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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.5.2009
COM(2009) 241 final

Proposal for a

COUNCIL DECISION

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached draft proposal for a Council Decision concerns the non inclusion of bifenthrin 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 France, 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 bifenthrin on 30 September 2008.

During the evaluation of this active substance, a number of concerns were identified. In particular, based on the data lodged by the notifier within the legal deadlines, it was not possible to assess the potential contamination of groundwater by a major soil degradation product (*TFP acid*). Furthermore, concerns have been raised as regards a possible underestimation of the risk to consumers, due to the limited number of residue data made available and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin. As regards ecotoxicology, the risk to aquatic vertebrates has not shown to generate acceptable uses, while there is a remaining uncertainty as regards the effects of the experienced bioaccumulation in fish of the active substance. Furthermore, high risks have been identified for mammals (long term risk and secondary poisoning), earthworms (long term risk) and non-target arthropods (in-field), while the risk to non-target plants and non-target soil macro-organisms has not been sufficiently addressed.

The draft decision for a non inclusion was submitted on 12 March 2009 to the Standing Committee on the Food Chain and Animal Health, where:

- 15 Member States voted in favour (164 votes)
- 9 Member States voted against (132 votes)
- 3 Member States abstained (49 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).

Proposal for a

COUNCIL DECISION

concerning the non-inclusion of bifenthrin 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)

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 bifenthrin.
- (3) For bifenthrin 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 bifenthrin the rapporteur Member State was France and all relevant information was submitted on 15 December 2005.

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 bifenthrin⁴. 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 12 March 2009 in the format of the Commission review report for bifenthrin.
- (5) During the evaluation of this active substance, a number of concerns have been identified. In particular, based on the data lodged by the notifier within the legal deadlines, it was not possible to assess the potential contamination of groundwater by a major soil degradation product (*TFP acid*). Furthermore, concerns have been raised as regards a possible underestimation of the risk to consumers, due to the limited number of residue data made available and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin. As regards ecotoxicology, the risk to aquatic vertebrates has not shown to generate acceptable uses, while there is a remaining uncertainty as regards the effects of the experienced bioaccumulation in fish of the active substance. Furthermore, high risks have been identified for mammals (long term risk and secondary poisoning), earthworms (long term risk) and non-target arthropods (in-field), while the risk to non-target plants and non-target soil macro-organisms has not been sufficiently addressed. Consequently, it was not possible to conclude, on the basis of the information made available within the legal deadlines, that bifenthrin 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 bifenthrin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) Bifenthrin 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 bifenthrin 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 bifenthrin 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 bifenthrin remain available to farmers for 18 months from the adoption of this Decision.

⁴ EFSA Scientific Report (2008) 186, Conclusion regarding the peer review of the pesticide risk assessment of the active substance bifenthrin, finalised 30 September 2008.

- (10) This Decision does not prejudice the submission of an application for bifenthrin 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.
- (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

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

Article 2

Member States shall ensure that:

- (a) authorisations for plant protection products containing bifenthrin are withdrawn by [... *INSERT DATE 6 MONTHS FROM THE DATE OF ADOPTION OF THIS DECISION*];
- (b) no authorisations for plant protection products containing bifenthrin 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

⁵ OJ L 15, 18.1.2008, p. 5–12.