Misimplementation of Pesticide

Regulation 1107/2009 by Member States

Pesticide Action Network (PAN) Europe
16 January 2025
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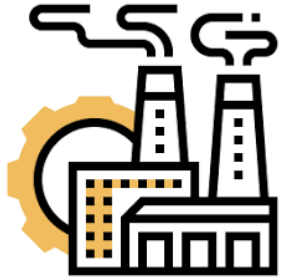
Regulation (EC) 1107/2009 *aka EU pesticides Law*

- To ensure "**a high level of protection for humans, animals and the environment**"
- Pay attention to the protection of **vulnerable** groups (e.g children)
- Consider the toxicity of active substances, products & their ingredients, residues & mixtures
- Ban hazardous chemicals from agriculture: Carcinogens, Mutagens, Toxic to reproduction, Endocrine disruptors, PBTs… (i.e. cut-offs) as well as neurotoxic, immunotoxic & toxic to bees
- Apply the Precautionary Principle

Pesticide active substance EU approval process



Pesticide Active Substance
(data requirements, reg. 283/2013)

Rapporteur Member State (RMS)

EFSA

Risk Assessment

ECHA

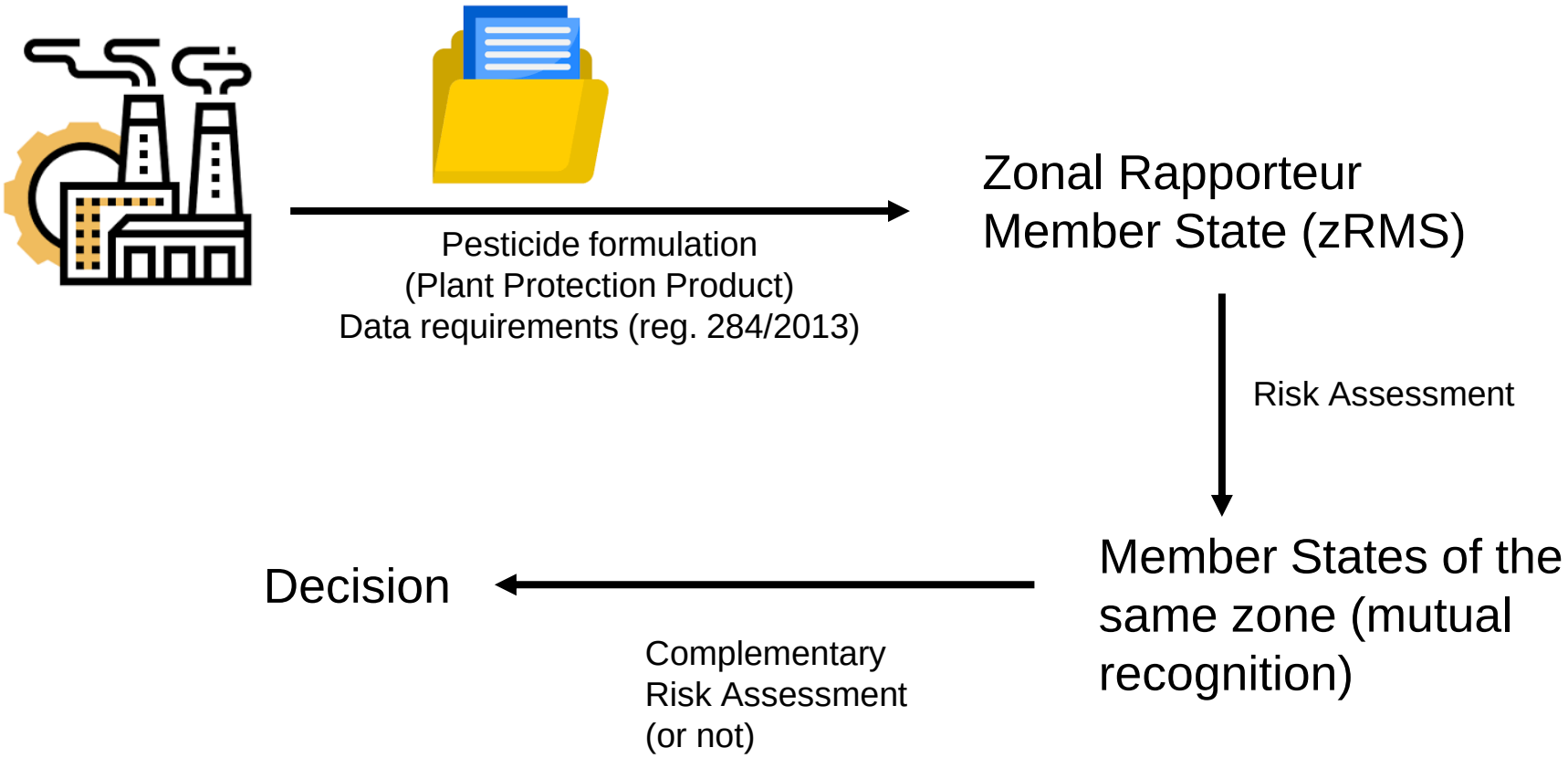
Hazard Assessment

European Commission

Standing Committee on phytopharmaceuticals (SCOPAFF)

Vote
(EC decision)

Pesticide formulations' approval process



Issue n°1: risk assessment for humans

- Pesticide formulation = a.s + co-formulants + safeners + synergists
- Synergies exist within the different substances of a formulation
- Member States must ensure that formulations have no effect on human health: acute and chronic toxicity
- Chronic (long-term toxicity) not assessed: carcinogenicity, mutagenicity, toxicity to reproduction (CMRs) and endocrine disruption (EDs): NO DATA REQUIREMENT (only for acute toxicity)
- DG Sante developing a “methodology” to risk assess long term toxicity; methodology based on single substances’ risk assessment

Issue n°1: risk assessment for humans

- Single-substance approach: synergies disregarded, which article 4 states that “PPPs shall have no unacceptable effect”

- Co-formulants: no data requirements; no CMR+ED assessment: MSs do not ensure that co-formulants have no long-term effect on human health as they do not ask for the missing data

- Possible legal action: challenge the non-evaluation of the long-term toxicity of formulations

Issue n°2: no taking into account of latest scientific or regulatory knowledge

- Art. 44: Withdrawal or amendment of the authorisations.

- §1: when a pesticide does not meet the safety criteria, MSs must adapt/withdraw authorisations. Ex.1: Thiacloprid was classified as R1B in 2015, which led to an EU ban in 2019. Reg. 1107/2009 forbids uses of R1B (unless negligible exposure). All outdoor uses should have been banned by MSs as from 2015.

- §3(a): if industry fails to respect reg. 1107/2009. Ex3: industry hid neurotoxicity studies to regulators for a series of a.s. No Member States has withdrawn the authorisations of such products.

Issue n°2: no taking into account of latest scientific or regulatory knowledge

- Art. 44: Withdrawal or amendment of the authorisations.

- §4: When a MSs bans a pesticide, MSs from the same zone should withdraw the authorisations of similar pesticides unless they can prove their national conditions must not lead to the same conclusions. Ex.2: Three cyazofamid-based pesticides were banned in January 23 as metabolites leak into groundwater. No Member State has acted.

Issue n°3: environmental risk assessment

- Reg. 1107/2009: no unacceptable effect on biodiversity and the environment; no unacceptable effect on bees

- Ex1: insects: when exposed to an environment that has been sprayed with a glyphosate-based herbicide, 100% of the tested insects die. 100% = unacceptable: this pesticide should not have been authorised.

- Ex2: abamectin restricted to greenhouses (= closed system) in 2023 in the EU as too toxic to aquatic life and non-target arthropods. MSs keep authorising abamectin-based insecticides in ‘leaky greenhouses’.

Issue n°4: administrative

- Ex: completeness check not done: MSs accept incomplete dossiers that leads to lengthy processes of asking for additional data, prolonging EU approvals or national authorisations for years
- Ex: deadlines for decision-making: Member States have 15 months to take a decision on a renewal process. It often takes them years because they are understaffed. They underuse the possibility to raise fees allowing to meet EU- and national deadlines.

Thank you

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