



# **RISK ASSESSMENT IN PEER REVIEW-STATE OF THE ART**

## **CHALLENGES AND OPPORTUNITIES**

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# WHY THIS PRESENTATION?

- Overview of the ongoing activities
- Analysis of positive success stories
- Where can we improve?
- In the pipeline



- 114 a.s. at different level of processing!

- |  | A                    | B              | E      | F   | G  | H                     | I        | J   | K  |
|--|----------------------|----------------|--------|---|--|-----------------------|----------|-----|--|
|  | EFSA question number | legal deadline | Reg.   | Active substance  | Dossier (NAS) or Supplementary dossier (renewal) receipt | ED submission DL APPL | Stage    | RMS | Status                                     |
|  | Q-2018-00109         | Q1 2025        |        | Ziram   |  | 10/01/2022            | AIR III  | IT  | Evaluation of additional information on ED |
|  | Q-2016-00158         |                |        | Triticonazole   |  |                       |          |     | ED clock-stop                              |
|  | Q-2020-00616         | 11/07/2025     | PRE TR | Trichoderma harzianum T78                                       |  | 07/09/2022            | NAS 1107 | NL  | Reporting table at RMS level               |
|  | Q-2017-00277         | 23/12/2024     |        | Trichoderma gamsii strain ICC080                                |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2017-00276         | 23/12/2024     |        | Trichoderma atroviride strain T11                               |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2020-00328         |                | PRE TR | Trichoderma atrobrunneum (formerly T. harzianum) strain ITEM908 |  |                       | NAS 1107 | NL  | 1st clock-stop                             |
|  | Q-2017-00278         | 23/12/2024     |        | Trichoderma asperellum strain TV1                               |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2017-00145         | 18/03/2025     | PRE TR | Trichoderma asperellum strain T34                               |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2020-00633         | 23/12/2024     |        | Trichoderma asperellum strain T25                               |  |                       | AIR V    | SE  | Reporting table at RMS level               |
|  | Q-2017-00144         | 23/12/2024     |        | Trichoderma asperellum strain ICC012                            |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2017-00143         | 23/12/2024     |        | Trichoderma afroharzianum (formerly T. harzianum) strain T-22   |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2017-00279         | Q3/Q4 2024     |        | Thymol  |  |                       | AIR IV   | SE  | On hold                                    |
|  | Q-2021-00017         |                |        |   |  |                       | AIR V    | ES  | On hold<br>1st clock-stop                  |



# MANDATES RELATED TO PEER REVIEWED A.S.

## MRL: 14 outputs

(under negotiation, ongoing, almost finalised, on hold)

Article	Type of output	Question number	Substance	Subject	RMS	Status	
Article 43	Scientific report	<a href="#">EFSA-Q-2022-00739</a>	IESTI methodology	Scientific report on the methodology for the assessment of acute risks of pesticide residues	-	04. Scientific assessment ongoing	EF M 3C
Article 29	Scientific opinion	<a href="#">EFSA-Q-2022-00329</a>	Bromide	Risks for human health related to the presence of bromide ion in food and risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion in	-	04. Scientific assessment ongoing	TI Pt TI
Article 43	Scientific report	<a href="#">EFSA-Q-2024-00016</a>	Assessment of fall-back MRLs for revoked CXLs - related to CCPR mandate 2024	Assessment of fall-back MRLs for CXLs revoked in 2024 CCPR/CAC		04. Scientific assessment ongoing	
Article 43	Technical report	<a href="#">EFSA-Q-2022-00740</a>	IESTI methodology	Technical report on the methodology for the assessment of acute risks of pesticide residues	-	On hold	EF fi M 3I
Article 43	Statement	<a href="#">EFSA-Q-2023-00665</a>	Copper - revision MRL review	Update of maximum residue levels (MRLs) for copper compounds in light of the EFSA scientific opinion on the re-evaluation of the Health-Based Guidance Values (HBGV) and exposure assessment from all sources.	-	07. Under finalisation	Fc 2C Ai re cl M Se
Article 29	Scientific opinion	<a href="#">EFSA-Q-2021-00358</a>	Fluoride	Scientific opinion on fluoride in food and drinking water	-	04. Scientific assessment ongoing	O e

## Peer review: 17 outputs

(under negotiation, ongoing, almost finalised, on hold)

All columns to be updated by SCs							
Article	Type of output	Question number	Substance	Subject	RMS	Status	
Article 21	Statement		Flupyradifurone	EFSA is requested to provide scientific and technical assistance and to deliver a statement on whether flupyradifurone still fulfils the applicable approval criteria, considering the information submitted by the applicant, its		2. Under negotiation	
Article 31	Statement		Pelargonic acid	Follow up mandate to EFSA Conclusion on pelargonic acid (EFSA Journal 2021;19(8):6813) The mandate aims to explore the risk to NTAs for the representative home and garden uses of 'MON 74134' for NTAs applying WoE considerations and addressing also lower risk GAP conditions. Similarly, EFSA is requested to assess for all representative uses and using weight of evidence approaches, the potential for recovery of the non-target invertebrates for	EL	2. Under negotiation	T r c s e c z E M S k c p r v S
Article 31	Updated conclusion	<a href="#">EFSA-Q-2022-00756</a>	Rimsulfuron	Completion of the assessment of ED properties of rimsulfuron	SI	4. Scientific assessment ongoing	r S I s
Article 23	Statement	<a href="#">link to DMS Q-2024-</a>	chitosan and chitosan hydrochloride (basics)	EFSA is requested to provide a scientific opinion regarding the safety of the approved	N/A	4. Scientific assessment ongoing	

# WHAT IS WORKING WELL

- Solid group of MSs knowledgeable on ED (co-working with EFSA)
- MSs leading some areas of risk assessment
- MSs volunteering to support the revision of GD (many guidance!)
- MSs supporting EFSA on several files through
  - Tasking grant
  - Negotiated Procedures

*In addition ISA ( Individual Scientific Advisors ) scheme*



Thank  
You!



# WHERE CAN WE IMPROVE?

- Coordination with MSs activities with ECHA (biocides, classification and labelling, coformulants)
- Participation in peer review meetings
- Timeliness of work steps
- Resources



# WHERE CAN WE IMPROVE?

- **Coordination with MSs activities with ECHA** (biocides, classification and labelling, coformulants)

joint discussions

alignment

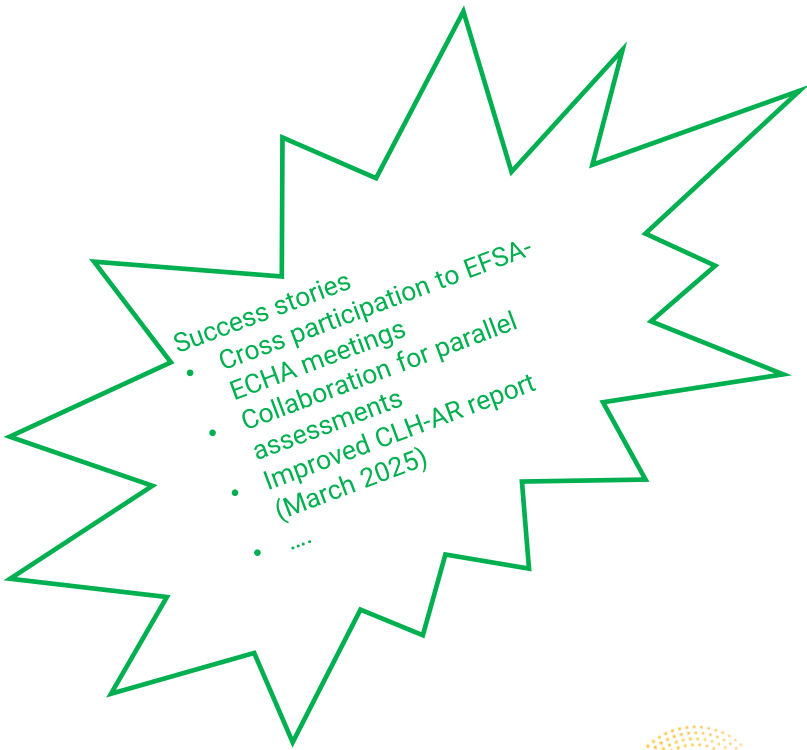
data sharing

## Questions for you:

Anything else we can do?

What are the issues you encounter?

Are you willing to share data? Are there blocking factors?

- 
- Success stories
    - Cross participation to EFSA-ECHA meetings
    - Collaboration for parallel assessments
    - Improved CLH-AR report (March 2025)
    - ....



# WHERE CAN WE IMPROVE?

- **Participation in peer review meetings**

- Number of experts (in 2023 on average <10 for mamtox; 15 for ecotox, 9 for residues)
- Duration of the meetings (many discussion points: result of incomplete assessment? Late discovery of issues?)
- Preparation and active role (e.g. dedicated presentations, key experts attending + junior colleagues as observers for learning purposes)
- Co-RMS: diversity of approaches
- Involvement of applicants as hearing experts

## Questions for you:

Would EFSA-RMS peer review preparatory meetings help)

Would it help creating dedicated working groups to support the preparation of discussions in peer review meeting or during pre-submission meetings?

Would a dedicated commitment to the preparation of specific areas/substances for each round help (e.g. MS X to support a.s. A and B, MS Y to support a.s. C and D)?





# WHERE CAN WE IMPROVE?

- **Timeliness of work steps**

- Time to adopt Conclusions of Pesticide Peer Reviews is, in the majority of cases, exceeding the maximum timeframe set out in the applicable regulation
- Quality of dossiers
- Quality of assessments (completeness check; no missing studies; reporting tables and evaluation tables; duration of experts' meetings)
- Role and involvement of applicants
- Impact on the assessment: eg outdated science, outdated literature searches

## Questions for you:

Are you considering dossiers even if not up to standards?

How does rework impact on your timetables?

Have you performed any internal analysis?



# WHERE CAN WE IMPROVE?

- Resources
  - Increased complexity
  - Transparency
  - Process
  - Tools

## Questions for you:

Do you see any margin to make the workflow less complex?

Can we optimise time and resources of some steps?

Can you identify bottlenecks, if any?

What are the most critical steps in your view?

Ideas?



# NEXT STEPS

- Collect your feedback (survey?)
- Propose solution measures (survey?)
- EFSA to prepare a workplan with actors and actions
- Rediscuss (next PSN)
- Piloting
- Implementing



# THANK YOU! - STAY CONNECTED

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