



# REFIT

of the Pesticide (EC 1107/2009) and Maximum Residue Limits in food (EC 396/2005) Regulations

## PAN-Europe observations

### Summary

The [REFIT evaluation](#) is a big disappointment. Commission claims that the pesticide Regulation has been effective to fulfil its goals “to a large extent”. However, no evidence is provided to assess whether the purpose of the Regulation to ensure a high level of protection of both human and animal health and the environment has been fulfilled. The claim is unsubstantiated [see point 1, ‘Pesticide policy- effective?’].

Moreover, the major problems of pesticide decision-taking process are not addressed. For example, the lack of testing for a range of health problems, the conflicts of interests with industry that designs its own guidelines, the failure to look at and incorporate independent literature in the assessment [see point 2, ‘Main problems - NOT considered’]

A large part of the REFIT report is dedicated to topics that aim to reduce the costs for industry. Elements like zonal authorisation, mutual recognition and minor uses constitute a big part of the report. These topics receive disproportionate attention compared to the real problems of the pesticide authorisation procedure [see below, point 3, ‘Cost reduction - for the industry’]. Evidently Commission’s ‘traditional love’ for the industry is by far, not over yet.

### 1. Pesticide Policy- effective?

The pesticide legislation is according to the published report “largely effective in protecting human health and the environment”. During the discussions, the RSB (Regulatory Scrutiny Board) had asked questions about this conclusion (cut-off criteria challenged, candidates for substitution not working, emergency authorisations increase by 300%, lack of cumulative assessment, etc.). Based on these remarks, DG SANTE, in the beginning of 2019, replied that “the conclusion will be revised to provide a more nuanced picture as regards the protection of human health”, however we see that this has not been the case.

Nevertheless, the legislation has the potential to be effective, but this potential remains to be materialised for various reasons. Some examples are the massive delays, derogations like Art. 53 misuse (emergency authorisations) [PAN-Europe’s reports [Chemical Agri](#)] and the approval of dossiers that fail to respect the criteria [PAN-Europe’s report [Resubmission](#)], the illegal agreements on overlooking environmental impact and the still ruling industrial agriculture with the ever increasing pesticide resistances.

Below we provide some evidence that the Regulation has not been properly implemented:

- There is a complete lack of pesticide use data and the Commission has no idea in which crops the use of pesticides has increased and in which ones has decreased. Most likely, the spraying frequency has increased in most crops due to increased resistance of pests against pesticides (for instance Italy sprays 110 different pesticide products on its wine grapes in one season, Belgium 82 on its potatoes, EFSA 2015<sup>1</sup>);
- The Commission also has no clue whether the harm to human health due to pesticide use has increased or decreased in the past decade. Most likely, the harm has increased due to the presence of a permanent layer of pesticides over large areas inside and outside agricultural fields<sup>2</sup>, or due to the chronic exposure to pesticides particularly of babies, children and the vulnerable groups of our population, or due to the cocktails of pesticides we're exposed to via food, water and air;
- The most hazardous pesticides are only now, 9 years after the Regulation came into force, starting to get banned after being kept in the market with the notorious derogation "prolongation" [PAN Europe's analysis [SANTE's prolongation policy](#)].
- The endocrine disrupting pesticides are still not tested with the appropriate tests [PAN Europe report [A vicious circle](#)], preventing their identification and ban;
- Consumers are still not protected from mixtures of pesticide residues. 15 years have passed since the pesticide Maximum Residue Limits Regulation 396/2005 entered into force calling to protect consumers against the harm caused by pesticide cocktails in food (25% of all food is with multiple pesticides<sup>3</sup>) yet the health impact of these food pesticide cocktails remains to be assessed. The claims that food is safe is scientifically untrue.
- The Commission and Member States agreed in 2005 (silently and evidently not in line with the law) to stop evaluating the risks of pesticide use for the environment (to birds, bees, insects etc) and approve the use of pesticides no matter how high the risks for the environment were. The collapse of biodiversity and ecosystems in agricultural areas is a clear sign that the pesticide system fails to protect the environment<sup>4,5</sup>;
- Half of the pesticide residue limit standards (MRLs) that were "relaxed" ('harmonised') in 2005 without a scientific justification, remain to be reviewed by EFSA and have not been reduced yet;
- On a large-scale, EU Member States implement 'minor uses', a system that allows pesticides to be used without a proper assessment; this is illegal while 'minor' in many cases is simply deceiving.

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<sup>1</sup> David Garthwaite et al., Collection of pesticide application data in view of performing Environmental Risk Assessments for pesticides, EFSA supporting publication 2015:EN-846

<sup>2</sup> Buijs. J. & M. Mantingh. 2019, Een onderzoek naar mogelijke relaties tussen de afname van weidevogels en de aanwezigheid van bestrijdingsmiddelen op veehouderijbedrijven, Commissioned by Province of Gelderland.

<sup>3</sup> EFSA (European Food Safety Authority), 2019. Scientific report on the 2017 European Union report on pesticide residues in food. EFSA Journal 2019;17(6):5743, 152 pp. <https://doi.org/10.2903/j.efsa.2019.5743>

<sup>4</sup> Francisco Sánchez-Bayo, Kris A.G. Wyckhuys, Worldwide decline of the entomofauna: A review of its drivers, Biological Conservation 232 (2019) 8–27

<sup>5</sup> Hallmann CA, Sorg M, Jongejans E, Siepel H, Hofland N, Schwan H, et al. (2017) More than 75 percent decline over 27 years in total flying insect biomass in protected areas. PLoS ONE 12 (10): e0185809.

<https://doi.org/10.1371/journal.pone.0185809>

## 2. Main problems - NOT considered

- **Insufficient safety testing.** For instance, there are no mandatory safety tests for pesticides on immunotoxicity, endocrine disruption and developmental neurotoxicity; several 'insensitive' protocols are used (low dose exposure, non-monotonic, in-utero exposure and sensitive endpoints are missing). This means that many potential (serious) adverse effects caused by exposure to pesticide will remain unnoticed;
- **Safety testing is done by the industry** for its own products- this is a huge conflict of interest. In the meantime, toxic effects might be kept hidden or results distorted;
- **Independent academic peer-reviewed literature is dismissed** as a source for information on the toxicity of chemicals [PAN Europe's analysis- [Missed & Dismissed](#)]
- **Guideline methodologies developed in collaboration with the industry.** Many of the guidelines for risk assessment used by Food Authority EFSA have been developed and promoted by industry and industry lobby groups and are biased to create a 'desired' outcome [PAN Europe's report [Writing IOR](#)]
- **Final decisions are not scientific.** In the final (political) step of decision-taking on pesticides by the different EU ministries of agriculture coordinated by EU Commission (DG SANTE), science is many times violated and derogations (e.g. 'confirmatory information'<sup>6</sup>) are applied on a large scale to give pesticide substances a market access, despite scientific data gaps
- The **close connections of industry** with EU institutions and the unbalanced decision-taking [PAN Europe's report on TTC [Toxic mixture](#) and on cumulative effects [Poisonous injection](#)]  
The completely **failure of the implementation of the Sustainable Use Directive 128/2009**, where member states failed to implement the Directive and the sustainable farming methods as required

## 3. Cost reduction - for the industry

- A major point made by Commission is the zonal authorisation and mutual recognition. Commission concludes that Member States are reluctant to use mutual recognition. PAN Europe is happy with this reluctance because with the current system the mutual recognition only serves to lower costs for the industry on the expense of the environment and biodiversity (allowing the environmental risk assessment to be bypassed). Only if pesticide products are thoroughly assessed for long term toxicity with sensitive tests and the number of pesticide products authorised is significantly reduced, such a system could be beneficial to increase the protection of human health and the environment from pesticide exposure.
- The eternal discussion on the hazard approach and the criticism by WTO/trading countries is repeated and Commission rightly defends the Regulation and its hazard-based approval criteria. We welcome its proposal to consider environmental aspects when assessing requests for import tolerances for substances no longer approved in EU to protect the competitiveness of EU agriculture, as well as the environment in third countries.

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<sup>6</sup> Data requirements are not met or risks for the environment are too high, and still the active substance is approved, to allow industry to supply 'information' at a later stage, while the pesticide is applied on the fields.

See also:

- [Citizens for Science in Pesticide Regulation](#) coalition website
- Robinson et al, 2020. Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions. *European Journal of Risk Regulation* 1-31.

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