# COMMISSION DIRECTIVE 2001/47/EC

## of 25 June 2001

## amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) as an active substance

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], as last amended by Commission Directive 2001/28/EC [2], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive') Belgium received on 18 May 1994 an application from Thermo Trilogy Corporation, ('the applicant') for the inclusion of the active substance *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) in Annex I to the Directive.

(2) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/164/EC [3] that the dossier submitted for *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) could be considered as satisfying, in principle, the data and information requirements of Annex II and, for a plant protection product containing this active substance, of Annex III to the Directive.

(3) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I for a period not exceeding 10 years if it may be expected that neither the use of, or residues from, plant protection products containing the active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

(4) For *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874), the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant. Belgium acting as nominated rapporteur Member State submitted a draft assessment report concerning the substance to the Commission on 9 December 1997.

(5) The draft assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 27 April 2001 in the format of the Commission review report for *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874). If this review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of DPX KE 459 *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) in Annex I to the Directive will also need to be amended in accordance with the Directive.

(6) The dossier and the information from the review of *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) were also submitted to the Scientific Committee on Plants for opinion on 16 December 1999. This Committee has given its opinion on 30 November 2000 [4].

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

(8) After inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) and in particular to review, existing provisional authorisations or to grant, by the end of this period at the latest, new authorisations in accordance with the provisions of the Directive. A longer period may also be required for plant protection products containing *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) and other active substances included in Annex I.

(9) As the uniform principles have still to be adopted for micro-organisms, it is appropriate that the Member States should apply the general provisions of Article 4 of the Directive when granting authorisations. It is also appropriate to provide Member States a reasonable period of time to re-evaluate authorisations granted in the light of the uniform principles after their adoption.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 113, 24.4.2001, p. 5.
[3] OJ L 64, 5.3.1997, p. 17.

[4] Opinion of the Scientific Committee on Plants regarding the evaluation *Paecilomyces fumosoroseus* in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/PAECIL/002 final dated 11 December 2000.

(10) It is appropriate to provide that the finalised review report (except for confidential information in the meaning of Article 14 of the Directive) is kept available or made available by the Member States for consultation by any interested parties.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 27 April 2001,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The table in Annex I to Directive 91/414/EEC shall be amended to include the entry in respect of *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) set out in the Annex hereto.

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, at the latest by 31 December 2001. They shall forthwith inform the Commission thereof.

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. However, with regard to the review of existing provisional authorisations granted in the light of the review report, the provisional authorisations shall be withdrawn and where appropriate, replaced by a full authorisation by 30 November 2002.

3. However, with regard to the application of the uniform principles, Member States shall re-examine authorisations granted as soon as possible after their adoption and at the latest within a period of 12 months from the date of adoption of such principles.

4. However, for plant protection products containing *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) together with another active substance which is in Annex I to Directive 91/414/EEC, the period referred to in paragraph 1 is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive amending Annex I to Directive 91/414/EEC to include that other substance in the Annex.

5. Member States shall keep available the review report for *Paecilomyces fumosoroseus* (Apopka strain 97, PFR 97 or CG 170, ATCC20874) (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

*Article 3*

This Directive shall enter into force on 1 July 2001.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 25 June 2001.

*For the Commission*

David BYRNE

*Member of the Commission*

*ANNEX*

**ENTRY TO BE INSERTED IN THE TABLE IN ANNEX I TO DIRECTIVE 91/414/EEC**

| No | Common name, and identification | IUPAC name | Purity | Entry into force | Expiration of inclusion | Specific provisions |
|---|---|---|---|---|---|---|
| 18 | *Paecilomyces fumosoroseus* Apopka strain 97, PFR 97 or CG 170, ATCC20874 | Not applicable | The absence of secondary metabolites should be checked in each fermentation broth by HPLC | 1 July 2001 | 30 June 2011 | Only uses as an insecticide may be authorised<br>Each fermentation broth should be checked by HPLC to ensure that no secondary metabolites are present<br>Date of Standing Committee on Plant Health at which the review report was finalised: 27 April 2001 |