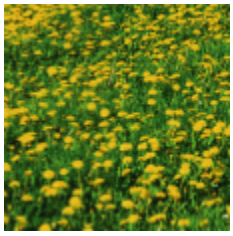
ECPA Position on the future revision of Regulations 1107/2009 and 396/2005



"ECPA believe that there is a need to review elements of both Regulation 1107/2009 and Regulation 396/2005 to improve efficiency and coordination between the two pieces of legislation, within the aim of Better Regulation. ECPA propose that the Commission come forward with a report to support a future proposal to amend the legislation."

Brussels
13 July 2015
PP/12/EJ/22085

Updated in July 2015
Original document published in March 2014

Executive Summary

- This paper has been developed to put forward the industry thinking on the expected review of the framework legislation for plant protection products. The paper focuses on areas of improvement in the general framework of Regulation 1107/2009 and Regulation 396/2005.

- Both Regulations include a review clause, with a requirement to report on the implementation of both pieces of legislation in 2014/2015.

- ***ECPA believe that there is an urgent need to analyse the current situation with the implementation of both pieces of legislation and proposes that the Commission initiate a detailed independent evaluation in 2015. Such a review needs to consider elements of both Regulation 1107/2009 and Regulation 396/2005, while also looking to improve efficiency and coordination between the two pieces of legislation.***

- ***EU legislators should ensure that the PPP regulatory framework is in line with the principles of Better Regulation and provides a decision-making framework which is coherent, efficient, predictable and scientifically robust.***

- The ECPA proposals include suggestions for improvements in the implementation of the current legislation and proposals for amendments to be considered in the review:

    - **Phase 1: Implementing the current legislative framework** – The focus is to improve the current system within the framework of the existing legislation. This phase includes proposals to provide greater support to improve the zonal system and suggestions on the implementation of Article 43. It also includes suggestions to streamline the MRL re-evaluation measures.

    - **Phase 2: Detailed legislative review** – A review should take place in 2015, to meet requirements for legislative reviews in Articles 62 & 82 of Regulation 1107/2009 and Article 47 of Regulation 396/2005. This is a major milestone in the evolution of both regulatory procedures. ECPA believes that this review should include options for amending and improving the current legislation, and should provide the Commission and Member States with a basis to amend the legislation. A proposal to amend the legislation should follow when there is clear political support and understanding of the need to improve the implementation of the legislation. Substantial changes are suggested in this paper, including a re-focusing of the regulatory process on risk assessment - away from hazard based assessment and substitution. Changes are proposed for active substance authorisations with unlimited authorisation period (linked to a requirement for a regular review) and a streamlined MRL setting procedure. Other suggestions include greater consideration of benefits during the evaluation, and the possible future centralisation of active substance evaluations.

- ***ECPA's intention in developing this paper is to continue a discussion with stakeholders and policy makers. We would expect the ECPA view to evolve following further discussions.***

Background

Following the implementation of Regulation 1107/2009 and early experience with the new process, discussions have already started about possible future improvements in the legislative framework. This paper has been developed to put forward the industry thinking on future changes in the legislation. The proposals focus on changes in the general framework of Regulation 1107/2009 and Regulation 396/2005[1].

ECPA's intention in developing this paper is to continue a discussion with stakeholders and policy makers. We would expect the ECPA view to evolve following further discussions.

In developing the suggestions on future changes in the legislation, ECPA pursues four improvement objectives:

- ***Greater harmonisation*** in the evaluation of both active substances and products.
- ***Simplification*** of an excessively complex regulatory system.
- ***Improving efficiency*** of the evaluation and decision making procedures in terms of both time and resources.
- ***Scientifically robust decision making*** based on risk assessments and not an assessment of identified hazards.

Legislative requirements for a review

Both Regulations 1107/2009 and 396/2005 require a review of the legislation in place. In this context, we highlight three specific reviews that are mentioned in the legislation:

- Article 82 of Regulation 1107/2009 states that the Commission is required to report ***by December 2014*** on the functioning of mutual recognition and the division of the Community into three zones as well as on the application of the criteria for the approval of active substances
- Article 47 of Regulation 396/2005 states that a report ***by the Commission*** is required ***by April 2015*** on the implementation of the Residues Regulation and any appropriate proposals.
- ***Article 62(5)*** of Regulation 1107/2009 states that the Commission is required to report ***by December 2016***, a report on the effects of the Regulation on data protection of tests and studies involving vertebrate animals.

There is an urgent need to analyse the current situation with the implementation of both pieces of legislation in order to ensure a better understanding of the main blockers, challenges and potential future opportunities. We would propose that the Commission initiate a detailed independent evaluation in 2015.

Such a review needs to consider elements of both Regulation 1107/2009 and Regulation 396/2005, including an analysis on how to improve the functioning of the current legislation and improve the coordination between the two pieces of legislation.

[1] *More specific and detailed suggestions to amend specific elements of the legislation are listed as a separate annex to this document.*

ECPA suggestions for phased improvements

While certain improvements in the regulatory system will require changes in the legislation in place, ECPA believe that certain improvements can be achieved within the current legislative framework. This paper therefore put forward a number of suggestions for procedural and legislative changes.

ECPA thinking and proposals are therefore set out in **two** stages:

- **Phase 1: Implementing the current legislative framework** – Looking at improving the current system within the framework of the existing legislation

- **Phase 2: 2015 review** – While the review should consider all elements included as part of the review of Articles 62 & 82 of Regulation 1107/2009 and Article 47 of Regulation 396/2005. Other elements for the improvement of the current legislative framework should also be considered, to provide relevant information for an eventual proposal to amend the legislation. This review should include options for amending and improving the current legislation, and should provide the Commission and Member States with a basis to amend the legislation. A proposal to amend the legislation should follow when there is clear political support and understanding of the need to improve the implementation of the legislation.

Phase 1: Implementing the current legislative framework

➢ Active substance approval system

Issue & Objective

The current evaluation system for active substances includes a high level of uncertainty and scientific conservatism, which negatively impacts on the predictability of the process and reduces the final product availability. Certain changes to the process would be helpful to provide an evaluation framework that ensures safety and encourages investment and innovation in new products

- ***Guidance document development, implementation and use***

  Recent scientific guidance documents have substantially (and unnecessarily) increased resource needs in both industry and authorities. Regulators at European and Member State level are highlighting that, given the additional complexity, the guidance documents are difficult to implement at the national level and they have inadequate resources and expertise to manage this additional complexity – thus impacting on the quality of the evaluation process. In order to better support the work of notifiers as well as risk assessors and risk managers in the relevant European authorities, changes are needed in the process of guidance document development under Regulation 1107/2009, in order to ensure a workable and predictable process, and to provide guidance documents that are 'fit for purpose' for efficient evaluation and decision making procedures for active substances and products.

  Once drafted, new guidance documents should pass a verification step, to include an analysis of their impact on the evaluation process. The implementation phase should also include realistic implementation timelines that have been agreed with the authorities and industry to allow a timely process for updating regulatory dossiers. In recent times, the transitional period for the implementation of new guidance documents has been inadequate for industry to perform the required studies. A more robust system would allow adequate time for data submission, thus ensuring that authorities can use resources more efficiently in focusing evaluations on dossiers that are complete.

- ***Dialogue during active substance risk assessment***

  To help ensure a predictable evaluation process, it is important that notifiers and evaluators have the opportunity to dialogue and better understand the issues and concerns of the other party. Dialogue between the notifier and the rapporteur Member States is important in the current process. We are strongly of the opinion that a formal opportunity for direct dialogue between EFSA and the notifier would provide a more robust final risk assessment..

Benefits

Further dialogue during the process of guidance document development and active substance evaluation would ensure a more transparent and predictable regulatory process.

➢ Zonal system improvements

Issue & Objective

The development of the zonal system has been supported by the crop protection industry and our aim is to ensure effective work sharing, within the framework of Regulation 1107/2009. However, there is real concern about the application of the zonal process, in particular linked to the lack of evaluating resources, with evaluations being substantially delayed beyond the legal timelines of the current legislation. We however believe that there are opportunities for greater efficiency and harmonisation.

The product re-authorisation provisions set out in Article 43 of Regulation 1107/2009 will substantially and unnecessarily increase complexity and frequency of product reviews. In the short term, a pragmatic interpretation of the existing legislation is needed but ultimately an amendment will be required to ensure a clear and workable process for future product reviews.

Proposals

- ***Application of Article 43***
  The provisions of Article 43 require regular and detailed dossier updates and reviews of all products following each decision for the approval of a concerned active substance. While a legislative amendment of this Article is required to fix this process, a short term agreement is needed on the practical application of this Article to provide a workable process for product reviews from 2016.

- ***Reducing national requirements***
  While there is only limited experience with the implementation of the zonal system under Regulation 1107/2009, it is clear that one of the major blockers is the maintenance of national requirements in the product authorisation process. ECPA have already stated that new requirements should not be developed at the national level and we believe that existing national requirements should be considered at the European level – and a decision being taken to either remove them or incorporate them as required in the European framework. This would also reduce complexity and improve efficiency as the need for national addenda would be reduced.

  There remains a lack of Member State trust in the evaluation of the zRMS, leading to unnecessary re-review of whole dossiers before granting national approvals. Acceptance of the work done by the rapporteur member state would reduce the evaluation capacity issues currently existing and ensure a more effective evaluation system - in-line with the aims of the legislation.

- ***Harmonised risk management measures***
  As part of the process of reducing national requirements, greater harmonisation in risk management measures would provide more clarity to evaluators and industry alike. Further support from the Commission is required for the continued development of a toolbox of EU harmonised risk management measures, reflecting the many effective risk management tools available across the European Union.

- ***Efficacy evaluation***
  With efficacy submissions and evaluations having been dealt with at the national level until the advent of Regulation 1107/2009, it is clear that coordination is required at the European

level to promote standardization – as well as the recognition and the wider acceptance of relevant data that has been generated in other countries to support the authorization of the products concerned.

- ***Inter-zonal cooperation in product evaluation***
  Where applications for the authorization of products concern more than one zone, we believe that opportunities exist for cooperation between the zonal rapporteurs to ensure a higher level of work-sharing, especially in looking to ensure that the common elements of the dossier are only evaluated by one of the zonal rapporteurs. This should reduce pressures on resource needs while also providing greater consistency in the final evaluation decisions. Member State evaluators and industry have a role in ensuring greater cooperation and further dialogue will be necessary to ensure that such a process becomes a reality at the working level.

- ***Coordination 'helpdesk' to provide support***
  To support the zonal evaluation process, there is a need to develop a coordination 'helpdesk' at the EU level. Such a helpdesk should help improve cooperation and communication between the Member State authorities and with notifiers. It would in particular be helpful to ensure coordination and efficiency in the evaluation of products being submitted in different zones.

Benefits

The application of the zonal system has provided little or no benefit in terms of efficiency in the evaluation process since its implementation in the framework of Regulation 1107/2009. The issues highlighted would help provide a streamlined evaluation, ensuring more efficient use of expert regulatory resources - for notifiers and in the regulatory bodies at national level.

➢ Evaluation of MRLs

Issue & Objective

The review of current European MRLs under Article 12 of Regulation 396/2005 is considerably delayed due to an in-efficient system and a clear lack of resources to carry out this substantial task. Procedural improvements are urgently needed to ensure a system that is more streamlined while making full use of all data relevant to make a decision.

Proposals

- ***Improving the process in the application of Article 12***
  To ensure a more coherent system, ECPA would propose that a clear process be developed and set out, providing clear roles and responsibilities for evaluators and the industry as well as timelines for completion of the various steps in the MRL setting process. Data collection is an important part of the process because only a complete and up-to-date data set can form the basis for a meaningful evaluation. Therefore, the full involvement of the notifier would help ensure that relevant data is made available to evaluators at an early stage and also, comments could are provided at relevant stages to reduce the risk of errors. Such a dialogue would help reduce the risk of duplicate reviews and opinions.

  Given the substantial delays, a derogation option also needs to be made available to the Member States in situations where the timelines are not met. A process is also needed for

the maintenance of 'safe' existing MRLs during the period needed for the generation of suitable supporting data to allow re-registration of existing uses.

- ***Evolution of the 'one-EMS' concept***
  In order to avoid duplication of evaluations by MSs for the same active and the same crop, a standardised procedure with one lead Evaluator–MS (EMS), preferably the RMS, would provide coherence while also economising time and effort. Given that the timelines indicated in Regulation 1107/2009 should be complimented with an MRL for the authorised use, MRL setting timelines should be shortened. Based on the proposed 12 months schedule for the MRL setting or modification procedure, there is a need to maintain a process whereby submissions for MRL modifications can be made 3-6 months earlier than for the authorisation.

- ***MRL revisions after active substance (re)approvals***
  Regulation 396/2005 requires the revision of MRLs after the approval of the active substance. Following active substances (re)approved under Regulation 1107/2009, the revision of MRLs is only required if deemed necessary during the renewal of the active substance or due to new toxicological and residue data. The regular review of active substances together with the review of MRLs that takes place within the Codex Alimentarius framework will ensure a robust review of existing MRLs, and in both cases the RMS (=EMS) is in a position to decide whether there is need to modify MRLs.

Benefits

The multiple evaluations of MRLs by different MSs in parallel procedures has negatively impacted efficiency in the evaluation process. Savings in time and capacities would be achieved by centralisation of the process for MRL evaluations to one MS. A mandatory lead role for the active substance RMS, would help the process as they would have all relevant information available to decide when an MRL modification is needed.

Phase 2: 2015 Review

➢ Re-focus on risk based system

Issue & Objective

The introduction of the cut-off criteria and the ECHA classification process for active substances as well as the comparative assessment of products has increased the complexity of the regulatory process. The expectation is that the hazard based system will also lead to a substantial reduction in the availability of crop protection solutions with potentially important implications on international trade and the competitiveness of EU agriculture–without providing any improvement in the protection of human health and the environment. To support sustainable agriculture and ensure the safety of authorized products, the regulatory system should be based on a robust risk evaluation.

Proposal

The ECPA proposal is to remove the hazard based authorization criteria that have been included in Annex II of Regulation 1107/2009. While these criteria may have some role in identifying areas of concern, they should not be the determining factors in deciding if an active substance or product is to be approved or authorized. In this context, it should be highlighted that EFSA's scientific committee has supported the use of risk assessment in relation to endocrine disruption. They conclude that in order "*…to inform on risk and level of concern for the purpose of risk management decisions […] risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information. EDs can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment.*"[2]

In addition, the process of comparative assessment should also be removed as it increases the workload for authorities who already have extremely limited resources. By removing the additional step of comparative assessment, resources could and should be focused on a detailed risk assessment decision making process for products.

Benefits

By focusing on risk assessment, there would be a clear emphasis on the safety of plant protection products. Where cut-off triggers are established based on hazard identification without further analysis of the consequences of action, this not only reduces the toolbox of farmers but may actually increase the overall level of risk. Before decisions are taken on the elimination of substances with certain hazard properties, an evaluation is needed to understand the risk impact for human and environmental health. If there is no evidence of risk reduction, a decision on the elimination of these substances should not be taken.

The removal of the hazard based criteria would take away a significant market barrier which will potentially impact on the availability of many products that have been used safely by European farmers over many years. It will impact on overall agricultural competitiveness as these solutions remain available to third countries. It also will impact on the rate of development and introduction of new innovation in chemical crop protection.

A process based on a detailed risk assessment will ensure a final evaluation that is robust and focused on sound science, ensuring a high level of protection for human health and

[2] EFSA Scientific Opinion on the hazard assessment of endocrine disruptors, EFSA Journal 2013;11(3):3132

environment. Hazard identification and hazard characterization results must be followed by a exposure assessment under conditions of use. Realistic conditions of use need to be considered, as the risk for operators, consumers and the environment for substances with identified hazard properties can be very low (and even much lower) compared to substances with less hazardous properties which are considered as alternative solutions.

➢ Active substance approval – Unlimited periods with regular reviews

Issue & Objective

The current system of limited approval periods (of 7, 10 or 15 years) for active substances is administratively burdensome and we believe that consideration must be given to an alternative system. As industry, we supported the Commission's initial proposal for unlimited active substance approvals, combined with the Commission's ability to review a substance at any time.

A key concern for industry is the uncertainty linked to the expiry dates, especially given the experiences to date where deadlines have been prolonged in many cases. Given the current situation, we expect that further prolongations will be required, which will negatively impact on workload and predictability. Changes to simplify the process are therefore needed, especially to separate the phases of active substance and product review.

Proposal

ECPA proposes a system whereby active substances are approved for an unlimited period, but with a requirement for the notifiers to update their dossiers upon request by the Commission.

Benefits

With unlimited periods of approval, regulatory decisions would only be needed when the active substance approval is amended or removed. This would avoid the need for an automatic administrative step to re-approve an active substance.

➢ De-coupling of the review of active substance and the renewal of product authorisations

Issue & Objective

The current system, whereby product renewals are automatically triggered by the re-approval of an active substance, is highly complex and burdensome. Changes to the process are therefore needed, to simplify the process and provide a process that improves the distribution of the re-evaluation workload for both notifiers and authorities.

Proposal

De-couple the renewal of active substances from the full review of product authorisations. This is already the process for Biocides based on Regulation 528/2012. Such a process allows notifiers and MS to deal with restrictions or changes in the approval conditions after renewal of the active substance. The full re-evaluation of the products should be reviewed separately; the timing of this re-evaluation should taking into consideration the expected timelines for the re-evaluation of the concerned active substances.

Benefits

By decoupling the renewal of active substances, it will facilitate a more efficient regulatory process in Europe.

➢ Zonal system improvements

Issue & Objective

The implementation of the zonal system has not provided the benefits that were suggested and expected when Regulation 1107/2009 was negotiated and agreed and the current situation has negatively impacted the 'time-to-market' for new products. Few Member States have adapted their historical national requirements – which results in a situation where national authorities are not fully accepting the evaluation of the zonal rapporteur Member State. There are clearly some examples where authorities have indicated that they will be unwilling to amend their practices in line with the principles of the zonal system. With such blockers remaining in place, the zonal system introduces an additional evaluation layer prior to the final product authorisation process in each Member State. Further consideration needs to be given to ensure a system that allows quicker time to market for products at the Member State level.

The product re-authorisation provisions set out in Article 43 of Regulation 1107/2009 are unworkable and changes in the provisions of this article are required to ensure a realistic process for product authorisation reviews.

Proposals

- ***Review and improvements in the zonal concept***

  A key aim for ECPA is to ensure that product evaluations are carried out quickly and efficiently. We believe that this can be achieved but substantial changes need to be considered within the framework of the zonal system.

  There are opportunities for Member States to make efficient use of the zonal system and mutual recognition as part of a more efficient product authorisation process. But we believe that an amendment of Regulation 1107/2009 would be needed to improve the functioning of the zonal system; and to help the future discussion on amending the zonal provisions, the different options and opportunities need to be fully evaluated and understood as part of the Article 82 review of the zonal provisions.

- ***Amendment of Article 43 of Regulation 1107/2009***

  The provisions of Article 43 require regular and detailed dossier updates and reviews of all products following each decision for the approval of a concerned active substance. Such regular updates and permanent product reviews are not necessary and not feasible when considering resource availability in the Member States particularly as it does not lead to increased safety of the consumer or environment. Changes in the provisions of this article are required to ensure realistic timelines for the reviews of product authorisations.

Benefits

A detailed evaluation of the zonal system will provide additional information on the legislative opportunities to support a better functioning and streamlined process, and where industry

would expect a more resource efficient process with shorter 'time to market' periods for product applications. An amendment to Article 43 would provide a similar more streamlined and workable process for product re-authorisation.

➢ Active substance dossier update and review – Data call-in system

Issue & Objective

The current system of active substance dossier updates and reviews provides a framework that is not well adapted to the needs of notifiers and regulators. ECPA believes that the active engagement of all authorization holders is required during the active substance review process, in order to improve the system of new data generation and ensure equal treatment and transparency for all notifiers.

Proposal

The ECPA proposal would be to initiate a data call-in system, whereby new data needs would need to be evaluated by the authorities – and all concerned notifiers would be encouraged to cooperate and contribute to the evaluation process. The process being put forward is similar to that currently in place in the US.

The active substance review process would set out the new data requirements and the date by which they need to be met. This would provide a clear framework for the development of one commonly agreed package of studies. It would minimize multiple submissions of the same new data and would avoid the current problem where the RMS may have to review several submissions for the same active substance. This would also facilitate evaluations and the derivation of new endpoints, while streamlining the use of regulators' resources.

The first step should be taken by the evaluating authority, who should conduct a periodic re-evaluation of the existing dossiers. Such a re-evaluation should identify any open point or, new concerns while also identifying the possible relevance of new guidance. A full review should only be triggered when justified – and a data call-in process would in that case be initiated, allowing notifiers adequate time to generate data. To ensure consistency, we believe that this work needs to be coordinated at the European level where possible.

Such a data call-in systems needs to include a consultation of all concerned notifiers, and the final agreement on the data submission requirements should take into consideration the views and proposals made by the notifiers. While we believe that the data required for submision should be proposed by the evaluating authority, an alternative process could be put in place whereby all authorization holders make specific proposals for dossier updates and a final decision on the data required, including a workable timeline, would be taken by the evaluating authority.

Benefits

Such a data call-in system has functioned successfully in the US for many years and we believe that it would be feasible in the EU, linked to the empowerment of a central evaluation body.

Such a process would also be helpful in dealing with confirmatory data. All necessary data would be identified by the authorities at the start of the review process. Any additional data required would be dealt with as part of a further data call-in when this data is considered necessary.

➢ Active substance re-approval – Task force cooperation; compulsory data access

Issue & Objective

A major difficulty in the current process arises when a number of notifiers have a commercial interest in an active substance and the submission of dossiers by multiple notifiers increases the workload of evaluators in assessing and comparing a number of dossiers. A key objective of this proposal is to ensure that the submission process is open and transparent for all concerned authorization holders.

Proposal

We believe that an amended regulatory process needs to promote and stimulate one single dossier application, whereby all authorization holders should be required to participate in the submission process by providing or having access to all the necessary data. To ensure that such a system is fair, a system of compulsory data sharing would be required for all new data in the submission.

In putting in place such a system, it is likely that many notifiers will cooperate in task forces and this is supported by ECPA. However, notifiers should be given the flexibility to decide on the most suitable commercial arrangement for the sharing of data. Legislation in this area should therefore focus on the compensation framework for the compulsory data sharing process – agreement on the level of compensation should then be a commercial negotiation between the parties, requiring no input from the regulatory authorities.

To ensure equal treatment, all current authorization holders would be required to participate in the submission process. Where authorization holders do not participate in the process, , their authorisations should be cancelled in a timely manner with a suitable grace period.

Benefits

Such a data compensation system has functioned successfully in the US for many years. The main advantage of this system is that authorization holders are encouraged to cooperate in providing dossier updates, while agreement on data access issues are managed by authorization holders without impacting the scarce resources of the evaluating authorities.

➢ The protection of regulatory data submitted for active substance re-approval

Issue & Objective

Regulation 1107/2009 has substantially changed the data protection rules, and the current provisions are now substantially different to that in place in other comparable legislation, in particular for biocides. The objective is to ensure a streamlined implementation while ensuring that the provisions for plant protection products are similar to comparable EU legislation.

Proposal

We believe that any new study necessary for a regulatory decision should be protected for a period of 10 years, regardless of submission stage (initial application, extension, renewal). In the case of data calls-in for the re-evaluation of active substances, the protection period for data should start from the submission of the ‘call-in’ data, this being linked to a system of obligatory access (with compensation) to that data.

Authorisation holders who are active substance task force members (or otherwise can show that they have access to the necessary data) would maintain their authorisation after the submission of the required updates to the active substance dossier; other authorisation holders would be removed from the market. Provisions should also be put in place to allow late entry into the task force (ensuring that any late entry is required to pay a suitable premium to join the task force).

Benefits

Europe wide data protection for active substance data would simplify the current system; the management of different data protection periods and starting dates in each individual Member State is unnecessarily complex and impacts on the use of the scarce resources in the national authorities. It also negatively impacts on the opportunities for greater harmonization especially in the product authorisation process.

➢ Considering the benefits of plant protection products

Issue & Objective

The current regulatory system has a clear focus on the risks (& hazards) associated with the use of products, with little or no formal consideration of the benefits of the products been evaluated. Consideration should be given to the benefits of substance and products in supporting sustainable agriculture.

Proposal

To support the regulatory decision making process, we believe that active substance dossier submission should include a formal section which sets out the benefits of the substance in supporting sustainable agriculture. This would allow future regulatory decisions to be based on a comprehensive risk/benefit analysis which is necessary to face the growing agricultural and crop protection challenges.

Such an evaluation should be considered as part of the risk management process and we believe that a 'benefits evaluation' should be undertaken, based on an objective methodology, in order to support the decision making process of the Standing Committee. Such an evaluation of the benefits would be particularly important in future given the changes in the EU decisions making procedures. With more responsibility given to the European institutions, it is essential that the decision makers have a full understanding of the products and their role in the agricultural systems of the Member States.

Benefits

By considering both the risks and the benefits of active substances and products, decisions makers would have a full understanding of particular products and active substances, in particular their role in different agricultural systems.

➢ Central evaluation

Issue & Objective

Looking at the future process for the evaluation and review of active substances, ECPA sets out its initial thinking on possible changes and considers some of the opportunities in the development of a more efficient process:

While the current system of active substance evaluation has been a suitable model over the last 15-20 years, we believe that a more efficient system needs to be put in place for the future. We believe that the current two-stage evaluation system leads to inefficiencies and future active substance evaluations should be managed by one central body.

Proposal

The main element of the proposal would be for the evaluation of active substances to be carried out once, being managed centrally, with the evaluation work being carried out with the support of experts in the Member State authorities.

At present, we believe that the EFSA structure and resources are not suitable to carry out this evaluation work, particularly as they are detached from the wider product authorization process. However, we see benefits in the EMA (Veterinary Medicines) system where the evaluation is clearly managed by EMA, but with much of the evaluation being delegated to experts in the competent national authorities. Such a system could also function in the evaluation of PPP active substances – and would ensure a close connection with the product evaluation process.

While the evaluation would need to be managed centrally, the use of expert committees made of Member State regulators, would be an important element of any future system. Such expert committees should have a key role in dealing with new scientific questions, and they should ensure close coordination between the central evaluation of active substances and the zonal evaluation of products.

A critical element in such a system would be to ensure that notifiers can dialogue with the relevant evaluators, as is currently the case in the dialogue with the rapporteur Member States. This is essential in order to efficiently manage any issues that may arise before or during the evaluation process.

Benefits

By moving to a more centralised system, the evaluation timelines could be substantially reduced and this would also improve the opportunities for the EU to participate in Global Joint Reviews. Today the process does not allow EFSA to participate fully in these joint reviews, which delays the product development process and negatively influences the return on the investment in new innovation.

➢ Fees for central evaluation

Issue & Objective

As an industry, we support a transparent and central 'fee for service' system in the evaluation process. The current system with substantially different fees in the Member States raises issues of consistency and equal treatment.

Proposal

With a centralised evaluation system for active substance, we believe that a single fee should be paid and managed by the central evaluation body. While much of the evaluation work for active substances and MRLs should be contracted out and carried out by Member State experts, the fee for the evaluation work should be managed centrally. It would therefore be the role of the central evaluation body to tender and contract out the work to the Member State authorities.

Support for a centralized fee system must be linked to the delivery of the evaluation both in terms of timelines and quality of review and the lack of resource should not lead to inefficiency or lack of predictability. In contracting out the evaluation work to experts in Member State authorities, consideration should be given to the fair distribution of work between Member States but the key consideration must be that the work is contracted out to those experts and authorities that have the available expertise and can ensure a quality and timely evaluation.

Benefits

Such a centralized fee system would be expected to ensure greater transparency in terms of costs and in terms of delivery of the relevant evaluation work.

➢ Future evaluation of MRLs

Issue & Objective

Article 47 of Regulation 396/2005 states that a review of the Regulation is required in early 2015. Changes are also required to ensure compliance with the Biocidal Products Directive. Within this framework, consideration needs to be given to a more efficient, streamlined and accelerated process for the setting of Maximum Residue Levels in the European Union.

Proposals

- ***Inclusion of Biocides and link to veterinary products MRLs***
  The main rules for MRL setting need to be better aligned for all the uses of each authorised substance. While the uses of the same active substance can currently be listed under two or even three different categories (as plant protection, veterinary product or biocide), a process needs to be put in place where all uses are considered in any consumer risk assessment.

- ***Review of existing MRLs***
  While improvements in the current process of applying Article 12 are feasible for active substances approved under Directive 91/414, we believe that changes are needed in the legislative act in order to provide a suitable regulatory framework that will improve the efficiency and transparency of the process. Amendments to Regulation 396/2005 are therefore required to ensure realistic criteria and procedures for reviews of MRLs, for example when endpoints linked to MRL setting are modified during (re)authorisations.

- ***Central body for MRL evaluations***
  ECPA believe that the evaluation of applications to set MRLs should also be carried out centrally, without the need for the information to be first submitted and evaluated by one of the Member State authorities. ECPA would however see a continued role for the experts in the Member States, acting as 'contacted evaluators' to support the central body; a similar system is already in place in the evaluation of pharmaceuticals in the EMA. ECPA would also support a single fee system for MRL application submissions, paid and managed by the central body.

- ***Specific timelines for MRL evaluations***
  The evaluation of MRLs should be clearly scheduled with time requirements for both notifiers and evaluators. Specific timelines for each step of the process should be provided in the legislation in order to ensure timely decisions for MRLs.

- ***On-line application and evaluation process***
  As part of the central evaluation, we also believe that there are opportunities to increase efficiency of the evaluation process and the introduction of an on-line application and evaluation process would appear to have long-term benefits.

- ***Scrutiny of all MRL decisions***
  The current decision making procedure with the scrutiny process for all decisions is unnecessarily burdensome and we believe that this system needs to be simplified to ensure more timely decisions.

- ***Fast track procedure: default MRLs and emergency authorisations***
  There are some situations where it is considered that the setting of MRLs is not necessary for the functioning of the market. In 'no-residue' situations where the 0.01 mg/kg default MRL would apply, we believe that the need for a legislative process should be removed or at least substantially simplified and replaced by a fast-track process. For example, the opinion of one MS should suffice to adopt a default MRL or to define that there is no need to set a specific MRL. A similar process could also be considered for the setting of MRLs for minor uses.

  In addition, there are some situations where a rapid decision is required on MRLs to support emergency authorisations. There is therefore an important need for an expedited procedure which would set the required MRLs within short timelines that fit with the timelines for granting the emergency authorisations. .

Benefits

Changes to Regulation 396/2005 is an excellent opportunity for the removal of some of the current blockers in the MRL system. It also provides an opportunity to ensure that the residues Regulation if fully complimentary with the authorisation framework set out in Regulation 1107/2009. The changes should be made in order to improve transparency and support a more efficient agricultural trade system.