COMMON POSITION (EC) No 1/2005
adopted by the Council on 19 July 2004
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:


(2) Differences in national maximum residue levels for pesticides can pose barriers to trade in products included in Annex I to the Treaty and products derived therefrom between Member States and trade between third countries and the Community. Accordingly, in the interest of free movement of goods and equal competition conditions among the Member States, as well as consumer protection, it is appropriate that maximum residue levels (MRLs) for products of plant and animal origin be set at Community level.

(3) A Regulation establishing MRLs does not require transposition into national law in the Member States. It is therefore the most appropriate legal instrument with which to set MRLs for pesticides in products of plant and animal origin, as its precise requirements are to be applied at the same time and in the same manner throughout the Community and accordingly permit a more efficient use of national resources.

The basic rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (1).

In addition to those basic rules, more specific rules are needed to ensure the effective functioning of the internal market and trade with third countries in relation to fresh, processed and/or composite plant and animal products intended for human consumption or animal feed in which pesticide residues may be present, whilst providing the basis for securing a high level of protection for human and animal health and the interests of consumers. Such rules should include the establishment of specific MRLs for each pesticide in food and feed products and the quality of the data underlying these MRLs.

Notwithstanding the fact that the principles of the general food law laid down in Regulation (EC) No 178/2002 apply only to feed for food-producing animals, in view of the difficulty of segregating products to be used as feed intended for animals which are not destined for food production and in order to facilitate the control and the enforcement of the provisions of this Regulation, it is appropriate to apply them also to feed which is not intended for food-producing animals. However, this Regulation should not be an obstacle to the tests which are necessary in order to assess pesticides.

Directive 91/414/EEC lays down basic rules with respect to the use and placing on the market of plant protection products. In particular the use of those products should have no harmful effects on humans or on animals. Pesticide residues resulting from uses of plant protection products may have harmful effects on the health of consumers. It is therefore appropriate that rules for MRLs for products intended for human consumption be defined that are linked to the authorisation for use of plant protection products as defined under Directive 91/414/EEC. Similarly that Directive needs to be adapted in order to take into account the Community procedure for the establishment of MRLs under this Regulation. Pursuant to that Directive, a Member State may be designated as rapporteur for the evaluation of an active substance. It is appropriate to use the expertise in that Member State for the purposes of this Regulation.

It is appropriate that specific rules concerning the control of pesticide residues be introduced to complement the general Community provisions on the control of food and feed.


Specific rules for animal feed including marketing, storage of feed and feeding of animals are provided for in Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (1). For certain products it is not possible to determine whether they will be transformed into food or animal feed. Therefore the pesticide residues in such products should be safe both for human and, where relevant, for animal consumption. Accordingly it is appropriate that the rules set out in this Regulation also apply to those products in addition to the specific rules for animal nutrition.

It is necessary to define at Community level certain terms used for the setting and control of MRLs for products of plant and animal origin.

Directive 76/895/EEC provides that Member States may authorise higher levels of MRLs than are currently authorised at Community level. That possibility should cease to exist as, in view of the internal market, it could create obstacles to intra-Community trade.

The determination of MRLs for pesticides requires lengthy technical consideration and includes an assessment of potential risks to consumers. Therefore, MRLs cannot be set immediately for the residues of pesticides currently regulated by Directive 76/895/EEC or for pesticides for which Community MRLs have not yet been set.

It is appropriate that the minimum data requirements to be used when considering the setting of MRLs for pesticides be laid down at Community level.

In exceptional circumstances, and in particular for unauthorised pesticides that may be present in the environment, it is appropriate to permit the use of monitoring data in setting MRLs.

MRLs for pesticides should be continually monitored and should be changed to take account of new information and data. MRLs should be set at the lower level of analytical determination where authorised uses of plant protection products do not result in detectable levels of pesticide residues. Where uses of pesticides are not authorised at Community level, MRLs should be set at an appropriately low level to protect the consumer from the intake of unauthorised or excessive levels of pesticide residues. In order to facilitate control of residues of pesticides, a default value is to be set for pesticide residues present in products or groups of products covered by Annex I for which no MRLs have been established in Annexes II or III, unless the active substance in question

is listed in Annex IV. It is appropriate to set the default value at 0.01 mg/kg and to provide for the possibility of setting it at a different level for active substances covered by Annex V, taking into account the routine analytical methods available and/or consumer protection.

For food and feed produced outside the Community, different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Community. It is therefore appropriate that MRLs be fixed for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce.

Regulation (EC) No 178/2002 establishes procedures for taking emergency measures in relation to food and feed of Community origin or imported from a third country. Those procedures allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned. It is appropriate that these measures and their effect on humans and, where relevant, animals be assessed by the European Food Safety Authority (the Authority).

The lifetime exposure, and where appropriate the acute exposure of consumers to pesticide residues via food products, should be evaluated in accordance with Community procedures and practices, taking account of guidelines published by the World Health Organisation.

Through the World Trade Organisation, the Community’s trading partners should be consulted about the MRLs proposed, and their observations should be taken into account before the MRLs are adopted. MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set.

It is necessary that the Authority assess MRL applications and evaluation reports prepared by the Member States with a view to determining the associated risks to consumers and, where relevant, to animals.

Member States should lay down rules on sanctions applicable to infringements of this Regulation and ensure that they are implemented. Those sanctions are to be effective, proportionate and dissuasive.

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The development of a Community-harmonised system for MRLs entails the development of guidelines, databases and other activities with associated costs. It is appropriate for the Community in certain cases to make a contribution to those costs.

It is good administrative practice and technically desirable to coordinate the timing of decisions on MRLs for active substances with decisions taken for those substances under Directive 91/414/EEC. For many substances for which Community MRLs have not yet been set, decisions are not due to be taken under that Directive before the date of entry into force of this Regulation.

It is therefore necessary to adopt separate rules providing for temporary but mandatory harmonised MRLs, with a view to setting MRLs progressively as decisions are taken on individual active substances as part of the evaluations under Directive 91/414/EEC. Such temporary harmonised MRLs should be based, in particular, on existing national MRLs established by the Member States and should respect the national arrangements by which they were established, provided that the MRLs do not present an unacceptable risk to consumers.

Following the inclusion of existing active substances in Annex I to Directive 91/414/EEC, Member States are to re-evaluate each plant protection product containing those active substances within four years of the date of inclusion. The MRLs concerned should be retained for a period of up to four years to provide for continuity of authorisations and, on completion of re-evaluation, should be made definitive if they are supported by dossiers which satisfy Annex III to Directive 91/414/EEC, or be set to a default level if they are not so supported.

This Regulation establishes MRLs for the control of pesticide residues in food and feed. It is therefore appropriate that Member States establish national programmes to control these residues. The results of the national control programmes are to be submitted to the Commission, the Authority and the other Member States and included in the Community annual report.

The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (1).

In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objectives of facilitating trade whilst protecting the consumer to lay down rules on MRLs for products of plant and animal origin. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin.

Article 2

Scope

1. This Regulation shall apply to products of plant and animal origin or parts thereof covered by Annex I to be used as fresh, processed and/or composite food or feed in or on which pesticide residues may be present.

2. This Regulation shall not apply to the products covered by Annex I where it may be established by appropriate evidence that they are intended for:

(a) the manufacture of products other than food or feed; or

(b) sowing or planting; or

(c) activities authorised by national law for the testing of active substances.

3. Maximum residue levels for pesticides set in accordance with this Regulation shall not apply to products covered by Annex I intended for export to third countries and treated before export, where it has been established by appropriate evidence that the third country of destination requires or agrees with that particular treatment in order to prevent the introduction of harmful organisms into its territory.

4. This Regulation shall apply without prejudice to Directives 98/8/EC (1) and 2002/32/EC and Regulation (EEC) No 2377/90 (2).

Article 3

Definitions

1. For the purpose of this Regulation, the definitions in Regulation (EC) No 178/2002 and in Article 2(1) and (4) of Directive 91/414/EEC shall apply.

2. The following definitions shall also apply:

(a) ‘good agricultural practice’ (GAP): means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed;

(b) ‘critical GAP’: means the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL;

(c) ‘pesticide residues’: means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2(1) of Directive 91/414/EEC, which are present in or on the products covered by Annex I to this Regulation, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide;

(d) ‘maximum residue level’ (MRL): means the upper legal level of concentration for a pesticide residue in or on food or feed;

(e) ‘CXL’: means an MRL set by the Codex Alimentarius Commission;

(f) ‘limit of determination’ (LOD): means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;

(g) ‘import tolerance’: means an MRL set for imported products where:

— the use of the active substance in a plant protection product on a given product is not authorised in the Community; or

— an existing Community MRL is not sufficient to meet the needs of international trade;

(h) ‘proficiency test’: means a comparative test in which several laboratories perform analyses on identical samples, allowing an evaluation of the quality of the analysis performed by each laboratory;

(i) ‘acute reference dose’: means the estimate of the amount of substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation;

(j) ‘acceptable daily intake’: means the estimate of the amount of substance in food expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation.

Article 4

List of groups of products for which harmonised MRLs shall apply

1. The products, product groups and/or parts of products referred to in Article 2(1) to which harmonised MRLs shall apply shall be defined in and covered by Annex I in accordance with the procedure referred to in Article 45(2). Annex I shall include all products for which MRLs are set, as well as the other products for which it is appropriate to apply harmonised MRLs in particular in view of their relevance in the diet of consumers or in trade. Products shall be grouped in such a way that MRLs may as far as possible be set for a group of similar or related products.

2. Annex I shall be first established within three months from the entry into force of this Regulation and shall be revised when appropriate, in particular at the request of a Member State.

Article 5

Establishment of a list of active substances for which no MRLs are required

1. Active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required shall be defined in accordance with the procedure referred to in Article 45(2) of this Regulation and listed in Annex IV hereto, taking into account the uses of those active substances and the matters referred to in Article 14(2), (a), (c) and (d) of this Regulation.


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

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. 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 decide 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 requests, 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 to delete an active substance from, or not to include an active substance in, 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 reassessed 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 reassessed 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 Articles 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.

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 not complying with Articles 18(1) or 20 with a view to placing them on the market as food or feed or feeding them to animals.

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.

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 (2) 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.

SECTION 2
COMMUNITY CONTROL PROGRAMME

Article 29

Community Control Programme

1. The Commission shall prepare a coordinated multiannual Community control programme, identifying specific samples to be included in the national control programmes and taking into account problems that have been identified regarding compliance with the MRLs set out in this Regulation, with a view to assessing consumer exposure and the application of current legislation.

2. The Community control programme shall be adopted and updated every year in accordance with the procedure referred to in Article 45(2). The draft Community control programme shall be presented to the Committee referred to in Article 45(1) at least six months before the end of each calendar year.

SECTION 3
NATIONAL CONTROL PROGRAMMES

Article 30

National control programmes for pesticide residues

1. Member States shall establish multiannual national control programmes for pesticide residues. They shall update their multiannual programme every year.

Those programmes shall be risk-based and aimed in particular at assessing consumer exposure and compliance with current legislation. They shall specify at least the following:

(a) the products to be sampled;

(b) the number of samples to be taken and analyses to be carried out;

(c) the pesticides to be analysed;


(d) the criteria applied in drawing up such programmes, including:

(i) the pesticide-product combinations to be selected;
(ii) the number of samples taken for domestic and non-domestic products respectively;
(iii) consumption of the products as a share of the national diet;
(iv) the Community Control Programme, and
(v) the results of previous control programmes.

2. Member States shall submit their updated national control programmes for pesticide residues, as mentioned in paragraph 1, to the Commission and to the Authority at least three months before the end of each calendar year.

3. Member States shall participate in the Community Control Programme as provided for in Article 29.

SECTION 4

INFORMATION BY THE MEMBER STATES AND ANNUAL REPORT

Article 31

Information by the Member States

1. Member States shall submit the following information concerning the previous calendar year to the Commission, the Authority and the other Member States by 31 August each year:

(a) the results of the official controls provided for in Article 26(1);
(b) the LODs applied in the national control programmes referred to in Article 30 and under the Community Control Programme referred to in Article 29;
(c) details of the participation of the analytical laboratories in the Community proficiency tests referred to in Article 28(3) and other proficiency tests relevant to the pesticide-product combinations sampled in the national control programme;
(d) details of the accreditation status of the analytical laboratories involved in the controls referred to in point (a);
(e) where permitted by national legislation, details of enforcement measures taken.

2. Implementing measures relating to the submission of information by the Member States may be established in accordance with the procedure referred to in Article 45(2) after consultation with the Authority.

Article 32

The Annual Report on pesticide residues

1. On the basis of the information provided by the Member States under Article 31(1) the Authority shall draw up an Annual Report on pesticide residues.

2. The Authority shall include information on at least the following in the Annual Report:

(a) an analysis of the results of the controls provided for in Article 26(2);
(b) a statement of the possible reasons why the MRLs were exceeded, together with any appropriate observations regarding risk management options;
(c) an analysis of chronic and acute risks to the health of consumers from pesticide residues;
(d) an assessment of consumer exposure to pesticide residues based on the information provided under point (a) and any other relevant available information, including reports submitted under Directive 96/23/EC.

3. Where a Member State has not provided information in accordance with Article 31, the Authority may disregard the information relating to that Member State when compiling the Annual Report.

4. The format of the Annual Report may be decided in accordance with the procedure referred to in Article 45(2).

5. The Authority shall submit the Annual Report to the Commission by the last day of February each year.

6. The Annual Report may include an opinion on the pesticides to be covered in future programmes.

7. The Authority shall make public the Annual Report, as well as any comments by the Commission or Member States.

Article 33

Submission of the Annual Report on pesticide residues to the Committee

The Commission shall submit the Annual Report on pesticide residues to the Committee referred to in Article 45(1) without delay, for review and recommendations on any necessary measures to be taken regarding reported infringements of the MRLs set out in Annexes II and III.
SECTION 5
SANCTIONS

Article 34
Sanctions

The Member States shall lay down rules on the sanctions applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

The Member States shall notify those rules and any subsequent amendment to the Commission without delay.

CHAPTER VI
EMERGENCY MEASURES

Article 35
Emergency measures

Articles 53 and 54 of Regulation (EC) 178/2002 shall apply where, as a result of new information or of a reassessment of existing information, pesticide residues or MRLs covered by this Regulation may endanger human or animal health requiring immediate action.

CHAPTER VII
SUPPORT MEASURES RELATING TO HARMONISED PESTICIDE MRLS

Article 36
Support measures relating to harmonised pesticide MRLs

1. Support measures relating to harmonised pesticide MRLs shall be established at Community level, including:

   (a) a consolidated database for Community legislation on MRLs of pesticide residues and for making such information publicly available;

   (b) Community proficiency tests as referred to in Article 28(3);

   (c) studies and other measures necessary for the preparation and development of legislation and of technical guidelines on pesticide residues;

   (d) studies necessary for estimating the exposure of consumers and animals to pesticide residues;

   (e) studies necessary to support control laboratories where analytical methods are not capable of controlling the MRLs established.

2. Any necessary implementing provisions concerning the measures referred to in paragraph 1 may be adopted in accordance with the procedure referred to in Article 45(2).

Article 37
Community contribution to the support measures for harmonised pesticide MRLs

1. The Community may make a financial contribution of up to 100 % of the cost of the measures provided for in Article 36.

2. The appropriations shall be authorised each financial year as part of the budgetary procedure.

CHAPTER VIII
COORDINATION OF APPLICATIONS FOR MRLS

Article 38
Designation of national authorities

Each Member State shall designate one or more national authorities to coordinate cooperation with the Commission, the Authority, other Member States, manufacturers, producers and growers for the purposes of this Regulation. Where more than one authority is designated by a Member State, it shall indicate which of the designated authorities shall act as a contact point.

The national authorities may delegate tasks to other bodies.

Each Member State shall inform the Commission and the Authority of the names and addresses of the designated national authorities.

Article 39
Coordination by the Authority of information on MRLs

The Authority shall:

(a) coordinate with the rapporteur Member State designated in accordance with Directive 91/414/EEC for an active substance;

(b) coordinate with the Member States and the Commission regarding MRLs, in particular for the purpose of fulfilling the requirements of Article 41.
Article 40

Information to be submitted by the Member States

Member States shall submit to the Authority, at its request, any available information necessary for the assessment of the safety of MRLs.

Article 41

Database of the Authority on MRLs

Without prejudice to the applicable provisions of Community and national law on access to documents, the Authority shall develop and maintain a database, accessible to the Commission and to the competent authorities of the Member States, containing the relevant scientific information and GAPs relating to the MRLs, the active substances and the processing factors set out in Annexes II, III, IV and VII. In particular it shall contain dietary intake assessments, processing factors and toxicological endpoints.

Article 42

Member States and Fees

1. Member States may recover the costs of work associated with setting, modifying or deleting MRLs, or with any other work arising from obligations under this Regulation, by means of a fee or charge.

2. Member States shall ensure that the fee or charge referred to in paragraph 1:
   (a) is established in a transparent manner; and
   (b) corresponds to the actual cost of the work involved.

   It may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

CHAPTER IX
IMPLEMENTATION

Article 43

Scientific opinion of the Authority

The Commission or the Member States may request the Authority for a scientific opinion on any measure related to the assessment of risks under this Regulation. The Commission may specify the time limit within which such an opinion shall be provided.

Article 44

Procedure for the adoption of the Authority’s opinions

1. When the Authority’s opinions pursuant to this Regulation require only scientific or technical work involving the application of well-established scientific or technical principles they may, unless the Commission or a Member State objects, be issued by the Authority without consulting the scientific committee or the scientific panels mentioned in Article 28 of Regulation (EC) No 178/2002.

2. The implementing rules pursuant to Article 29(6)(a) of Regulation (EC) No 178/2002 shall specify the cases in which paragraph 1 above shall apply.

Article 45

Committee Procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) No 178/2002 (hereinafter referred to as ‘the Committee’).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

   The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 46

Implementing measures

In accordance with the procedure referred to in Article 45(2) and, where appropriate, taking into account the opinion of the Authority, the following shall be established or may be amended:

(a) implementing measures to ensure the uniform application of this Regulation;

(b) the dates in Articles 23, 29(2), 30(2), 31(1) and 32(5);

(c) technical guidance documents to assist in the application of this Regulation;

(d) detailed rules concerning the scientific data required for the setting of MRLs.

Article 47

Report on implementation of this Regulation

Not later than 10 years after the entry into force of this Regulation, the Commission shall forward to the European Parliament and to the Council a report on its implementation and any appropriate proposals.
CHAPTER X

FINAL PROVISIONS

Article 48

Repeal and adaptation of legislation

2. Article 4(1)(f) of Directive 91/414/EEC shall be replaced by the following:
   
   '(f) where appropriate, the MRLs for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No …/2004 (*).

   (*) OJ L ....

Article 49

Transitional Measures
1. The requirements of Chapter III shall not apply to products lawfully produced or imported into the Community before the date referred to in the second paragraph of Article 50.

   However, in order to ensure a high level of consumer protection, appropriate measures concerning those products may be taken in accordance with the procedure referred to in Article 45(2).

2. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, further transitional measures may be laid down for the implementation of certain MRLs provided for in Articles 15, 16, 21, 22, and 25.

   Those measures, which shall be without prejudice to the obligation to ensure a high level of consumer protection, shall be adopted in accordance with the procedure referred to in Article 45(2).

Article 50

Entry into force

This Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union.

Chapters II, III and V shall apply as from six months from the publication of the last of the Regulations establishing Annexes I, II, III and IV.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament

The President

For the Council

The President
STATEMENT OF THE COUNCIL’S REASONS

I. INTRODUCTION

On 14 March 2003 the Council received from the Commission a proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin.


The Council adopted its common position on 19 July 2004, in accordance with the procedure laid down in Article 251 of the Treaty.

II. OBJECTIVES

The proposal overhauls and streamlines European pesticides legislation by replacing four existing Council Directives with a single Regulation. The aim of the new, harmonised provisions is twofold: to facilitate trade within the Single Market and with third countries, import tolerances being granted to exporters to the EU in certain cases, and to ensure a consistent level of consumer protection across the Community. The proposal also provides for the role of the European Food Safety Authority (EFSA) in this field. Under the new provisions, as amended by the Council, following a transitional period, MRLs would only be set at Community level through a procedure where Member States assess the need for an MRL and submit an evaluation report to the Commission. EFSA would be responsible for risk assessment based on the Member State evaluation report and data received from applicants, while the Commission would handle risk management by setting MRLs.

III. ANALYSIS OF THE COMMON POSITION

A. GENERAL OBSERVATIONS

The Council’s common position broadly accords with the positions taken by the Commission and the Parliament, inasmuch as it:

— confirms the objectives and most of the arrangements proposed by the Commission and supported by the European Parliament;

— includes a large number of the amendments adopted at first reading by the European Parliament.

In particular, the Council agreed with a series of parliamentary amendments aiming to ensure the smooth functioning of the new procedures and to increase consistency between the new Regulation and other Community legislation. In addition, the Council felt that it was appropriate to introduce further amendments, for example, to allow Member States the flexibility to deal with MRL exceedences that arise in certain exceptional cases. The Council also reordered and reformatted parts of the text of the Regulation so as to clarify the roles of the Member States, EFSA and the Commission and to separate transitional provisions from the standard procedures under the new regime. A number of technical and editorial amendments were also introduced.

B. SPECIFIC COMMENTS

(a) Application procedure: the respective roles of the EFSA and the Member States

In its proposal, the Commission had foreseen an exclusive role for EFSA in scientific evaluation work and the setting of MRLs. However, the Council agreed with the Parliament that Member States should perform a preliminary analysis of MRL applications in line with established procedures under Directive 91/414/EEC. In addition, the Council agreed that a copy of MRL applications received by Member States should immediately be sent to the Commission and to EFSA (Article 8).
(b) Procedure for routine work performed by EFSA

In the light of the substantial workload foreseen for EFSA, the Council introduced a new article designed to avoid unnecessary consultation of scientific bodies on matters of routine, i.e. in cases where EFSA issues opinions purely based on well-established scientific principles (Article 44). This provision is analogous to Article 31 of Regulation 178/2002/EC.

(c) Administrative review

A new article was added with a view to providing a form of legal redress regarding decisions taken by EFSA and also in the event of non-action by EFSA (Article 13).

(d) Time scale and transition to the new procedures

To ensure a smooth transition to the new provisions, the Council followed the Parliament in setting down specific deadlines for the completion of the principal technical annexes, which will set out a list of harmonised MRLs (Annex II), a list of harmonised temporary MRLs (Annex III) and a list of active substances for which no MRLs are required (Annex IV). In the same spirit, the Council also introduced a deadline for drawing up the annex listing the products to which harmonised MRLs will apply (Annex I). Like Parliament, the Council considered that the Regulation should not apply in full until after the crucial annexes have been drawn up (Articles 4, 5, 21, 22 and 50).

(e) Possibility to extend the validity of temporary MRLs

In order to facilitate a smooth transition to a fully harmonised regime (e.g. where Member States indicate that extra time is required to complete scientific studies on substances that have been authorised nationally), the Council decided that it should be possible for temporary MRLs, which will normally be valid for one year, to be maintained in Annex III for up to three additional years in certain cases (Article 15).

(f) The use of pesticides for post-harvest treatment

A derogation was introduced in order to provide for the practice of post-harvest fumigation of products (e.g. with a view to protecting them against pests during storage and transport, which can entail the temporary exceedence of MRLs while the product remains in storage or transit) (Article 18(3)).

(g) The use of pesticides in exceptional circumstances

In order to provide for exceptional circumstances (e.g. when an emergency use of a plant protection product is required to control pest(s) in accordance with Article 8(4) of Directive 91/414/EEC), emergency provisions were introduced allowing a Member State to authorise the placing on the market and/or the feeding to animals within its territory of food or feed that is not in compliance with the MRLs laid down in the Regulation. Such authorisations are to be notified to the other Member States, the Commission and EFSA, with a view to setting temporary MRLs and taking any other necessary actions. Such authorisations can only be granted provided that the treated food or feed does not constitute an unacceptable risk to consumers (Article 18(4)).

(h) Definitions

In redrafting the text to improve legal clarity, the Council added two new definitions, namely ‘critical GAP’ (i.e. the Good Agricultural Practice that forms the basis for a harmonised MRL under the Regulation) and ‘CXL’ (i.e. an MRL set by the Codex Alimentarius Commission), and deleted the definition of ‘composite foodstuffs’. In addition, the Council followed the European Parliament in clarifying the definition of ‘pesticide residues’ (Article 3).
(i) Technical and editorial amendments
A large number of other changes, including technical adjustments and clarifications, were also made.

(ii) Amendments not accepted by Council
Further discussion is needed, in particular, on issues associated with risk assessment, and on provisions concerning the use of plant protection products, where Council was unable to agree to a number of Parliament’s amendments at this stage. Such items concern, in particular, approaches to exposure assessment in the context of MRL-setting, considerations surrounding the most appropriate way of providing information to the public, and the drafting of provisions concerning good agricultural practice and pest management.