Chapter II

Procedure for applications for MRLs

SECTION 1

SUBMISSION OF APPLICATIONS FOR MRLS

Article 6

Applications

1. Where a Member State envisages granting an authorisation or a provisional authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, that Member State shall consider whether, as a result of such use, an existing MRL set out in Annex II or III to this Regulation needs to be modified, whether it is necessary to set a new MRL, or whether the active substance should be included in Annex IV. If necessary it shall require the party requesting the authorisation to submit an application in accordance with Article 7.

2. Parties demonstrating, through adequate evidence, a legitimate interest, including manufacturers, growers and producers of products covered by Annex I may also submit an application to a Member State in accordance with Article 7.

3. Where a Member State considers that the setting, modification or deletion of an MRL is necessary, that Member State may also compile and evaluate an application for setting, modifying, or deleting the MRL in accordance with Article 7.

4. Applications for import tolerances shall be submitted to rapporteur Member States designated pursuant to Directive 91/414/EEC or, if no such rapporteur has been designated, , applications shall be made to Member States designated by the Commission in accordance with procedure referred to in Article 45(2) of this Regulation at the request of the applicant. Such applications shall be made in accordance with Article 7 of this Regulation.

Article 7

Requirements relating to applications for MRLs

1. The applicant shall include in an application for an MRL the following particulars and documents:

(a) the name and address of the applicant;

(b) a presentation of the application dossier including:

(i) a summary of the application;

(ii) the main substantive arguments;

(iii) an index of the documentation;

(iv) a copy of the relevant GAP applying to the specific use of that active substance.

(c) where appropriate, scientifically substantiated reasons for concern;

(d) the data listed in Annexes II and III to Directive 91/414/EEC relating to data requirements for the setting of MRLs for pesticides including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories, as well as plant and animal metabolism data.

However, where relevant data are already publicly available, in particular when an active substance has already been evaluated under Directive 91/414/EEC or when a CXL exists and such data are submitted by the applicant, a Member State may also use such information in evaluating an application. In such cases, the evaluation report shall include a justification for using or not using such data.

2. The evaluating Member State may, where appropriate, request the applicant to provide supplementary information in addition to information required under paragraph 1 within a time limit specified by the Member State.

Article 8

Evaluation of Applications

1. A Member State to which an application complying with Article 7 is submitted pursuant to Article 6 shall immediately forward a copy to the European Food Safety Authority established by Regulation (EC) No 178/2002 (hereinafter referred to as "the Authority") and the Commission and draw up an evaluation report without undue delay.

2. Applications shall be evaluated in accordance with the relevant provisions of the Uniform Principles for the Evaluation and Authorisation of Plant Protection Products set out in Annex VI to Directive 91/414/EEC or specific evaluation principles to be laid down in a Commission Regulation in accordance with the procedure referred to in Article 45(2) of this Regulation.

3. By way of derogation from paragraph 1 and by agreement between the Member States concerned, evaluation of the application may be carried out by the rapporteur Member State designated pursuant to Directive 91/414/EEC for that active substance.

4. Where a Member State encounters difficulties in evaluating an application or in order to avoid duplication of work, it may be decided in accordance with the procedure referred to in Article 45(2) which Member State shall evaluate particular applications.

Article 9

Submission of Evaluated Applications to the Commission and the Authority

1. After completion of the evaluation report, the Member State shall forward it to the Commission. The Commission shall without delay inform the Member States and forward the application, the evaluation report and the supporting dossier to the Authority.

2. The Authority shall acknowledge in writing receipt of the application to the applicant, the evaluating Member State and the Commission without delay. The acknowledgement shall state the date of receipt of the application and the accompanying documents.

SECTION 2

CONSIDERATION OF APPLICATIONS CONCERNING MRLS BY THE AUTHORITY

Article 10

The Authority's opinion on applications concerning MRLs

1. The Authority shall assess the applications and the evaluation reports and give a reasoned opinion on, in particular, the risks to the consumer and where relevant to animals associated with the setting, modification or deletion of an MRL. That opinion shall include:

(a) an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;

(b) the anticipated LOD for the pesticide/product combination;

(c) an assessment of the risks of the acceptable daily intake or acute reference dose being exceeded as a result of the modification of the MRL; the contribution to the intake due to the residues in the product for which the MRLs was requested;

(d) any other element relevant to the risk assessment.

2. The Authority shall forward its reasoned opinion to the applicant, the Commission and the Member States. The reasoned opinion shall clearly define the basis for each conclusion reached.

3. Without prejudice to Article 39 of Regulation (EC) No 178/2002, the Authority shall make its reasoned opinion public.

Article 11

Time limits for the Authority's opinion on applications concerning MRLs

1. The Authority shall give its reasoned opinion as provided for in Article 10 as soon as possible and at the latest within three months from the date of receipt of the application;

2. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until that information has been provided. Such suspensions are subject to Article 13.

Article 12

Assessment of existing MRLs by the Authority

1. The Authority shall, within a period of 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC after the entry into force of this Regulation, submit a reasoned opinion based in particular on the relevant assessment report prepared under Directive 91/414/EEC to the Commission and the Member States on:

(a) existing MRLs for that active substance set out in Annex II or III to this Regulation;

(b) the necessity of setting new MRLs for that active substance, or its inclusion in Annex IV to this Regulation;

(c) specific processing factors as referred to in Article 20(2) of this Regulation that may be needed for that active substance;

(d) MRLs which the Commission may consider including in Annex II and/or Annex III to this Regulation and on those MRLs which may be deleted related to that active substance.

2. For substances included in Annex I to Directive 91/414/EEC before the entry into force of this Regulation, the reasoned opinion referred to in paragraph 1 of this Article shall be delivered within 12 months of the entry into force of this Regulation.

Article 13

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

For that purpose, a request shall be submitted to the Commission within two months after the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act within a set time-limit.

SECTION 3

Setting, modifying or deletion of MRLs

Article 14

Decisions on applications concerning MRLs

1. Upon receipt of the opinion of the Authority and taking into account that opinion, a Regulation on the setting, modification or deletion of an MRL or a Decision rejecting the application shall be prepared by the Commission without delay and at the latest within three months, and submitted for adoption in accordance with the procedure referred to in Article 45(2).

2. With regard to the acts referred to in paragraph 1, account shall be taken of:

(a) the scientific and technical knowledge available;

(b) the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances;

(c) the results of an assessment of any potential risks to the consumer and, where appropriate, to animals;

(d) the results of any evaluations and decisions to modify the uses of plant protection products;

(e) a CXL or a GAP implemented in a third country for the legal use of an active substance in that country;

(f) other legitimate factors relevant to the matter under consideration.

3. The Commission may request at any time that supplementary information be provided by the applicant or by the Authority. The Commission shall make available any supplementary information received to the Member States and the Authority.

Article 15

Inclusion of new or modified MRLs in Annexes II and III

1. The Regulation referred in Article 14(1) shall:

(a) set new or modified MRLs and list them in Annex II to this Regulation where the active substances have been included in Annex I to Directive 91/414/EEC; or

(b) where the active substances have not been included in Annex I to Directive 91/414/EEC and where they are not included in Annex II to this Regulation, set or modify temporary MRLs and list them in Annex III to this Regulation; or

(c) in the cases mentioned in Article 16, set temporary MRLs and list them in Annex III to this Regulation.

2. Where a temporary MRL is set as provided for in paragraph 1(b), it shall be deleted from Annex III by a Regulation one year after the date of the inclusion or non-inclusion in Annex I to Directive 91/414/EEC of the active substance concerned, in accordance with the procedure referred to in Article 45(2) of this Regulation. However, where one or more Member States so request, it may be maintained for an additional year pending confirmation that any scientific studies necessary for supporting an application for setting a MRL have been undertaken. In cases where such confirmation is provided, the temporary MRL shall be maintained for a further two years, provided that no unacceptable safety concerns for the consumer have been identified.

Article 16

Procedure for setting temporary MRLs in certain circumstances

1. The Regulation referred to in Article 14(1) may also set a temporary MRL to be included in Annex III in the following circumstances:

(a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Article 8(4) of Directive 91/414/EEC; or

(b) where the products concerned constitute a minor component of the diet of consumers and, where relevant, of animals; or

(c) for honey; or

(d) where essential uses of plant protection products have been identified by a Decision not to include in or to delete an active substance from Annex I to Directive 91/414/EEC.

2. The inclusion of temporary MRLs as referred to in paragraph 1 shall be based on the opinion of the Authority, monitoring data and an assessment demonstrating that there are no unacceptable risks to consumers or animals.

The continued validity of the temporary MRLs referred to in paragraph 1(a), (b) and (c) shall be re-assessed at least once every 10 years and any such MRLs shall be modified or deleted as appropriate.

The MRLs referred to in paragraph 1(d) shall be re-assessed at the expiry of the period for which the essential use was authorised.

Article 17

Modifications of MRL following revocation of authorisations of plant protection products

Amendments to Annexes II or III needed to delete an MRL following the revocation of an existing authorisation for a plant protection product may be adopted without seeking the opinion of the Authority.

Chapter III

MRLs applicable to products of plant and animal origin

Article 18

Compliance with MRLs

1. The products covered by Annex I shall not contain, from the time they are placed on the market as food or feed, or fed to animals, any pesticide residue exceeding:

(a) the MRLs for those products set out in Annexes II and III;

(b) 0,01 mg/kg for those products for which no specific MRL is set out in Annexes II or III, or for active substances not listed in Annex IV unless different default values are fixed for an active substance in accordance with the procedure referred to in Article 45(2) while taking into account the routine analytical methods available. Such default values shall be listed in Annex V.

2. Member States may not prohibit or impede the placing on the market or the feeding to food-producing animals within their territories of the products covered by Annex I on the grounds that they contain pesticide residues provided that:

(a) such products comply with Articles 18(1) and 20; or

(b) the active substance is listed in Annex IV.

3. By way of derogation from paragraph 1, Member States may authorise, further to a post-harvest treatment with a fumigant on their own territory, residue levels for an active substance which exceed the limits specified in Annexes II and III for a product covered by Annex I where the active substance/product combinations are listed in Annex VII provided that:

(a) such products are not intended for immediate consumption;

(b) appropriate controls are in place to ensure that such products cannot be made available to the end user or consumer, if they are supplied directly to the latter, until the residues no longer exceed the maximum levels specified in Annexes II or III;

(c) the other Member States and the Commission have been informed of the measures taken.

The active substance/product combinations listed in Annex VII shall be defined in accordance with the procedure referred to in Article 45(2).

4. In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or in pursuance of obligations in Directive 2000/29/EC [1], a Member State may authorise the placing on the market and/or the feeding to animals within its territory of treated food or feed not complying with paragraph 1, provided that such food or feed does not constitute an unacceptable risk. Such authorisations shall immediately be notified to the other Member States, the Commission and the Authority, together with an appropriate risk assessment for consideration without undue delay in accordance with the procedure referred to in Article 45(2), with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products.

Article 19

Prohibition concerning processed and/or composite products

The processing, and/or mixing for dilution purposes with the same or other products, of the products covered by Annex I not complying with Article 18(1) or 20 with a view to placing them on the market as food or feed or feeding them to animals shall be prohibited.

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1 Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169,10.7.2000, p. 1). Directive as last amended by Commission Directive 2004/70/EC (OJ L 127, 29.4.2004, p. 97).

Article 20

MRLs applicable to processed and/or composite products

1. Where MRLs are not set out in Annexes II or III for processed and/or composite food or feed, the MRLs applicable shall be those provided in Article 18(1) for the relevant product covered by Annex I, taking into account changes in the levels of pesticide residues caused by processing and/or mixing.

2. Specific concentration or dilution factors for certain processing and/or mixing operations or for certain processed and/or composite products may be included in the list in Annex VI in accordance with the procedure referred to in Article 45(2).

Chapter IV

Special provisions relating to the incorporation of existing MRLs into this Regulation

Article 21

First establishment of MRLs

1. MRLs for products covered by Annex I shall be first established and listed in Annex II in accordance with the procedure referred to in Article 45(2), incorporating the MRLs provided for under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC, taking into account the criteria mentioned in Article 14(2) of this Regulation.

2. Annex II shall be established within 12 months from the entry into force of this Regulation.

Article 22

First establishment of temporary MRLs

1. Temporary MRLs for active substances for which a decision on inclusion or non-inclusion in Annex I to Directive 91/414/EEC has not yet been taken shall be first established and listed in Annex III to this Regulation, unless already listed in Annex II hereto, in accordance with the procedure referred to in Article 45(2), taking into account the information provided by the Member States, where relevant the reasoned opinion mentioned in Article 24, the factors referred to in Article 14(2) and the following MRLs:

(a) remaining MRLs in the Annex to Directive 76/895/EEC; and

(b) hitherto unharmonised national MRLs.

2. Annex III shall be established within 12 months from the entry into force of this Regulation in accordance with Articles 23, 24 and 25.

Article 23

Information to be provided by the Member States on national MRLs

Where an active substance is not yet included in Annex I to Directive 91/414/EEC and where a Member State has set, by the date of entry into force of Annex I to this Regulation at the latest, a national MRL for that active substance for a product covered by Annex I to this Regulation, or has decided that no MRL is required for that active substance, the Member State concerned shall notify the Commission, in a format and by a date to be established in accordance with the procedure referred to in Article 45(2) of the national MRL, or the fact that no MRL is required for an active substance, and where relevant and at the request of the Commission:

(a) the GAP;

(b) where the critical GAP is applied in the Member State and, where available, summary data on supervised trials and/or monitoring data;

(c) the acceptable daily intake and, if relevant, the acute reference dose used for the national risk assessment, as well as the outcome of the assessment.

Article 24

Opinion of the Authority on data underlying national MRLs

1. At the request of the Commission, the Authority shall provide a reasoned opinion to the Commission on potential risks to consumer health arising from:

(a) temporary MRLs that may be included in Annex III;

(b) active substances that may be included in Annex IV.

2. In preparing the reasoned opinion referred to in paragraph 1, the Authority shall take into account the scientific and technical knowledge available, and in particular, information provided by the Member States as required by Article 23.

Article 25

Setting of temporary MRLs

Taking into account the opinion of the Authority, if such opinion is requested, temporary MRLs for active substances referred to in Article 23 may be set and listed in Annex III pursuant to Article 22(1) or, as appropriate, the active substance may be included in Annex IV pursuant to Article 5(1).

Chapter V

Official controls, reports and sanctions

SECTION 1

OFFICIAL CONTROLS OF MRLS

Article 26

Official controls

1. Without prejudice to Directive 96/23/EC [1], Member States shall carry out official controls on pesticide residues in order to enforce compliance with this Regulation, in accordance with the relevant provisions of Community law relating to official controls for food and feed.

2. Such controls on pesticide residues shall, in particular, consist of sampling and subsequent analysis of the samples and identification of the pesticides present and their respective residue levels.

[1] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

Article 27

Sampling

1. Each Member State shall take a sufficient number and range of samples to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of supply as is reasonable, to allow for any subsequent enforcement action to be taken.

2. The sampling methods necessary for carrying out such controls of pesticide residues in products other than those provided for in Directive 2002/63/EC [1] shall be determined in accordance with the procedure referred to in Article 45(2) of this Regulation.

Article 28

Methods of Analysis

1. The methods of analysis of pesticide residues shall comply with the criteria set out in the relevant provisions of Community law relating to official controls for food and feed.

2. Technical guidelines dealing with the specific validation criteria and quality control procedures in relation to methods of analysis for the determination of pesticide residues may be adopted in accordance with the procedure referred to in Article 45(2).

3. All laboratories analysing samples for the official controls on pesticide residues shall participate in the Community Proficiency Tests for pesticide residues organised by the Commission.

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1 Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC (OJ L 187, 16.7.2002, p. 30).