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INTRODUCTION	METHOD
Low-Concern Active Substances (LCAS) are active substances with a favourable hazard profile and low concern for human health and the environment such as inorganic substances and biopesticides (= botanical active substances and active substances of natural origin including microbials and semiochemicals). In line with the EFSA Supporting Publication by Vryzas et al. (2025)¹, groundwater (GW) risk assessment strategies considering factors such as natural occurrence, distribution in the environment, and biodegradability have been developed . To evaluate whether such approaches are supported by EU regulatory practice, a review of previously assessed inorganic substances and biopesticides was conducted, focusing on cases where: • GW modelling was waived, • Natural occurrence was considered sufficient justification enabling a tailored assessment, • Representative compounds or metabolites were used, • Conservative worst-case assumptions were applied.	Approved active substances were retrieved from the EU Pesticides Database² (Regulation (EC) No 1107/2009). Inorganic substances and biopesticides were divided into LRAS (Low Risk Active Substance) or non-LRAS following the classification according to Regulation (EC) No 1107/2009. The dataset includes: - 21 inorganic substances (8 LRAS, 13 non-LRAS) - 28 biopesticides (10 LRAS, 18 non-LRAS) EFSA Conclusions, peer review reports as well as e.g. DARs and RARs were reviewed for each substance. The analysis focused on GW exposure assessment, especially arguments used for waiving GW risk assessment. The utility of worst-case assumptions and default parameters, and justifications based on natural occurrence, biodegradability or physicochemical properties were assessed. LRAS and non-LRAS substances were compared to evaluate consistency with the recent publication by Vryzas <i>et al.</i> (2025). Only the most illustrative case studies are presented.

RESULTS

	Inorganic Substances		Biopesticides	
Assessment details	LRAS	Non-LRAS	LRAS	Non-LRAS
GW risk assessment	Generally not performed	Generally performed	Variable approaches: some substances assessed using conservative FOCUS GW modelling, others exempted due to e.g. natural occurrence, and biological origin.	Variable approaches: majority of substances assessed using conservative FOCUS GW modelling others exempted due to e.g. background levels, volatility.
Examples for active substances	Calcium carbonate, Quartz sand, Iron, Ferric phosphate, Ferric pyrophosphate, KHCO ₃ , NaHCO ₃ , Aluminium silicate	Copper, Aluminium ammonium sulphate, Iron sulphate, Aluminium phosphide, Sulphur (sulphates), Potassium phosphonates	Assessed: Gibberellins, Maltodextrin, Hydrolysed proteins exempted: COS-OGA, Lavandulyl senecioate and Heptamaloxylglucan	Assessed: Abamectin, Margosa extract, Extract from tea tree, Geraniol, Clove oil, Spear mint oil, S-abscisic acid exempted: Garlic extract, Limonene – main component of Orange oil.
Adapted approaches for GW modelling	Not required	Applied when standard approaches were unsuitable (e.g. Copper).	Applied, often using representative worst-case constituent(s) (e.g. Hydrolysed proteins).	Applied, often based on comparison with natural background levels (e.g. Garlic extract).
General waiving based on natural occurrence / background concentrations	Main argument. Natural constituents of geological formations and aquifers (e.g. Calcium carbonate, Quartz sand). Application rates lower than background levels.	Considered, but generally not sufficient alone to waive GW risk assessment. Background concentrations often incorporated into risk assessments.	Not always sufficient to waive GW risk assessment (e.g. Gibberellins, Hydrolysed proteins, Maltodextrin).	Not always sufficient to waive GW risk assessment (e.g. Extract from tea tree, Geraniol, Clove oil, Spear mint oil, S-abscisic acid).
Selection of representative compounds or transformation products	Low relevance. Transformation products not considered relevant metabolites.	Low relevance.	Important for mixtures, UVCB, e.g. Glycine as surrogate (Hydrolysed proteins) or worst-case metabolites (Gibberellins).	Important for plant extracts and mixtures depending on their complexity and characteristics, e.g. Pyrethrins: Pyrethrin I was accepted as a representative compound, whereas for Margosa extract, Azadirachtin A as leading compound is under discussion.
Importance of worst-case assumptions for GW modelling	Not required	Worst-case assumptions applied where necessary.	Based on conservative default parameters, except where experimental values represented a more conservative worst-case scenario, in which case these values were used in preference to the defaults (e.g. Laminarin).	Experimental parameters were frequently replaced by conservative default values. Where experimental parameters resulted in a more conservative (worst-case) estimate, these values were retained.
Drinking water limits	Comparison with 0.1 µg/L generally not required.	Substance-specific reference values applied.	Comparison with 0.1 µg/L required, but exceptions possible.	Comparison with 0.1 µg/L generally required.
Frequently used additional arguments for inorganic substances				
	LRAS		Non-LRAS	
Solubility	Low solubility/insolubility limits leaching potential (e.g. Elemental Iron, Ferric phosphate, Ferric pyrophosphate).		Mobility assessed case-by-case despite low solubility or dissociation properties.	
Dissociation products	Rapid dissociation into naturally occurring substances (e.g. water, CO ₂ and ions).		Dissociation products evaluated according to environmental behaviour, i.e., speciation).	

CONCLUSION

The analysis demonstrates that EU GW risk assessments already incorporate substantial flexibility through waivers, alternative modelling approaches and substance-specific considerations. Vryzas et al. (2025) highlights similar alternative methods but embedded in an innovative fit-for-purpose approach. This approach provides a structured methodology based on problem formulation, pathways to harm and likelihood assessment which could considerably support the implementation of alternative methods. As also identified in this analysis, clearer criteria are required for negligible exposure, natural occurrence, and the use of representative compounds. Methodological development is still needed for inorganic substances, highly volatile compounds and complex natural mixtures. Overall, this approach may enhance consistency across regulatory assessments while maintaining current protection goals

¹ Vryzas *et al.* (2025). Fit-for-purpose and innovative risk assessment for low-concern pesticide active substances and uses. EFSA Supporting publication 2026:EN-9791. 42 pp. doi:10.2903/sp.efsa.2026.EN-9791

² <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances> (last access: 12.08.2026)

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