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Guidance document on renewal, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009

COMMISSION STAFF WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT THE VIEW OF THE COMMISSION SERVICES

This document has been conceived as a working document of the Commission Services which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation 1107/2009 nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

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1. Background

This guidance document has been developed to elaborate the procedures contained in Regulation 1107/ 2009 (hereinafter called "the Regulation") for renewal, withdrawal and amendment of authorisations.

It starts from the basic principle that products which will be renewed under Regulation 1107/2009 have already been authorised in accordance with the Directive 91/414/EEC, and therefore comply with the data requirements and Uniform Principles of that Directive.

The procedures described in this guidance document only apply to renewals of authorisations based on substances which are renewed under the Regulation 1107/2009, i.e. active substances (a.s.) for which the first approval expires after 14 December 2012 (cf. Article 80 (4) of the Regulation).

2. Legal basis

The procedure to be followed when an application for renewal, withdrawal or amendment of an authorization is submitted is described in Articles 43-46 of the Regulation.

Main legal provisions:

Art. 43.1 provides that renewal of authorisations shall be made following the submission of an application when requirements of Article 29 are still met. The timeframe is not specified but in par. 2 of the same Article an obligation has been included for authorisation holders to submit within 3 months from the renewal of the approval of an active substance any new data with evidence that new data are results of new data requirements or criteria or are necessary to amend original conditions of approval.

The second subparagraph of Article 43.3 provides that **coordination within a specific zone for the compliance check and assessment of the information submitted should be done by the zonal rapporteur Member State (zonal RMS)**. Within 12 months after the renewal of approval of an active substance, Member States (MS) have to decide on renewal of authorisations (article 43 (5)). This gives the zonal RMS the role of a coordinator, but the zonal RMS is not necessarily assessing the information submitted.¹

Article 43.2 focuses the submission of data on new information necessary as a result of progress in science or risk management. This may be important in the framework of the renewal of authorisations of mixed products, i.e. products containing more than

¹ This means that a "coordinating MS" should in some way be able to ensure that the cost they have for this work is covered. If the ZRMS also evaluates the application the application fee can cover the total work for the coordination and assessment.

one active substance, where several subsequent renewals of the authorisation become necessary.

When a MS in a zone withdraws or amends an authorisation, this decision should be immediately communicated to the other MSs of the zone and **the other MSs should withdraw or amend the relevant authorisation taking into account national conditions and risk mitigation measures** request. In this framework, an efficient system of exchange of information is fundamental. This provision does not apply to decisions taken in the framework of Article 36(3), i.e. when it is based on the special environmental or agricultural conditions in that MS.

In addition, Article 45 gives the possibility (it is not an obligation) for authorisation holders to withdraw an authorisation at the authorisation holder's request.

Article 45 also gives the possibility to amend an existing authorisation at request of an authorisation holder, if the requirements from Article 29 continue to be met.

Finally, in Article 46 the maximum grace period when an authorisation is withdrawn is harmonised throughout the EU.

3. Renewal of an authorisation after renewal of approval

3.1 Commission decision on renewal of approval

It should be clear from the documents accompanying the renewal of approval where critical endpoints have been changed during the active substance renewal procedure. An amended Review Report accompanied by a "List of Endpoints" with amended endpoints highlighted should be considered. This is likely to be one of the crucial elements for the implementation of an efficient and streamlined procedure in MS to renew authorisations. This process needs some further discussion and elaboration and should be included in a guidance document for evaluation of active substances.

With a view on data protection for additional information, it is necessary that the Commission decision on renewal of approval takes into account a reasonable delay in order to allow market access also for all applicants which need to update their dossiers.

To this end, it is important that the RMS makes available the list of test and study reports according to Article 60(1) immediately when the decision on renewal of approval is published. In addition, the zonal RMS shall provide the lists according to article 60(2) together with the publication of the respective renewed authorisations. The DAR as published by EFSA is considered helpful to make applicants aware of tests and studies which might fall under the provisions of article 60(1).

3.2 Non-application for renewal

3 month after the renewal of an approval of an a.s., all authorisation holders must apply to renew the approvals of plant protection products containing that a.s. If no

application is submitted within that deadline, the authorisation should be revoked in line with the provisions of Article 44(3) and (4).

3.3 Application by authorisation holder

At the time of application for renewal of an a.s., the applicant shall also discuss with the zonal RMS all intended renewals of authorisations.

An application should include (according to Article 43 (2)):

- a copy of the authorisation;
- new information required as a result of amendments in data requirements and criteria and changes to endpoints arising from the active substance renewal, or as a result of a new guidance (new data are required from the date of implementation of the concerned guidance document);
- evidence that these data are required as due to new data requirements or criteria (e.g. guidance) or for amendment of conditions of approval;
- any info to demonstrate that the product complies with the requirements from the Regulation on approval;
- monitoring data when required;
- List of intended uses

A complete draft registration report should be submitted with the changes to the risk assessment highlighted and restricted to the uses already authorised. A full dossier is not explicitly required. The assessment and format should reflect the most recent applicable guidance.

3.4 Zonal RMS

Assessment should normally be conducted by zonal RMS for the product. As planning will start in advance the zonal RMS should be appointed before application for renewal of authorisation. In the case of multiple applicants they shall be encouraged to cooperate. One first step would be agreeing prior to application on a common zonal RMS, where possible.

If the zonal RMS has not been appointed yet the procedures outlined in the guidance document on zonal evaluation and mutual recognition should be followed.

Because data protection is a national issue in Regulation 1107/2009 the zonal RMS will not be able to conclude on data protection for all MS.

3.5 Assessment by zonal RMS

The Regulation foresees that the zonal RMS shall **coordinate** the compliance check and the assessment of information. However, in line with the overall approach of the

Regulation on harmonisation of authorisations, it is recommended to establish rules for an assessment of information by the zonal RMS. In order to gain experience, the assessment should be limited for the time being to establishing:

- Identification of essential studies only for the purpose of data protection.
- Impact of changes in (critical) end points
- Impact of changes in guidance – critical points only (impacting on risk assessment)
- Impact of changes in data requirements and uniform principles
- Technical equivalence only if the specification or the source of the active substance has changed (in accordance with the provisions of Article 38).
- Any new conditions of approval of the substance

The zonal RMS should also, if possible, seek consensus with other MS of the same zone on re-authorisation decisions and conditions.

3.6 Assessment by other MS

Comparative assessment for candidates for substitution will need to be conducted in all cases by all MS where an application for authorisation is made. Pre-assessment by a lead country is welcomed.

The applicant should add to his application a proposal for comparative assessment, based on his knowledge of the concerned products (product applied for and alternatives). Such proposal should address the criteria foreseen in Article 50(1).

The precise data protection position will have to be determined by each Member State.

3.7 Timelines

The zonal RMS should complete their assessment and provide the results to other MS electronically (via CIRCA?) 6 months after receipt of the information. At the same time they should communicate the results of their assessment to the applicant and other MS for information. This allows three months for the other MS to renew (or not) their authorisations.

If in exceptional circumstances more time is required which are beyond the control of the applicant then Article 43(6) allows MS to extend the authorisation for the period necessary to complete the examination and adopt a renewal decision. This is only where the applicant has fulfilled all the requirements of the Regulation. It is not foreseen that the applicant provides further information during that time.

4. Products containing more than one active substances

For products containing two or more active substances the authorisation must be renewed after the renewal of each a.s. contained in the product, respectively. A

detailed review should be performed following approval of the first a.s. in the product. In subsequent renewals, the review can be restricted to the additional information from the renewal of the approval of the subsequent a.s.

5. Withdrawal and amendment of authorisations according to Article 44

Article 44 lays down detailed provisions on withdrawal and amendment of an authorisation.

When a withdrawal or amendment is intended the applicant should be informed in advance stating the reasons and terms of the withdrawal. The applicant will have the possibility to submit comments or further information within an appropriate delay.

The Commission, EFSA and other MS must be immediately informed on every amendment and withdrawal of an authorisation in order to consider further action, as appropriate. This would be best done through an efficient electronic communication system.

An appropriate period of grace can be granted on a case by case basis in accordance with Article 46.

An electronic 'rapid alert' system in order to exchange information between MS about safety concerns and harmonisation of the grace period should be considered and alerts could be co-ordinated by the zonal steering groups.

6. Withdrawal and amendment of authorisations according to Article 45

Article 45 lays down the possibility for withdrawal or amendment of an authorisation at the request of an authorisation holder. Except that the authorisation holder shall state the reason for his request no further provisions are made with regard to application modalities, procedures, timelines etc.

Such requests can be made for a number of reasons e.g.

- Change in the chemical composition regarding the co-formulants
- New source of the technical active substance
- Amendment of the GAP (without being an application for a new product)
- Change in packaging size and material
- Change of the name of the authorised products
- Change of authorisation holder or marketing company

Amendments of authorisation may generally be divided in two groups: those which require an assessment and therefore fall under the zonal system and those who do not.

The amendments dealt with under article 45 are amendments which often do not require any assessment. These are amendments of solely administrative nature. In those cases, the request (the application) should be made to those MS where the

amendment is applicable. The concerned MS will inform the other MS via an electronic communication system/authorisation database on the amendment made.

An assessment is NOT required for the following amendments of applications:

- Change of the name of the authorised products
- Change of authorisation holder (transfer of authorisation), or change of the name or address of the authorisation holder
- Change in packaging size and material (within existing range)
- Authorisations of the same product by using different trade names and registration numbers (back-to-back authorisations, new authorizations but same product and GAP as already authorized, this implies no evaluation except of checking access to protected data, extension of the product range of a PPP by diversification - expanded product line)
- Amendments according to previously agreed standards or criteria, e.g. change of source of the technical active substance to an equivalent declared source; minor change of formulation (= change within the range as determined by the (future) guidance document on minor changes);
- *Further examples to be inserted...*

The provisions of article 45 shall not be used in cases where the amendments are linked to new information on potentially harmful or unacceptable effects from the use of the product. In these cases, the procedure from article 56 shall be considered first.

If an assessment is required the amendment should be dealt with according to Article 33. For those amendments which fall under the zonal system similar procedures as described in the Guidance Document on zonal evaluation and mutual recognition under Regulation 1107/2009 shall be applied, e.g. the principles of:

- application at the zonal RMS,
- information to all other MS having an authorisation of the same product at the same time with the indication that the zonal RMS is asked for assessment,
- assessment by the zonal RMS,
- commenting procedure for the assessment.

Evaluation time after submission should be appropriate to the kind of amendment being assessed, e.g. for minor assessments taking a maximum of 6 months for the zonal RMS, including the commenting period. Results of these amendments should be made available as early as possible for other MS to consider further action. This would be best done through an efficient electronic communication system/authorisation database. The other MS should bring in line their authorisations within 120 days at the latest, preferably shorter depending on the kind of amendment.

[The provisions of this chapter outline the concept which should be applied. A more detailed framework of procedures to be applied for different types of formulation changes might be inserted here later on, if considered necessary].

RENEWAL, WITHDRAWAL AND AMENDMENT OF AUTHORISATIONS UNDER REGULATION (EC) No. 1107/2009 AFTER APPROVAL (ANNEX I INCLUSION OR ITS RENEWAL) OF AN ACTIVE SUBSTANCE (Art. 43 – 46)

