

COMMISSION DIRECTIVE 2000/50/EC**of 26 July 2000****including an active substance (prohexadione-calcium) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market**

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 2000/10/EC ⁽²⁾, hereafter referred to as 'the Directive', and in particular Article 6(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of the Directive, on 10 February 1994, France received an application from BASF AG, hereafter referred to as 'the applicant', for the inclusion of the active substance prohexadione-calcium 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 96/520/EC ⁽³⁾ that the dossier submitted for prohexadione-calcium 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 prohexadione-calcium, 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. France acting as nominated rapporteur Member State, submitted to the Commission on 9 June 1998 the draft assessment report concerned.
- (5) The submitted report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 16 June 2000 in the format of the Commission review report for prohexadione-calcium. It may be necessary to update this report to take account of technical and scientific developments. In such case the conditions for the inclusion of prohexadione-calcium in Annex I to the Directive will also need to be amended pursuant to Article 6(1) of that Directive.
- (6) The dossier and the information from the review were also submitted to the Scientific Committee for Plants for opinion on 26 November 1999. This Committee gave its opinion on 6 June 2000.
- (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 prohexadione-calcium and in particular to review, within this period, 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 prohexadione-calcium and other active substances included in Annex I.
- (9) 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.
- (10) The review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Annex VI to the Directive, where these principles refer to the evaluation of the Annex II data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 16 June 2000,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Prohexadione-calcium is hereby designated as an active substance in Annex I to Directive 91/414/EEC, as set out in the Annex hereto.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 57, 2.3.2000, p. 28.

⁽³⁾ OJ L 220, 30.8.1996, p. 19.

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 1 January 2001.
2. However, with regard to evaluation and decision-making pursuant to 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 thereto, the period laid down in the first paragraph is extended for existing provisional authorisations of plant protection products containing prohexadione-calcium to 1 January 2002.
3. However for plant protection products containing prohexadione-calcium 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 concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC.
4. Member States shall keep available the review report (except for confidential information in the meaning of Article

14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

5. When Member States adopt the measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The Member States shall lay down the procedure for such reference.

Article 3

This Directive shall enter into force on 1 October 2000.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 July 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

1. Prohexadione-calcium

1. Identity: (IUPAC) Calcium 3,5-dioxo-4-propionylcyclohexanecarboxylate
 2. Particular conditions to be fulfilled:
 - 2.1. The active substance shall have a minimum purity of 890 g/kg.
 - 2.2. Only uses as plant growth regulator may be authorised.
 - 2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prohexadione-calcium, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 16 June 2000 shall be taken into account.
 3. Expiry date of the inclusion: 1 October 2010.
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