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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.5.2009
COM(2009) 240 final

Proposal for a

COUNCIL DECISION

concerning the non-inclusion of diphenylamine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The attached draft proposal for a Council Decision concerns the non inclusion of diphenylamine as active substance in the positive list (Annex I) of Council Directive 91/414/EEC and the withdrawal of plant protection products containing that substance. The proposal for a non inclusion is based on a number of concerns identified during the evaluation of this active substance.

Council Directive 91/414/EEC creates a harmonised framework for the authorisation and placing on the market of plant protection products. Active substances to be used as plant protection products are assessed and authorised at Community level and are listed in Annex I to the Directive. Individual plant protection products containing active substances are assessed and authorised by Member States under harmonised rules.

The data submitted by industry have been initially evaluated by a rapporteur Member State, in this case Ireland, which submitted a draft assessment report. The European Food Safety Authority has organised a peer review of the initial evaluation and has provided the Commission with a conclusion of the risk assessment for diphenylamine on 30 September 2008.

During the evaluation of this active substance, a number of concerns were identified. In particular, it was not possible to perform a reliable consumer exposure assessment, as data are missing on the presence and toxicity of unidentified metabolites of the substance, as well as on the possible formation of nitrosamines during storage of the active substance and during processing of treated apples. Moreover, no data was available on the potential breakdown or reaction product of diphenylamine residues in processed commodities.

The draft decision for a non inclusion was submitted on 26 February 2009 to the Standing Committee on the Food Chain and Animal Health, where:

- 16 Member States voted in favour (165 votes)
- 9 Member States voted against (139 votes)
- 2 Member States abstained (41 votes)

The Committee delivered no opinion. Consequently, pursuant to article 19 of Directive 91/414/EEC and in accordance with Article 5 of Council Decision 1999/468/EC the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority.

The draft Decision is not subject to the right of scrutiny of the European Parliament (Article 8 of Council Decision 1999/468/EC).

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(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market¹, and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I to that Directive that are already on the market two years after the date of notification, while those substances are gradually being examined within the framework of a programme of work.
- (2) Commission Regulations (EC) No 451/2000² and (EC) No 1490/2002³ lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes diphenylamine.
- (3) For diphenylamine the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifier. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10 (1) of Regulation (EC) No 1490/2002. For diphenylamine the rapporteur Member State was Ireland and all relevant information was submitted on 20 June 2007.

¹ OJ L 230, 19.8.1991, p. 1.

² OJ L 55, 29.2.2000, p. 25.

³ OJ L 224, 21.8.2002, p. 23.

- (4) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on 30 September 2008 in the format of the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance diphenylamine⁴. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 February 2009 in the format of the Commission review report for diphenylamine.
- (5) During the evaluation of this active substance, a number of concerns have been identified. In particular, it was not possible to perform a reliable consumer exposure assessment, as data are missing on the presence and toxicity of unidentified metabolites of the substance, as well as on the possible formation of nitrosamines during storage of the active substance and during processing of treated apples. Moreover, no data was available on the potential breakdown or reaction product of diphenylamine residues in processed commodities. Consequently, it was not possible to conclude on the basis of the information available that diphenylamine met the criteria for inclusion in Annex I to Directive 91/414/EEC.
- (6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing diphenylamine satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) Diphenylamine should therefore not be included in Annex I to Directive 91/414/EEC.
- (8) Measures should be taken to ensure that authorisations granted for plant protection products containing diphenylamine are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.
- (9) Any period of grace granted by a Member State for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing diphenylamine should be limited to twelve months in order to allow existing stocks to be used in one further growing season, which ensures that plant protection products containing diphenylamine remain available to farmers for 18 months from the adoption of this Decision.
- (10) This Decision does not prejudice the submission of an application for diphenylamine according to the provisions of Article 6 (2) of Directive 91/414/EEC, the detailed implementation rules of which have been laid down in Commission Regulation (EC) No 33/2008⁵, in view of a possible inclusion in its Annex I.

⁴ EFSA Scientific Report (2008) 188, Conclusion on the peer review of diphenylamine, finalised 30 September 2008.

⁵ OJ L 15, 18.1.2008, p. 5–12.

(11) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman,

HAS ADOPTED THIS DECISION:

Article 1

Diphenylamine shall not be included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

- (a) authorisations for plant protection products containing diphenylamine are withdrawn by [... *INSERT DATE 6 MONTHS FROM THE DATE OF ADOPTION OF THIS DECISION*];
- (b) no authorisations for plant protection products containing diphenylamine are granted or renewed from the date of publication of this Decision.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and shall expire on [... *INSERT DATE 18 MONTHS FROM ADOPTION OF THIS DECISION*] at the latest.

Article 4

This Decision is addressed to the Member States.

Done at Brussels,

*For the Council
The President*