# COMMISSION REGULATION (EC) No 416/2008

## of 8 May 2008

## amending Regulation (EEC) No 3600/92 as regards the assessment of the active substance metalaxyl in the framework of Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market

**(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 on the market [1], and in particular the third subparagraph of Article 8(2) thereof,

Whereas:

(1) Metalaxyl is one of the active substances listed in Annex I to Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [2].

(2) As a consequence of the judgment of the Court of Justice of the European Communities of 18 July 2007 in Case C-326/05 P [3], which annulled Commission Decision 2003/308/EC [4] concerning the non-inclusion of metalaxyl in Annex I to Council Directive 91/414/EEC, the Commission adopted Regulation (EC) No 1313/2007 of 8 November 2007 amending Regulations (EC) No 2076/2002 as regards the extension of the time period referred to in Article 8(2) of Council Directive 91/414/EEC with respect to metalaxyl and (EC) No 2024/2006 as regards the deletion of the derogation concerning metalaxyl [5].

(3) Article 233 of the Treaty requires the institution whose act has been declared void to take the necessary measures to comply with the judgment of the Court of Justice. Further measures are thus necessary as regards Regulation (EEC) No 3600/92 in particular with regard to the time limits for the submission of results of additional trials and additional information.

(4) Those further measures should be viewed against the unique factual situation of the judgment in case C-326/05 P. IQV had never lodged a complete dossier and wished instead to invoke studies lodged by another notifier. IQV claimed that it should only be required to add any further material not found in the latter's dossier, which incidentally also contained gaps. IQV was however refused access to the dossier by the other notifier, who had withdrawn in the meantime. Throughout the proceedings, the Commission insisted that IQV bore the burden of proof of demonstrating that metalaxyl met the criteria for inclusion in Annex I to Directive 91/414/EEC. This position was not contested by the Court. Since IQV did not have access to the other notifier's dossier, the Commission took the view that the peer review could not be carried out successfully, since the peer review would raise questions about the studies contained in the other dossier. IQV, having been refused access to the dossier, would not be able to answer such questions. The rapporteur Member State submitted the Draft Assessment Report for the substance on 26 January 2001 on the basis of all the studies available at that time. However, during the evaluation, the data gaps that had been identified were of such nature that an inclusion of the substance in Annex I of Directive 91/414/EEC could not be envisaged.

(5) During contacts with IQV on 17 September and 14 November 2007, the Commission informed IQV of its intention to complete the evaluation of the substance.

(6) The information on metalaxyl submitted to the Commission till to date is incomplete and does not allow an inclusion of metalaxyl in Annex I to Directive 91/414/EEC. The Commission is not in a position to guarantee that the studies and data that will be provided by IQV for the evaluation under Regulation (EEC) No 3600/92 will be sufficient to fill the gaps identified and, thus, be sufficient to demonstrate that metalaxyl may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(7) The Commission and Member States will take a pragmatic approach to rely as much as legally possible on the already existing data. It is common that during the peer review questions are brought forward. These questions could be raised on all elements of the dossier, and it is IQV's sole responsibility to address them should this situation occur.

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[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2008/45/EC (OJ L 94, 5.4.2008, p. 21).
[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).
[3] European Court Reports 2007, I-6557.
[4] OJ L 113, 7.5.2003, p. 8.
[5] OJ L 291, 9.11.2007, p. 11.

(8) To complete the assessment of metalaxyl by the date laid down in Regulation (EC) No 2076/2002, it is essential that strict deadlines are applied in the different steps of the procedure. Therefore, it can not be assumed that any gaps identified later in the dossier can be remedied by providing further studies as this would delay the assessment.

(9) To allow metalaxyl to be examined, certain time periods provided for in Regulation (EEC) No 3600/92 should be adapted.

(10) Regulation (EEC) No 3600/92 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*

In the first subparagraph of Article 7(4) of Regulation (EEC) No 3600/92 the first and the second indents are replaced by the following:

'— the time limit within which the results or information concerned must be submitted to the rapporteur Member State and the experts designated according to paragraph 2 above, this time limit will be 25 May 2002, however, as regards metalaxyl the time limit will be at the latest 31 October 2008, unless an earlier time limit is established by the Commission for a particular active substance except for the results of long-term studies, identified as being necessary by the rapporteur Member State and the Commission during the examination of the dossier and which are not expected to be fully completed by the deadline established, provided that the information submitted contains evidence that such studies have been commissioned and that their results will be submitted at the latest on 25 May 2003. In exceptional cases, where it has not been possible for the rapporteur Member State and the Commission to identify such studies by 25 May 2001, an alternative date may be established for the completion of such studies, provided the notifier supplies the rapporteur Member State with evidence that such studies have been commissioned within three months of the request to undertake the studies, and with a protocol and progress report of the study by 25 May 2002.

— the time limit within which the notifiers concerned must communicate to the rapporteur Member State and to the Commission their undertaking to submit the required results or information within the time limit laid down in the first indent. However, as regards metalaxyl that time limit shall be one month after the entering into force of this Regulation.'

*Article 2*

This Regulation shall enter into force on the day following that of 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, 8 May 2008.

*For the Commission*
Androulla VASSILIOU
*Member of the Commission*