



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



CURRENT PEER REVIEW ACTIVITIES

- 114 a.s. at different level of processing!
 - Scientific check
 - Reporting table at MS
 - Column 4
 - Clock stop
 - Evaluation additional information
 - Experts' meeting
 - Output under finalisation
 - On hold

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	II	Evaluation of additional information on ED
Q-2016-00158								ED clock-stop
Q-2020-00616	11/07/2025	PRE TR	Triticonazole					Reporting table at RMS level
Q-2017-00277	23/12/2024		Trichoderma harzianum T78		07/09/2022	AIR III	AT	
Q-2017-00276	23/12/2024		Trichoderma gamsii strain ICC080					
Q-2020-00328	23/12/2024		Trichoderma atroviride strain T11					
Q-2017-00278		PRE TR	Trichoderma atroviride strain 778					
Q-2017-00145	23/12/2024		Trichoderma atrobrunneum (formerly T. harzianum) strain ITEM908					
Q-2020-00633	23/12/2024		Trichoderma asperellum strain TV1					
Q-2017-00144	18/03/2025	PRE TR	Trichoderma asperellum strain T34					
Q-2017-00143	23/12/2024		Trichoderma asperellum strain T25					
Q-2017-00279	23/12/2024		Trichoderma asperellum strain ICC012					
Q-2021-00017	Q3/Q4 2024		Trichoderma afroharzianum (formerly T. harzianum) strain T-22					
			Thymol					



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	EFSA-Q-2022-00739	IESTI methodology	Scientific report on the methodology for the assessment of acute risks of pesticide residues	-	04. Scientific assessment ongoing
Article 29	Scientific opinion	EFSA-Q-2022-00329	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
Article 43	Scientific report	EFSA-Q-2024-00016	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	EFSA-Q-2022-00740	IESTI methodology	Technical report on the methodology for the assessment of acute risks of pesticide residues	-	On hold
Article 43	Statement	EFSA-Q-2023-00665	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
Article 29	Scientific opinion	EFSA-Q-2021-00358	Fluoride	Scientific opinion on fluoride in food and drinking water	-	04. Scientific assessment ongoing

Peer review: 17 outputs

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

Article	Type of output	Question number	Substance	Subject	RMS	Status
All columns to be updated by SCs						
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
Article 31	Updated conclusion	EFSA-Q-2022-00756	Rimsulfuron	Completion of the assessment of ED properties of rimsulfuron	SI	4. Scientific assessment ongoing
Article 23	Statement	Link to DMS Q-2024-1	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



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?



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 seen 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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