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► **B** REGULATION (EC) No 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 February 2005

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)

(OJ L 70, 16.3.2005, p. 1)

Amended by:

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		No	page	date
► <u>M1</u>	Commission Regulation (EC) No 178/2006 of 1 February 2006	L 29	3	2.2.2006
► <u>M2</u>	Commission Regulation (EC) No 260/2008 of 18 March 2008	L 76	31	19.3.2008
► <u>M3</u>	Regulation (EC) No 299/2008 of the European Parliament and of the Council of 11 March 2008	L 97	67	9.4.2008



**REGULATION (EC) No 396/2005 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**

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**on maximum residue levels of pesticides in or on food and feed of
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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 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:

- (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 ⁽³⁾, Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ⁽⁴⁾, 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 ⁽⁵⁾, 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 ⁽⁶⁾, 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 In the interests of clarity and simplicity, those Directives should be repealed and replaced by a single act.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) This Regulation directly concerns public health and is relevant to the functioning of the internal market. 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 a high level of consumer protection, it is appropriate that maximum residue

⁽¹⁾ OJ C 234, 30.9.2003, p. 33.

⁽²⁾ Opinion of the European Parliament of 20 April 2004 (not yet published in the Official Journal), Council Common Position of 19 July 2004 (OJ C 25 E, 1.2.2005, p. 1) and Position of the European Parliament of 15 December 2004 (not yet published in the Official Journal) and Council Decision of 24 January 2005.

⁽³⁾ 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).

⁽⁴⁾ 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).

⁽⁵⁾ OJ L 221, 7.8.1986, p. 43. Directive as last amended by Directive 2004/61/EC.

⁽⁶⁾ OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2004/95/EC (OJ L 301, 28.9.2004, p. 42).

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levels (MRLs) for products of plant and animal origin be set at Community level, taking into account good agricultural practice.

- (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.
- (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 in order to prevent a reduction in yield or damage to them, and ensure both the quality of the products harvested and high agricultural productivity. To this end, different methods are available, including non-chemical methods, practices such as using resistant varieties, crop rotation, mechanical weeding, biological control and chemical methods such as the use of plant protection products.
- (5) One of the most common 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. According to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽¹⁾, public health should be given priority over the interests of crop protection, thus 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. MRLs should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn.
- (6) It is also important to carry out further work to develop a methodology to take into account cumulative and synergistic effects. In view of human exposure to combinations of active substances and their cumulative and possible aggregate and synergistic effects on human health, MRLs should be set after consultation of the European Food Safety Authority established by 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⁽²⁾ (hereinafter the Authority).
- (7) Directive 91/414/EEC 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 agricultural 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 the use of amounts of pesticides at levels consistent with efficient pest control.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/99/EC (OJ L 309, 6.10.2004, p. 6).

⁽²⁾ 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).

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- (8) 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 ⁽¹⁾. 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.
- (9) The basic rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002.
- (10) 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.
- (11) 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.
- (12) 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.
- (13) 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.
- (14) Whilst considering MRLs of pesticides, it should also be recognised that few consumers are aware of the risks arising from pesticides. It would be valuable to fully explain such risks to the public.
- (15) Member States should look into the possibility of publishing the names of companies whose products contain higher pesticide residues than the maximum permitted levels.

⁽¹⁾ OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 850/2004 of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 7. Regulation as corrected in OJ L 229, 29.6.2004, p. 5).

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- (16) 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.
- (17) It is necessary to define at Community level certain terms used for the setting, control and reporting on controls of MRLs for products of plant and animal origin. It is important that the Member States apply proper sanctions in accordance with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽²⁾.
- (18) 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.
- (19) 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.
- (20) 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.
- (21) 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.
- (22) 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.
- (23) 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

⁽¹⁾ 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).

⁽²⁾ OJ L 165, 30.4.2004, p. 1. Regulation as corrected in OJ L 191, 28.5.2004, p. 1.

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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 Authority.

- (24) 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.
- (25) 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, taking into account the corresponding good agricultural practices.
- (26) 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 are set 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.
- (27) It is necessary that the Authority assess MRL applications and evaluation reports prepared by the Member States, taking into account the full range of toxicological effects such as immunotoxicity, endocrine disruption and developmental toxicity, with a view to determining the associated risks to consumers and, where relevant, to animals.
- (28) 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.
- (29) 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.
- (30) 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.
- (31) 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.
- (32) 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

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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.

- (33) 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.
- (34) To ensure that consumers are kept adequately informed, Member States should, in accordance with Regulation (EC) No 882/2004, publish the results of national monitoring residues annually on the Internet, providing all individual data, including the place of collection and the names of retailers, traders and/or producers.
- (35) 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⁾.
- (36) 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, in particular the need to ensure a high level of consumer protection and 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

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

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- (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⁾, 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 the definitions in Article 2, points 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. It also implies the application, in conformity with Directive 91/414/EEC, of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained;
- (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 a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers;
- (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 to meet the needs of international trade where:

⁽¹⁾ 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). Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ 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 1875/2004 (OJ L 326, 29.10.2004, p. 19).

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- the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use; or
 - a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use;
- (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 day, without appreciable risk to the consumer on the basis of the data produced by appropriate studies and taking into account sensitive groups within the population (e.g. children and the unborn);
- (j) ‘acceptable daily intake’ means the estimate of the amount of substances in food expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable risk to any consumer on the basis of all known facts at the time of evaluation, taking into account sensitive groups within the population (e.g. children and the unborn).

*Article 4***List of groups of products for which harmonised MRLs shall apply****▼M3**

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. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3). 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.

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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****▼M3**

1. Active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required shall be defined and listed in Annex IV to this Regulation, taking into account the uses of those active substances and the matters referred to in points (a), (c) and (d) of Article 14(2). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4).

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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. All parties demonstrating, through adequate evidence, a legitimate interest in health, including civil society organisations, as well as commercially interested parties such as manufacturers, growers, importers 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 the 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) a comprehensive overview of relevant concerns raised in the available scientific literature about the plant protection product and/or its residue;
 - (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.

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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. In no event may this period exceed two years.

*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 Authority and the Commission and draw up an evaluation report without undue delay.

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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. That regulation, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3).

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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.

In exceptional cases where more detailed evaluations need to be carried out, the time limit laid down in the first subparagraph may be extended to six months from the date of receipt of the valid 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;

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(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****▼M3**

1. Upon receipt of the opinion of the Authority and taking account of that opinion, one of the following shall be prepared by the Commission without delay and at the latest within three months:

- (a) a regulation on the setting, modification or deletion of an MRL. That regulation, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 45(5) in order to ensure a high level of consumer protection;
- (b) a decision rejecting the application, which shall be adopted in accordance with the regulatory procedure referred to in Article 45(2).

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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, and their known cumulative and synergistic effects, when the methods to assess such effects are available;
- (c) the results of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals;
- (d) the results of any evaluations and decisions to modify the uses of plant protection products;

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- (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.

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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. That regulation, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 45(5) in order to ensure a high level of consumer protection.

However, where one or more Member States so request, the temporary MRL 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 consumers have been identified.

▼B*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 do not constitute a major part of the diet of relevant subgroups, and, where relevant, of animals; or
 - (c) for honey; or
 - (d) for herbal infusions; or

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- (e) 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; or
 - (f) where new products, product groups and/or parts of products have been included in Annex I, and one or more Member States so request, in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated, provided that no unacceptable safety concerns for the consumer have been identified.
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 paragraphs 1(a), (b), (c) and (d) 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(e) shall be reassessed at the expiry of the period for which the essential use was authorised. The MRLs referred to in paragraph 1(f) shall be reassessed when the scientific studies have been completed and evaluated, but no later than four years after their inclusion in Annex III.

*Article 17***Modifications of MRLs 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**▼M3***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 while taking into account the routine analytical methods available. Such default values shall be listed in Annex V. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 45(5) in order to ensure a high level of consumer protection.
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:

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- (a) such products comply with paragraph 1 and Article 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.

Measures designed to amend non-essential elements of this Regulation and defining the active substance/product combinations listed in Annex VII shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3).

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 pursuant to obligations set out 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 with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 45(5) in order to ensure a high level of consumer protection.

▼B*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

⁽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 2007/41/EC (OJ L 169, 29.6.2007, p. 51).

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Annex I, taking into account changes in the levels of pesticide residues caused by processing and/or mixing.

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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. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3).

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CHAPTER IV

**SPECIAL PROVISIONS RELATING TO THE
INCORPORATION OF EXISTING MRLS INTO THIS
REGULATION**

*Article 21***First establishment of MRLs****▼M3**

1. MRLs for products covered by Annex I shall be first established and listed in Annex II, incorporating the MRLs provided for under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC, taking into account the criteria listed in Article 14(2) of this Regulation. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3).

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

*Article 22***First establishment of temporary MRLs****▼M3**

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, taking into account the information provided by the Member States, where relevant the reasoned opinion referred to 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.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3).

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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.

▼B*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. 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 an opinion is necessary, 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). Temporary MRLs shall be set at the lowest level that can be achieved in all Member States on the basis of good agricultural practice.

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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. Such controls shall also be carried out at the point of supply to the consumer.

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.

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2. Measures designed to amend non-essential elements of this Regulation by supplementing it and determining 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 adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3) of this Regulation.

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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).

⁽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 882/2004.

⁽²⁾ 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).

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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. They shall, on an annual basis, publish all results of national residue monitoring on the

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Internet. Where MRLs are exceeded, Member States may name the retailers, traders or producers concerned.

*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).

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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) No 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. The time limit within which the Commission must take its decision shall be reduced to seven days in the case of fresh produce.

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:

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- (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, aimed, in particular, at developing and using methods of assessing aggregate, cumulative and synergistic effects;
 - (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.

▼B*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 from the Authority 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.

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

▼M3*Article 45***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002.

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. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 46***Implementing measures**

1. Implementing measures to ensure the uniform application of this Regulation, technical guidance documents to assist in its application and detailed rules concerning the scientific data required for the setting of MRLs shall be established or may be amended in accordance with the regulatory procedure referred to in Article 45(2), taking into account, where appropriate, the opinion of the Authority.

2. Measures designed to amend non-essential elements of this Regulation and relating to the establishment or amendment of the dates referred to in Article 23, Article 29(2), Article 30(2), Article 31(1) and Article 32(5) shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(3), taking into account, where appropriate, the opinion of the Authority.

▼B*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.

▼B**CHAPTER X
FINAL PROVISIONS***Article 48***Repeal and adaptation of legislation**

1. Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC are hereby repealed with effect from the date referred to in the second paragraph of Article 50.

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 396/2005 (*)’

(*) OJ L 70, 16.3.2005, p. 1.

▼M3*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. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(5).

2. Where necessary 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, designed to amend non-essential elements of this Regulation by supplementing it, and without prejudice to the obligation to ensure a high level of consumer protection, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 45(4).

▼B*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.



ANNEX I

Products of plant and animal origin referred to in Article 2(1)

Code number (¹)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name (²)	Examples of related varieties or other products included in the definition to which the same MRL applies	Parts of the products to which the MRLs apply
0100000	1. FRUIT FRESH OR FROZEN; NUTS				
0110000	(i) Citrus fruit				Whole product
0110010		Grapefruit	<i>Citrus paradisi</i>	Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids	
0110020		Oranges	<i>Citrus sinensis</i>	Bergamot, bitter orange, chinotto and other hybrids	
0110030		Lemons	<i>Citrus limon</i>	Citron, lemon	
0110040		Limes	<i>Citrus aurantifolia</i>		
0110050		Mandarins	<i>Citrus reticulata</i>	Clementine, tangerine and other hybrids	
0110990		Others (³)			
0120000	(ii) Tree nuts (shelled or unshelled)				Whole product after removal of shell (except chestnuts)
0120010		Almonds	<i>Prunus dulcis</i>		
0120020		Brazil nuts	<i>Bertholletia excelsa</i>		
0120030		Cashew nuts	<i>Anacardium occidentale</i>		
0120040		Chestnuts	<i>Castanea sativa</i>		
0120050		Coconuts	<i>Cocos nucifera</i>		
0120060		Hazelnuts	<i>Corylus avellana</i>	Filbert	
0120070		Macadamia	<i>Macadamia ternifolia</i>		
0120080		Pecans	<i>Carya illinoensis</i>		
0120090		Pine nuts	<i>Pinus pinea</i>		
0120100		Pistachios	<i>Pistachia vera</i>		
0120110		Walnuts	<i>Juglans regia</i>		
0120990		Others (³)			

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Code number (¹)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name (²)	Examples of related varieties or other products included in the definition to which the same MRL applies	Parts of the products to which the MRLs apply
0130000	(iii) Pome fruit				Whole product after removal of stems
0130010		Apples	<i>Malus domestica</i>	Crab apple	
0130020		Pears	<i>Pyrus communis</i>	Oriental pear	
0130030		Quinces	<i>Cydonia oblonga</i>		
0130040		Medlar (⁴)	<i>Mespilus germanica</i>		
0130050		Loquat (⁴)	<i>Eriobotrya japonica</i>		
0130990		Others (³)			
0140000	(iv) Stone fruit				Whole product after removal of stems
0140010		Apricots	<i>Prunus armeniaca</i>		
0140020		Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	Sweet cherries, sour cherries	
0140030		Peaches	<i>Prunus persica</i>	Nectarines and similar hybrids	
0140040		Plums	<i>Prunus domestica</i>	Damson, greengage, mirabelle	
0140990		Others (³)			
0150000	(v) Berries and small fruit				Whole product after removal of caps/crowns and stems except in the case of currants: fruits with stems
0151000	(a) Table and wine grapes				
0151010		Table grapes	<i>Vitis euveitica</i>		
0151020		Wine grapes	<i>Vitis euveitica</i>		
0152000	(b) Strawberries		<i>Fragaria × ananassa</i>		
0153000	(c) Cane fruit				

▼ **M1**

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0153010		Blackberries	<i>Rubus fruticosus</i>		
0153020		Dewberries	<i>Rubus ceasius</i>	Loganberries, Boysenberries, and cloudberries	
0153030		Raspberries	<i>Rubus idaeus</i>	Wineberries	
0153990		Others (³)			
0154000	(d) Other small fruit and berries				
0154010		Blueberries	<i>Vaccinium corymbosum</i>	Bilberries; cowberries (red bilberries)	
0154020		Cranberries	<i>Vaccinium macrocarpon</i>		
0154030		Currants (red, black and white)	<i>Ribes nigrum</i> , <i>Ribes rubrum</i>		
0154040		Gooseberries	<i>Ribes uva-crispa</i>	Including hybrids with other ribes species	
0154050		Rose hips	<i>Rosa canina</i>		
0154060		Mulberries (⁴)	<i>Morus</i> spp	Arbutus berry	
0154070		Azarole (⁴) (mediteranean medlar)	<i>Crataegus azarolus</i>		
0154080		Elderberries (⁴)	<i>Sambucus nigra</i>	Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other tree-berries	
0154990		Others (³)			
0160000	(vi) Miscellaneous fruit				Whole product after removal of stems or the crown (pine-apples)
0161000	(a) Edible peel				
0161010		Dates	<i>Phoenix dactylifera</i>		
0161020		Figs	<i>Ficus carica</i>		

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0161030		Table olives	<i>Olea europaea</i>		
0161040		Kumquats (⁴)	<i>Fortunella species</i>	Marumi kumquats, nagami kumquats	
0161050		Carambola (⁴)	<i>Averrhoa carambola</i>	Bilimbi	
0161060		Persimmon (⁴)	<i>Diospyros kaki</i>		
0161070		Jambolan (⁴) (java plum)	<i>Syzygium cumini</i>	Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry	
0161990		Others (³)			
0162000	(b) Inedible peel, small				
0162010		Kiwi	<i>Actinidia deliciosa</i> syn. <i>A. chinensis</i>		
0162020		Lychee (Litchi)	<i>Litchi chinensis</i>	Pulasan, rambutan (hairy litchi)	
0162030		Passion fruit	<i>Passiflora edulis</i>		
0162040		Prickly pear (⁴) (cactus fruit)	<i>Opuntia ficus-indica</i>		
0162050		Star apple (⁴)	<i>Chrysophyllum cainito</i>		
0162060		American persimmon (⁴) (Virginia kaki)	<i>Diospyros virginiana</i>	Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote	
0162990		Others (³)			
0163000	(c) Inedible peel, large				
0163010		Avocados	<i>Persea americana</i>		
0163020		Bananas	<i>Musa × paradisiaca</i>	Dwarf banana, plantain, apple banana	
0163030		Mangoes	<i>Mangifera indica</i>		
0163040		Papaya	<i>Carica papaya</i>		

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0163050		Pomegranate	<i>Punica granatum</i>		
0163060		Cherimoya (⁴)	<i>Annona cherimola</i>	Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae	
0163070		Guava (⁴)	<i>Psidium guajava</i>		
0163080		Pineapples	<i>Ananas comosus</i>		
0163090		Bread fruit (⁴)	<i>Artocarpus altilis</i>	Jackfruit	
0163100		Durian (⁴)	<i>Durio zibethinus</i>		
0163110		Soursop (⁴) (guanabana)	<i>Annona muricata</i>		
0163990		Others (³)			
0200000	2. VEGETABLES FRESH OR FROZEN				
0210000	(i) Root and tuber vegetables				Whole product after removal of tops (if any) and adhering soil by rinsing or brushing
0211000	(a) Potatoes		Tuber form <i>Solanum</i> spp.		
0212000	(b) Tropical root and tuber vegetables				
0212010		Cassava	<i>Manihot esculenta</i>	Dasheen, eddoe (Japanese taro), tannia	
0212020		Sweet potatoes	<i>Ipomoea batatas</i>		
0212030		Yams	<i>Dioscorea</i> sp.	Potato bean (yam bean), Mexican yam bean	
0212040		Arrowroot (⁴)	<i>Maranta arundinacea</i>		
0212990		Others (³)			

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0213000	(c) Other root and tuber vegetables except sugar beet				
0213010		Beetroot	<i>Beta vulgaris</i> subsp. <i>vulgaris</i>		
0213020		Carrots	<i>Daucus carota</i>		
0213030		Celeriac	<i>Apium graveolens</i> var. <i>rapaceum</i>		
0213040		Horseradish	<i>Armoracia rusticana</i>		
0213050		Jerusalem artichokes	<i>Helianthus tuberosus</i>		
0213060		Parsnips	<i>Pastinaca sativa</i>		
0213070		Parsley root	<i>Petroselinum crispum</i>		
0213080		Radishes	<i>Raphanus sativus</i> var. <i>sativus</i>	Black radish, Japanese radish, small radish and similar varieties	
0213090		Salsify	<i>Tragopogon porrifolius</i>	Scorzoneria, Spanish salsify (Spanish oysterplant)	
0213100		Swedes	<i>Brassica napus</i> var. <i>napobrassica</i>		
0213110		Turnips	<i>Brassica rapa</i>		
0213990		Others (³)			
0220000	(ii) Bulb vegetables				Whole product after removal of easily detachable skin and soil (when dry) or roots and soil (when fresh)
0220010		Garlic	<i>Allium sativum</i>		
0220020		Onions	<i>Allium cepa</i>	Silverskin onions	
0220030		Shallots	<i>Allium ascalonicum</i> (<i>Allium cepa</i> var. <i>aggregatum</i>)		

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0220040		Spring onions	<i>Allium cepa</i>	Welsh onion and similar varieties	
0220990		Others (³)			
0230000	(iii) Fruiting vegetables				Whole product after removal of stems (in case of sweet corn without husks)
0231000	(a) Solanacea				
0231010		Tomatoes	<i>Lycopersicon esculentum</i>	Cherry tomatoes	
0231020		Peppers	<i>Capsicum annuum</i> , var <i>grossum</i> and var. <i>longum</i>	Chilli peppers	
0231030		Aubergines (egg plants)	<i>Solanum melongena</i>	Pepino	
0231040		Okra, lady's fingers	<i>Hibiscus esculentus</i>		
0231990		Others (³)			
0232000	(b) Cucurbits — edible peel				
0232010		Cucumbers	<i>Cucumis sativus</i>		
0232020		Gherkins	<i>Cucumis sativus</i>		
0232030		Courgettes	<i>Cucurbita pepo</i> var. <i>melo</i>	Summer squash, marrow (patisson)	
0232990		Others (³)			
0233000	(c) Cucurbits-inedible peel				
0233010		Melons	<i>Cucumis melo</i>	Kiwano	
0233020		Pumpkins	<i>Cucurbita maxima</i>	Winter squash	
0233030		Watermelons	<i>Citrullus lanatus</i>		
0233990		Others (³)			
0234000	(d) Sweet corn		<i>Zea mays</i> var. <i>saccharata</i>		Kernels plus cob without husks
0239000	(e) Other fruiting vegetables				
0240000	(iv) Brassica vegetables				

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0241000	(a) Flowering brassica				Curd only
0241010		Broccoli	<i>Brassica oleracea</i> var. <i>italica</i>	Calabrese, Chinese broccoli, Broccoli raab	
0241020		Cauliflower	<i>Brassica oleracea</i> var. <i>botrytis</i>		
0241990		Others (³)			
0242000	(b) Head brassica				Whole plant after removal of roots and decayed leaves
0242010		Brussels sprouts	<i>Brassica oleracea</i> var. <i>gemmifera</i>		Only cabbage buttons
0242020		Head cabbage	<i>Brassica oleracea</i> convar. <i>capitata</i>	Pointed head cabbage, red cabbage, savoy cabbage, white cabbage	
0242990		Others (³)			
0243000	(c) Leafy brassica				Whole plant after removal of roots and decayed leaves
0243010		Chinese cabbage	<i>Brassica pekinensis</i>	Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage	
0243020		Kale	<i>Brassica oleracea</i> convar. <i>Acephalea</i>	Borecole (curly kale), collards	
0243990		Others (³)			
0244000	(d) Kohlrabi		<i>Brassica oleracea</i> convar. <i>acephala</i> , var. <i>gongylodes</i>		Whole product after removal of roots, tops and adhering soil (if any)

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0250000	(v) Leaf vegetables and fresh herbs				Whole product after removal of roots and decayed outer leaves and soil (if any)
0251000	(a) Lettuce and other salad plants including Brassicacea				
0251010		Lamb's lettuce	<i>Valerianella locusta</i>	Italian cornsalad	
0251020		Lettuce	<i>Lactuca sativa</i>	Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce	
0251030		Scarole (broad-leaf endive)	<i>Cichorium endiva</i>	Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf	
0251040		Cress (⁴)	<i>Lepidium sativum</i>		
0251050		Land cress (⁴)	<i>Barbarea verna</i>		
0251060		Rocket, Rucola (⁴)	<i>Eruca sativa</i> (<i>Diplotaxis spec.</i>)	Wild rocket	
0251070		Red mustard (⁴)	<i>Brassica juncea</i> var. <i>rugosa</i>		
0251080		Leaves and sprouts of <i>Brassica</i> spp (⁴)	<i>Brassica</i> spp.	Mizuna	
0251990		Others (³)			
0252000	(b) Spinach and similar (leaves)				
0252010		Spinach	<i>Spinacia oleracea</i>	New Zealand spinach, turnip greens (turnip tops)	

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0252020		Purslane (⁴)	<i>Portulaca oleracea</i>	Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort	
0252030		Beet leaves (chard)	<i>Beta vulgaris</i>	Leaves of beetroot	
0252990		Others (³)			
0253000	(c) Vine leaves (grape leaves) (⁴)		<i>Vitis euveitis</i>		
0254000	(d) Water cress		<i>Nasturtium officinale</i>		
0255000	(e) Witloof		<i>Cichorium intybus</i> var. <i>foliosum</i>		
0256000	(f) Herbs				
0256010		Chervil	<i>Anthriscus cerefolium</i>		
0256020		Chives	<i>Allium schoenoprasum</i>		
0256030		Celery leaves	<i>Apium graveolens</i> var. <i>seccalinum</i>	Fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea	
0256040		Parsley	<i>Petroselinum crispum</i>		
0256050		Sage (⁴)	<i>Salvia officinalis</i>	Winter savory, summer savory	
0256060		Rosemary (⁴)	<i>Rosmarinus officinalis</i>		
0256070		Thyme (⁴)	<i>Thymus</i> spp.	Marjoram, oregano	
0256080		Basil (⁴)	<i>Ocimum basilicum</i>	Balm leaves, mint, peppermint	
0256090		Bay leaves (⁴) (laurel)	<i>Laurus nobilis</i>		
0256100		Tarragon (⁴)	<i>Artemisia dracunculus</i>	Hyssop	

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0256990		Others (³)			
0260000	(vi) Legume vegetables (fresh)				Whole product
0260010		Beans (with pods)	<i>Phaseolus vulgaris</i>	Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans	
0260020		Beans (without pods)	<i>Phaseolus vulgaris</i>	Broad beans, Flageolets, jack bean, lima bean, cowpea	
0260030		Peas (with pods)	<i>Pisum sativum</i>	Mangetout (sugar peas)	
0260040		Peas (without pods)	<i>Pisum sativum</i>	Garden pea, green pea, chickpea	
0260050		Lentils (⁴)	<i>Lens culinaris</i> syn. <i>L. esculenta</i>		
0260990		Others (³)			
0270000	(vii) Stem vegetables (fresh)				Whole product after removal of decayed tissue, soil and roots
0270010		Asparagus	<i>Asparagus officinalis</i>		
0270020		Cardoons	<i>Cynara cardunculus</i>		
0270030		Celery	<i>Apium graveolens</i> var. <i>dulce</i>		
0270040		Fennel	<i>Foeniculum vulgare</i>		
0270050		Globe artichokes	<i>Cynara scolymus</i>		Whole flowerhead including receptacle
0270060		Leek	<i>Allium porrum</i>		
0270070		Rhubarb	<i>Rheum hybridum</i> ×		Stalks after removal of roots and leaves
0270080		Bamboo shoots (⁴)	<i>Bambusa vulgaris</i>		

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0270090		Palm hearts (⁴)	<i>Euterpa oleracea</i> , <i>Cocos nucifera</i> , <i>Bactris gasipaes</i> , <i>daemonorops schmidtiana</i>		
0270990		Others (³)			
0280000	(viii) Fungi (⁴)				Whole product after removal of soil or growing medium
0280010		Cultivated		Common mushroom, Oyster mushroom, Shi-take	
0280020		Wild		Chanterelle, Truffle, Morel, Cep	
0280990		Others (³)			
0290000	(ix) Sea weeds (⁴)				Whole product after removal of decayed leaves
0300000	3. PULSES, DRY				Whole product
0300010		Beans	<i>Phaseolus vulgaris</i>	Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas	
0300020		Lentils	<i>Lens culinaris</i> syn. <i>L. esculenta</i>		
0300030		Peas	<i>Pisum sativum</i>	Chickpeas, field peas, chickling vetch	
0300040		Lupins (⁴)	<i>Lupinus</i> spp.		
0300990		Others (³)			
0400000	4. OILSEEDS AND OILFRUITS				Whole product after removal of shell, stone and husk when possible
0401000	(i) Oilseeds				

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0401010		Linseed	<i>Linum usitatissimum</i>		
0401020		Peanuts	<i>Arachis hypogaea</i>		
0401030		Poppy seed	<i>Papaver somniferum</i>		
0401040		Sesame seed	<i>Sesamum indicum</i> syn. <i>S. orientale</i>		
0401050		Sunflower seed	<i>Helianthus annuus</i>		
0401060		Rape seed	<i>Brassica napus</i>	Bird rapeseed, turnip rape	
0401070		Soya bean	<i>Glycine max</i>		
0401080		Mustard seed	<i>Brassica nigra</i>		
0401090		Cotton seed	<i>Gossypium</i> spp.		
0401100		Pumpkin seeds (⁴)	<i>Cucurbita pepo</i> var. <i>oleifera</i>		
0401110		Safflower (⁴)	<i>Carthamus tinctorius</i>		
0401120		Borage (⁴)	<i>Borago officinalis</i>		
0401130		Gold of pleasure (⁴)	<i>Camelina sativa</i>		
0401140		Hempseed (⁴)	<i>Cannabis sativa</i>		
0401150		Castor bean	<i>Ricinus communis</i>		
0401990		Others (³)			
0402000	(ii) Oilfruits				
0402010		Olives for oil production (⁴)	<i>Olea europaea</i>		Whole fruit after removal of stems (if any) after removal of soil (if any)
0402020		Palm nuts (palmoil kernels) (⁴)	<i>Elaeis guineensis</i>		
0402030		Palmfruit (⁴)	<i>Elaeis guineensis</i>		
0402040		Kapok (⁴)	<i>Ceiba pentandra</i>		
0402990		Others (³)			

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0500000	5. CEREALS				Whole product
0500010		Barley	<i>Hordeum</i> spp.		
0500020		Buckwheat	<i>Fagopyrum esculentum</i>		
0500030		Maize	<i>Zea mays</i>		
0500040		Millet (⁴)	<i>Panicum</i> spp.	Foxtail millet, teff	
0500050		Oats	<i>Avena fatua</i>		
0500060		Rice	<i>Oryza sativa</i>		
0500070		Rye	<i>Secale cereale</i>		
0500080		Sorghum (⁴)	<i>Sorghum bicolor</i>		
0500090		Wheat	<i>Triticum aestivum</i>	Spelt Triticale	
0500990		Others (³)			
0600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA				
0610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)		<i>Camellia sinensis</i>		Whole product
0620000	(ii) Coffee beans (⁴)				Beans only
0630000	(iii) Herbal infusions (⁴) (dried)				
0631000	(a) Flowers				Whole flowers after removal of stalks and decayed leaves
0631010		Camomille flowers	<i>Matricaria recutita</i>		
0631020		Hybiscus flowers	<i>Hibiscus sabdariffa</i>		
0631030		Rose petals	<i>Rosa</i> spec.		
0631040		Jasmine flowers	<i>Jasminum officinale</i>		
0631050		Lime (linden)	<i>Tilia cordata</i>		
0631990		Others (³)			
0632000	(b) Leaves				Whole product after removal of roots and decayed leaves

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0632010		Strawberry leaves	<i>Fragaria ananassa</i> ×		
0632020		Rooibos leaves	<i>Aspalathus</i> spp.		
0632030		Maté	<i>Ilex paraguayensis</i>		
0632990		Others (³)			
0633000	(c) Roots				Whole product after removal of tops and adhering soil by rinsing or brushing
0633010		Valerian root	<i>Valeriana officinalis</i>		
0633020		Ginseng root	<i>Panax ginseng</i>		
0633990		Others (³)			
0639000	(d) Other herbal infusions				
0640000	(iv) Cocoa (⁴) (fermented beans)		<i>Theobroma cacao</i>		Beans after removal of shells
0650000	(v) Carob (⁴) (St Johns bread)		<i>Ceratonia siliqua</i>		Whole product after removal of stems or the crown
0700000	7. HOPS (dried), including hop pellets and unconcentrated powder		<i>Humulus lupulus</i>		Whole product
0800000	8. SPICES (⁴)				Whole product
0810000	(i) Seeds				
0810010		Anise	<i>Pimpinella anisum</i>		
0810020		Black caraway	<i>Nigella sativa</i>		
0810030		Celery seed	<i>Apium graveolens</i>	Lovage seed	
0810040		Coriander seed	<i>Coriandrum sativum</i>		
0810050		Cumin seed	<i>Cuminum cyminum</i>		
0810060		Dill seed	<i>Anethum graveolens</i>		
0810070		Fennel seed	<i>Foeniculum vulgare</i>		

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0810080		Fenugreek	<i>Trigonella foenumgraecum</i>		
0810090		Nutmeg	<i>Myristica fragans</i>		
0810990		Others (³)			
0820000	(ii) Fruits and berries				
0820010		Allspice	<i>Pimenta dioica</i>		
0820020		Anise pepper (Japan pepper)	<i>Zanthoosylum piperitum</i>		
0820030		Caraway	<i>Carum carvi</i>		
0820040		Cardamom	<i>Elettaria cardamomum</i>		
0820050		Juniper berries	<i>Juniperus communis</i>		
0820060		Pepper, black and white	<i>Piper nigrum</i>	Long pepper, pink pepper	
0820070		Vanilla pods	<i>Vanilla fragrans</i> syn. <i>Vanilla planifolia</i>		
0820080		Tamarind	<i>Tamarindus indica</i>		
0820990		Others (³)			
0830000	(iii) Bark				
0830010		Cinnamon	<i>Cinnamomum verum</i> syn. <i>C. zeylanicum</i>	Cassia	
0830990		Others (³)			
0840000	(iv) Roots or rhizome				
0840010		Liquorice	<i>Glycyrrhiza glabra</i>		
0840020		Ginger	<i>Zingiber officinale</i>		
0840030		Turmeric (Curcuma)	<i>Curcuma domestica</i> syn. <i>C. longa</i>		
0840040		Horseradish	<i>Armoracia rusticana</i>		
0840990		Others (³)			
0850000	(v) Buds				
0850010		Cloves	<i>Syzygium aromaticum</i>		
0850020		Capers	<i>Capparis spinosa</i>		
0850990		Others (³)			

▼ **M1**

Code number (¹)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name (²)	Examples of related varieties or other products included in the definition to which the same MRL applies	Parts of the products to which the MRLs apply
0860000	(vi) Flower stigma				
0860010		Saffron	<i>Crocus sativus</i>		
0860990		Others (³)			
0870000	(vii) Aril				
0870010		Mace	<i>Myristica fragrans</i>		
0870990		Others (³)			
0900000	9. SUGAR PLANTS (⁴)				
0900010		Sugar beet (root)	<i>Beta vulgaris</i>		Whole product after removal of tops and adhering soil by rinsing or brushing
0900020		Sugar cane	<i>Saccharum officinarum</i>		Whole product after removal of decayed tissue, soil and roots
0900030		Chicory (⁴) roots	<i>Cichorium intybus</i>		Whole product after removal of tops and adhering soil by rinsing or brushing
0900990		Others (³)			
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS				
1010000	(i) Meat, preparations of meat, offals, blood, animal fats; fresh, chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals; other processed products such as sausages and food preparations based on these				Whole product or the fat fraction only (⁵)
1011000	(a) Swine		<i>Sus scrofa</i>		
1011010		Meat			

▼ M1

Code number (¹)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name (²)	Examples of related varieties or other products included in the definition to which the same MRL applies	Parts of the products to which the MRLs apply
1011020		Fat free of lean meat			
1011030		Liver			
1011040		Kidney			
1011050		Edible offal			
1011990		Others (³)			
1012000	(b) Bovine		<i>Bos spec.</i>		
1012010		Meat			
1012020		Fat			
1012030		Liver			
1012040		Kidney			
1012050		Edible offal			
1012990		Others (³)			
1013000	(c) Sheep		<i>Ovis aries</i>		
1013010		Meat			
1013020		Fat			
1013030		Liver			
1013040		Kidney			
1013050		Edible offal			
1013990		Others (³)			
1014000	(d) Goat		<i>Capra hircus</i>		
1014010		Meat			
1014020		Fat			
1014030		Liver			
1014040		Kidney			
1014050		Edible offal			
1014990		Others (³)			
1015000	(e) Horses, asses, or mules or hinnies		<i>Equus spec.</i>		
1015010		Meat			
1015020		Fat			
1015030		Liver			
1015040		Kidney			
1015050		Edible offal			

▼ M1

Code number (¹)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name (²)	Examples of related varieties or other products included in the definition to which the same MRL applies	Parts of the products to which the MRLs apply
1015990		Others (³)			
1016000	(f) Poultry — chicken, geese, duck, turkey and Guinea fowl — ostrich, pigeon		<i>Gallus gallus</i> , <i>Anser anser</i> , <i>Anas platyrhynchos</i> , <i>Meleagris gallopavo</i> , <i>Numida meleagris</i> , <i>Coturnix coturnix</i> , <i>Struthio camelus</i> , <i>Columba sp.</i>		
1016010		Meat			
1016020		Fat			
1016030		Liver			
1016040		Kidney			
1016050		Edible offal			
1016990		Others (³)			
1017000	(g) Other farm animals			Rabbit, Kangaroo	
1017010		Meat			
1017020		Fat			
1017030		Liver			
1017040		Kidney			
1017050		Edible offal			
1017990		Others (³)			
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd				Whole product or the fat fraction only (⁶)
1020010		Cattle			
1020020		Sheep			
1020030		Goat			
1020040		Horse			
1020990		Others (³)			
1030000	(iii) Birds' eggs, fresh preserved or cooked; Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved				Whole product or the fat fraction only (⁷)

▼ M1

Code number (¹)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific Name (²)	Examples of related varieties or other products included in the definition to which the same MRL applies	Parts of the products to which the MRLs apply
	whether or not containing added sugar or sweetening matter				
1030010		Chicken			
1030020		Duck			
1030030		Goose			
1030040		Quail			
1030990		Others (³)			
1040000	(iv) Honey		<i>Apis mellifera</i> , <i>Melipona spec.</i>	Royal jelly, pollen	
1050000	(v) Amphibians and reptiles		<i>Rana spec.</i> <i>Crocodilia spec.</i>	Frog legs, crocodiles	
1060000	(vi) Snails		<i>Helix spec.</i>		
1070000	(vii) Other terrestrial animal products				
1100000	11. FISH, FISH PRODUCTS, SHELL FISH, MOLLUSCS AND OTHER MARINE AND FRESHWATER FOOD PRODUCTS (⁸)				
1200000	12. CROPS EXCLUSIVELY USED FOR ANIMAL FEED (⁸)				

(¹) The code number is introduced by this Annex and is intended to set a classification under this and other related Annexes of Regulation (EC) No 396/2005.

(²) The scientific name of the items listed in the column 'Examples of individual products within the groups to which the MRLs apply', where possible and relevant, is mentioned. As much as possible the International System of Nomenclature is followed.

(³) The word 'others' covers anything not explicitly mentioned under the rest of the codes within 'Groups to which the MRLs apply'.

(⁴) MRLs in Annex II and III for the product apply only for the product when used for human consumption. For parts of the product used exclusively as ingredients for animal feed, separate MRLs will be applicable.

(⁵) Where the pesticide and/or metabolites (included in the residue definition) is/are water soluble ($\log P_{ow}$ less than 3) the MRL is expressed as mg/kg of meat (including fat), preparations of meat, offal and animal fats. Where the pesticide and/or metabolite (included in the residue definition) is/are fat soluble ($\log P_{ow}$ greater than or equal to 3) the MRL is expressed as mg/kg of fat contained in the meat, preparations of meat, offal and animal fats. In the case of foodstuffs with a fat content of 10 % or less by weight, the residue is related to the total weight of the boned foodstuff. In such cases, the maximum level is one-tenth of the value related to fat content, but must be no less than 0,01 mg/kg. The latter does not apply for cow's milk and whole cream cow's milk. It applies neither for the other products when the MRL is set at the LOD.

(⁶) Where the pesticide and/or metabolites (included in the residue definition) is /are water soluble ($\log P_{ow}$ less than 3) the MRL is expressed as mg/kg of milk and milk products. Where the pesticide and/or metabolite (included in the residue definition) is/are fat soluble ($\log P_{ow}$ greater than or equal to 3) the MRL is expressed as mg/kg of cow's milk and whole cream cow's milk. In determining the residues in raw cow's milk and whole cream cow's milk, a fat content of 4 % by weight should be taken as a basis. For raw milk and whole cream milk of another animal origin the residues are expressed on the basis of the fat. For the other foodstuffs listed with a fat content of less than 2 % by weight, the maximum level is taken as half that set for raw milk and whole cream milk, with a fat content of 2 % or more by weight, the maximum level is expressed in mg/kg of fat. In such cases, the maximum level is 25 times that set for raw milk and whole cream milk. The latter does not apply when the MRL is set at the LOD.

(⁷) Where the pesticide and/or metabolites (included in the residue definition) is/are water soluble ($\log P_{ow}$ less than 3) the MRL is expressed as mg/kg of shelled fresh eggs, for bird's eggs and egg yolks; Where the pesticide/or metabolite (included in the residue definition) is/are fat soluble ($\log P_{ow}$ greater than or equal to 3) the MRL is also expressed as mg/kg of shelled fresh eggs, for bird's eggs and egg yolks. However, for eggs and egg products with a fat content higher than 10 %, the maximum level is expressed in mg/kg fat. In this case, the maximum level is 10 times higher than the maximum level for fresh eggs. The latter does not apply when the MRL is set at the LOD.

(⁸) MRLs not applicable until the individual products are identified and listed.

▼ M2

ANNEX VII

Active substance/product combinations, as referred to in Article 18(3)

Active substance	Product in Annex I (Code number)
Hydrogen phosphide	Fruit (0100000), Vegetables (0200000), Pulses (0300000), Oilseeds and oil fruits (0400000), Cereals (0500000), Tea, coffee, herbal infusions and cocoa (0600000), Spices (0800000).
Aluminiumphosphide	Fruit (0100000), Vegetables (0200000), Pulses (0300000), Oilseeds and oil fruits (0400000), Cereals (0500000), Tea, coffee, herbal infusions and cocoa (0600000), Spices (0800000).
Magnesiumphosphide	Fruit (0100000), Vegetables (0200000), Pulses (0300000), Oilseeds and oil fruits (0400000), Cereals (0500000), Tea, coffee, herbal infusions and cocoa (0600000), Spices (0800000).
Sulfurylfluoride	Fruit (0100000), Cereals (0500000).