



ECPA's position on the implementation of Article 43 of Regulation (EC) 1107/2009

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Introduction

The new Regulation 1107/2009 brings new challenges to stakeholders on all aspects of registering plant protection products (PPPs) in Europe. This is true for product authorisations through the zonal system, but also particularly for the renewal of authorisations. This paper highlights the key issues for renewal of authorisations, and makes proposals to help a smooth transition to the new process, as PPPs will need to be re-authorised based on Article 43 from June 2011 onwards.

We understand that this issue will be discussed at the 'Braunschweig workshop' at the end of January 2010 and industry welcomes the opportunity to input into this discussion.

Key Issue

Article 43 of Regulation 1107/2009 sets out the new provisions for the renewal of product authorisations following an approval of an active substance. It should be noted that under Regulation 1107/2009, all active substances should have received at least their first approval at EU level. The re-authorisations process after a substance is re-approved will therefore apply in future to all products at the same time.

According to article 43, information for product re-authorisation should be submitted 3 months after entry into force (EIF) of the renewal of the approval of an active substance. These timelines are different to those used today following an Annex I inclusion decision under Directive 91/414/EEC.

It is essential that a clear process is put in place for the implementation of Article 43, minimising the workload and the impact on product availability while ensuring compliance with the legislation in place. A restrictive definition of the Article 43 provision could have a major impact, in particular if all studies and risk assessments required to maintain product authorisations have to be submitted within the three month deadline set out in paragraph 2. The given time period would in many cases not allow the generation of new studies (and the subsequent completion of the registration report) that may result from the active substance approval 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).

The product authorisation procedure for mixtures containing two or more active substances is also an area that requires further consideration given the potential for overlapping or early repeat evaluations based on the approval dates of the active substances.

ECPA proposal for product renewals

ECPA believes that there should be a flexible process for the submission of information for product re-authorisation to facilitate efficient use of resources, especially for products containing several substances.

The flexible approach would include:

- The submission of information three months after the entry into force of the active substance approval Regulation, in compliance with the provisions of Article 43.2.
- Submission of additional studies and information required for the full re-approval of the plant protection product. This could include all information that is not specifically referred to in Article 43.2.

Information to be submitted under Article 43.2

In order for the timelines of Article 43 to be met efficiently, ECPA proposes that the authorisation holder not be requested to submit a full registration report for all products containing that substance three months after EIF.

The information to be submitted 3 months after the entry into force of the active substance approval is set out in Article 43.2, and in particular in points (b) and (d). Further clarity is required in particular regarding the definition of point (d) and the detailed requirements should be clearly set out in the legislative act for the approval of the active substance. It is ECPA's view that this phase should ensure compliance with the step 1 procedure currently in place, including:

- Proof of access to the studies that are to be granted protection having been necessary for the decision on active substance approval.
- Demonstration of compliance with specifications of the active substance(s)

It is understood that additional requirements may also be included at this stage and ECPA believes that it would be feasible for the additional information set out below to be provided for evaluation by the zonal rapporteur MS, by the given deadline :

- o List of new information required
- o Studies already available
- o Timetable of ongoing studies and available protocols
- o Timetable for confirmatory data
- o Timetable for a complete risk assessment.

Submission of additional information for the renewal of product authorisations

ECPA requests the submission of the following at a later stage, based on deadlines to be agreed between the authorisation holder and the ZRMS:

- o Confirmatory data
- o All other data ongoing including additional studies and risk assessments triggered by new requirements or new endpoints from the active substance renewal
- o Risk assessments
- o Registration report for all formulations containing the first re-approved substance.

In particular where there are numerous uses and/or formulations for a particular active substance, a process should be put in place as part of the active substance approval Regulation which gives clear deadlines for the submission and evaluation of this data, in line with the provisions set out under article 43.6.

Proposal for mixture products

To avoid unnecessary workload and redundant evaluations of the same product, ECPA suggests that for products containing two or more active substances a full re-authorisation of the product should only take 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, the registration holders should be required to submit the additional data needed during the next full review of that product after the first substance is re-approved at EU level for a third time. To implement such a process will require a clear wording of the active substance renewal decision.

ECPA accepts that the first phase evaluation (mentioned above) needs to be carried out for all products following an active substance approval.

Mixtures and the transition from Annex I inclusions

There is some potential for overlapping dates for product renewal following the approval of the active substances contained within the product, this is potentially the case for mixtures containing an active substance that has been evaluated and approved following a re-submission under Regulation 33/2008, but also product re-authorisations containing new, AIR-1 and List 3 active substances. ECPA has identified a number of situations where this may arise and believes that further consideration is required to ensure a workable process.

Conclusion

ECPA recognises the complexity of the process for the renewal of product authorisation, and hopes for the development of a smooth and efficient process. The new Regulation does potentially provide some flexibility and further clarity in the process will need to be provided in each active substance approval Regulation.