



# GUIDANCE ON THE ASSESSMENT OF PESTICIDE RESIDUES IN ROTATIONAL CROPS

Hermine Reich (PREV)

# OUTLINE

Regulatory background for assessment of pesticide residues in rotational crops

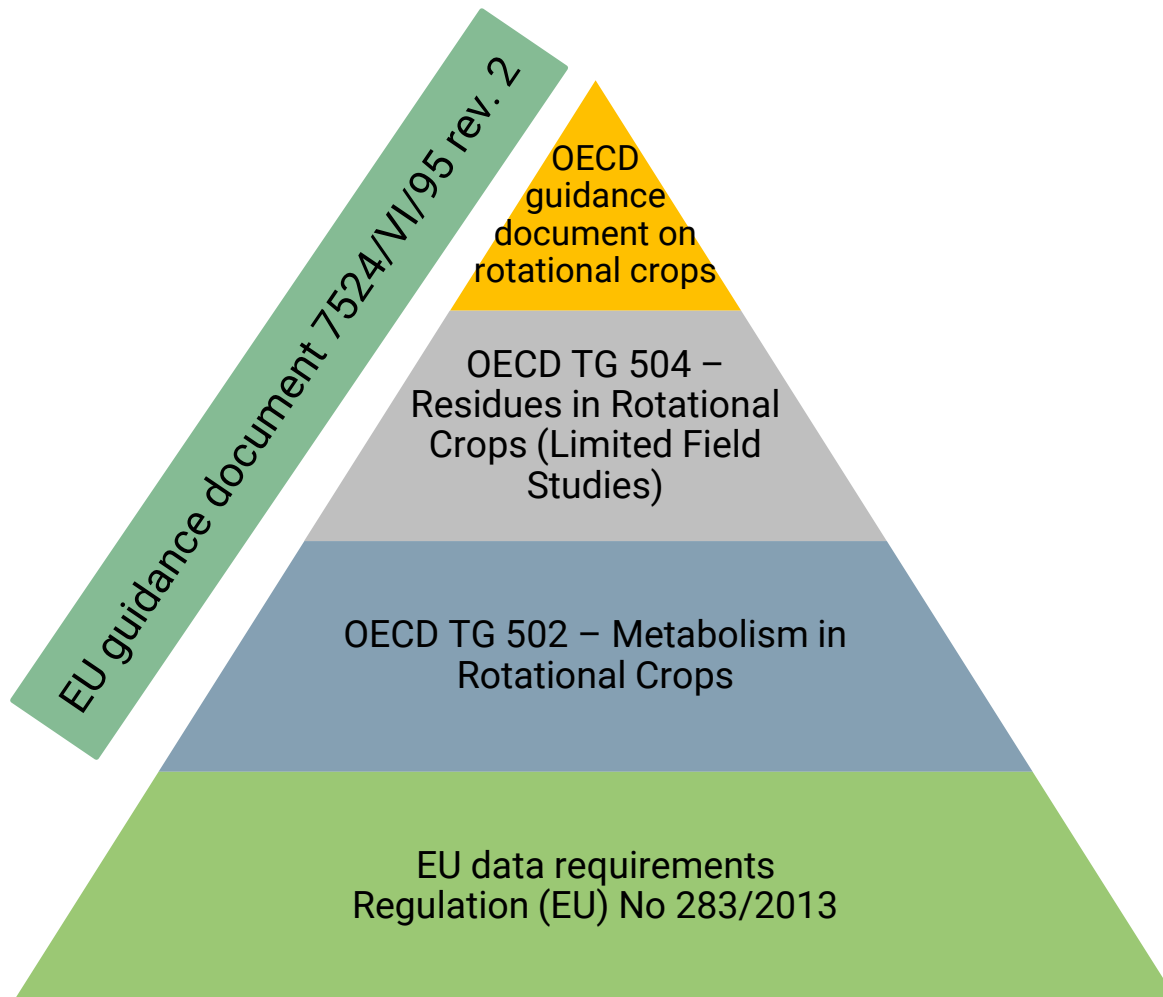
Process to develop the guidance document

Content of the guidance document

What's next



# REGULATORY FRAMEWORK FOR ASSESSMENT OF RESIDUES IN ROTATIONAL CROPS



Provisions of the different guidelines and guidance documents are not fully compatible, leave room for interpretations, are not fully aligned with the EU data requirements and do not define clear criteria for assessment (trigger values, thresholds).

EFSA initiated the work on this topic in 2020, drafting a technical report.

In 2022, EFSA received a mandate from the European Commission to draft a new guidance document, that should fill the gaps of OECD TG and GD and provide clear guidance and practical solutions for the assessment of residues in rotational crops compatible with the regulatory framework (a.s. approval, MRL applications, MRL reviews).



# TERMS OF REFERENCE

The Commission requested EFSA, in accordance with Article 31 of Regulation (EC) No 178/2002, to provide **scientific and technical assistance** to the Commission by **preparing an EU Guidance Document on the assessment of rotational crop studies**, as defined in Section 6.6 of the Annex to Regulation (EU) No 283/2013. In particular, the Guidance Document should address the following aspects:

- describe under which circumstances studies investigating the nature and magnitude of residues in rotational/succeeding crops are required,
- provide details on the design of rotational crop studies (metabolism studies in rotational crops, rotational crops field studies),
- develop guidance on the interpretation of the studies in view of performing the consumer risk assessments and develop options on risk mitigation measures, including options for setting MRLs,
- to derive recommendations for the development of tools necessary to perform the assessment consistent with OECD and the recommendations derived in the current guidance document.

The Guidance Document should support the practical implementation of the relevant OECD Test Guidelines (TGs) and Guidance Documents in a harmonised way respecting the EU regulatory framework on data requirements. In order to facilitate the assessment of rotational crops, EFSA is requested to describe in detail how to perform the relevant assessments, illustrated by calculation examples, and calculation templates.



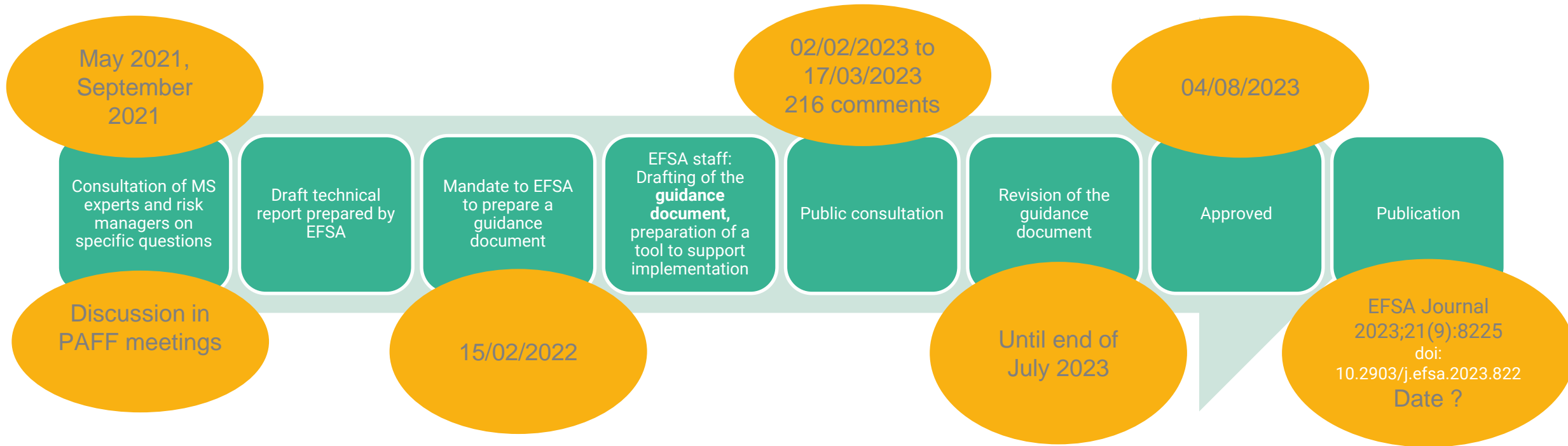


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# Process to prepare the guidance document



# PROCESS TO PREPARE THE GUIDANCE DOCUMENT





## Content of the guidance document

# SECTION 4 – WHEN IS AN ASSESSMENT ROTATIONAL CROP METABOLISM STUDIES

## When is the assessment of rotational crops is not required?



Pesticide is used only in permanent or semi-permanent crops

- Crop classification for annual and permanent/semipermanent crops in Appendix A



Uses do not lead to residues in soil

- Examples



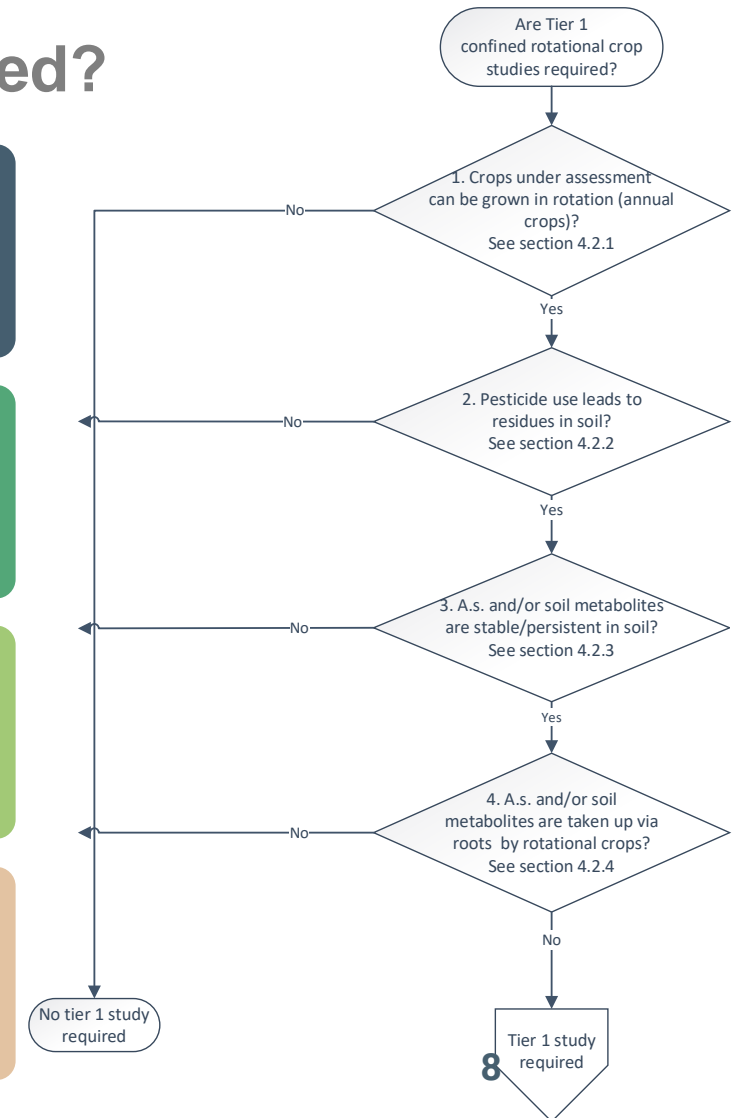
No uptake of a.s. and soil metabolites

- Examples how to provide evidence that no uptake from soil is expected, e.g. from metabolism studies in primary crops (root crops)



a.s. and metabolites are not stable in soil, significant concentrations in soil do not occur

- Clarifications on trigger values for stability of a.s., considerations on metabolites
- Examples how to retrieve the relevant end points





# STRUCTURE OF THE DOCUMENT

Section	Title
1	Background
2	Terms of Reference
3	Introduction
4	Rotational crops metabolism studies (OECD TG 502)
5	Studies investigating the magnitude of residues in rotational crops: Limited field studies (OECD TGL 504)
6	Extended field studies for MRL setting and/or determination of appropriate risk mitigation measures (Tier 3)
7	Higher tier studies (monitoring data)
8	Uncertainty analysis
9	Recommendations
Appendix A –	Supporting information
Appendix B –	Examples illustrating the assessment of residues in rotational crops
Annex A –	Outcome of the public consultation on the draft Guidance Document on the assessment of pesticide residues in rotational crops

- Set of questions
- Flowcharts, visualisations
- Design of the studies
- Interpretation of the studies



## SECTION 4 –ROTATIONAL CROP METABOLISM STUDIES

### Guidance on study design

- Which crops should be used in rotational crop metabolism studies?
- Which parts of the crops need to be analysed?
- Which plant back intervals?
- Which soils?
- Application rates for a.s.
- How to ensure that soil metabolites are sufficiently addressed?

### Interpretation of results of limited field studies

- Reporting results
- Scaling if studies were performed with higher (or lower) dose rates than expected under realistic conditions



# SECTION 5 – LIMITED FIELD STUDIES

When are limited field studies required (triggered)?

Guidance on study design

- Which crops? Number of studies?
- In which soils?
- Practical examples to calculate the application rates for a.s.
- How to ensure that soil metabolites are sufficiently addressed?
- Scaling if studies were performed with higher (or lower) dose rates than expected under realistic conditions

Interpretation of results of limited field studies

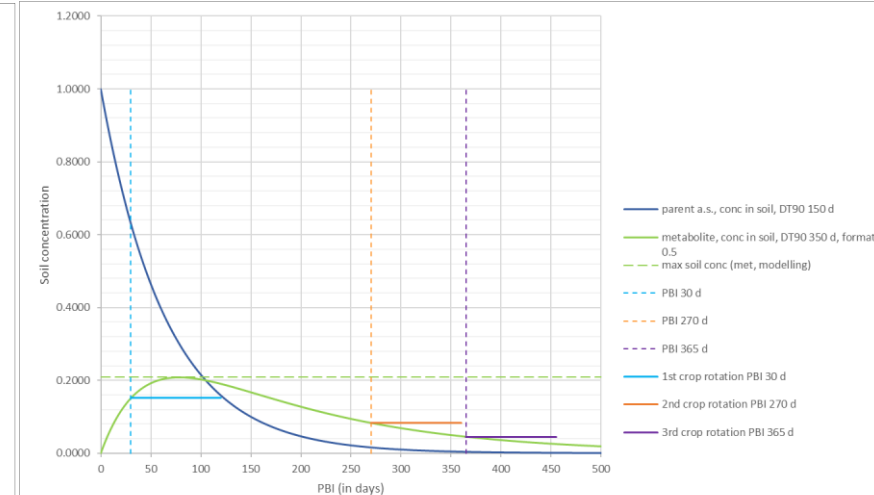
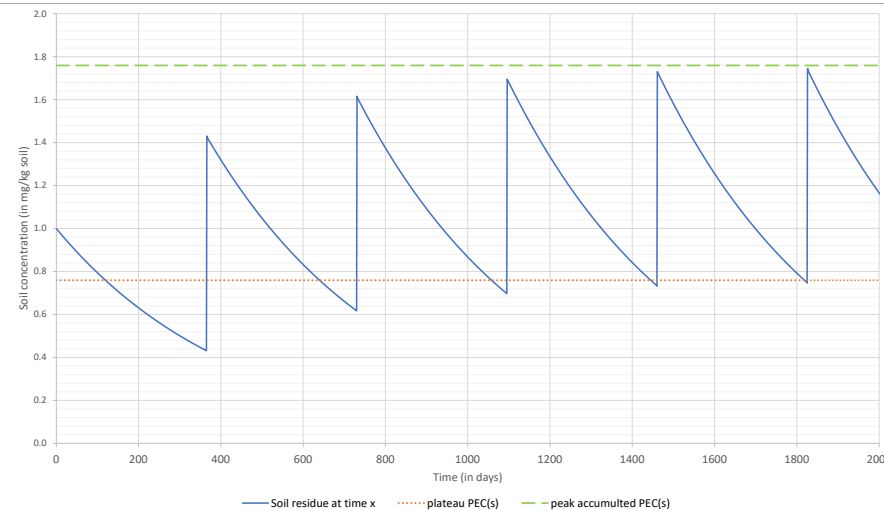
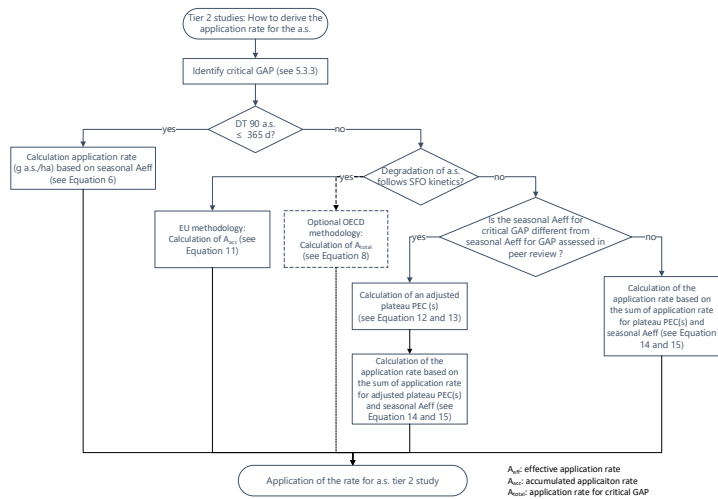


# SECTION 5 – LIMITED FIELD STUDIES

## Further guidance on study design

- Where to perform the studies?
- Which crops? In which soils?
- Practical examples to calculate the application rates for a.s. and metabolites
- Options for studies investigating parent and soil metabolites in separate studies or in a combined study
- Scaling if studies were performed with higher (or lower) dose rates than expected under realistic conditions

## Interpretation of results of limited field studies



## SECTION 6 – EXTENDED FIELD STUDIES

### Further guidance on study design

- When are these studies triggered? Which crops? In which soils?

### Interpretation of results of limited field studies

- How to derive input values for dietary risk assessment for consumers and for dietary burden calculation for livestock?
- Calculation of dietary burden
- Dietary risk assessment for consumers
- Deriving MRL proposals
- Possible risk mitigation measures to avoid/reduce residues in rotational crops



**Next steps**



# IMPLEMENTATION

The guidance document was intended to give pragmatic advice for future assessments, noting that the proposed approach needs to be further refined, based on the experience gained;

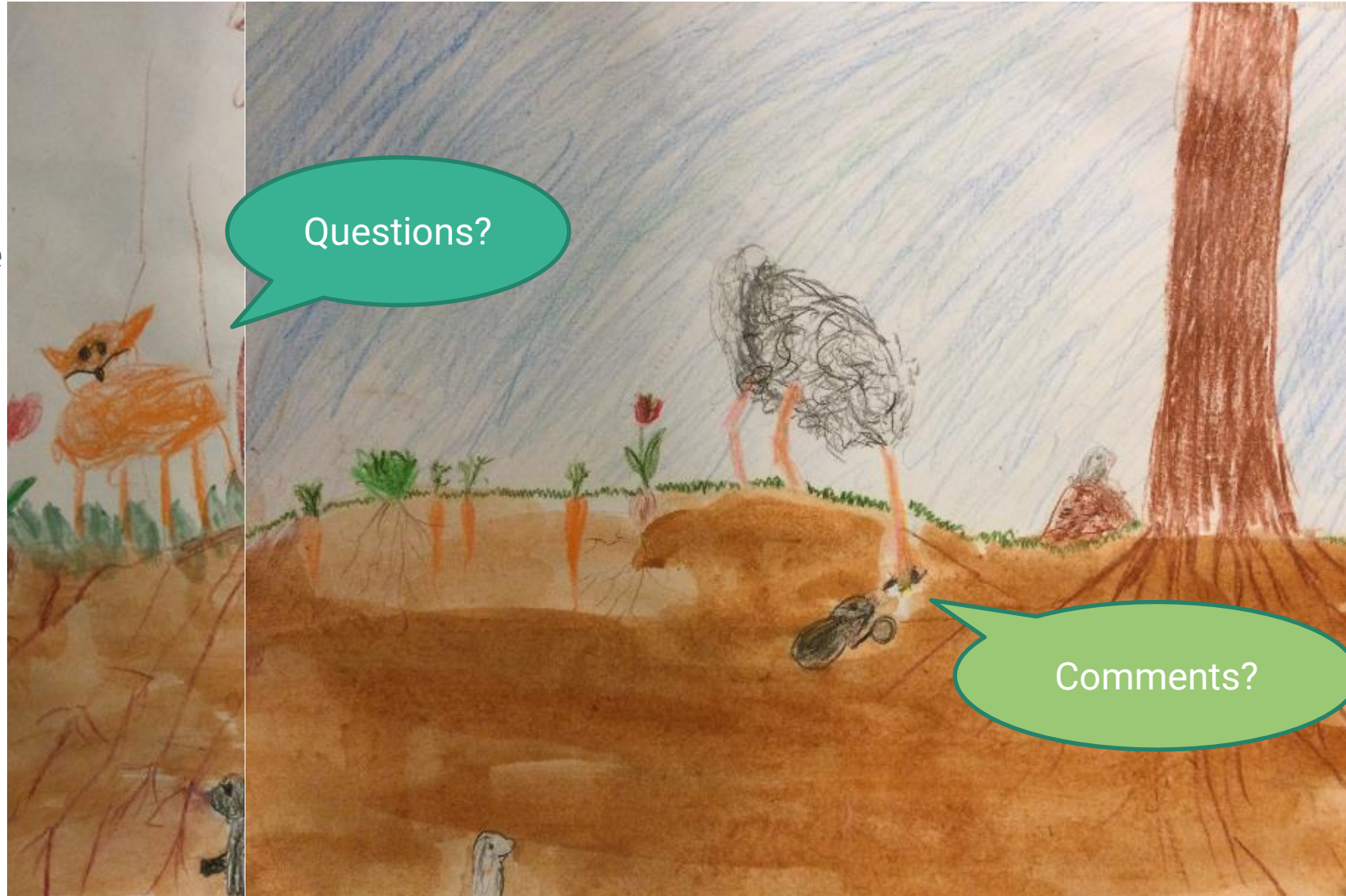
Guidance document lists 20 recommendations, inviting Member State experts and risk managers to discuss them/prioritizing them for follow-up actions to further refine the risk assessment approach for rotational crops.

- Recommendations on procedural and scientific topics
  - Recommendation 8: **Modelling of soil concentrations** for a.s. and metabolites would allow deriving more realistic estimation for the assessment of residues in rotational crops, including options for refinements. Hence, the development of tools for soil modelling for parameters relevant for the assessments of rotational crops (based on tools that are also used in fate modelling, e.g. PERSAM) should be promoted.
  - Recommendation 20: Discuss and agree on an **implementation plan** for the current the guidance document **for the different workflows** affected, i.e. Art.10 applications, Art. 12 MRL reviews, assessment of confirmatory data identified in Art. 12 reviews, approval/renewal of the approval of a.s., assessment of Codex MRLs.



# THANKS TO ALL WHO CONTRIBUTED

- MS experts, providing comments and sharing experiences
- Commenters in public consultation
- EFSA staff who contributed to the preparation of the document and sharing examples and experiences
- Colleagues in European Commission



Comments?





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