Workshop on the study supporting the REFIT evaluation of the pesticide regulations

Location: Albert Borschette Congress Centre
Date: 12 September, 2017, 09:30 – 17:30

1) Opening

The contractor (Ecorys) to whom the Commission awarded the contract to conduct a study to gather evidence for the REFIT evaluation welcomed all participants and thanked the Commission for organising the workshop. He presented briefly the aims of the workshop, i.e. to discuss the most important elements of the methodology used for the study, explaining that there will be numerous occasions in the near future for the participants to provide further input.

2) Background of the study

The contractor presented the study in detail, including the overall approach and the consultation strategy. The presenter explained the criteria upon which the evaluation questions (EQs) were defined, indicating that there are 28 evaluation questions on effectiveness, efficiency, relevance, EU added value, and coherence. A baseline will be included in the analysis referring to the situation before the Regulations came into force. The planning of the study was presented in detail to the workshop participants, the contractor informed that the research team is at the moment in the evaluation structuring phase (the outcome will be included in the inception report) and following this the data-collection phase will begin. The outcomes from the data analysis will be presented in a final report.

Discussion

One Member State considered that import tolerances need to be discussed and suggested involving DG TRADE.

An NGO regretted the fact that they were not given the opportunity to comment on the study's roadmap and ToR. It considered that the objectives of the Regulations are not properly reflected in the Evaluation Questions, in particular the primary objective of a high level of protection of health and environment.

Answering questions from industry associations, the contractor confirmed that associations which did not respond to the Roadmap will have the opportunity to contribute to the study, especially through the stakeholder survey. Individual companies, research organisations and academia will, in addition to the stakeholder survey, be contacted for follow-up interviews.

3) Discussion

General discussion on the performance of Regulations No. 1107/2009 and 396/2005.

The contractor opened the floor for a discussion on the general performance of Regulations No. 1107/2009 and 396/2005.

Two NGOs criticised the lack of implementation of the precautionary principle. This was challenged by some Member States who considered that the precautionary principle is taken seriously and by

industry associations who claimed that the precautionary principle is actually overused. One NGO considered that biodiversity is not taken into account sufficiently by EFSA in some of its conclusions related to active substances. Another NGO criticised the fact that the precautionary principle was not mentioned in the thought-starter. An environmental NGO commented on the health objective, regretted the fact that the provisions of the Regulation on hazard based cut-offs are not implemented, and that the list of unacceptable co-formulants has not been established yet. It was also suggested to centralise risk assessment (at EU level) in order to standardise and harmonise the procedure.

One Member State noted that the global picture should be taken into account (and not only measures implemented within the EU). Another Member State supported cut-off criteria as a vital element of the Regulation; it suggested adding to the questionnaire a point on these criteria and whether they are also relevant or applicable for metabolites. The same Member State highlighted the problem of non-accessibility to certain confidential studies that are not accessible to other experts for peer review. A different Member State noted the delays in the process of application of cut-off criteria and stressed that more harmonisation is needed in the application of derogations.

A trade association drew the contractor's attention to an OECD report that followed a seminar on niche products, and supported that Regulation 1107/2009 fails to really foster the approval and authorisation of these products. An industry association claimed that the regulations are over-restrictive and stressed that they should be based on scientific and realistic risk assessment. Another industry association considered that some fundamental aspects of the regulations are problematic: studies provided by applicants are not fully public which harms businesses producing generic products as it creates barriers to obtain products authorisations. The association also stressed the need for strong independence of the Agencies. Some industry associations also raised the issue of active substances of natural/biological origin and expressed the view that very high standards hinder the placing on the market of new products containing these, which has a negative impact on agricultural production. Another issue that was raised by industry was competitiveness – it was stressed that there is a danger to SMEs and that other companies aim for authorisations first in the US and Canada and then Asia (due to the EU's non-predictable system).

Specific issues related to the implementation of the regulations

The Commission presented the main topics that are or could be problematic in the future, as raised by Member States and stakeholders, e.g. consistency of the two Regulations, scope and definition in Regulation 396/2005, evaluation procedure, need for flexibility, and data protection.

A trade association stressed the need to improve the link between the two Regulations and to include more transitional measures taking into account shelf life of certain products, cross-contamination and differences in crop cycles globally. The industry also referred to the need for flexibility and responsiveness to scientific progress, especially with regard to progress outside of the EU. Other elements of the Regulations that were mentioned as problematic by the industry are: the timing of the procedures to be followed under the two Regulations, definition of minor uses, need for harmonisation for mutual recognition of authorisations already granted.

One Member State stressed the need to depart from the current approach (based on a single product) with regards to dealing with multiple residues. Another Member State suggested including a reference to trade in the objectives of the Regulations. The notion of "representative use" was mentioned as problematic by one Member State. Some other issues raised by Member States as requiring improvement are: extension of grace period for substances which do not entail risks and administrative burdens on competent authorities. On the matter of cut-off criteria divergent views

were expressed. Two Member States indicated that there are several provisions in the Regulations that do not include a reference/reasoning in the preamble.

An NGO stressed that the hazard based "cut-off criteria" are not really implemented yet. The Commission replied and explained that many active substances did not have a harmonised classification in place when Regulation 1107/2009 came into force. The industry commented on this point expressing the view that the hazard based cut-off criteria might actually result in a greater risk (banned products will be replaced by other products). An environmental NGO claimed that several provisions are not fully implemented; e.g. hazard based cut-offs, time limit of 10 years for initial approvals. The length of the time required for making a decision at EU level was also mentioned.

4) Session on the questionnaires, results from the group discussions

The contractor explained that the results of the group discussion will be taken into consideration for adjustments to the questionnaires. Rapporteurs presented the results of the group discussions on the two questionnaires (groups A and B for the questionnaire for member States Competent Authorities, group C and D for the Stakeholder Questionnaire).

Group A – Member State Competent Authorities (MS CA)

- Member States believed that five weeks should be sufficient to fill in the questionnaire.
- Some questions need to be clarified and/or explained better.
- Specific suggestions for minor changes were submitted for some questions.
- It was suggested to add the possibility to include further comments (the contractor will reflect on this taking into consideration the time required for analysis).
- Some missing elements were indicated: revenues generated from the legislation, need for approval of beneficial organisms and perception of the public (which will be covered by the Open Public Consultation).

Group B - Member State Competent Authorities (MS CA)

- It was suggested to address the questionnaire to one body/authority per country, which will then coordinate the response from all authorities.
- Two questions should be deleted.
- In the identification section Norway should be added.
- Clustering of MRL and PPP questions should be avoided.
- References to specific provisions and articles should be added.
- Commenting boxes for some more qualitative information should be added.

Groups C & D - Stakeholder questionnaire

- Commenting boxes should be added so that respondents can explain the options chosen.
- One question could be deleted and other questions could be merged while the possibility for multiple choices should be added.
- Academic organisations should be added in the identification section
- Refined categories for some questions should be included such as extension of authorisations to minor use / authorisation of low risk substances, basic substances. The possibility to insert comments should be foreseen.
- Include international trade in the questions related to the objectives of the Regulations.
- Two questions should be clarified (approval of active substances or authorisation process)
- When specific articles are referred to, these should be cited to facilitate answering the questionnaire.

- The term "minor uses" needs to be clarified (which articles).

Conclusion

The contractor thanked participants for their contribution to the questionnaires and informed that all four surveys are planned to be launched at the same time: SME; Open Public Consultation (OPC); Stakeholder Survey and the Member State Competent Authority Survey. After the surveys, the interviews will take place. The OPC questionnaire will be translated into all official EU-languages and it will be open for 12 weeks. It will be open to citizens and questions will be in a non-technical language.

5) Case studies

The contractor informed participants that it is not yet decided which specific cases will be used for the case studies. He explained that the case studies will illustrate specific elements – the following three different themes with regard to the Regulations will be examined.

From application to market

In the introduction the contractor explained the objective of the case study mentioning that it will illustrate with five different active substances what worked well and what could be improved between application and bringing the product on the market. The main difficulty lies in the identification of five suitable cases.

Industry associations confirmed that the list of 22 substances is good, one identified the problem of no products (with active substances approved this year) yet on the market. A trade association mentioned that at least one case of low risk should be included in the case study, as it could highlight some problems associated with the procedure.

One Member State suggested the following active substances, listed in the thought-starter: halauxifen-methyl, cyantraniliprole, for chemicals, *Beauveria bassiana* strain NPP111B005 for micro-organisms and ferric phosphate for low risk substances. Another Member State highlighted the importance to include active substances where MRLs have been set in order to address the MRL setting process as well.

Trade implications of MRL setting

The contractor explained that the objective is to identify positive or negative trade impacts.

A trade association suggested adding dimethoate on cherries. An industry association suggested looking into Technical Barriers to Trade notifications by the Commission. Another trade association suggested that the case of rice with tricyclazole from Cambodia would be more interesting than from India.

The Commission indicated that positive trade effects should also be looked at, the contractor confirmed. The Commission also suggested looking at Codex MRLs, and implementation of import tolerances.

Comparative assessment and candidates for substitution

One Member State suggested to not limiting the scope to complete substitution (include cases where use areas have been substituted).

One industry association suggested to look at insecticides and fungicides where more alternatives are available than for herbicides. Another association supported that the study should also look at the amount of resources required for a comparative assessment in relation to the benefits, the contractor confirmed mentioning that effectiveness and efficiency are the main criteria of the evaluation.

6) Final Remarks

The contractor thanked all participants for their valuable contribution and assured them that they will be informed about any further updates with regard to the study. He noted the overall validation of the consultation strategy and the remarks that will be used to finalise the questionnaires.

Participants thanked the contractor and the Commission for organising the workshop and providing the opportunity for a first exchange of views on the performance of the legislation, they mentioned their commitment to cooperate in the future steps of the study.

The Commission also thanked participants for an interactive and constructive discussion, noted that the study is a complicated task and that stakeholders' contribution is vital to its completion.

Annex 1. Participants

Austria: AGES
Belgium: Federal Public Service Health Food Chain safety and Environment
Slovakia: Ministry of Agriculture and Rural Development
Greece: MRDF
France: Ministry of Agriculture
Hungary: National Food Chain Safety Office
Sweden: Swedish Chemicals Agency
Germany: Ministry of Agriculture and Food
Denmark: Federal Ministry of Food and Agriculture
European Food Safety Authority
Minor Uses Coordination Facility
European Crop Protection Association
International Biocontrol Manufacturers Association
Food Drink Europe
European Fresh Produce Association
Pesticide Action Network Europe
Health and Environment Alliance
Greenpeace
International Federation of Organic Agriculture Movements
Eurogroup for Animals
COCERAL
European Seed Association
COPA-COGECA
European Crop Care Association
Corporate Observatory Europe
DG SANTE
DG ENV
DG AGRI
DG GROW