Commission Directive 1999/73/EC of 19 July 1999 including an active substance (spiroxamine) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (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 market(1), as last amended by Council Directive 99/1/EC(2), hereafter referred to as the Directive, and in particular Article 6(1);
(1) Whereas in accordance with Article 6(2) of Directive 91/414/EEC Germany received on 13 October 1995 an application from Bayer AG, hereafter referred to as the applicant, for the inclusion of the active substance spiroxamine in Annex I to the Directive;
(2) Whereas in accordance with the provisions of Article 6(3) of the Directive the Commission confirmed in Decision 96/522/EC of 29 July 1996 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of spiroxamine in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market(3) that the dossier submitted for spiroxamine 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) Whereas, in accordance with Article 5(1) of the Directive, an active substance should be included for a period not exceeding 10 years in Annex I when it may be expected that there will not be any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment;
(4) Whereas for spiroxamine, 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; whereas Germany acting as nominated rapporteur Member State, has submitted to the Commission on 5 February 1997 the assessment report concerned;
(5) Whereas the submitted report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health; whereas this review has been finalised on 12 May 1999 in the format of the Commission review report for spiroxamine; whereas it may be necessary to update this report to take account of technical and scientific developments; whereas in such case the conditions for the inclusion of spiroxamine in Annex I to Directive 91/414/EEC will also need to be amended pursuant to Article 6(1) of that Directive;
(6) Whereas the dossier and the information from the review have also been submitted to the Scientific Committee on Plants for opinion; whereas this Committee has given its opinion on 18 December 1998(4); whereas this Committee identified potential risks to algae, sediment - dwelling organisms and possibly plants; whereas therefore, where appropriate, risk mitigation measures must be taken; whereas for operator exposure, this Committee concluded that with the use of personal protective equipment (PPE), the estimated operator exposure was acceptable; whereas therefore appropriate protective measures will need to be taken in order to ensure operator safety; whereas these conclusions are also consistent with the issues highlighted in the review carried out within the framework of the Standing Committee on Plant Health;
(7) Whereas 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; whereas therefore it is necessary 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) Whereas after inclusion a reasonable period is necessary to permit Member States to implement the provisions of Directive 91/414/EEC on plant protection products containing spiroxamine 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; whereas a longer period may also be required for plant protection products containing spiroxamine and other active substances included in Annex I;
(9) Whereas 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) Whereas 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 of the Directive;
(11) Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on the 12 May 1999;
HAS ADOPTED THIS DIRECTIVE:

Article 1
Spiroxamine is hereby designated as an active substance in Annex I to Directive 91/414/EEC, as 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 1 January 2000.
2. However, for plant protection products containing spiroxamine 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 the other active substance in Annex I to Directive 91/414/EEC.
3. 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.
4. 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 procedure for such reference shall be laid down by the Member States.

Article 3
This Directive shall enter into force on 1 September 1999.

Article 4
This Directive is addressed to the Member States.

Done at Brussels, 19 July 1999.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

SPIROXAMINE

1. Identity

(IUPAC) (8-tert-Butyl-1,4-dioxa-spiro [4.5] decan-2-ylmethyl)-ethyl-propyl-amine

2. Conditions to be fulfilled:

2.1. The active substance shall have a minimum purity of 940 g/kg technical product (diastereomers A and B combined).

2.2. Only uses as a fungicide may be authorised.

2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on spiroxamine, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 May 1999 shall be taken into account. Furthermore, in this overall assessment Member States:

- must pay particular attention to operator safety and must ensure that the conditions of authorisation include appropriate protective measures,

and,

- must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

3. Expiry date of the inclusion: 1 September 1999.