

COMMISSION DIRECTIVE 2004/71/EC
of 28 April 2004
amending Council Directive 91/414/EEC to include *Pseudomonas chlororaphis* as active substance
(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 the Swedish authorities received on 15 December 1994 an application from Bio Agri AB, hereafter referred to as the applicant, for the inclusion of the active substance *Pseudomonas chlororaphis* in Annex I to the Directive. Decision 97/248/EC ⁽²⁾ of 25 March 1997 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) For this active substance, 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 nominated rapporteur Member State submitted a draft assessment report concerning the substance to the Commission on 7 April 1998.
- (3) The draft assessment report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 30 March 2004 in the format of the Commission review report for *Pseudomonas chlororaphis*.
- (4) The dossier and the information from the review were also submitted to the Scientific Committee for Plants. The Committee was asked to comment (a) on residue levels in food and feed; (b) on operator exposure; (c) whether with regard to possible hazard to humans a tiered approach should include repeated dosing as part of the primary data set; (d) on the toxicological safety of the antibiotic metabolites of the active substance; (e) on

the necessity to monitor the health of workers; and (f) on a potential of *Pseudomonas chlororaphis* to cause wound infection or other pathogenic effects.

In its opinion ⁽³⁾ the Committee concluded that (a) the issue of residues has been adequately addressed that there is no cause for concern; (b) operator exposure to *Pseudomonas chlororaphis* formulations has been adequately addressed; (c) in the specific case of *Pseudomonas chlororaphis*, and in the light of the results of the available studies, repeated dosing is not necessary to assess hazard to humans; (d) more studies would be needed for a more complete assessment of the mutagenicity potential of the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR). However, the Committee considered the potential for human exposure to DDR as well as to other possible antibiotic metabolites so low that, even in the absence of further information, no major concern exists for consumer and operator safety; (e) a study based on the medical surveillance of workers should be conveniently carried out when introducing this agent in the field as a microbial pesticide; (f) there is no cause for concern for human safety with regard to wound infection.

The recommendations of the Scientific Committee as well as further information by the notifier were taken into account during the further review and in this Directive and in the Review Report, where the need for monitoring of operators and worker based on medical surveillance to detect negative effects without delay as well as monitoring studies to quantify DDR contamination under practical conditions is stressed. The evaluation within the Standing Committee concluded that there would be no unacceptable risk for operators if appropriate risk mitigation measures are applied.

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

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/20/EC (OJ L 70, 9.3.2004, p. 32).

⁽²⁾ OJ L 98, 15.4.1997, p. 15.

⁽³⁾ Opinion of the Scientific Committee on Plants on specific questions from the Commission regarding the evaluation of *pseudomonas chlororaphis* in the context of Council Directive 91/414/EEC scp/pseudom/002-final adopted on 20 December 2001.

- (6) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing *Pseudomonas chlororaphis* and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of 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 March 2005 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 April 2005.

2. 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.

Article 3

1. Member States shall review the authorisation for each plant protection product containing *Pseudomonas chlororaphis* to ensure that the conditions relating to this active substance set

out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 31 March 2005 at the latest.

2. For each authorised plant protection product containing *Pseudomonas chlororaphis* 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 September 2004 at the latest, Member States shall re-evaluate the product on the basis of a dossier satisfying the requirements of Annex III thereto. 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 *Pseudomonas chlororaphis* as the only active substance, where necessary, amend or withdraw the authorisation by 31 March 2006 at the latest; or
- (b) in the case of a product containing *Pseudomonas chlororaphis* as one of several active substances, where necessary, amend or withdraw the authorisation by 31 March 2006 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 October 2004.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 28 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I the following row is added at the end of the table.

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
'90	<i>Pseudomonas chlororaphis</i> Strain: MA 342 CIPAC No 574	Not applicable	The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the fermentate at the point of formulation of the product must not exceed the LOQ (2 mg/l).	1 October 2004	30 September 2014	Only uses as fungicide for seed dressing in closed seed dressing machinery may be authorised. When granting authorisations, the conclusions of the review report on <i>Pseudomonas chlororaphis</i> , and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account. In this overall assessment, Member States should pay particular attention to the safety of operators and workers. Risk mitigation measures should be applied where appropriate.

⁽¹⁾ Further details on identity and specification of active substances are provided in the review report.'