

2nd Workshop on the study supporting the REFIT evaluation of the pesticide regulations

Date: 16 May 2018
Time: 09:30 – 17:00
Location: Albert Borschette Congress Centre
Participants: List of attendees (available in annex 1)

1. Opening

The Contractor welcomed the participants to the workshop, presented the agenda and explained the structure of the four sessions. The Contractor invited the participants to provide their feedback on the preliminary findings presented, as the objective of the workshop was to validate the preliminary findings. The Contractor explained that a first draft of the final report has been submitted to the Commission and that the comments raised during the workshop will be considered during the revision of the draft final report. The revised version of the report will be submitted to the Commission at the end of June 2018.

2. Introduction to the study

The Contractor presented the approach for the study which comprises 28 evaluation questions assessing the effectiveness, efficiency, relevance, coherence, and the EU added value of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. After the Contractor began working on the study in July 2017, a first workshop was held on 12 September 2017 to present the methodology and to discuss the consultation activities and the questionnaires with stakeholders.

The Contractor presented the consultation activities that had been carried out. Surveys, interviews, focus groups, an Open Public Consultation (OPC) and the workshops have provided a wealth of information. In a brief presentation, the Contractor highlighted some of the findings from the OPC.

The Contractor thanked the stakeholders present for their contributions during the study.

3. Preliminary findings

Session 1: Effectiveness and efficiency of Regulation (EC) No 1107/2009

The Contractor presented the main findings for the evaluation questions that assess the effectiveness and efficiency of Regulation (EC) No 1107/2009.

The preliminary findings from the study reveal that the availability of active substances in Europe has not significantly changed since 2011 when Regulation (EC) No 1107/2009 came into force. Participants at the workshop generally confirmed this finding. However, one of the participants pointed to the fact that the absolute number of substances approved does not reveal the full story – a more detailed analysis regarding the availability of substances for particular crop/pest combinations would reveal that a decreasing number of active substances are being used in mainstream agriculture. Another participant added that delays in the approval procedures explain the small change in availability of active substances to date while further changes are expected in

the future. Participants emphasised that it would be relevant to present data in the study report on the evolution of the number of active substances over time.

One of the preliminary findings from the study is that the number of available PPPs in many Member States has increased, but that many very similar products are on the market. Participants stressed that this number should be put into context as it is important to look at the uses covered. Participants highlighted that it would be interesting to have information on the different types of PPPs available in Member States in the report. In case data are not available, participants proposed to highlight the fact that there is a lack of relevant data.

Furthermore, participants emphasised that the number of active substances alone does not provide sufficient insight in terms of the availability and use of PPPs in the Member States. There are substances that may be applied on a large number of crops, whereas other substances may be applied only to a single or a limited number of crops. Also, for minor uses there is a shortage of products available in the Member States and it was proposed by one participant to introduce EU wide authorisations for minor uses. Participants discussed that the evolution of the number of uses of PPPs over time would provide greater insight. The Contractor explained that they are aware of this limitation and highlighted that data on the uses is not available. The Contractor invited participants to provide data on the uses of PPPs if they have access to this information.

The study shows that there has been a steady increase in the number of emergency authorisations since 2011 with the conclusion that this may have a negative impact on human health and the environment. One participant pointed to a study by the European Parliament that contains more recent data from 2017 on the number of emergency authorisations. Another participant highlighted that the findings appear contradictory: the number of active substances available in Europe is increasing while at the same time there is an increase in the number of emergency authorisations.

One Member State explained that most of the emergency authorisations that are issued are granted for non-chemical products as applicants for such products do not have the capacity or financial capital to make the investment and go through the regular authorisation process. Other authorisations are issued for minor uses which often are without coverage because the market is small and with low profit. Furthermore, organic farmers rely on a limited range of active substances compared to conventional farming which often are not covered by existing authorisations. Another Member State also highlighted that most of their emergency authorisations issued are for active substances approved in the EU for products authorised in other Member States. Thus, the conclusion that emergency authorisations have a negative impact on human health and environment should be reconsidered.

The study shows that there is no clear evidence for a reduction of animal tests over the last years. One participant stated that it would be good if authorities would engage in a dialogue with relevant stakeholders to promote alternatives to animal testing.

Participants agreed with the preliminary finding that national requirements for authorisations are a barrier to mutual recognition. In addition, the difference in quality of the assessments performed by Member States may impact the use of mutual recognition negatively.

Session 2: Effectiveness and efficiency of Regulation (EC) No 396/2005

The Contractor presented the main findings for the evaluation questions that assess the effectiveness and efficiency of Regulation (EC) No 396/2005.

The study found that there are delays in the review of MRLs and that Article 12 of Regulation (EC) No 396/2005 is not working well. Participants agreed with the finding and Member States highlighted this as a particular concern where steps should be taken in order to improve the situation. One Member State, even though agreeing that it is useful to have timelines, is of the opinion that they should not be specified in primary legislation. Since timelines are difficult to meet they should rather be included in secondary legislation or guidance documents.

One participant stressed that an important element missing from the conclusions from the study is the insufficient use of IT systems. The use of IT systems and new technological advancements may help to attain a higher level of efficiency. This may be particularly relevant for the review of MRLs according to Article 12 of Regulation (EC) No 396/2005.

Both in Regulation 1107/2009 and in Regulation 396/2005, it is foreseen that the possible presence of pesticides residues arising from sources other than current plant protection uses of active substances and their known cumulative and synergistic effects shall be taken into account when the methods to assess such effects are available. While the regulatory framework exists, the methods are not yet ready to be used in practice.

Some participants called for the introduction into regulatory practice of cumulative risk assessment as soon as possible due to the potential implications for the health of consumers. At the same time, participants acknowledged that it is not necessarily a weakness of Regulation (EC) No 396/2005 itself, but that the methodology is not yet ready which results in a problem of implementation. It was however acknowledged that EFSA, the Commission and Member States have made progress in developing a framework for the cumulative risk assessment, but that the issue was very complex and therefore would need further time.

The study reveals that the non-implementation of MRLs for fish, feed and processed products creates barriers to trade as enforcement varies across Member States. Participants emphasised that harmonised processing factors would be needed for harmonised enforcement practices across Member States. At the same time, the participants acknowledge that it will be difficult to come up with a list of generic processing factors since processes can be very different. Similar to cumulative risk assessment, it is not considered a deficiency of the legislation since the legislation foresees the establishment of processing factors, but they are rather very difficult to establish.

The preliminary findings from the study reveal that the potential benefits of the zonal system are not yet fully realised. Participants generally agreed with this finding. Several participants suggested that the zonal system should be reconsidered, especially when it would make sense to assign parts of a Member State to different zones. One of the Member States pointed to a study that has been performed ten years ago by the OECD that assessed the effects of residue behaviour in relation to climatic conditions, and showed no scientific evidence supporting the creation of different zones.

One of the participants shared their concerns with regards to the EUs trading partners, highlighting the issue that import tolerances are often set without taking the consequences sufficiently into account, e.g. with regards to product shelf-life and crop cycles.

A last comment was made as regards the findings on naturally occurring and multiple use substances. In the text by the Contractor, they are presented as closely linked issues; however, these two aspects should be considered and evaluated separately.

Session 3: Relevance, coherence and EU added value of the two Regulations.

The Contractor presented the main findings for the evaluation questions that assess the relevance, coherence and EU added value of Regulations (EC) No 396/2005 and 1107/2009.

Several participants shared their concerns as regards the availability of PPPs for farmers in the future. New active substances placed on the market have fewer uses whereas active substances that have disappeared from the market, covered many uses. At the same time, the EU may lose active substances in the near future that may not be replaced by new active substances. It is difficult for companies to find different modes of action and farmers may therefore experience difficulties in the future. As regards low-risk substances, one issue is that many active substances considered as low-risk in the market are approved as low-risk only after a lengthy approval process.

The conclusions from the study highlight that there is a growing societal and consumer demand for an EU agriculture that is more sustainable, with reduced impact on the environment. Some of the participants agreed with this finding. One Member State stressed that in the future, precision techniques and non-chemical alternatives will become more important. Integrated Pest Management will become the norm. However, farmers may still need PPPs to grow their crops thus having access to a range of pesticides will still be needed. One participant called for a more holistic regulatory framework.

Results from the study reveal that the two Regulations succeeded to some extent to establish a coherent policy. Participants generally shared this conclusion. Some participants identified a lack of coherence between Regulation (EC) No 1107/2009, and other EU legislation, e.g. the biocides and REACH legislation. Participants further discussed whether Regulation (EC) No 1107/2009 should be considered to be based on mainly hazard or risk. There was no consensus on this point as Regulation (EC) No 1107/2009 contains both elements.

As regards technical and scientific progress, the study found that there are difficulties related to the growing number and the complexity of the guidance documents. Several participants highlighted that there is a particular need for regular updates of test methods to avoid animal testing while acknowledging that this may translate into additional burden.

The study found that there is general consensus among stakeholders that Regulation (EC) No 1107/2009 and the harmonisation of MRLs under Regulation (EC) No 396/2005 in the EU have an EU added value. This finding was validated by the participants. Participants agreed that further harmonisation of procedures may improve the functioning of the internal market. In terms of subsidiarity, some Member States argued that there is a need to strike a balance; regional differences are necessary but they require attention as they may create obstacles to mutual recognition.

Regulation (EC) No 1107/2009 has been in place for seven years. Participants generally agree that this is a relatively short period. The real consequences of the legislation may not be visible yet. A comparison with the previous legislation will demonstrate how the current legislation on PPPs and MRLs is functioning. Participants also stressed that it is important to keep history in mind during this evaluation and to be aware of the reasons behind the introduction of certain provisions in Regulation (EC) No 1107/2009 compared to the preceding Directive 91/414/EEC.

Session 4: Conclusion: main issues requiring attention

The Contractor presented the main conclusions from the study after which participants were invited to provide additional comments during a roundtable.

Overall, the participants agreed that the preliminary findings present a valid basis for the evaluation and welcomed the conclusions presented by the Contractor. They reiterated some of the points of particular importance to them:

- Revise and verify the figures presented. Participants asked the Contractor again to focus on uses of PPPs rather than the number of active substances and PPPs available.
- State more explicitly which aspects of the Regulations are not yet implemented. While a non-compliance with timelines is reported in the preliminary findings, many other aspects are not considered to be properly reflected yet. Participants discussed that delays and lack of implementation are not only linked to limited capacity and resources, but also linked to an incorrect implementation of provisions by Member States. Mutual recognition was mentioned as a good example where Member States who use it are able to keep the deadlines.
- Participants discussed opportunities to simplify the legislation. Although some participants claimed that the procedures could be streamlined, others emphasised the importance of the current procedures to provide the right level of detail in order to reach the objectives of the Regulations.
- Some participants highlighted that the procedures should be streamlined as regards innovative active substances that potentially do not pose a threat to health and environment (such as low risk substances and micro-organisms). In their view, this could be a viable solution to the issue of PPP availability, and would encourage SMEs, the latter facing the barrier of very long periods of return on investment.
- The better use of IT tools could help to streamline procedures and reduce workload and delays.
- Participants highlighted the need for a more holistic approach to agriculture and plant protection that is more coherent with the Sustainable Use Directive.
- Participants called for more clarity, in particular concerning data requirement and timelines.
- One participant stressed that the consequences of the legislation on international trade should be better addresses, focusing especially on EU Member States relying on import from third countries.
- Other issues raised were the need of further reducing animal testing, the possibility to have a stop-the-clock to include new scientific findings during the risk assessment and, in general, more balance between central (EU level) and national (Member State level) decisions during the decision-making process.

Final remarks

The Contractor thanked all participants for their valuable contribution and invited participants to provide additional comments until 22 May 2018.

The Commission concluded by thanking the Contractor for their work and the participants in the workshop for an interesting and constructive discussion. The Commission informed that the final report of the external study will be published on the Europa webpage. The findings of the external study will be taken into account in a Staff Working Document to be drafted by the Commission. The report on the evaluation to the European Parliament and the Council is expected to be presented during the first half of 2019.

Annex 1. Participants

Belgium
Denmark
Estonia
Finland
France
Germany
Hungary
Ireland
Latvia
Lithuania
Netherlands
Norway
Poland
Slovakia
Sweden
United Kingdom

European Beekeeping Coordination (Bee Life)
Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures (COCERAL)
Association of European Farmers and European Agri-Cooperatives (COPA-COGECA)
European Crop Care Association (ECCA)
European Crop Protection Association (ECPA)
Eurogroup for Animals
European Seed Association (ESA)
Food Drink Europe (FDE)
Federation for European Oil and Proteinmeal Industry (FEDIOL)
European Fresh Produce Association (FRESHFEL)
European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices and Honey (FRUCOM)
Greenpeace
Health and Environment Alliance (HEAL)
International Biocontrol Manufacturers Association (IBMA)
International Federation of Organic Agriculture Movements (IFOAM)
Pesticide Action Network (PAN)
Minor Uses Coordination Facility (MUCF)

DG ENV
DG SANTE
DG GROW
DG REGIO
DG TRADE
EFSA