European Crop Protection

POSITION PAPER
28/11/2016 – POS/16/EJ/27064

ECPA view on the Evaluation and Fitness check roadmap for the evaluation of the EU legislation on plant protection products and pesticides residues

Introduction

The European Crop Protection Association welcomes the opportunity to comment on the Evaluation and Fitness check roadmap for the evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

General comments

The scope of the document provides a very good framework to cover the many challenges being faced in the implementation of both Regulations and we support the additional focus areas that have been identified for the review. We do however believe that some additional elements warrant attention as part of the review and we highlight below those additional areas that we have identified.

We would also hope that the review framework will provide adequate flexibility to consider additional issues that may arise in the coming months.

New active substances **-** We would in particular highlight the fact that the current legislation has had a substantial negative impact on the time to market for new active substances and products and this needs to be urgently addressed.

Future policy options **-** Within the document, a small reference is made (under point C.2) to the review of potential alternative policy mechanisms. We welcome the fact that this is referenced and we would stress that this should be a major element of the review to better inform policy makers on future options for legislative improvements.

Attached with this submission is the ECPA position paper setting out our view and proposals for the future amendment of both pieces of legislation. We hope that this provides useful additional information to be considered during the review.

Specific comments:

We would make the following specific comments and suggestions on issues that should be considered as part of the review:

- ***(C.1) Topics covered*** *(New active substances – page 4)* – The roadmap refers to new products in section B2; this need to be reflected in the review where the delays in the approval of new active substances and in the setting of MRLs have had a significant impact on the market entry of new products. Both areas of delay should be evaluated in detail as part of the review.
- ***(C.1) Topics covered*** *(timelines – page 4 & 5)* - Regarding the scope of the evaluation, we believe the timeframe should be until 31st December 2016, as the consultant's report will only start in 2017.
- ***(C.1) Topics covered*** *(issues to be covered – page 5)* – We support the additional elements identified and to be considered as part of the review. We would also suggest that the following points be included:

  - The impact of risk assessment guidance document development on the regulatory process (impact on harmonisation and use of resources in industry and authorities)
  - As part of renewal of authorisations, an evaluation is needed of the blockers in the evaluation process between evaluators (RMSs, EFSA) and Commission/SCoPAFF as decision makers, and possible remedies to support more effective and efficient ways of working between risk assessors and risk managers
  - The impact of the process on animal testing is needed (data requirements and impact of additional requests during evaluation)

- ***(C.1) Topics covered*** *(classification – page 5)* – We understand that the report does not include a link to C&L – but there is a need to evaluate and clarify the respective roles of EFSA & ECHA in the process of classification during EU active substance reviews
- ***(C.1) Topics covered*** *(residues– page 6)* – There is a need to review transitional periods when changes are made to existing MRLs. This should in particular consider the impact on trade and should consider what options are available to ensure a workable and predictable system – especially for commodities with long shelf-lives where a change in the MRL does have a substantial impact on compliance.
- ***(C.1) Topics covered*** *(transparency)* – Transparency in the review and decision making process needs to be evaluated and options for improvements need to be considered. This should include transparency for the food-chain stakeholders who do not have transparency of the evaluation timelines and have no formal opportunity to input relevant additional information.
- ***(C.1) Topics covered*** *(Consistency with other relevant food legislation – page 6)* – We would suggest that this section should also look at links with other legislation such as Regulation 609/2013 (baby food) and the supplementing act Regulation 2016/127 which impose additional limitations for the PPPs and impact the implementation of the MRLs in the foods market.
- ***C.2 Issues to be examined*** *(Coherence – page 6)*: We welcome the reference to coherence with international rules and agreements related to trade, food, environment and chemicals. We would emphasize that the WTO in particular is based on implementation of the principles of *proportionality, non-discrimination, predictability and the discouragement of unfair practices* and this should be an important consideration in the review.
- ***C.2 Issues to be examined*** *(International cooperation)*: The evaluation should look at the impact of the EU legislation and the EU risk assessment practices on international cooperation. It should also look at possible changes to facilitate greater cooperation for resource saving in the future.
- ***D.2 Previous evaluations and other reports*** *(Zonal system):* The report/conclusion of the Dublin Workshop should be considered. The results of this workshop in June 2015 on Zonal authorisation and Mutual recognition concluded that more work needs to be done to improve the zonal system and promote mutual recognition.