Commission Directive 2007/50/EC of 2 August 2007 amending Council Directive 91/414/EEC to include beflubutamid and Spodoptera exigua nuclear polyhedrosis virus as active substances (Text with EEA relevance)

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amending Council Directive 91/414/EEC to include beflubutamid and *Spodoptera exigua* nuclear polyhedrosis virus as active substances

(Text with EEA relevance)

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 Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC Germany received on 27 June 2000 an application from a Task Force consisting of UBE Europe GmbH and Stähler Agrochemie GmbH & Co. KG (UBE Europe GmbH having later left the Task Force) for the inclusion of the active substance beflubutamid in Annex I to Directive 91/414/EEC. Commission Decision 2000/784/EC[(2)] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 12 July 1996 an application from Biosys (now: Certis USA) for the inclusion of the active substance *Spodoptera exigua* nuclear polyhedrosis virus (hereinafter *Spodoptera exigua* NPV) in Annex I to Directive 91/414/EEC. Commission Decision 97/865/EC[(3)] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 13 August 2002 (beflubutamid) and 1 November 1999 (*Spodoptera exigua* NPV) respectively.

(4) For those substances the draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 15 May 2007 in the format of the Commission review reports for beflubutamid and *Spodoptera exigua* NPV.

(5) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include beflubutamid and *Spodoptera exigua* NPV in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.

(6) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing provisional authorisations of plant protection products containing beflubutamid or *Spodoptera exigua* NPV to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should transform existing provisional authorisations into full authorisations, amend them or withdraw them in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(7) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

1 Member States shall adopt and publish by 31 May 2008 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 June 2008.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1 Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing

beflubutamid or *Spodoptera exigua* NPV as active substance by 31 May 2008. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to beflubutamid or *Spodoptera exigua* NPV, respectively, are met, with the exception of those identified in part B of the entry concerning the active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13(2) of that Directive.

2 By way of derogation from paragraph 1, for each authorised plant protection product containing beflubutamid or *Spodoptera exigua* NPV as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 30 November 2007 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning beflubutamid or *Spodoptera exigua* NPV. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

a in the case of a product containing beflubutamid or *Spodoptera exigua* NPV as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2009 at the latest; or

b in the case of a product containing beflubutamid or *Spodoptera exigua* NPV as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2009 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 December 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 2 August 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC the following rows are added at the end of the table:

No	Common name, identification numbers	IUPAC Name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions	
'164	Beflubutamid CAS No 113614-08-7 CIPAC No 662	*(RS)-N*-benzyl-2-(4-fluoro-3-trifluoromethylphenoxy) butanamide	≥ 970 g/kg	1 December 2007	30 November 2017	Part A	Only uses as herbicide may be authorised.
						Part B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on beflubutamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

a Further details on identity and specification of active substances are provided in the review report.

						Chain and Animal Health on 15 May 2007 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.
165	*Spodoptera exigua* nuclear polyhedrosis virus CIPAC No Not allocated	Not applicable		1 December 2007	30 November 2017	Part A Only uses as insecticide may be authorised. Part B For the implementation of the uniform principles of

a Further details on identity and specification of active substances are provided in the review report.

						Annex VI, the conclusions of the review report on *Spodoptera exigua* NPV, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 May 2007 shall be taken into account.’

a Further details on identity and specification of active substances are provided in the review report.

(**1**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/31/EC (OJ L 140, 1.6.2007, p. 44).

(**2**) OJ L 311, 12.12.2000, p. 47.

(**3**) OJ L 351, 23.12.1997, p. 67.