

How can we ensure alignment of plant protection product authorisation under Regulation 1107/2009 with the establishment of Maximum Residue Levels under Regulation 396/2005? A Position Paper addressing:

- 1) The interim period during which Regulation 1107/2009 and Regulation 396/2005 operate in tandem**
- 2) Preparing the ground for a future amendment of Regulation 396/2005**

Introduction

Within the European Union, the authorisation of plant protection products (PPPs) is governed by Regulation 1107/2009/EC (Regulation 1107). It is influenced by a number of other pieces of legislation, key among them being Regulation 396/2005/EC (Regulation 396) which governs the setting of Maximum Residue Levels (MRLs) in food or feed. Before a product can be brought to market and be available to the farmer both regulations have to be satisfied. Regulation No 396 was designed to fit the authorisation system set by Directive 91/414/EEC. On 14 June 2011, the Directive will be repealed by Regulation 1107, which will introduce strict binding timelines for almost every step in the approval of active substances and authorisation of PPPs processes. Regulation 396 has not yet been amended to be fully compatible with Regulation 1107. This may lead to situations where MRLs will be the time limiting process in the authorisation of PPPs, and consequently restrict the speed at which new solutions are available to the farmer.

This document seeks to highlight the issues raised by this situation and to propose potential solutions for minimizing them¹. The issues highlighted can be addressed by means of regulatory guidance, an update or amendment of the existing regulations, or a combination of the two.

¹ These recommendations apply for active substance MRLs and also, in due course, for safeners and synergists if specific data requirements (to be developed under Regulation 1107, Articles 25 & 26) require the setting of MRLs for their use in PPPs

Background

- Regulation 1107 provides that MRLs established according to Regulation 396 are required for the authorisation of plant protection products.²
- Regulation 1107 refers to Regulation 396 but the latter currently refers to Directive 91/414/EEC. The revision of Regulation 396 is expected to be addressed by the Commission in the near future, but realistically a new regulation is unlikely to enter into force until 2014.
- Regulation 1107 requires the evaluating Member State (zonal Rapporteur) to decide whether an application fulfils the criteria for authorisation within 12 months³. The guidance document SANCO 01981/2008 suggests it is possible for a new EU MRL to be set within 1 year, but recent statistics indicate otherwise with at least 15 months from submission to entry into force of a new EU MRL being more typical. This incompatibility with the authorisation timelines given in Regulation 1107 will delay introductions of new PPPs and additional uses of existing PPPs.
- There is a need to consider formally linking Regulations 1107 and 396. The MRL setting process needs to respect the given timelines for active substance approval and PPP authorisations given in Regulation 1107 and not compromise them.

Scenarios

The following paragraphs discuss in further detail three common potential scenarios and assess whether the lack of a link between the two regulations could lead to delays in operational PPP authorisations.

Scenario 1 - Approval of a New Active Substance and first authorisations

When applying for approval of a new active substance, it would be normal practice to include in the approval application all the data necessary to allow the setting of MRLs for the most important commercial uses.

Assuming the review of the active substance is completed according to the timelines given in Regulation 1107, then it follows that:

- a) All MRLs requested in the approval application will be evaluated and included in the DAR, which can then serve as the evaluation report.
- b) The EFSA conclusions on the peer review for the active substance would serve as a “reasoned opinion” on the MRLs proposed in the DAR.
- c) The active substance approval and the associated MRLs are likely to be published and enter into force more or less simultaneously, possibly with both elements being dealt with by means of a single co-ordinated legislative procedure.

Consequently, commercial authorisations of PPPs should not be delayed following the approval of the active substance as the necessary MRLs would be in force.

If the active substance review is delayed such that a decision on approval cannot be finalized within 30 months from the date of admissibility of the application, then Member States are allowed to grant provisional

² Regulation 1107/2009, Article 29.1(i)

³ Regulation 1107/2009, Article 37.1; the 12-month period applies to situations where the evaluation clock does not need to be stopped

authorisations⁴. For these to be granted the necessary MRLs must be in force. Setting of these MRLs will follow the procedure given in Regulation 396 and it is expected that the EFSA reasoned opinion will be based on the data evaluation in the DAR. Regulation 1107 specifies that delayed EFSA conclusions on the active substance should not delay the EFSA evaluation of MRLs and their adoption⁵, therefore in principle, MRLs should not delay provisional authorisations. However, depending on the reason for the delay, it cannot be completely excluded that situations could arise where the MRLs may not be in force when Member States are allowed to grant provisional authorisations, and this potential scenario needs careful consideration.

Scenario 2 - Renewal of an Existing Active Substance Approval

Regulation 396 requires a review of MRLs for an active substance once a decision on inclusion or non-inclusion in Annex I of Directive 91/414/EEC has been made. It is assumed that a similar requirement for MRL re-evaluation will apply following renewal decisions according to Regulation 1107.

Regulation 1107 requires that all PPP authorisations are reviewed and where appropriate renewed, amended or withdrawn within 12 months following the entry into force of the active substance renewal regulation⁶. If the active substance renewal decision triggers the need for a modification of MRLs and new data are needed, this timeline does not allow for this data to be generated and reviewed, and for MRLs to be amended according to Regulation 396 before PPP authorisations need to be renewed. There is a risk that this will result in a delay in completion of the review and a resultant temporary loss of PPPs from the market. The following proposals are offered to minimise the likelihood of this happening.

When the need to amend an existing MRL is identified during the final stages of the active substance approval review:

- a) If the MRL change is not a result of an identified consumer safety concern, there is no urgent need to change the MRL. The existing MRL should remain in place for a transition period to allow additional data to be generated to allow setting of a new MRL. It is recommended that this transition period should be 4 years to allow for data generation, review and entry into force of the new MRL.
- b) Where the required MRL change is due to a potential consumer risk being identified, a safe transitional MRL is set using for example the proportionality principle⁷. Using this approach, a “safe” transitional MRL would be set and the recommended application rate of the product would be reduced proportionately so any residues would be expected to match the new MRL. This transitional MRL would be valid for a period not exceeding 4 years to allow data generation and evaluation as above.

When during the active substance review it becomes clear that additional residue trial data are required to support existing uses and MRLs, it is suggested that a transition period of up to 4 years is given. As above, this will allow generation and evaluation of the necessary data and subsequent entry into force of the new MRLs.

In both these situations, renewal of PPP authorisations under Regulation 1107 could continue within the timelines set in Article 43.5 on the basis of the existing MRLs. If these are subsequently modified, the PPP authorisations could also need modification.

Scenario 3 - Application of a New or Modified Use for an Active Substance

When an application for a new or modified MRL is made in parallel with an application for authorisation of a PPP (at zonal level) it is likely, based on current experience, that the MRL will not enter into force in time to

⁴ Regulation 1107/2009, Article 30.1(a)

⁵ Regulation 1107/2009, Article 12.8

⁶ Regulation 1107/2009, Article 43.5

⁷ Maclachlan and Hamilton, Proportionality in crop residue data and possible use in MRL estimation. Presentation available on request.

allow the zonal rapporteur Member State the 12 months review period stated in Regulation 1107. This would subsequently delay authorisation in other countries in the same zone.

To address this potential issue, it is suggested that an application for a new or amended MRL(s) should be possible before the application for the authorisation of the PPP. This should happen typically 3 months before the application in order not to delay the authorisation of the PPP.

Conclusions and recommendations

The establishment of appropriate MRLs according to Regulation 396 is a prerequisite for the (re-)authorisation of plant protection products according to Regulation 1107. However, the review timelines prescribed in the two regulations are not synchronised so situations may arise where PPP (re-)authorisations will be delayed while the necessary MRLs are evaluated and adopted. For example, this could happen when applying for an approval of a new active substance; when EU MRLs need to be modified following the review of an existing active substance at EU level; or when applying for a new use for an active substance.

In order to better align the two processes and to minimize situations where MRLs are the time-limiting step in the process, ECPA offers the following recommendations:

- Any revision of Regulation 396 should seek to align the processes and timelines for setting MRLs with the timelines given for active substance and PPP review in Regulation 1107. A period of 12 months from application for an MRL to entry into force would match the timelines stated in Articles 37.1 and 43.5 of Regulation 1107.
- It should be possible to apply for an MRL before an application for authorisation of a PPP is made.
- Consistent with the aim for better integrated processes, a single Member State (preferably the Rapporteur Member State responsible for the substance authorisation review) should evaluate all MRL applications for an active substance through the European authorisation cycle, including applications for import tolerances.
- When the need for an MRL modification is identified during active substance review, this need and its rationale should be clearly stated in the active substance renewal assessment report (RAR) and/or the EFSA conclusion report on the active substance. A process and relevant transition measures should be proposed.
- In many cases, the need to amend existing MRLs triggered by the review of an active substance could be considered to be for “reasons outside the control of the applicant”. Where the amendment process is likely to exceed the deadline set in Article 43.5 of Regulation 1107 for reviewing/renewing authorisations, this situation must be considered as “beyond the control of the applicant” and article 43.6 should apply. Concerned authorisations should be extended until the necessary MRLs are amended.
- Timelines and transition periods should be defined that allow sufficient time to generate the necessary additional data to support MRLs affected following an active substance review. One option is to adopt an “open position” approach as used in the past in Europe for the harmonisation of MRLs and to allow up to 4 years for data generation where an incomplete database was identified.
- Transitional measures should also consider sell-off periods and the shelf life of treated commodities when authorisations are withdrawn. The time of treatment defines the legally allowed residues, not the time of use/consumption.

- Article 12.2 should be removed from a future amended version of Regulation 396 since by then EFSA should have reviewed all MRLs, and consideration should be given as to whether it is necessary to retain the provisions of Article 12.1.
- In order to help ensure consistency in terms of time-lines and decision-making between Regulation 1107 and Regulation 396, the procedure for adopting or updating MRLs under a future amended Regulation 396 should be the “examination procedure” (which also includes the right of scrutiny for the European Parliament and Council), as provided for in Article 5 of Regulation 182/2011.