European Crop Protection

POSITION PAPER
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ECPA Position Paper on the REFIT evaluation of Regulations 1107/2009 and 396/2005

The European Crop Protection Association welcomes the REFIT exercise for the two key pieces of EU legislation that regulate the plant protection sector delivering a high level of protection of both human and animal health and the environment and at the same time safeguarding the competitiveness of EU agriculture: *Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market* and *Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin*.

We believe that any necessary improvements in the system can be achieved by ensuring better and stronger implementation of the current system that is widely acknowledged to be the most stringent in the world, rather than through the need to re-open the legislation.

The suggestions made by ECPA in this document support the following objectives, in line with the Commission's Better Regulation principles:

- **Greater coordination** in the evaluation of both active substances and products
- **Simplification** and streamlining of complex processes
- **Improved efficiency** in the evaluation and decision-making procedures
- **Scientifically robust decision making** based on risk assessments, sound and workable guidance and clear criteria agreed at international level
- **Support of food and feed trade** within and outside of the EU

ECPA's recommendations on the better implementation of Regulation No 1107/2009

- **Involve Member States more consistently in developing and updating scientific guidance.** Technical guidance documents are currently developed by the European Food Safety Authority (EFSA). Given that Member States are the ultimate users of this guidance, ECPA believes that they should be involved in the development of these guidance documents. The Commission should also take a more active role in coordinating this work, proposing new or updating old guidance documents if/when necessary. Whether the Commission mandates a Member State or EFSA to develop or update a guidance document, it is important that all Member States contribute to the content and that the guidance is tested for fitness prior to implementation. A study commissioned by the European Parliament's PEST Committee highlighted the complex set of guidance documents that already exist, with some including requirements for which no validated test guidelines exist and there are some data requirements for which there are no guidance documents or guidelines[1].
- **Increase the efficiency of the zonal system.** The zonal system could be a more effective process for work sharing, however so far this has not been optimised. Some evaluations are substantially delayed beyond the legal timelines provided by the current legislation. Member States should systematically contribute comments to the evaluation of the zonal Rapporteur Member State in order to increase trust in the latter's conclusions and minimise duplication. ECPA believes that a significant part of the zonal evaluation could be conducted inter-zonally, so that zonal rapporteurs can focus resources on truly zonal issues.
- **Ensure experts can have dialogue as necessary.** Currently, there is very limited contact between the experts at EFSA and those working for the applicant. Applicants do not have a concrete list of tests and studies that are required to authorise their active substance or PPP, which means that they cannot guarantee to provide all the studies to meet the requirements of evaluators. It is important that notifiers and evaluators have the opportunity to discuss and provide clarity on exactly what information is

[1] Nganga, J., Bisonni, M., & Christodoulou M., (2018), 'Guidelines for submission and evaluation of applications for the approval of active substances in pesticides', pg. 45-48. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2018/626072/IPOL_STU(2018)626072_EN.pdf

needed at the start of the process. We strongly believe that a formal opportunity for direct dialogue would significantly improve the robustness of the review, transparency and the overall predictability of the approval process. This can be done by agreeing in advance exactly what data need to be generated. The recently amended General Food Law regulation will encourage such exchanges through the mandatory notification of studies and the pre-submission advice of EFSA. Issues could also be clarified by expert scientific exchanges as needed during the active substance review. It is interesting to note that procedures for the pharmaceutical sector allows such dialogue throughout the review procedure.

- **Perform more efficient controls of illegal and counterfeit pesticides.** ECPA believes that Article 68 of Regulation No 1107/2009 could be better implemented. We welcome the excellent work that has been carried out by Europol's Silver Axe Operation, seizing 1222 tonnes of illegal or counterfeit products since its launch[2]. We would recommend a broader scope and higher frequency of controls at the operator level (eg. suppliers, producers / manufacturers, importers / exporters etc). We also promote more harmonised control methods across countries at the EU external and internal borders and increased sanctions at EU level.

ECPA's recommendations on the better implementation of Regulation No 396/2005

- **Streamline MRL setting and PPP authorisation processes for a more predictable system.** The authorisation of commercial plant protection products (PPPs) cannot be granted unless appropriate MRLs have been set. This has a big impact on the predictability of the regulatory system, where use of a new, authorised PPP can be delayed unnecessarily for around a year. Minimising delays in MRL setting may be achieved by: i) ensuring as often as possible that the Evaluating Member State for MRLs (EMS) is the Rapporteur Member State for the active substance assessment (RMS), so that the knowledge of the active substance is applied to its MRLs; and ii) submitting the application for MRLs, where possible, 6-9 months earlier than for the PPP authorisation so that assessment processes complete at roughly the same time.
- **Coordinate the review of MRLs with that of active substances and PPPs to avoid undue delays.** Following the review of an active substance, delays can often occur when there are new 'end points' set which requires a full review of all MRLs. The review of MRLs, outlined in Art.12 of 396/2005, should be coordinated with the review of the active substance or PPP (Art.14 and Art.43 of 1107/2009 respectively) as consistently as possible. Reviews of MRLs should involve dialogue with applicants as often as necessary to ensure that the review process is fully informed.
- **Provide transitional MRLs to facilitate trade and avoid disruption for EU farmers.** When the end points change following a review of an active substance, which requires the amendment of MRLs, ECPA believes that the existing MRLs and labels should be maintained during a "period" during which the necessary information will be generated and, where necessary, the MRLs amended. Rapid adoption of safe MRLs (a fast track process) is essential to maintain safe uses and to avoid disruption for farmers using the products or third country stakeholders trading food and feed commodities with the EU.
- **Extend the adoption of Codex MRLs in the EU.** The adoption of Codex MRLs by the EU is a welcome process, which facilitates global trade. A greater level of global harmonisation could be achieved by a better alignment on global guidelines for evaluating and setting MRLs.
- **Set import tolerances whenever necessary and safe.** When an active substance has lost its approval in the EU, there are cases where it is necessary to maintain or set MRLs for trading purposes (known as import tolerances) for continued food and feed trade with the rest of the world. An example would be those commodities that the EU cannot produce, for instance cocoa, coffee, tea, coconuts or bananas, which are grown in more tropical and humid climates. These types of food often require specific crop protection protocols and products to protect them from different pest, insect and disease threats, that can be different to those used in EU agriculture. Of course, EU food law ensures that all food placed on the market be it EU or other origin must be safe for consumers and EFSA routinely finds no significant problems with pesticide residues in food wherever it has been grown[3]. Adequate "transitional periods for MRLs" should be agreed for the active substances that will have reduced MRLs, to allow that goods legally produced and already placed on the market continue to comply with the regulation in place during their production.

[2] Europol, (2019), 'Operation Silver axe strikes for the fourth time seizing over 550 tonnes of illegal pesticides', press release. Available at : https://www.europol.europa.eu/newsroom/news/operation-silver-axe-strikes-for-fourth-time-seizing-over-550-tonnes-of-illegal-pesticides

[3] https://www.efsa.europa.eu/en/press/news/190626