



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.12.2006  
COM(2006) 908 final

2006/0294 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL**

**amending**

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

(presented by the Commission)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL**

**amending**

**Regulation (EC) No 396/2005  
on maximum residue levels of pesticides in or on food and feed 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<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>4</sup>

Whereas:

- (1) 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<sup>5</sup> 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<sup>6</sup>.
- (2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

---

<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C , , p. .

<sup>4</sup> ...

<sup>5</sup> OJ L 70, 16.3.2005, p. 1. Regulation as amended by Commission Regulation (EC) No 178/2006 (OJ L 29, 2.2.2006, p. 3).

<sup>6</sup> OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

- (3) In accordance with the joint statement of the European Parliament, the Council and the Commission<sup>7</sup> on Decision 2006/512/EC, instruments which are already in force must be adjusted in accordance with the applicable procedures. The aforesaid statement indicates a list of instruments that should be adjusted as a matter of urgency, including Regulation (EC) No 396/2005.
- (4) In particular power should be conferred on the Commission to define the scope of that Regulation and the criteria necessary for the establishment of certain maximum levels of pesticide residues in or on food and feed of plant and animal origin listed in the relevant Annexes to that Regulation. Since those measures are of general scope and are designed to amend or delete non-essential elements of that Regulation, or supplement that Regulation by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (5) In order to guarantee economic operators a rapid decision-making process, whilst ensuring a high level of consumer protection, it should be possible to curtail the time-limits foreseen by the new procedure on grounds of efficiency. On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the setting, inclusion, implementation, modification or deletion of MRLs and for the establishment of a list of active substances for which no MRLs are required as well as a list of active substance/product combinations where the active substances are used as fumigant for post-harvest treatment. Where on imperative grounds of urgency, in particular where a risk to human or animal health exists, and the time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be authorised to apply for the setting, inclusion, implementation, modification or deletion of MRLs the urgency procedure provided for in Article 5a (6) of Decision 1999/468/EC.
- (6) Regulation (EC) No 396/2005 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

#### *Article 1*

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

- (1) In Article 4, paragraph 1 is 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. 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)."

---

<sup>7</sup> OJ C 255, 21.10.2006, p.1

- (2) In Article 5, paragraph 1 is 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 hereto, taking into account the uses of those active substances and the matters referred to in Article 14(2), (a), (c) and (d) of this Regulation. 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) In Article 8, paragraph 2 is 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) In Article 14, paragraph 1 is replaced by the following:
- "1. Upon receipt of the opinion of the Authority and taking into account 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 designed to amend non-essential elements of this Regulation which 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 use the urgency procedure referred to in Article 45(5);
  - (b) a Decision rejecting the application which shall be adopted in accordance with the procedure referred to in Article 45(2)."
- (5) In Article 15, paragraph 2 is 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 use the urgency procedure referred to in Article 45(5).

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 the consumer have been identified."

(6) Article 18 is replaced by the following:

- "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. 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). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 45(5).
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 to define the active substance/product combinations listed in Annex VII which are 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).

4. In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or in pursuance of obligations in Directive 2000/29/EC, 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 use the urgency procedure referred to in Article 45(5)."

(7) In Article 20, paragraph 2 is 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. 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). "

(8) In Article 21, paragraph 1 is 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 mentioned 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(4)."

(9) In Article 22, paragraph 1 is replaced by the following:

"1. Temporary MRLs for active substances for which a decision on inclusion or non-inclusion in Annex I to Directive 91/414/EEC has not yet been taken shall be first established and listed in Annex III to this Regulation, unless already listed in Annex II hereto, taking into account the information provided by the Member States, where relevant the reasoned opinion mentioned in Article 24, the factors referred to in Article 14(2) and the following MRLs:

- (a) remaining MRLs in the Annex to Directive 76/895/EEC; and
- (b) hitherto unharmonised national MRLs.

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)."

(10) In Article 27, paragraph 2 is replaced by the following:

"2. Measures to determine the sampling methods necessary for carrying out such controls of pesticide residues in products other than those provided for in Directive 2002/63/EC which are 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) of this Regulation."

(11) Article 45 is replaced by the following:

"Article 45

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) No 178/2002 (hereinafter referred to as the Committee).
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

3. 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 the 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), (4) (b) and (4) (e) of Decision 1999/468/EC shall be 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."

(12) Article 46 is replaced by the following:

- "1. Implementing measures to ensure the uniform application of this Regulation; shall be established or may be amended in accordance with the procedure referred to in Article 45(2) and, where appropriate, taking into account the opinion of the Authority.
2. Measures to establish or amend the dates in Article 23, Article 29(2), Article 30(2), Article 31(1) and Article 32(5) which are 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)."

(13) Article 49 is replaced by the following:

- "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 it is necessary in order to allow for the normal marketing, processing and consumption of products, further transitional measures may be laid down for the implementation of certain MRLs provided for in Articles 15, 16, 21, 22, and 25. Those measures which are designed to amend non-essential elements of this Regulation by supplementing it and shall be 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)."

*Article [2]*

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

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*