COMMISSION DECISION

of 30 September 2008

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

(notified under document number C(2008) 5108)

(Text with EEA relevance)

(2008/770/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 tricyclazole.

(3) For tricyclazole 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 8(1) of Regulation (EC) No 451/2000. For tricyclazole the rapporteur Member State was France and all relevant information was submitted on 26 June 2006.

(4) The Commission examined tricyclazole in accordance with Article 11a of Regulation (EC) No 1490/2002. A draft review report for that substance was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 20 May 2008 in the format of the Commission review report.

(5) During the examination of this active substance by the Committee, taking into account comments received from Member States, it was concluded that there are clear indications that it may be expected that it has harmful effects on human health and in particular the crucial missing data does not allow to set reliable ADI, ARfD and AOEL and such values are necessary to conduct the risk assessment. Moreover, other concerns which were identified by the rapporteur Member States in its assessment report are included in the review report for the substance.

(6) The Commission invited the notifier to submit its comments on the results of the examination of tricyclazole 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 forwards by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing tricyclazole satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(7) Tricyclazole 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 tricyclazole 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.