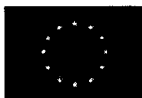


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**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 9 July 2004  
(OR. en)**

**9262/04**

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**Interinstitutional File:  
2003/0052 (COD)**

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**LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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Subject : Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

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**REGULATION (EC) No /2004 OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL  
of**

on maximum residue levels of pesticides in or on food  
and feed of plant and animal origin  
and amending Council Directive 91/414/EEC  
(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 Article 37 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee <sup>1</sup>,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>2</sup>,

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<sup>1</sup> OJ C 234, 30.9.2003, p. 33.

<sup>2</sup> Opinion of the European Parliament of 20 April 2004 (not yet published in the Official Journal), Council Common Position of ..... not yet published in the Official Journal) and position of the European Parliament of ..... (not yet published in the Official Journal).

Whereas:

- (1) Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables <sup>1</sup>, Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals <sup>2</sup>, Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin <sup>3</sup>, and Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on products of plant origin, including fruit and vegetables <sup>4</sup>, have been substantially amended several times. In the interests of clarity and simplicity, those Directives should be repealed and replaced by a single act.
- (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, 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.

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<sup>1</sup> OJ L 340, 9.12.1976, p. 26. Directive as last amended by Regulation (EC) No 807/2003, (OJ L 122, 16.5.2003, p. 36).

<sup>2</sup> OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2004/61/EC, (OJ L 127, 29.4.2004, p. 81).

<sup>3</sup> OJ L 221, 7.8.1986, p. 43. Directive as last amended by Directive 2004/61/EC.

<sup>4</sup> OJ L 350, 14.12.1990, p. 71. Directive as last amended by Directive 2004/61/EC.

- (4) The production and consumption of plant and animal products play a very important role in the Community. The yield from plant production is continually being affected by harmful organisms. It is essential to protect plants and plant products against such organisms, not only to prevent a reduction in yield or damage to them but also in order to ensure the quality of the products harvested, to increase agricultural productivity, and to protect the natural environment by limiting the surface area needed for agricultural production.
- (5) One of the most important methods of protecting plants and plant products from the effects of harmful organisms is the use of active substances in plant protection products. However, a possible consequence of their use may be the presence of residues in the treated products, in animals feeding on those products and in honey produced by bees exposed to those substances. It is necessary to ensure that such residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals.
- (6) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market <sup>1</sup> provides that Member States, when issuing authorisations, are to prescribe that plant protection products be used properly. Proper use includes the application of the principles of good plant protection practice as well as the principles of integrated control. Where the MRLs arising from an authorised use of a pesticide under Directive 91/414/EEC present a risk to the consumer such use should be revised to decrease the levels of pesticide residues. The Community should encourage the use of methods or products favouring a reduction in risk, and a reduction in the amounts of pesticides used to levels consistent with efficient pest control.

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<sup>1</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/71/EC (OJ L 127, 29.4.2004, p. 14).

- (7) A number of active substances are banned under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances.<sup>1</sup> At the same time, many other active substances are not currently authorised under Directive 91/414/EEC. The residues of active substances in products of plant and animal origin arising from unauthorised use or from environmental contamination or from use in third countries should be carefully controlled and monitored.
- (8) 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.<sup>2</sup>
- (9) 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.

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<sup>1</sup> OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 807/2003.

<sup>2</sup> OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

- (10) 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.
- (11) 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.
- (12) 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.

- (13) 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.<sup>1</sup> 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.
- (14) 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.
- (15) 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.
- (16) 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.
- (17) 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.
- (18) 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.

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<sup>1</sup> OJ L 140, 30.5.2002, p. 10. Directive as last amended by Commission Directive 2003/100/EC (OJ L 285, 1.11.2003, p. 33).

- (19) 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 pesticides 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.
- (20) 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.
- (21) 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").



- (22) 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 Organization.
- (23) Through the World Trade Organization, 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.
- (24) 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.
- (25) 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.
- (26) 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.
- (27) 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.

- (28) 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.
- (29) 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.
- (30) 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.
- (31) 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. <sup>1</sup>

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<sup>1</sup> OJ L 184, 17.7.1999, p. 23.

(32) 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 <sup>1</sup>, 2002/32/EC and Regulation (EEC) No 2377/90 <sup>2</sup>.

### Article 3

#### Definitions

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

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<sup>1</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

<sup>2</sup> Directive as last amended by Regulation (EC) No 1882/2003, (OJ L 284, 31.10.2003, p. 1).  
Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 546/2004 (OJ L 87, 25.3.2004, p. 13).

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, point 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.