



## ECPA's position on Annex I renewal process

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## Executive Summary

The new Authorisation Regulation requires the Commission to put forward a work programme for the review of active substances listed on Annex I of Directive 91/414/EEC. ECPA would like to take this opportunity to make comments and suggestions related to the process to be put in place. A key issue for industry is the need for a system that is predictable and provides adequate time to comply with the new provisions that will be set out in the new Authorisation Regulation.

The following sets the key suggestions of the crop protection industry that we would ask you to consider in the development of a predictable and workable review programme:

- **The Commission should review the resources available and develop a project to ensure that the workload is proportionate to the resources available.**
- **The timing of the new review programme should take into account the need to catch-up with the evaluation of new active substances**
- **Extend the Annex I inclusion period of all active substances that currently expire in the period 2011-2015, and the respective product authorisations in Member States**
- **The system should allow the submission of newly identified, seasonal and long-term studies after the prescribed deadline, or that these studies would be considered of confirmatory nature for both active substances and products**
- **The system should provide for a stop-the-clock process after the commenting period to allow notifiers to address concerns raised in the comments**
- **Keep the efficacy part summarized in the active substances dossier, and maintain the detailed efficacy assessment at Member States / product level**
- **Commission to clearly indicate which guidance documents will be applicable for the evaluation**
- **The provisions of Article 43 on data requirements need to be clarified in the regulation setting out the work programme for the review of active substances.**
- **A plant protection product containing several active substances shall be renewed only once when the first active substance is renewed**
- **Requirements should include the concise 'living document' currently under consideration in PRAPeR and Pesticide Steering Committee, which needs to be agreed by December 2010**
- **The submission for Annex I Renewal should be a supplement for new studies and risk assessment prepared since the entry into force of each substance, and required as a result of new guidance and new data requirements.**

## Introduction

Article 19 requires the Commission to develop the procedure to renew the approval of active substances currently listed on Annex I of Directive 91/414/EEC.

Given the fact that the inclusion period for a number of the listed active substances will start to expire from 2011, ECPA would like to take this opportunity to make comments and suggestions related to the process to be put in place.

A key issue for industry to continue to invest in safe and effective plant protection products is the need for a system that is predictable and provides adequate time for industry to comply with the new requirements that will be set out in the new Authorisation Regulation as well as in the regulations setting out the new data requirements and detailing the new review programme.

ECPA is committed to support the workload planning and asked its member companies to notify the Commission of their support for Annex I Renewal. We understand that the regulation currently under preparation in the Commission is aimed at simplifying the renewal process, which is most welcome by industry. In addition ECPA would like to make comments as summarized below regarding different aspects of the Annex I Renewal process.

## Review of resources and workload

In developing the new review programme, we would highlight the importance of ensuring that adequate resources are available at the EU and national level to deliver a predictable process. We understand that the Commission is intending to share the work by requesting two batches of submissions per year which is a step that ECPA welcome. As active substances have already been evaluated during the review programme under Directive 91/414 for their first Annex I inclusion, the workload for their Annex I renewal should be lightened by a pragmatic approach of only reviewing new data and where new guidance is employed.

ECPA believe that consideration needs to be given to ensure that the resources available are adequate to deliver on the review programme project to be put in place. Article 75(3) of the new Regulation does require that "*Member States shall ensure that competent authorities have a sufficient number of suitable qualified and experienced staff*". A similar provision is not included for the Commission and EFSA and a review needs to be carried out to avoid a repeat of the situation where the workload has exceeded the resources available. It should however be noted that the review of active substances under the new Regulation is starting at a time when the re-authorisation of products, which follows the inclusion of their active substance in Annex I of Directive 91/414 under its review programme, is still not finished.

- **Industry recommendation: The Commission should review the resources available and develop a project to ensure that the workload is proportionate to the resources available.**

## Completing new active substances first!

In considering the timetable for reviewing those active substances that are currently on Annex I of Directive 91/414/EEC, some deliberation should be given to the evaluation of new active substances. One of the most efficient ways to implement the sustainable use of plant protection products is to facilitate the replacement of old chemistry lost in the 91/414 review programme by more recent and safer products. ECPA and the R&D based industry are

particularly concerned about the delays in the evaluation of new active substances, especially given the clear message from the Commissioner and Parliament that industry need to develop new and better crop protection solutions. Indeed, we now note that no Annex I decisions have been taken for any new active substances submitted in the last six years.

New active substances evaluation has been delayed due to tight deadlines to complete the review of List 3 and 4 substances, and we understand that as the withdrawn/resubmitted substances will take priority in 2009-2010, this will further delay the evaluation of new active substances (on 25 August 2009, 59 new active substances were pending). It would be unacceptable and incompatible with the new Regulation if the review of existing active substances would further delay the evaluation of new active substances. Having considered the different steps of the evaluation process, industry is of the opinion that the backlog from the new active substances could be cleared by 2013, before the start of the second phase of Annex I Renewals.

- **Industry recommendation: The timing of the new review programme should take into account the need to catch-up with the evaluation of new active substances and ensure that the timelines set out in the new Authorisation Regulation can be met.**

### Extensions to the Annex I inclusion periods

For those active substances that will expire in 2011 and 2012, we understand that it is the Commission's intention to extend their Annex I inclusion period of those active substances in order to allow adequate time for their re-evaluation. This step is welcome as it will provide companies with a clearer and more predictable framework. ECPA would recommend that this extension be adopted as quickly as possible, and would further request that similar provisions be granted for those active substances that will expire in the period 2013-2015. From initial discussions with member companies, we do expect that a very large majority (if not all) of the active substances that will expire in this period will be supported during the forthcoming review programme. To ensure a straightforward and predictable process that minimises the administrative burden, we would therefore suggest that an extension be given as quickly as possible.

- **Industry recommendation: Extend the Annex I inclusion period of all active substances that currently expire in the period 2011-2015, and the respective product authorisations in Member States .**

ECPA believe that the extension of the Annex I inclusion should allow a period of 4 years from the time of dossier submission, which should be strictly observed. This extension would allow one year of flexibility if there are delays in the evaluation process, in addition to the three years that we believe would be required to complete the steps set out below:

- One year for the evaluation by the rapporteur Member State (RMS)
- One year for the peer review of EFSA and the eventual publication of the active substance approval
- One year for the re-evaluation of national product authorisations (in line with article 43 of the new plant protection products Authorisation Regulation).

Such a four-year period would be particularly important for the first substances being reviewed; the time period could however be reviewed depending on the experiences with the first substances that have gone through the new process.

- **Industry recommendation: Annex I inclusion extension should provide a period of 4 years from the time of dossier submission.**

### Amending the data requirements and the impact on dossier submissions dates

An important issue for industry is the technical data requirements the Annex I Renewal (AIR) dossiers will have to comply with. We understand that it is the Commission's intention to apply the current 91/414 Annex II and III requirements to the next wave of active substances expiring in 2011-2012 and due to be submitted in 2012. This is welcome and we urge the Commission to pursue this intention. Indeed exhaustive compliance with new data requirements in 2012 would be virtually impossible since dossiers have started to be upgraded in 2009 or earlier while amended technical requirements will not be adopted before 2010. However industry would like to highlight the importance to set requirements as soon as possible for the next wave of active substances, expiring from 2013 onwards, and which we understand will be evaluated under the amended requirements.

The amended data requirements have been under discussion for over 4 years and we understand that some of the sections are now being reviewed by EFSA's PPR Panel for a second time, which makes planning difficult for preparation of AIR dossiers. The amended data requirements may trigger the generation of new long term and/or seasonal studies. Therefore the next review regulation should allow supplementing the initial submission with studies that may not be ready in time to be part of it. This practicality was provided in Regulation No 1490/2002 (list 3b) and in Regulation No 737/2007 (AIR I). Alternatively the next AIR regulation should provide the possibility for the RMS to stop the evaluation clock for a period necessary to generate new information needed by the evaluators. Finally it is important to adapt the Uniform Principles to the amended data requirements early enough to allow their revision to be the evaluation basis of dossiers compliant with the new requirements.

- **Industry recommendation: The system should allow the submission of newly identified, seasonal and long-term studies after the initial submission deadline, or that these studies be considered of confirmatory nature (for both active substance and product) to be submitted after the second EU approval**
- **Industry recommendation: The system should provide for a stop-the-clock process after the commenting period to allow notifiers to address concerns raised in the comments**
- **Industry recommendation: Adjust Uniform Principles to the amended data requirements.**

### Efficacy

Contrary to Directive 91/414 which establishes the efficacy assessment at Member States level i.e. during the product evaluation, the new Authorisation Regulation introduces an efficacy assessment at EU level: Annex II point 3.2 sets efficacy as a condition for an active substance approval, while this criteria still refers to the efficacy of the product containing the active substance and to the Uniform Principles for the product authorisation. ECPA believes that a clear process needs to be put in place for the efficacy evaluation of the active substance AIR dossier. This should however be a simplified process that does not increase the evaluation burden on Member States and EFSA, and maintains the detailed efficacy assessment during the product evaluation at Member States level.

We believe that an efficient efficacy package could include two short sections:

1. Summary including nature of substance, scope of use and function (uptake, translocation and mode of action), and application details
  2. High level overview of the performance of representative uses submitted in the AIR dossier, without providing individual trial results.
- **Industry recommendation: Keep the efficacy part summarized in the active substances dossier, and maintain the detailed efficacy assessment at Member States / product level.**

## Guidance documents

ECPA welcome the provision of article 12.2 of the future Authorisation Regulation which requires that EFSA use guidance document available at the time of application. In addition to the new data requirements, notifiers will need clear indications on which guidance documents apply at the time of dossier submission. It will be essential to have a clear communication from the Commission and EFSA regarding the guidance documents to be used.

- **Industry recommendation: Commission to clearly indicate which guidance documents will be applicable for the evaluation, to ensure dossier submissions are based on the correct guidance.**

## Rapporteurs

Article 18 of the new Regulation provides that the choice of rapporteur must ensure a balance in the responsibilities and the work to be done. ECPA also believe that it would be helpful to maintain the practice of allowing industry to suggest a rapporteur, with justification for such a request.

To support the development of a predictable review of active substances, the early designation of rapporteur Member States is essential in order to allow pre-submission meetings between notifiers and RMS experts. This would ensure early identification of requirements and data gaps and an early agreement on submission conditions for the mutual benefit of notifiers and regulators. Feedback from the AIR I process suggests that access to the RMS expert resources would optimally be granted about 18 months before submission.

- **Industry recommendation: The designation of rapporteur Member States should be agreed as soon as possible. To maximise predictability the rapporteur Member States should be identified by end 2009, especially for those substances expiring before end 2013.**

Given the number of substances to be evaluated, industry accepts that the final choice on the rapporteur will be taken by the Commission to ensure a sensible distribution of the work. ECPA would however stress that the key element in deciding on the fair distribution of the work must be based on the resources available in the Member States to carry out the work. Whether the active substance is registered in a Member State shall also be considered since existing authorisations assume that the substance has already been reviewed by authorities in that Member State. We believe that not all Member States that joined the EU since 2004, have developed the capacity to be rapporteur Member State, with some still implementing the provisions of Directive 91/414/EEC as part of the *acquis communautaire*. The decision on the rapporteur should also ensure that Member States are rapporteurs for active substances that are registered within their territory.

- **Industry recommendation: Ensure that notifiers have the opportunity to propose a suitable rapporteur**
- **Industry recommendation: Ensure that the availability of resources is taken into account when assigning rapporteur responsibility to a Member State, and where appropriate if the active substance is locally registered.**

## Grouping active substances in the work programme

We understand that the Commission is still considering grouping active substances to simplify the renewal process. Having considered a number of different options, industry believes that the most practical system for the review of active substances should be linked to the date of expiry of the substances. Other clustering options have been considered but the disadvantages and inconveniences in terms of inconsistent and uneven workload sharing outweigh any possible advantages.

## Shadow-rapporteurs

With the development of the zonal authorisation system, the crop protection industry would support a system whereby 'shadow rapporteurs' are nominated for each active substance. The system of co-rapporteurs proved helpful indeed during the Annex I Renewal pilot project. The nomination of up to two shadow rapporteurs to ensure coverage of the three zones would ensure that considerable experience has been gathered with an active substance when such rapporteurs start the zonal product evaluation after (re-)approval of the active substance. To ensure that benefits are achieved during the zonal process, products containing the active substance in question must be registered in the territory of the shadow rapporteur Member States. Where there is no commercial authorisation for a certain active substance in a zone (or where it is limited to one Member State and Article 40.1.b on mutual recognition in a Member State from a different zone could apply), a shadow rapporteur from that zone should only be appointed at the request of the notifier.

The role of the shadow rapporteur should be to support the main rapporteur. We believe that this role could include an informal peer review. In some cases, it may be helpful for the shadow rapporteurs to evaluate certain sections of the dossier on behalf of the rapporteur. Such a division of work should only take place at the specific request of the rapporteur Member State and with the notifier's agreement. Overall the practical conditions of collaboration should be decided by the main rapporteur.

- **Industry recommendation: ECPA support a system whereby up to two shadow RMSs are nominated to support the work of the rapporteur Member State – therefore ensuring coverage in all the zones where the active substance is approved**
- **Industry recommendation: Peer review by shadow rapporteurs would be helpful but should not be a formal step. Exceptionally, and with the notifier's agreement, the main rapporteur could delegate the review of specific sections to the shadow rapporteurs.**

## EFSA Consultation

Consistently with one of the objectives of the new Regulation replacing Directive 91/414 – the preservation of regulatory resources – the consultation of the EFSA should be decided on a case-by-case basis by the Commission, which should take into account the recommendation of the RMS. If needed, the EFSA may be consulted for an opinion on the entire dossier or on specific points only, as appropriate.

## Dossier formats

ECPA welcomes the recent consideration in the PRAPeR unit and the Pesticide Steering Committee of the formatting of future active substance dossiers. In particular, we welcome the discussion on the development of a 'living document' to be drafted by the notifier and which will evolve into an EFSA conclusion report, and eventually into the review report linked to the regulation approving active substances. ECPA believes that such a 'living document' could replace both the Annex II dossier and the DAR, and at the same time would avoid for addenda as new studies would be added directly to the document. The concept of a 'living document' would be to concentrate, in one document to be kept as concise as possible, all information regulators need to recommend a decision on renewal, with a particular focus on new information, available since the entry into force of each substance. It would prevent the reformatting and re-writing of the complete dossier for the mutual preservation of notifiers' and evaluators' resources, which would require strong guidance from Commission to the Member States.

We would welcome the rapid agreement on the format to be used since it is a key element in the dossier, ensuring greater efficiency in the evaluation of the active substances under

review. With the first active substances expiring in 2011, the format shall be agreed by end 2010 at the latest to allow timely submissions.

- **Industry recommendation: The work programme regulation set out clearly the submission requirements, and this should include the concise 'living document' currently considered in PRAPeR and Pesticide Steering Committee to be agreed by end 2010.**
- **Industry recommendation: The submission for AIR should be a supplement for new studies and risk assessment prepared since the entry into force of each substance, and required as a result of new guidance and new data requirements. This is consistent with efficient use of resources for notifiers, Member States and Commission.**

## Products

For plant protection products containing several active substances, the new Authorisation Regulation requires that the authorisation is renewed after each of the component active substances is approved or re-approved, and does not wait until the last active substance is renewed, as was the case under Directive 91/414. To avoid unnecessary workload and redundant evaluations of the same product, ECPA suggest that a product renewal only takes place once, at the time of renewal of the first expiring active substance. In a situation where some endpoints are updated following the renewal of the other active substance(s) contained in the product, notifiers should be required to submit the additional data needed through an updated dossier only at the time of the next full review of that product when the first substance is re-approved at EU level. This will require a clear wording of the renewal decision.

- **Industry recommendation: a plant protection product containing several active substances shall be renewed only once when the first active substance is renewed.**

## Article 43 of the new Regulation

In evaluating the new Authorisation Regulation, ECPA have identified article 43 as being open to interpretation and requiring further clarification, which will be essential in the active substance approval regulations. However, we believe that further clarification is required in the new Regulation in order to provide notifiers with the guidance required following active substance approval.

A key provision requiring clarification is paragraph 2(d) of the article which requires information demonstrating the product compliance with "*...the requirements set out in the Regulation on the renewal of the approval of the active substance ...*" within three months of the renewal of the active substance. It is essential to understand that this deadline may not allow the generation of new studies that may result from the renewal process and be needed to re-authorise products. This may be particularly true for seasonal work (e.g. triggered by a modification of the GAP or a change in the residue definition during the renewal process). Given the possible changes that will be introduced to the approval conditions of the active substance following the review, we believe that this provision should be the equivalent of today's step 1 compliance following Annex I inclusion, with step 2 compliance at a later stage which would allow sufficient time to provide the necessary additional data. This provision does however need clarification in order to ensure that notifiers are fully prepared to comply with article 43 after the re-approval of the active substance.

- **Industry recommendation: The provisions of article 43 need to be clarified in the regulation setting out the work programme for the review of active substances**
- **Industry recommendation: Clear and early agreement on the wording of the future approval regulations is required in order to define the new timelines and processes, to avoid repeated review of the same product.**