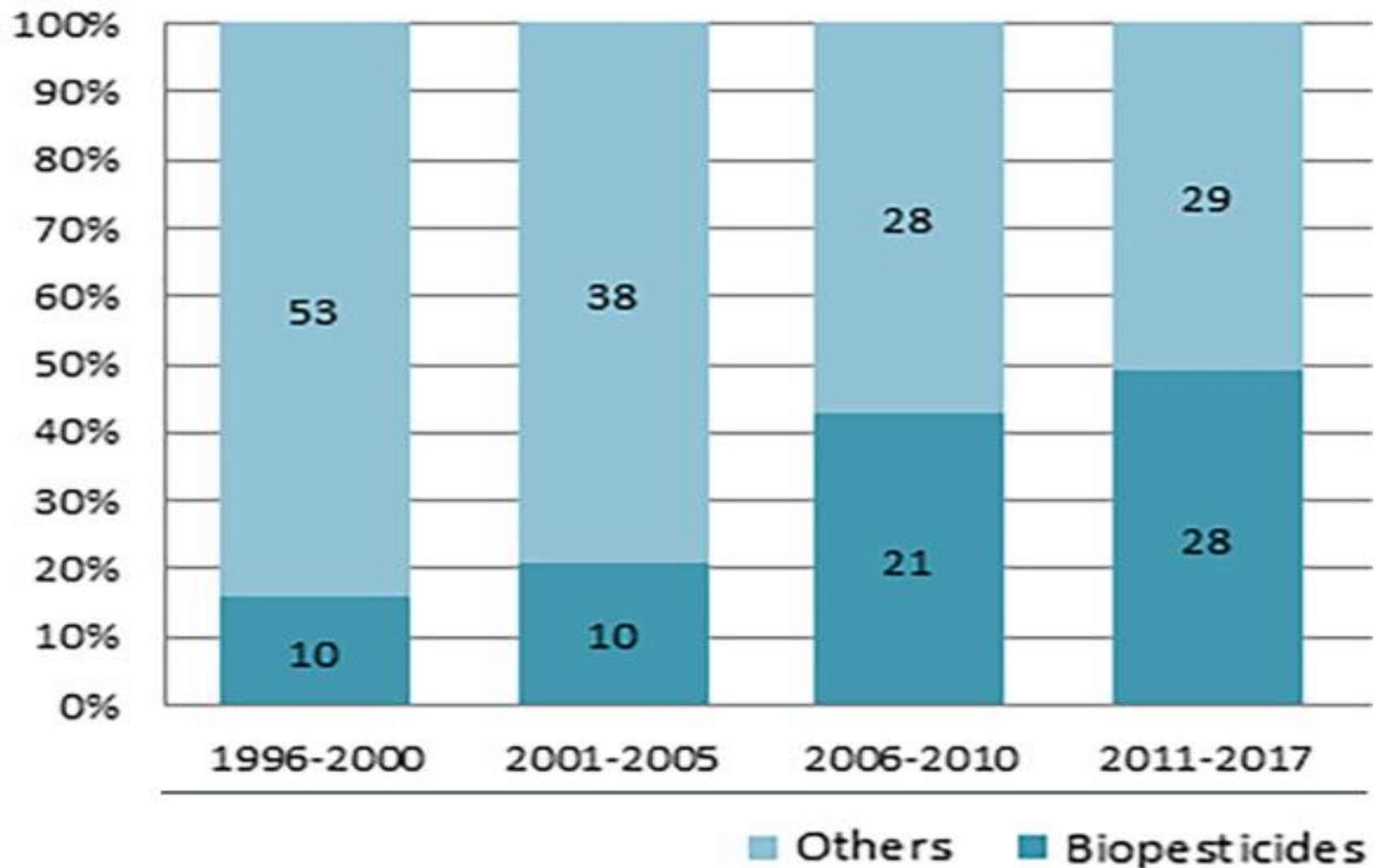
# Conclusions: the positives (PPP only)

- **Regulatory frameworks for PPPs and MRLs are fulfilling the objective of protecting human health and environment**
  - Since Dir. 91/414, number of active substances have declined by 50%
  - Reg. 1107/2009 introduced further elements that increased the level of protection e.g. cut off criteria
  - Share of Hazardous Active Substances declined to 2%, share of Active Substances with low hazard profile increased to 37%
- **EU is recognised as the benchmark for the most stringent regulations on pesticides in the world**
  - Role model for other countries: many third countries adopt EU scientific conclusions

# Hazard Profiles of Active Substances



## APPLICATION FOR NEW ACTIVE SUBSTANCES SINCE 1996



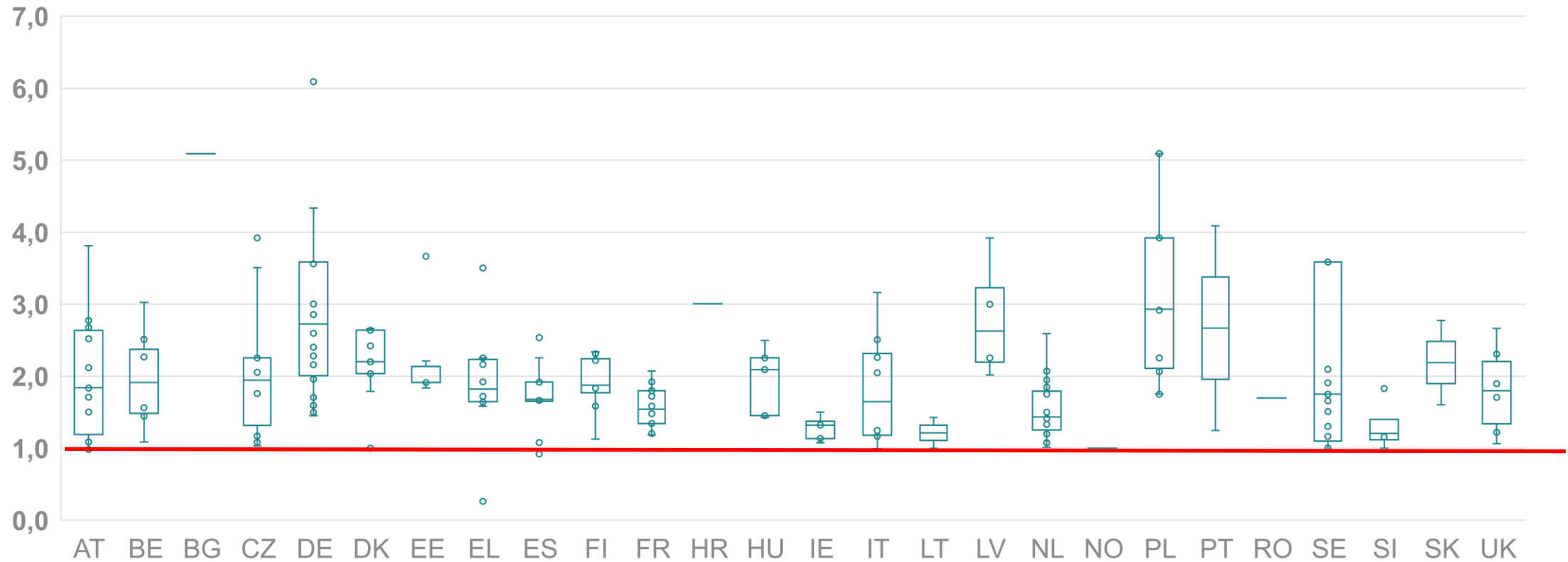


# Conclusions: need for action (PPP only)

- Efficiency and implementation of Plant Protection Products and MRL Regulations need to be improved
- Need for sustainable agriculture must be better addressed

# Area for improvement: delays

Renewal of approval  
Assessment delivery time (years) by MS and the UK  
(1 year is the legal requirement)



# Solutions... **Delays**

- MS should increase resources and review fees and charges
- MS should only accept complete dossiers of high quality as admissible
- Pre-submission advice by RMS & EFSA (transparency GFL & its implementation)
- COM / EFSA cooperation to improve clarity of the EFSA Conclusions (fit for the purpose of decision making)
- Establishment of list of unacceptable co-formulants
  - voted 17 July 2020, now under scrutiny of EP and Council until 14 Dec 2020, adoption if no objection
  - procedure for adding other co-formulants will be prepared once list is adopted.
- Work programme for the assessment of safeners and synergists, discussion on-going since early 2020 at Standing Committee, applicant associations consulted.

# Solutions...

## Transparency

- Publication of draft acts and draft review reports under Section B (for vote) and Section C (for discussion) of the Standing Committee meetings via Comitology Register
- Publication of Emergency Authorisations (notifications under Art. 53 via PPPAMS) & updated guidance document in preparation

# Solutions...

## Transparency

- Transparency Regulation amending the GFL Regulation will apply from 27 March 2021
- Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 (replaces Regulation (EU) No 844/2012 to align with Transparency Regulation, voted 23 Oct 2020).
  - IUCLID for submission of dossiers from 27 March 2021 (act for NAS dossier submissions in preparation)
  - Application & submission of dossiers “merged” → applications → extensions granted to keep submission date of dossier (1<sup>st</sup> submissions of IUCLID dossiers in July 2021), voted 23 Oct 2020
  - Dossiers will be publicly available for public consultation (implementation of transparency regulation)
  - Art 13 (Conclusion of EFSA) → under some circumstances “*the applicant may also submit additional information ...within the two-week period*”
- Implementing act setting data format (IUCLID) for new active substances in preparation (PAFF Dec 2020)
- Update of the GD on basic substances in preparation

# Sustainability and low-risk products

## What Works

- PPP and MRL Regulations contribute to achieving some of the Sustainable Development Goals
- PPP and MRL Regulation together with the SUD and the CAP set a frame for sustainable agriculture in the EU
- PPP Regulation contains provisions to favour low-risk active substances and PPP

## Needs Improvement

- Insufficient availability of low risk active substances (including microorganisms) and PPP as well as basic substances
- Reduced timelines for authorisation of low-risk PPP are not respected
- Risk reduction through exploring and use of new application techniques (e.g. robotics, digitalisation)

## Planned Actions

- Facilitate market access for micro-organisms through revision of data requirements and assessment methodologies
- BTSF training for assessment of micro-organisms
- Call on MS to implement actions to increase availability of low-risk products
- Continued funding for research on sustainable plant protection
- Clarify procedures for approval of basic substances
- EC/EFSA/MS: assess potential of risk mitigation measures incl. new application technologies

# Solutions...

## Low risk AS (cont) and others...

- Update of data requirements for micro-organisms
  - Regulations 283/2013 (AS), 284/2013 (PPPs), 546/2011 (uniform principles), Annex II of Reg 1107/2009 (limited to MO approval criteria)
  - Detailed discussions at Standing Committee expected soon, vote end of 2021, stakeholders will be consulted (feedback mechanism).
- Risk mitigation measures – discussions initiated
  - workshop with MS in January 2020
- Comparative Risk Assessment (Annex IV), discussions initiated at PAFF and PAI WG

# Developments on Guidance documents...





# EFSA mandates...

- Mandate to EFSA and ECHA to develop GD on impact of water treatment processes to residues of AS or metabolites – on-going
- Mandate to EFSA on a statement on transition metals when used as PPPs (copper)
- Mandate to EFSA to review bee GD
  - work on-going, including consultation of Member States (risk managers) and stakeholders on-going
- EFSA GD on isomers (note taking PAFF expected Dec 2020)

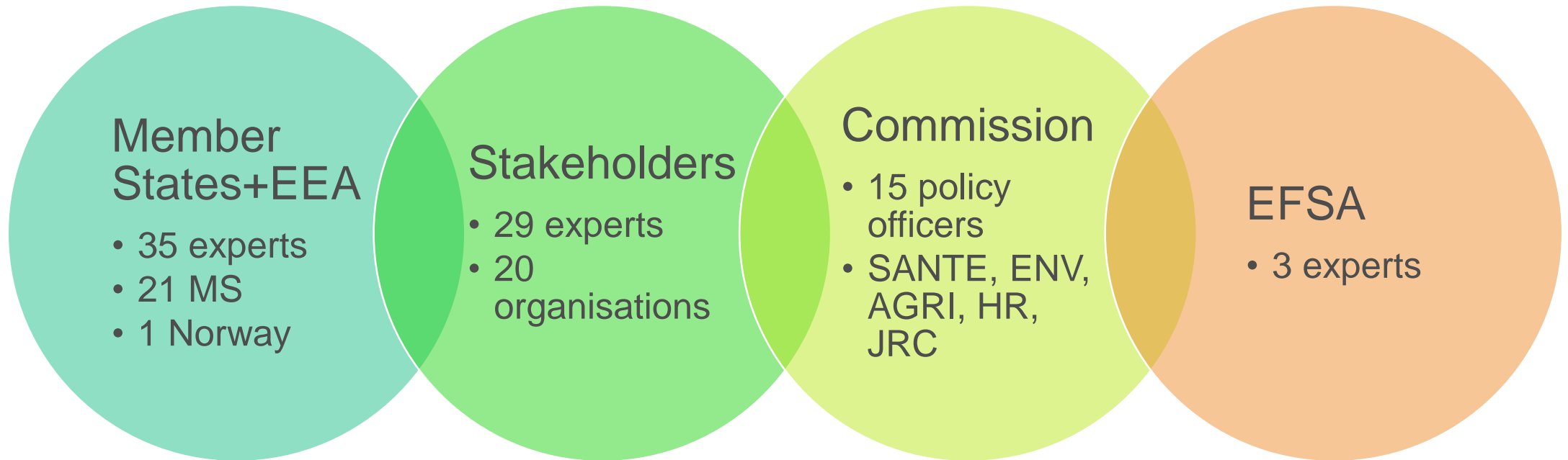
# Other GDs...

- GDs on secondary metabolites (micro-organisms)
- GD on anti microbial resistance (micro-organisms)
- Draft GD on time dependent sorption of pesticides in soil (Aged sorption for groundwater leaching)
- Draft GD on seed treatments and placing on the market of treated seeds
- Update of GD on emergency authorisations
- Draft GD on negligible exposure

# Ecotoxicology GDs & specific protection goals

- July 2018: kick-off discussions PAFF
- In 2019: „Training“ workshops on EFSA method (2010/2016)
  - Member States (June 2019)
  - Stakeholders (September 2019)
- 3-4 February 2020: „Hands-on workshop“

# Participation to Workshop 3-4 Feb 2020



# Outputs so far

- Report was sent to participants, exercises of the workshop is included in the report
- Discussion as regards next steps are on-going at PAFF and internally
- Follow-up info meeting with participants of workshops is planned for early 2021 (delayed because of COVID 19)

# Thank you for your attention !

For further information:

[https://ec.europa.eu/food/plant/pesticides/refit\\_en](https://ec.europa.eu/food/plant/pesticides/refit_en)

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