



CURRENT SITUATION FOR ACTIVE SUBSTANCES EVALUATIONS AND APPROVALS

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OUTLINE

- Workplan peer review 2024
- Ad hoc mandates
- Lessons learnt:
 - new/emerging topics
 - most frequent issues not finalised
 - most frequent critical areas of concern
- Ongoing activities



PEER REVIEW

What we expect for 2024 based on MSs feedback

- AIR: 36 RAR
- NAS: 13 DAR



PEER REVIEW: 9 AD HOC MANDATES

Article	Type of output	Question number	Substance	Subject	Status
Article 31	Updated conclusion	EFSA-Q-2022-00756	Rimsulfuron	Completion of the assessment of ED properties of rimsulfuron in view of the renewal process under Regulation (EU) No 844/2012	4. Scientific assessment ongoing
Article 23	Statement	link to DMS Q-2024-00037	chitosan and chitosan hydrochloride (basics)	EFSA is requested to provide a scientific opinion regarding the safety of the approved use(s) of the substances chitosan and chitosan hydrochloride as basic substances. In particular: • mammalian toxicology: toxicological properties of chitosan and chitosan hydrochloride and possible bridging; • environmental fate and behaviour: investigation of the environmental levels 'naturally present' vs the ones resulting from the regulated uses (e.g. basics, novel food); • ecotoxicology: (this one only if triggered according to the e-fate outcome).	4. Scientific assessment ongoing
Article 31	Technical report	EFSA-Q-2023-00649	Co-formulants	Identification of co-formulants which fulfil criteria according to the Regulation (EC) No 574/2023. EFSA is requested to assess by which of the substances, if any, listed in the EFSA technical report mentioned above fulfil any of the criteria 1 to 9 in the Annex to Regulation (EC) No 574/2023 and are not already listed in Annex III to Regulation (EC) No 1107/2009.	4. Scientific assessment ongoing
Article 29	Statement		Rape seed oil, pelargonic acid, aluminium silicate, sulfur,	Env RA naturally occurring active substances	2. Under negotiation
Article 31	Reasoned Opinion	EFSA-Q-2022-00589	Acetamiprid	Scientific and technical assistance on toxicological properties and maximum residue levels of acetamiprid and its metabolites	4. Scientific assessment ongoing
Generic mandate	Updated conclusion		S-metolachlor	Update the conclusion on S-metolachlor with the ED assessment on HH	4. Scientific assessment ongoing
Article 31	Conclusion	Q-2024-000064	Difenoconazole	Mandate to EFSA to proceed with the organisation of a peer review on confirmatory data concerning difenoconazole	4. Scientific assessment ongoing
	Conclusion	Q-2019-00025	Phenmedipham	Update of the 'ED mandate' to cover also other aspects other than ED left open from the former conclusion (genotox and setting of TRVs)	4. Scientific assessment ongoing
Article 31	Updated conclusion	Q-2024-00098	Metalaxyl-M	Therefore, EFSA is requested to provide risk assessment conclusions for birds and mammals to take into account the following aspects. Given the current outcome, as reported in the ESFA Conclusion (2023), the assessment should be limited to the lowest application rate on spinach seeds. A consideration of lower, realistic seed sowing densities than the maximum value specified in the GAP should be undertaken – based on feedback from the applicant and from Member States, sowing densities for spinach range between 1-12 million seeds per hectare. A consideration of precision sowing techniques - Member States have confirmed that the use of precision drilling equipment for sowing of treated seeds is already being used and is a realistic method of application, therefore the use of such equipment should be taken into account in the risk assessment. The risk to birds and mammals in each zone of the EU should be reported, taking into account the relevant higher tier refinements (e.g., focal species).	4. Scientific assessment ongoing




PEER REVIEW

Hot topics in 2023

- Categorisation of data gap
- Coformulants
- Biodiversity
- Microbiome
- ED, CLP



PEER REVIEW: ISSUES NOT FINALISED

	Most frequent									
Phys chem	Reference specification	Reference specification	Level of impurities in tech spec vs tox batches	Reference specification	Reference specification vs mamtox batches					
Mamtox	Gentox potential of metabolites	Interspecies differences in metabolism	assessment of phototoxic and photomutagenic potential	Interspecies differences in metabolism	Phototoxicity	Immunotoxicity	Phototoxicity	Phototoxicity		
Residue	consumer dietary risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment	consumer risk assessment
Efate	hazard identification and additional contribution of the groundwater metabolites	Environmental exposure assessment								
Ecotox	RA honey bee larvae	Risk assessment to metabolites for birds and mammals and bees	Risk assessment to metabolites for aquatic and soil organisms	Aquatic risk assessment	Aquatic risk assessment	chronic risk to honeybee larvae	long-term risk to birds	Risk to honey bee larvae		
ED	ED assessment for the EAS-modalities for non-target organisms other than mammals	Assessment of the endocrine-disrupting properties for non-target organisms	Risk assessment for aquatic macrophytes due to contact exposure via spray drift	ED potential for NTO for T-modality	ED potential for NTO for EAS-modalities					

PEER REVIEW: CRITICAL CONCERNS

	Most frequent									
Phys chem	Technical specification not covered by the (eco)toxicological assessment									
Mamtox	Non dietary RA	bystander and resident exposure estimates	Harmonised classification Repro 1B	Non dietary RA						
Residue										
Efate	High potential for groundwater contamination by groundwater relevant metabolites									
Ecotox	High acute risk to aquatic invertebrates	available higher tier studies for bees were not sufficient to exclude high risk to bees	high long-term risk for wild mammals	high risk to aquatic organisms	high in-field risk for NTAs					
ED	ED criteria met for the T-modality for humans	ED criteria met for humans and wild mammals as non-target organisms for the EAS-modalities	ED criteria met for humans and wild mammals as non-target organism	ED criteria met for humans for the T-modality						



ONGOING ACTIVITIES

- Environmental neurotoxics
- EFSA pesticides genotoxicity database
- Development of a semi-automated workflow in the OECD QSAR Toolbox for data gathering and decision scheme for toxicological assessment of metabolites
- Evaluation of new evidence on Non-Dietary Exposure to Plant Protection Products for the next update of the OPEX Guidance and Calculator
- Develop an AOP network for mammalian reproductive toxicity originating from disruption of the EAS signalling
- Generate data on food consumption of bees
- PERA - Advancing the ERA of PPP to system-based approach
- CRA of pesticides





Thanks for your attention



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