Regulation (EC) No 299/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission

REGULATION (EC) No 299/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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amending Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission

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)],

After consulting the Committee of the Regions,

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

Whereas:

(1) Regulation (EC) No 396/2005 of the European Parliament and of the Council[(3)] provides that certain measures are to 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[(4)].

(2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, inter alia by deleting some of those elements or by supplementing the instrument with new non-essential elements.

(3) In accordance with the statement by the European Parliament, the Council and the Commission[(5)] concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny to be applicable to instruments adopted in accordance with the procedure referred to in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

(4) The Commission should be empowered to define the scope of Regulation (EC) No 396/2005 and the criteria necessary for the establishment of certain maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin listed in its relevant annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 396/2005, inter

alia by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(5) On grounds of efficiency and in order to guarantee economic operators a rapid decision-making process, whilst ensuring a high level of consumer protection, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of measures setting, including, implementing, modifying or deleting MRLs and establishing a list of active substances for which no MRLs are required, as well as a list of active substance/product combinations where active substances are used as fumigant for post-harvest treatment.

(6) When, on imperative grounds of urgency, and in particular where a risk to human or animal health exists, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures setting, including, implementing, modifying or deleting MRLs.

(7) Regulation (EC) No 396/2005 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments

Regulation (EC) No 396/2005 is hereby amended as follows:

1. Article 4(1) shall be replaced by the following:

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.;

2. Article 5(1) shall be replaced by the following:

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).;

3. Article 8(2) shall be replaced by the following:

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).;

4. Article 14(1) shall be replaced by the following:

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).;

5. Article 15(2) shall be replaced by the following:

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.;

6. Article 18 shall be replaced by the following:

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:

a such products comply with paragraph 1 and Article 20; or

b the active substance is listed in Annex IV.

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

a such products are not intended for immediate consumption;

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

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

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

4 In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or pursuant to obligations set out in Directive 2000/29/EC[(6)], 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.;

7. Article 20(2) shall be replaced by the following:

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).;

8. Article 21(1) shall be replaced by the following:

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)