This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

# $\blacktriangleright\underline{B}$ 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:

Journal

		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

#### 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)

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 In the interests of clarity and simplicity, those Directives should be repealed and replaced by a single act.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

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

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

<sup>24</sup> 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).

<sup>(4)</sup> OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2004/61/EC (OJ L 127, 29.4.2004, p. 81).

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

<sup>(6)</sup> 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).

- 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.
- One of the most common methods of protecting plants and plant (5) 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 amounts of pesticides at levels consistent with efficient pest control.

<sup>(1)</sup> 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).

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

- (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.
- 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.

<sup>(</sup>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).

- (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.
- 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

<sup>(</sup>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).

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

- 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

- 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

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

- (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).

#### **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:

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).
 Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a

<sup>(2)</sup> 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).

#### **▼**B

- 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

### **▼**<u>M3</u>

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.

#### **▼**<u>B</u>

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).

### **▼**B

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.

#### **▼**B

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.

#### **▼** M3

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).

#### **▼**B

- 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;

#### **▼**B

- (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).

### **▼**B

- 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;

#### **▼**B

- (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.

#### **▼** M3

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.

## **▼**<u>B</u>

#### 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

- (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:

#### **▼** M3

- (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).

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

<sup>(</sup>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).

**▼**<u>B</u>

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

#### **▼** M3

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).

**▼**B

#### 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).

**▼**<u>B</u>

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).

#### **▼**<u>B</u>

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.

## 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.

#### 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.

### **▼**M3

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.

#### **▼**<u>B</u>

#### 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).

<sup>(1)</sup> 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.

<sup>(2)</sup> 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).

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

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).

- 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.

## 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:

- (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).

## 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.

#### 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.

**▼**B

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.

**▼**<u>M3</u>

#### 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.

**▼**<u>B</u>

#### Article 47

#### Report on implementation of this Regulation

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

#### CHAPTER X

#### FINAL PROVISIONS

#### Article 48

#### Repeal and adaptation of legislation

- 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).

## **▼**<u>B</u>

### 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.

 $\label{eq:annex} \textit{ANNEX I}$  Products of plant and animal origin referred to in Article 2(1)

Code number	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	Citrus paradisi	Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids	
0110020		Oranges	Citrus sinensis	Bergamot, bitter orange, chinotto and other hybrids	
0110030		Lemons	Citrus limon	Citron, lemon	
0110040		Limes	Citrus auran- tifolia		
0110050		Mandarins	Citrus reti- culata	Clementine, tangerine and other hybrids	
0110990		Others (3)			
0120000	(ii) <b>Tree nuts</b> (shelled or unshelled)				Whole product after removal or shell (excep chestnuts)
0120010		Almonds	Prunus dulcis		
0120020		Brazil nuts	Bertholletia excelsa		
0120030		Cashew nuts	Anacardium occidentale		
0120040		Chestnuts	Castanea sativa		
0120050		Coconuts	Cocos nucifera		
0120060		Hazelnuts	Corylus avellana	Filbert	
0120070		Macadamia	Macadamia ternifolia		
0120080		Pecans	Carya illi- noensis		
0120090		Pine nuts	Pinus pinea		
0120100		Pistachios	Pistachia vera		
0120110		Walnuts	Juglans regia		
0120990		Others (3)			

Code number	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	Malus domesticus	Crab apple	
0130020		Pears	Pyrus communis	Oriental pear	
0130030		Quinces	Cydonia oblonga		
0130040		Medlar (4)	Mespilus germanica		
0130050		Loquat (4)	Eriobotrya japonica		
0130990		Others (3)			
0140000	(iv) Stone fruit				Whole product after removal of stems
0140010		Apricots	Prunus armeniaca		
0140020		Cherries	Prunus cerasus, Prunus avium	Sweet cherries, sour cherries	
0140030		Peaches	Prunus persica	Nectarines and similar hybrids	
0140040		Plums	Prunus domestica	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	Vitis euvitis		
0151020		Wine grapes	Vitis euvitis		
0152000	(b) Strawberries		Fragaria × ananassa		
0153000	(c) Cane fruit				

Code number (1)	Groups to which the MRLs apply	Examples of indi- vidual 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
0153010		Blackberries	Rubus fruticosus		
0153020		Dewberries	Rubus ceasius	Loganberries, Boysenberries, and cloud- berries	
0153030		Raspberries	Rubus idaeus	Wineberries	
0153990		Others (3)			
0154000	(d) Other small fruit and berries				
0154010		Blueberries	Vaccinium corymbosum	Bilberries; cowberries (red bilberries)	
0154020		Cranberries	Vaccinium macrocarpon		
0154030		Currants (red, black and white)	Ribes nigrum, Ribes rubrum		
0154040		Gooseberries	Ribes uva- crispa	Including hybrids with other ribes species	
0154050		Rose hips	Rosa canina		
0154060		Mulberries (4)	Morus spp	Arbutus berry	
0154070		Azarole (4) (mediteranean medlar)	Crataegus azarolus		
0154080		Elderberries (4)	Sambucus nigra	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	Phoenix dacty- lifera		
0161020		Figs	Ficus carica		

Examples of individual products of individual products of included pro						
Kumquats (*)   Fortunella species   Kumquats   Kumqua		Groups to which the MRLs apply	vidual products within the groups to which the MRLs	Scientific Name (2)	related varieties or other products included in the definition to which the same MRL	products to which the
Species   Kumquats   Ranagami   Kumquats	0161030		Table olives	Olea europaea		
O161060 Persimmon (*) Diospyros kaki  O161070 Jambolan (*) Syzygium (water apple), pomerac, rose apple, graminam cherry  O162000 (b) Inedible peel, small  O162010 Kiwi Actinidia deliciosa syn. A. chinensis  O162020 Lychee (Litchi) Litchi chinensis Pulasan, rambutan (hairy litchi)  O162030 Passion fruit Passiflora edulis  O162040 Prickly pear (*) (cartus fruit) indica  O162050 Star apple (*) Chrysophyllum cainito  O162060 American American persimmon (*) (Virginia kaki)  O162060 Chrysophyllum cainito  O162060 American American Passione, canisted (yellow sapote), and manniney sapote (canisted (yellow sapote), and manniney sapote (canisted (yellow sapote), and manniney sapote (canisted indica)  O163010 Avocados Persea americama  O163020 Bananas Musa × paradisica Dwarf banana, plantain, apple banana  O163030 Mangoes Manggera indica	0161040		Kumquats (4)		kumquats, nagami	
Jambolan (*) (java plum)   Syzygium cumini   Dava apple (water apple), pomerae, rose apple, Brazilean cherry (grumichama), Surinam cherry	0161050		Carambola (4)		Bilimbi	
Giava plum   Cumini	0161060		Persimmon (4)	Diospyros kaki		
O162010   Small   Peel, small	0161070				(water apple), pomerac, rose apple, Brazilean cherry (grumichama),	
Small   Kiwi   Actinidia deliciosa syn. A. chinensis	0161990		Others (3)			
deliciosa syn. A. chinensis  Uychee (Litchi)  Litchi chinensis  Pulasan, rambutan (hairy litchi)  0162030  Passion fruit  Passiflora edulis  Prickly pear (4) Opuntia ficusindica  0162050  Star apple (4) Chrysophyllum cainito  O162060  American persimmon (4) (Virginia kaki)  O162060  American persimmon (5) (Virginia kaki)  O162090  Others (3)  Others (4)  Others (4)  Others (5)  Others (6)  Avocados  Persea americana  O163020  Bananas  Musa × paradisica  Divarf banana, plantain, apple banana  O163030  Mangoes  Mangifera indica	0162000					
Passion fruit   Passiflora edulis	0162010		Kiwi	deliciosa syn.		
O162040   Prickly pear (4)   Opuntia ficusindica	0162020		Lychee (Litchi)	Litchi chinensis	rambutan (hairy	
(cactus fruit) indica  O162050  Star apple (4)  Others (3)  O163010  American persimmon (4) (Virginia kaki)  Others (3)  O163020  Balack sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote  O163030  Mangoes  Mangifera indica	0162030		Passion fruit			
Cainito  American persimmon (4) (Virginia kaki)  Ol62060  American persimmon (4) (Virginiana  Olfinia kaki)  Olfinia kakii  Olfinia kaki)  Olfinia kaki)  Olfinia kaki)  Olfinia kaki)  Ol	0162040			1 3		
persimmon (4) (Virginia kaki) virginiana white sapote, green sapote, canistel (yellow sapote), and mammey sapote  Others (3)  Others (3)  Others (3)  Avocados Persea americana  O163010 Bananas Musa × para-disica Dwarf banana, plantain, apple banana  O163030 Mangoes Mangifera indica	0162050		Star apple (4)			
0163000 (c) Inedible peel,  0163010 Avocados Persea americana  0163020 Bananas Musa × para- disica Dwarf banana, plantain, apple banana  0163030 Mangoes Mangifera indica	0162060		persimmon (4)		white sapote, green sapote, canistel (yellow sapote), and mammey	
0163010 Avocados Persea americana  0163020 Bananas Musa × para-disica Dwarf banana, plantain, apple banana  0163030 Mangoes Mangifera indica	0162990		Others (3)			
0163020 Bananas Musa × para- disica Dwarf banana, plantain, apple banana  0163030 Mangoes Mangifera indica	0163000					
0163030 Mangoes Mangifera indica	0163010		Avocados			
indica	0163020		Bananas		plantain, apple	
0163040 Papaya Carica papaya	0163030		Mangoes			
	0163040		Papaya	Carica papaya		

tops (if any) and adhering soil by						
Cherimoya (4)   Annona   Custard apple, sugar apple (wweetspin)   lama and other medium sized Annonaceae		Groups to which the MRLs apply	vidual products within the groups to which the MRLs	Scientific Name (2)	related varieties or other products included in the definition to which the same MRL	products to which the
cherimola sugar apple (sweetsop), Hama and other medium sized Annonaceae  0163070 Guava (*) Psidium guajava (annonaceae  0163080 Pineapples Anna (annonaceae)  0163090 Bread fruit (*) Artocarpus altilis  0163100 Durian (*) Durio (*) Durio (*) Exibethinus  0163110 Soursop (*) (guanabana) Annona muricata  0163990 Others (*) Whole product after removal of tops (ff any) and adhering soil by rinsing or brushing  0210000 (i) Root and tuber vegetables  0211000 (a) Potatoes  0212000 (b) Tropical root and tuber vegetables  0212010 Cassava Manihot (a) Dasheen, eddoe (a) Glapanese tarro), tannia  0212020 Sweet potatoes Ipomoca batatas  0212020 Yams Dioscorea sp. Potato bean (yam bean), Mexican yam bean)  0212040 Arrowroot (*) Maranta arundinacea	0163050		Pomegranate			
Discorea sp.   Disc	0163060		Cherimoya (4)		sugar apple (sweetsop), llama and other medium sized	
Description   Bread fruit (*)   Artocarpus altilis   Jackfruit altilis	0163070		Guava (4)			
Olicition   Durian (*)   Durio zibethinus	0163080		Pineapples			
2   2   2   2   2   2   2   2   2   2	0163090		Bread fruit (4)		Jackfruit	
(guanabana) muricata  Others (³)  Ozooooo 2. VEGETABLES FRESH OR FROZEN  Oz10000 (i) Root and tuber vegetables  Oz10000 (a) Potatoes  Tuber form Solamum spp.  Oz12000 (b) Tropical root and tuber vegetables  Oz12010 Cassava Manihot esculenta (Japanese taro), tannia  Oz12020 Sweet potatoes  Oz12030 Yams  Dioscorea sp. Potato bean (yam bean), Mexican yam bean  Oz12040 Arrowroot (4) Maranta arundinacea	0163100		Durian (4)			
O200000   Canal Content   O210000   Canal	0163110					
OR FROZEN  (i) Root and tuber vegetables  (a) Potatoes  Tuber form Solanum spp.  (b) Tropical root and tuber vegetables  Cassava  Manihot esculenta  O212010  Cassava  Manihot esculenta  O212020  Sweet potatoes  Ipomoea batatas  O212030  Yams  Dioscorea sp. Potato bean (yam bean), Mexican yam bean) Mexican yam bean) Mexican yam bean Maroutout (4)  Maranta arundinacea	0163990		Others (3)			
vegetables    Product after removal of tops (if any) and adhering soil by rinsing or brushing    Dasheen, eddoe (Japanese taro), tannia	0200000					
Solanum spp.	0210000					product after removal of tops (if any) and adhering soil by rinsing or
and tuber vegetables  Cassava  Manihot esculenta  Dasheen, eddoe (Japanese taro), tannia  0212020  Sweet potatoes  Ipomoea batatas  O212030  Yams  Dioscorea sp. Potato bean (yam bean), Mexican yam bean  Maranta arundinacea  Arrowroot (4)  Maranta arundinacea	0211000	(a) Potatoes				
esculenta (Japanese taro), tannia  0212020 Sweet potatoes Ipomoea batatas  0212030 Yams Dioscorea sp. Potato bean (yam bean), Mexican yam bean  0212040 Arrowroot (4) Maranta arundinacea	0212000	and tuber vege-				
0212030 Yams Dioscorea sp. Potato bean (yam bean), Mexican yam bean  0212040 Arrowroot (4) Maranta arundinacea	0212010		Cassava		(Japanese taro),	
0212040 Arrowroot (4) Maranta arundinacea	0212020		Sweet potatoes			
dinacea	0212030		Yams	Dioscorea sp.	(yam bean), Mexican yam	
0212990 Others ( <sup>3</sup> )	0212040		Arrowroot (4)			
	0212990		Others (3)			

Code number	Groups to which the MRLs apply	Examples of indi- vidual 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
0213000	(c) Other root and tuber vegetables except sugar beet				
0213010		Beetroot	Beta vulgaris subsp. vulgaris		
0213020		Carrots	Daucus carota		
0213030		Celeriac	Apium graveolens var. rapaceum		
0213040		Horseradish	Armoracia rusticana		
0213050		Jerusalem arti- chokes	Helianthus tuberosus		
0213060		Parsnips	Pastinaca sativa		
0213070		Parsley root	Petroselinum crispum		
0213080		Radishes	Raphanus sativus var. sativus	Black radish, Japanese radish, small radish and similar varieties	
0213090		Salsify	Tragopogon porrifolius	Scorzonera, Spanish salsify (Spanish oysterplant)	
0213100		Swedes	Brassica napus var. napo- brassica		
0213110		Turnips	Brassica rapa		
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	Allium sativum		
0220020		Onions	Allium cepa	Silverskin onions	
0220030		Shallots	Allium ascalonicum (Allium cepa var. aggregatum)		

Code number (¹)	Groups to whice	ch the MRLs apply	Examples of indi- vidual 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
0220040			Spring onions	Allium cepa	Welsh onion and similar varieties	
0220990			Others (3)			
0230000	(iii) Frui	iting vegetables				Whole product after removal of stems (in case of sweet corn without husks)
0231000	(a)	Solanacea				
0231010			Tomatoes	Lycopersicum esculentum	Cherry tomatoes	
0231020			Peppers	Capsicum annuum, var grossum and var. longum	Chilli peppers	
0231030			Aubergines (egg plants)	Solanum melongena	Pepino	
0231040			Okra, lady's fingers	Hibiscus escu- lentus		
0231990			Others (3)			
0232000	(b)	Cucurbits — edible peel				
0232010			Cucumbers	Cucumis sativus		
0232020			Gherkins	Cucumis sativus		
0232030			Courgettes	Cucurbita pepo var. melopepo	Summer squash, marrow (patisson)	
0232990			Others (3)			
0233000	(c)	Cucurbits- inedible peel				
0233010			Melons	Cucumis melo	Kiwano	
0233020			Pumpkins	Cucurbita maxima	Winter squash	
0233030			Watermelons	Citrullus lanatus		
0233990			Others (3)			
0234000	(d)	Sweet corn		Zea mays var. saccharata		Kernels plus cob without husks
0239000	(e)	Other fruiting vegetables				
0240000	(iv) Bras	ssica vegetables				

Code number (1)	Groups to which the MRLs apply	Examples of indi- vidual 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
0241000	(a) Flowering brassica				Curd only
0241010		Broccoli	Brassica oleracea var. italica	Calabrese, Chinese broccoli, Broccoli raab	
0241020		Cauliflower	Brassica oleracea var. botrytis		
0241990		Others (3)			
0242000	(b) Head brassica				Whole plant after removal of roots and decayed leaves
0242010		Brussels sprouts	Brassica oleracea var. gemmifera		Only cabbage buttons
0242020		Head cabbage	Brassica oleracea convar. capitata	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	Brassica peki- nensis	Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage	
0243020		Kale	Brassica oleracea convar. Acephalea	Borecole (curly kale), collards	
0243990		Others (3)			
0244000	(d) Kohlrabi		Brassica oleracea convar. acephala, var. gongylodes		Whole product after removal of roots, tops and adhering soil (if any)

Code number	Groups to which the MRLs apply	Examples of indi- vidual 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
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	Valerianella locusta	Italian cornsalad	
0251020		Lettuce	Lactuca sativa	Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce	
0251030		Scarole (broad- leaf endive)	Cichorium endiva	Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf	
0251040		Cress (4)	Lepidium sativum		
0251050		Land cress (4)	Barbarea verna		
0251060		Rocket, Rucola (4)	Eruca sativa (Diplotaxis spec.)	Wild rocket	
0251070		Red mustard (4)	Brassica juncea var. rugosa		
0251080		Leaves and sprouts of Brassica spp (4)	Brassica spp.	Mizuna	
0251990		Others (³)			
0252000	(b) Spinach and similar (leaves)				
0252010		Spinach	Spinacia oleracea	New Zealand spinach, turnip greens (turnip tops)	

Examples of individual products within the groups to which the MRLs apply   Examples of individual products within the groups to which the MRLs apply   Scientific Name (*)   Examples of related varieties or other products included in the definition to which the same MRL applies	
oleracea (miner's lettuce), garden purslane, common purslane, sorrel, glassworth  Description of the purslane	ts to the
(chard) beetroot  0252990 Others (³)  0253000 (c) Vine leaves (grape leaves) (⁴)  0254000 (d) Water cress Nasturtium officinale  0255000 (e) Witloof Cichorium intybus. var. foliosum  0256000 (f) Herbs  0256010 Chervil Anthriscus cerefolium  0256020 Chives Allium schoenoprasum  0256030 Celery leaves Apjum graveolens var. Coriander	
0253000 (c) Vine leaves (grape leaves) (4)  0254000 (d) Water cress Nasturtium officinale  0255000 (e) Witloof Cichorium intybus. var. foliosum  0256000 (f) Herbs  0256010 Chervil Anthriscus cerefolium  0256020 Chives Allium schoenoprasum  0256030 Celery leaves Apium graveolens var. Fennel leaves, Coriander	
(grape leaves) (4)  0254000  (d) Water cress  Nasturtium officinale  Cichorium intybus. var. foliosum  0256000  (f) Herbs  Chervil Anthriscus cerefolium  0256020  Chives Allium schoenoprasum  Celery leaves Apium graveolens var. Coriander	
Cichorium intybus. var. foliosum	
continue	
0256010 Chervil Anthriscus cerefolium  0256020 Chives Allium schoenoprasum  0256030 Celery leaves Apium graveolens var. Coriander	
0256020     Chives     Allium schoenoprasum       0256030     Celery leaves     Apium graveolens var.     Fennel leaves, Coriander	
0256030 Celery leaves Apium Fennel leaves, Coriander	
graveolens var. Coriander	
leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea	
0256040 Parsley Petroselinum crispum	
0256050 Sage (4) Salvia officinalis Winter savory, summer savory	
0256060 Rosemary (4) Rosmarinus officinalis	
0256070 Thyme (4) Thymus spp. Marjoram, oregano	
0256080 Basil (4) Ocimum Balm leaves, mint, peppermint	
0256090 Bay leaves (4) Laurus nobilis (laurel)	_
0256100 Tarragon (4) Artemisia dracunculus Hyssop	

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

Code number	Groups to which the MRLs apply	Examples of indi- vidual 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
0270090		Palm hearts (4)	Euterpa oleracea, Cocos nucifera, Bactris gasipaes, daemonorops schmidtiana		
0270990		Others (3)			
0280000	(viii) Fungi ( <sup>4</sup> )				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	Phaseolus vulgaris	Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas	
0300020		Lentils	Lens culinaris syn. L. esculenta		
0300030		Peas	Pisum sativum	Chickpeas, field peas, chickling vetch	
0300040		Lupins (4)	Lupinus spp.		
0300990		Others (3)			
0400000	4. OILSEEDS AND OILFRUITS				Whole product after removal of shell, stone and husk when possible
0401000	(i) Oilseeds				

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

Code number	Groups to which the MRLs apply	Examples of indi- vidual 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
0500000	5. CEREALS				Whole product
0500010		Barley	Hordeum spp.		
0500020		Buckwheat	Fagopyrum esculentum		
0500030		Maize	Zea mays		
0500040		Millet (4)	Panicum spp.	Foxtail millet, teff	
0500050		Oats	Avena fatua		
0500060		Rice	Oryza sativa		
0500070		Rye	Secale cereale		
0500080		Sorghum (4)	Sorghum bicolor		
0500090		Wheat	Triticum aestivum	Spelt Triticale	
0500990		Others (3)			
0600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA				
0610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)		Camellia sinensis		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	Matricaria recutita		
0631020		Hybiscus flowers	Hibiscus sabdariffa		
0631030		Rose petals	Rosa spec.		
0631040		Jasmine flowers	Jasminum officinale		
0631050		Lime (linden)	Tillia cordata		
0631990		Others (3)			
0632000	(b) Leaves				Whole product after removal of roots and decayed leaves

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

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

Sugar cane   Saccharum officinarum   Whole product after removal of decayed tissue, soil and roots	-					
0860010  0860090  Others (¹)  Others (¹)  Osymptote from the product after removal of decayed fissue, soil and roots  Osymptote from the product after removal of the product after removal after removal after removal aft		Groups to which the MRLs apply	vidual products within the groups to which the MRLs	Scientific Name (2)	related varieties or other products included in the definition to which the same MRL	products to which the
0870000 (vii) Aril 0870010 Mace Myristica frograms 0870910 Others (*) 0900000 9. SUGAR PLANTS (*) 0900000 Sugar beet froot) 0900000 Sugar beet froot) 0900000 Sugar cane Saccharum officinarum 0900000 Chicago	0860000	(vi) Flower stigma				
0870000   (vii) Aril	0860010		Saffron	Crocus sativus		
0870010 Mace Myristica fragrans  0870990 Others (?)  0900000 9. SUGAR PLANTS (*)  0900010 Sugar beet (root) beet Beta vulgaris Whole product after removal of tops and adhering soil by rinsing or brushing  0900020 Sugar cane Saccharum officinarum  Chicory (*) roots intybus  Chicory (*) roots Whole product after removal of tops and adhering soil of tops an	0860990		Others (3)			
Others (2)   Others (3)	0870000	(vii) <b>Aril</b>				
O900000   SUGAR PLANTS (*)   Sugar beet (root)   beet   Beta vulgaris   Whole product after removal of tops and adhering soil by rinsing or brushing	0870010		Mace			
Sugar cane   Sugar cane   Saccharum officinarum   Whole product after removal of tops and adhering soil by rinsing or brushing	0870990		Others (3)			
Chicory (4)   Cichorium   Whole product after removal of tops and adhering soil by rinsing or brushing	0900000	9. SUGAR PLANTS (4)				
cinarum product after removal of decayed tissue, soil and roots  Chicory (*) Cichorium intybus Product after removal of tops and adehering soil by finsing or brushing  O900990 Others (*)  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 as flours	0900010			Beta vulgaris		product after removal of tops and adhering soil by rinsing or
roots intybus product after removal of tops and adehering soil by rinsing or brushing  O900990  Others (³)  1000000  10. PRODUCTS OF ANIMAL ORIGINTERRESTRIAL 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  1011000  (a) Swine  Sus scrofa	0900020		Sugar cane			product after removal of decayed tissue, soil
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  1011000 (a) Swine  Sus scrofa	0900030					product after removal of tops and adehering soil by rinsing or
ANIMAL ORIGIN- TERRESTRIAL ANIMALS  (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  (a) Swine  Whole product or the fat fraction only (5)	0900990		Others (3)			
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  1011000 (a) Swine   product or the fat fraction only (5)  Sus scrofa	1000000	ANIMAL ORIGIN- TERRESTRIAL				
	1010000	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				product or the fat fraction
1011010 Meat	1011000	(a) Swine		Sus scrofa		
	1011010		Meat			

Code number	Groups to which the MRLs apply	Examples of indi- vidual 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		Bos spec.		
1012010		Meat			
1012020		Fat			
1012030		Liver			
1012040		Kidney			
1012050		Edible offal			
1012990		Others (3)			
1013000	(c) Sheep		Ovis aries		
1013010		Meat			
1013020		Fat			
1013030		Liver			
1013040		Kidney			
1013050		Edible offal			
1013990		Others (3)			
1014000	(d) Goat		Capra hircus		
1014010		Meat			
1014020		Fat			
1014030		Liver			
1014040		Kidney			
1014050		Edible offal			
1014990		Others (3)			
1015000	(e) Horses, asses, mules or hinnies		Equus spec.		
1015010		Meat			
1015020		Fat			
1015030		Liver			
1015040		Kidney			
1015050		Edible offal			
<u> </u>		· <del></del>	· <del></del>	<u> </u>	

Code number	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		Gallus gallus, Anser anser, Anas platyr- hynchos, Meleagris gallopavo, Numida meleagris, Coturnix coturnix, Struthio camelus, Columba sp.		
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 ti 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 to fat fraction only (7)

#### **▼**M1

Code number	Groups to which the MRLs apply	Examples of indi- vidual 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		Apis melifera, Melipona spec.	Royal jelly, pollen	
1050000	(v) Amphibians and reptiles		Rana spec. Crocodilia spec.	Frog legs, crocodiles	
1060000	(vi) Snails		Helix spec.		
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)				

- 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<sub>ow</sub> 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<sub>ow</sub> 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<sub>ow</sub> 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<sub>ow</sub> 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<sub>ow</sub> 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<sub>ow</sub> 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.

## **▼**<u>M2</u>

 ${\it ANNEX~VII}$  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).			