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SANCO/03440/2006 rev. 4



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.3.2007
SANCO/03440/2006 rev 4

Draft

COMMISSION DECISION

of

concerning the non-inclusion of benfuracarb 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)

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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 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 of 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 703/2001³ lay down the detailed rules for the implementation of the second 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 benfuracarb.

¹ OJ L 230, 19.8.1991, p. 1. Directive as last amended by *[INSERT LAST AMENDMENT]*.

² OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).

³ OJ L 98, 7.4.2001, p. 6.

- (3) For benfuracarb 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 703/2001 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 benfuracarb the Rapporteur Member State was Belgium and all relevant information was submitted on 2 August 2004.
- (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 28 July 2006 in the format of the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance benfuracarb⁴. 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 16 March 2007 in the format of the Commission review report for benfuracarb.
- (5) During the evaluation of this active substance, a number of concerns have been identified. Benfuracarb is a substance of which the main metabolite is carbofuran, itself an active substance which has been reviewed under Directive 91/414. The use of benfuracarb leads to the presence of the metabolite carbofuran which is considerably more toxic than the parent compound benfuracarb. For the carbofuran residues, resulting from the use of benfuracarb, the assessment has raised a concern about the acute exposure of vulnerable groups of consumers, in particular children. However, the EFSA has stated that it is not possible to assess the risk for consumers completely due to a lack of data in the dossier presented by the notifier. Furthermore, the data lodged within the legal deadlines were insufficient for the EFSA to allow a full assessment of the risk of ground water contamination from metabolites other than carbofuran. Finally, based on the available data, it has not been demonstrated that the risk to birds and mammals, aquatic organisms, ground dwelling organisms, earthworms and other non-target organisms is acceptable. Consequently, it was not possible to conclude on the basis of the information available that benfuracarb 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 forwards 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 benfuracarb satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) Benfuracarb 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 benfuracarb are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.

⁴ EFSA Scientific Report (2006) 89, 1-81, Conclusion on the peer review of benfuracarb.

- (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 benfuracarb 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 benfuracarb 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 benfuracarb according to the provisions of Article 6 (2) of Directive 91/414/EEC in view of a possible inclusion in its Annex I. An early reapplication, referring to all the data submitted during the review process and eventually accompanied by any new relevant elements, should allow an evaluation and subsequent decision on a possible inclusion in Annex I before the availability of plant protection products containing benfuracarb has lapsed.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Benfuracarb 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 benfuracarb are withdrawn by *[INSERT DATE 6 MONTHS FROM THE DATE OF ADOPTION OF THIS DECISION]*;
- (b) no authorisations for plant protection products containing benfuracarb 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 DATA 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 Commission
Markos KYPRIANOU
Member of the Commission