PAN Europe's briefing on REFIT of PPP and MRL Regulations (EC No 1107/2009 and 396/2005)

1. Overall

The REFIT evaluation of the Pesticide and MRL Regulation[1] recognises the important value of the Pesticides Regulation that aims "to ensure a high level of protection for humans, animal and the environment" and sets clear hazard-based cut-off criteria for the approval of active substances. Nevertheless, the evaluation falls short in identifying several important shortcomings of the current pesticide authorisation system – raised by civil society, scientists and policy makers- that obstruct the Regulation to fulfil its purpose.

Strangely enough, rather than evaluating the Pesticide's Regulation central aim "to ensure that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment", the Commission chooses to evaluate whether the Regulation has been successful "to minimise their impact on human health and the environment".

By tweaking the central aim of the Pesticide Regulation, the Commission concludes that the two Regulations **are generally effective**, in particular with regard to the protection of human health and the environment. This is due to the hazard-based approval criteria[2] for pesticide substances and although we disagree that they have been properly implemented, we are pleased that their value is recognised. Further, the report concludes that the Regulations are **not entirely efficient** and, in several areas, burdens can be reduced. Here the Commission refers to administrative burdens. **Coherence** across Regulations (among EU legislation and non-EU one) **is ensured**, and both **Regulations are relevant** for the needs of society and towards Sustainable Development goals. The Commission highlights the need to reduce the dependency on chemical pesticides and contribute to more sustainable food production systems (in line with European Green Deal, Farm to fork and Biodiversity strategies).

The Commission proposes 16 areas where actions can be taken to improve the implementation of the Pesticides Regulation, under 8 sections/objectives of the two Regulations. Most of these actions are directed to the Member States and the Commission seems to take little commitment to revise the quality of its own procedures.

Considering that the Farm to Fork and Biodiversity strategies call to reduce pesticide use and risk reduction 50% by 2030 and hazardous pesticides by 50%, it will be impossible to truly reach these targets if all the shortcomings of the current pesticide authorisation system are not addressed and resolved to ensure that pesticides that cause harm to human health and the environment are properly identified.

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[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0208

[2] According to the Pesticide Regulation 1107/2009 active substances that meet the hazard cut-off criteria cannot be approved in the EU or can only be approved under restricted conditions. These are active substances that fall under the following classes of hazardous chemicals: mutagenic; carcinogenic; toxic for reproduction; have endocrine disrupting properties; are persistent organic pollutants (POPs); are persistent, bioaccumulative and toxic (PBT); or are considered to be very persistent and very bioaccumulative (vPvB).

2. Background

The need to address the shortcomings of the Pesticide authorisation system in Europe have been previously addressed by the European Parliament (in September 2018[3] and January 2019[4] by the PEST Committee) as well as by the Civil Society in a manifesto[5] (Coalition Citizens for Science in Pesticide Regulation) and recently by a group of experts in law, policy, and toxicology in an academic publication[6].

For civil society, the most important element of the European Regulation on pesticides 1107/2009 is that it aims to ensure "a high level of protection for humans, animals and the environment". For this, the Regulation requires that the assessment of a pesticide active substance is "independent, objective and transparent" and is performed "in the light of current scientific and technical knowledge". It is "underpinned by the precautionary principle" to ensure that pesticide substances or products placed on the market "do not adversely affect human or animal health or the environment".

However, a growing body of evidence shows that the Regulation is not implemented properly in practise as several pesticides that have passed through this process and are authorised for use may harm humans, animals and the environment.

In the Public Manifesto, European Citizens call upon Regulators to urgently reform the current pesticide risk assessment and risk management system, and suggests practical solutions to the major failings.

These fall under three sections and can be summarised as follows:

A. Prioritise public health, the environment and sustainable agriculture – pesticides must be used only as a last resort when all other non-chemical alternatives have been applied and failed.

B. Ensure that decision makers rely on data that is complete, public, up to date and free from industrial bias – safety testing must not be carried out by the pesticide industry itself and data requirements for pesticides should be updated according to the most recent scientific findings to address human developmental diseases and impact on ecosystems.

C. Enable decision makers, civil society and the scientific community to scrutinise the integrity and effectiveness of European pesticide policy – results and data of all pesticide safety tests shall be published on the internet in a consistent and searchable format.

In relation to the pesticide authorisation procedure, experts have identified the following shortcomings that urgently need to be resolved:

- Widespread misuse and misinterpretation of scientific research, with cherry-picking of favorable (for approval) studies, plagiarism and uncritical repetition of findings presented as independent validation, and misuse of statistical and analytical tools

[3] https://www.europarl.europa.eu/doceo/document/TA-8-2018-0356_EN.html
[4] https://www.europarl.europa.eu/doceo/document/TA-8-2019-0023_EN.html
[5] https://citizens4pesticidereform.eu/wp-content/uploads/2018/10/Manifesto_Citizens-for-Science-in-Pesticide-Regulation_30102018_Final.pdf
[6] 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. https://doi.org/10.1017/err.2020.18

- On going failure to address mixture effects (formulations or mixtures of pesticides), including of additives which, even though they can change the toxicity profile of the active ingredient, are not part of the pesticide approval process
- Failure to properly address conflicts of interest within regulatory agencies, undermining the independence and objectivity of pesticide assessments.

In addition, there is a clear lack of data when it comes to pesticides, particularly in relation to:

- Pesticides used in Member States, types and quantities per crop, including spraying frequency
- Monitoring data on human and environmental levels of pesticides, with a link to epidemiology data and field research.

Finally, the civil society has criticised repeatedly the shortcomings of the current environmental risk assessment procedure that fails to protect the environment and its ecosystems from the harm cause by pesticides, contributing to the biodiversity degradation we experience today.

3. Findings

Some of the shortcomings of the pesticide regulation have been identified in the REFIT evaluation, but the weight is given predominately to the Member States and not to the quality of the procedure itself. Several other shortcomings were not identified at all, whereas the Commission seems to be giving particular attention to practices that are risking to lower the level of environmental protection and reduce industry costs.

The shortcomings that have been addressed by the Commission are:

- Rapporteur Member States (RMS) must only accept complete dossiers of high quality as admissible. *Here we understand that dossiers of poor quality or data deficient (including missing out academic peer reviewed literature) should not be considered admissible, as explained in SWD*
- Resources and expertise must be improved in Member States
- RMS should not continue the risk assessment if the cut-off criteria are met
- It commits to improve the comparative risk assessment of PPP that contain active substances that are candidates for substitution- in order for them to be substituted with substances (or practices) of lower or no risk.
- It commits to intensify the monitoring of environmental concentrations and effects, as part of the Green Deal, and where necessary to set obligations to monitor AS and metabolites in the environment in the approval decisions
- Will update the Guidance Documents on environmental risk assessment methodologies and also examine whether all relevant non-target species are included
- Addresses the problem of the abuse of the “emergency authorisations” by Member States and commits to take actions and prevent these
- It commits to improve the procedures for the authorisation of low-risk or basic substances and boost their availability; support training in MS on the use of microorganisms and biopesticides, and research programmes on sustainable plant protection methods.
- It calls MS to implement the principles of IPM and via CAP to implement methods and practices targeting reduction of pesticide use and use of alternative methods
- Commits to strengthen the enforcement of PPP and MRL Regulations in relation to use of illegal products or placing foods in EU marker that contain pesticides above the legal limits.

- Commits to consider environmental aspects (not only human-health ones) when assessing requests for import tolerances for substances no longer approved in the EU while respecting WTO standards and obligations; to promote more selective and less toxic substances as alternatives to older and more toxic substances in non-EU countries

The shortcomings that are missing are:

- Taking responsibility for requesting "confirmatory information" in relation to data-gaps in the dossiers after proposing a renewal for an active substance and committing to put an end to this practice, as also addressed by Ombudsman in her letter to the President of the Commission[7].
- Committing to stop prolongations of the approvals of pesticides that meet the cut-off criteria
- Improving the scientific quality and objectivity of the assessment by implementing the principles of systematic review and strengthening the independence policy throughout the authorisation process. The Commission should ensure that there is no conflict of interests in experts involved in any stage of the process and should consult experts with no ties to pesticides industry to:
    - Revise and update all guidance documents used in risk assessment, especially the old ones
    - Update data requirements and include sensitive toxicity studies
    - Revise previous scientific assessments for bias in the reporting of adverse effects (misinterpretation of data, misuse of statistical and analytical tools, lack of scientific studies cherry picking of favourable studies, plagiarism) and set directions to avoid such errors in the future
- Start setting up a system for centralised independent testing, where pesticide industry is not carrying out the testing of its own products
- Committing to collect data on types and quantities of pesticide used in agriculture in Member States, and make it publicly available
- Evaluating thoroughly the toxicity of pesticide formulations as sold and used rather than just the isolated "active" ingredients that are tested and assessed for safety in regulatory purposes – since the formulations can be far more toxic.
- Taking action to address the issue of exposure to mixture and pesticides and other chemicals. The Commission should propose to incorporate a mixtures assessment factor for pesticide residues found in food or in the environment.
- Ban the export of EU-banned pesticides to third countries, including of coated seeds

Some particular worrisome additions are:

The Commission is committing to take actions on:

- Zonal System. Recommending to "remove" national requirements for PPPs without ensuring that the most protective methodology is dangerous and may lower the level of protection in certain EU regions.

[7] Letter from the European Ombudsman to the European Commission on the Preliminary findings of the European Ombudsman in the joint cases 1570/2018/JF-JN and 1973/2018/JF-JN on how the European Commission approves substances used in plant protection products (pesticides) https://www.ombudsman.europa.eu/en/correspondence/en/129445

- Minor uses. Extending “minor” uses is already happening, and since there are no environmental protection for minor uses, extending the number of crops that are called minor is dangerous.