ECPA suggestions to amend Article 43

Introduction

ECPA has communicated on the need to amend Article 43 of Regulation 1107/2009, in order to have a workable process for product re-registration. This document sets out the ECPA thinking and a proposal for the amendment of Article 43.

While we believe that the proposal sets out a sensible and workable framework proposal, we would welcome discussion to further develop and progress this issue.

ECPA proposal

The ECPA proposal includes two elements:

1. A suggestion for the amendment of Article 43, and
2. A suggested text for the relevant section of the active substance approval Regulation.

Given the need to link between Article 43 and the AS approval Regulation, we have developed both texts in parallel, with the aim of ensuring that we have a complete proposal that can be discussed - and tested ï as a package.

Having evaluated the options, ECPAôs proposal suggests that an amendment is only necessary in Article 43(6). The proposal however makes substantial changes to paragraph 6 ï these changes are believed to be necessary to allow a more workable procedure for product re-registration; similar to the previous procedure within the framework of Directive 91/414.

The re-registration timelines of the proposal

As mentioned, the proposal suggests a procedure similar to that used under Directive 91/414. However, given the framework set out in paragraphs 1-5 of Article 43, the timelines in this proposal are slightly different to that historically in place.

The timelines proposed are as follows:
(Note all dates are from entry into force of the AS approval Regulation)

- Submission of information at 3 months for compliance with conditions of AS approval (in line with Article 43(2))
- Evaluation by Member States ï with decision within 12 months (9 months after data submission - in line with Article 43(5))
- Submission of additional data for full re-registration at 2 years ï but timelines for mixture products will depend on the timelines for the mixture partner ASs
- Decision on the approval following evaluation of the additional data at 4 years ï or 2 years after submission

We would stress that the first two elements are similar to ñ*Step 1*ò and are set out in the existing Article 43. The last two elements are similar to ñ*Step 2*òand the changes proposed to Article 43(6) have been made to allow such a process

Suggested amended text for Article 43

The following table sets out the ECPA proposal to amend Article 43:

Article 43

Renewal of authorisation

1. An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.
2. Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product, the applicant shall submit the following information:
   (a) a copy of the authorisation of the plant protection product;
   (b) any new information required as a result of amendments in data requirements or criteria;
   (c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;
   (d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;
   (e) a report on the monitoring information, where the authorisation was subject to monitoring.
3. Member States shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the Regulation renewing the approval under Article 20. The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.
4. Guidelines on the organisation of compliance checks may be established in accordance with the advisory procedure referred to in Article 79(2).
5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.
6. By derogation from paragraph 2, where the competent authority intends to maintain, cancel or amend an authorisation, the authorisation holder(s) shall be given the opportunity to submit comments or additional information within a specified time limit which shall be defined in the Regulation for the approval of the active substance renewal, as referred to in Article 20.1(a).

   ~~Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the~~ Member State~~s in question~~ shall extend the authorisation for the period necessary to complete the review ~~examination~~ and adopt a decision ~~on the renewal~~. The time limit to review and adopt a decision shall be defined in the Regulation for the approval of the active substance renewal, as referred to in Article 20.1(a).

Comments on the proposed amendment to Article 43

The proposed wording have been influenced by the Biocides Regulation; in particular, the proposed first sub-paragraph is based on Article 48(2) of the Biocides Regulation. For reference, we include the wording of Article 48(2):

Where the competent authority intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating competent authority or, in the case of a Union authorisation, the Commission, shall take due account of those comments when finalising its decision.

Wording of the active substance approval Regulation

The ECPA proposal does not include suggested wording for the complete approval Regulation; it focuses on one Article which sets out the process and timelines for the re-registration process. The proposed text has been drafted to be consistent with the wording in Article 43 ï including the proposed wording in Article 43(6).

We would in particular highlight the text in the last section under points (a), (b) and (c). This text sets out the deadlines for submitting additional data for products containing single active substances as well as for products with two or more active substances.

ACTIVE SUBSTANCE APPROVAL REGULATION

Article 2

Re-authorisation of plant protection products

1. In accordance with Article 43(2), notifiers shall provide relevant information to the Member State authorities by ***[3 months after EiF]***, in particular to ensure compliance with the conditions of approval set out in Annex I to this Regulation.

Member States shall in accordance with Regulation 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing ***[active substance]*** as an active substance by ***[1 year after EiF]***.

By that date they shall in particular verify that the conditions in Annex I to this Regulation relating to ***[active substance]*** are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Regulation 1107/2009 in accordance with the conditions of Article 59 of Regulation 1107/2009.

2. By way of derogation from paragraph 1, where the competent authority intends to maintain, amend or withdraw an authorisation, the authorisation holder(s) shall be given the opportunity to submit comments or additional information for each authorised plant protection product containing ***[active substance]*** as either the only active substance or as one of several active substances all of which were listed in the Annex to implementing Regulation no. 540/2011 by ***[date of EiF]*** at the latest.

Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of information satisfying the requirements of Article 43(2), taking into account the specific provisions set out in Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

The deadlines for completing the procedures set out in sub-paragraphs 1 and 2 shall be:

(a) in the case of a product containing ***[active substance]*** as the only active substance, comments or additional information shall be submitted by ***[2 years after EiF]*** at the latest. Where necessary, Member States shall amend or withdraw the authorisation by ***[4 years after EiF]*** at the latest; or

(b) in the case of a product containing ***[active substance]*** as one of several active substances, and where all the active substances in the product have been re-approved after ***14th June 2011***, comments or additional information shall be submitted by ***[2 years after EiF]*** at the latest. Where necessary, Member States shall amend or withdraw the authorisation by ***[4 years after EiF]*** at the latest; or

(c) in the case of a product containing ***[active substance]*** as one of several active substances, and where all the active substances in the product have yet to be re-approved after ***14th June 2011***, the a deadline for providing comments or additional information shall be set out in the Regulation approving or re-approving the last of the active substances to be (re)approved.