Commission Regulation (EC) No 1335/2005 of 12 August 2005 amending Regulation (EC) No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Council Directive 91/414/EEC and the continued use of certain substances not included in its Annex I (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1335/2005

of 12 August 2005

amending Regulation (EC) No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Council Directive 91/414/EEC and the continued use of certain substances not included in its Annex I

(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 the third and fourth subparagraph of Article 8(2) thereof,

Whereas:

(1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification, except where a decision has been taken not to include the substance concerned in Annex I.

(2) Commission Regulations (EEC) No 3600/92[(2)] and (EC) No 451/2000[(3)] lay down the detailed rules for the implementation of the first and second stages of the programme of work referred to in Article 8(2) of the above directive. This programme is ongoing and it has not been possible yet to complete decision making on a number of active substances.

(3) As regards the 90 active substances covered by the first stage of the above programme of work, 67 have been the subject of a directive or a decision. This leaves 23 active substances for which work continues. As regards the 53 active substances covered by the second stage of the above programme of work, one has been the subject of a decision. This leaves 52 active substances for which work continues. For the first stage of the work programme, the Commission organised the peer review, after submission of the draft assessment report by the Rapporteur Member State. This cycle of peer reviews has been finalised meanwhile and decisions or directives on the last substances are currently under preparation. For the second stage, the peer review comes under the responsibility of the European Food Safety Authority (EFSA), which has one year

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from the submission of the draft assessment report, to communicate its opinion to the Commission. As the dates of submission being part of the arrangements agreed between the Commission and EFSA, it is possible to predict when the latest opinion will become ready. To date, three have been delivered to the Commission, while the last should be made available to the Commission at the end of 2005. Consequently, more time should be allocated to the assessment of the second stage substances than to those covered by the first stage which already have passed this part of the process.

(4) The Commission's progress report of 26 July 2001[(4)] explained why progress has not been as good as was originally anticipated. The main reasons for the delay were a slow start, due to the identification and priority classification of the substances, the need to bring together the necessary resources and to provide more elaborated procedural schemes for evaluation and decision-making. Based on the conclusions of this report the deadline was extended by Commission Regulation (EC) No 2076/2002[(5)] for those substances still under review. Meanwhile, the Commission and Member States have worked actively to improve the procedures for assessing active substances, and the considerable increase rate of decisions over the last years show that the learning cycle can be considered closed. EFSA, which bears responsibility in the second stage of the review programme, is also entering an operational phase, and its first opinions have now been delivered. However, some of the reasons identified in the report of 2001 still apply. These include the further need to make the best use of the limited resources by appropriate methods of work-sharing and to ensure that the currently reached number of yearly decisions is maintained. The initial slowness, the technical complexity of certain dossiers, the necessity to obtain the opinion of independent scientific circles and other unforeseen factors, have eroded, in a number of cases, the time necessary for the decision-making and the implementing measures.

(5) It is envisaged that all the substances covered by the first and second stage of the above review programme should be the subject of a specific act adopted before 31 December 2005 (for the first stage) or 30 September 2006 (for the second stage). However, time must be allowed for these acts to come into force, in order to permit Member States and interested parties to prepare themselves to meet the new requirements.

(6) For these reasons it is appropriate to extend the transitional period for the first stage by one year and for the second stage by twenty one months.

(7) Regulation (EC) No 2076/2002 and Commission Decisions 2002/928/EC of 26 November 2002 concerning the non-inclusion of benomyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance[(6)], 2004/129/EC of 30 January 2004 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances[(7)], 2004/140/EC of 11 February 2004 concerning the non-inclusion of fenthion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance[(8)], 2004/247/EC of 10 March 2004 concerning the non-inclusion of simazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations

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for plant protection products containing this active substance[9] and 2005/303/EC of 31 March 2005 concerning the non-inclusion of cresylic acid, dichlorophen, imazamethabenz, kasugamycin and polyoxin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances[10] contain provisions for the non-inclusion of certain active substances in Annex I to Directive 91/414/EEC and for the withdrawal by Member States of all authorisations for plant protection products containing those substances. Those acts provide for derogations permitting the continued use of some of those substances for a limited period of time while alternatives are being developed.

(8) Member States have presented new evidence demonstrating the need for further essential uses. Such information has been evaluated by the Commission with Member State experts.

(9) Derogations should only be granted for cases which appear justified and which do not give rise to concern and should be restricted to the control of harmful organisms for which no efficient alternatives exist.

(10) Regulation (EC) No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2076/2002 is amended as follows:

1. Article 1 is replaced by the following:

> The time period of 12 years referred to in Article 8(2) of Directive 91/414/EEC is extended until 31 December 2006 for the active substances which are assessed in the framework of Regulation (EEC) No 3600/92, until 30 September 2007 for the active substances which are assessed in the framework of the second stage under Regulation (EC) No 451/2000, and until 31 December 2008 for the active substances which are assessed in the framework of Regulation (EC) No 1490/2002, unless a decision has been taken or is taken before the relevant date to include or not include the active substance concerned in Annex I to Directive 91/414/EEC. During those periods Member States may continue to authorise or authorise again the placing on the market of plant protection products containing those active substances, in accordance with the provisions of Article 8(2) of Directive 91/414/EEC.

2. Annex II is amended in accordance with Part I of the Annex to this Regulation.

Article 2

The Annex to Decision 2002/928/EC is amended in accordance with Part II of the Annex to this Regulation.

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Article 3

The Annex to Decision 2004/129/EC is amended in accordance with Part III of the Annex to this Regulation.

Article 4

The Annex to Decision 2004/140/EC is amended in accordance with Part IV of the Annex to this Regulation.

Article 5

The Annex to Decision 2004/247/EC is amended in accordance with Part V of the Annex to this Regulation.

Article 6

The Annex to Decision 2005/303/EC is amended in accordance with Part VI of the Annex to this Regulation.

Article 7

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 August 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission