COMMISSION DECISION

of 30 November 2009

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

(notified under document C(2009) 9271)

(Text with EEA relevance)

(2009/860/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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 market [1], 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 451/2000 [2] and (EC) No 1490/2002 [3] 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 triazoxide.

(3) For triazoxide 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 triazoxide the rapporteur Member State was the United Kingdom and all relevant information was submitted on 25 June 2007.

(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 triazoxide [4]. 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 triazoxide.

(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 risk assessment as data are missing to determine the nature of residues in plant commodities and the possible transfer of residues in animal products. Moreover, the available data did not demonstrate that the long-term risk to mammals, birds, fish and earthworms are acceptable. Consequently, it was not possible to conclude on the basis of the information available that triazoxide 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 triazoxide satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(7) Triazoxide 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 triazoxide are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.

[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] *EFSA Scientific Report* (2008), 193. Conclusion regarding the peer review of the pesticide risk assessment of the active substance triazoxide (finalised 26 September 2008).

(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 triazoxide should be limited to 12 months in order to allow existing stocks to be used in one further growing season, which ensures that plant protection products containing triazoxide 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 triazoxide 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 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [1], in view of a possible inclusion in its Annex I.

(11) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion on the measures provided for in this Decision within the time limit laid down by its Chairman and the Commission therefore submitted to the Council a proposal relating to these measures. Since, on the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed measures nor indicated its opposition to them, they should be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Triazoxide 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 triazoxide are withdrawn by 30 May 2010;

(b) no authorisations for plant protection products containing triazoxide 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 30 May 2011 at the latest.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 30 November 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 15, 18.1.2008, p. 5.