# COMMISSION REGULATION (EU) No 78/2010

## of 27 January 2010

## amending Regulation (EC) No 33/2008 as regards the scope and the period granted under the regular procedure to the Authority for the adoption of its conclusions concerning the inclusion of certain active substances in Annex I to Directive 91/414/EEC

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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(5) thereof,

Whereas:

(1) Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [2] applies to third and fourth stage substances which had been evaluated but not included into Annex I to Directive 91/414/EEC by 31 December 2008. As regards third and fourth stage substances evaluated after that date it does not apply.

(2) However, Commission Regulation (EC) No 2076/2002 [3] and Commission Decision 2003/565/EC [4] have been amended to extend the time period for the programme of work until 31 December 2009 as regards third and fourth stage substances. It is necessary to adapt the respective date in Regulation (EC) No 33/2008.

(3) As regards the regular procedure, it has become obvious that the time period granted to the Authority to prepare its conclusions should be extended due to the complexity and the amount of work involved. This should only apply with respect to active substances for which the draft assessment report is submitted to the Commission after entry into force of this Regulation.

(4) Regulation (EC) No 33/2008 should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 33/2008 is amended as follows:

1. In Article 1, point (c) is replaced by the following:

'(c) for third and fourth stage substances, by 31 December 2009.'

2. Article 10 is replaced by the following:

*'Article 10*

**Conclusion by the Authority**

1. The Authority shall adopt a conclusion on whether the active substance can be expected to meet the requirements of Article 5 of Directive 91/414/EEC within six months from the end of the period provided for in the third paragraph of Article 9 of this Regulation and communicate it to the applicant, the Member States and the Commission.

Where appropriate, the Authority shall address in its conclusion the risk mitigation options in relation to the intended uses identified in the draft assessment report.

2. Where the Authority needs additional information, it shall, in consultation with the rapporteur Member State, set a time period of maximum ninety days for the applicant to supply it to the Authority and the rapporteur Member State. It shall inform the Commission and the Member States. Only information submitted within the time period granted shall be taken into account.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 15, 18.1.2008, p. 5.
[3] OJ L 319, 23.11.2002, p. 3.
[4] OJ L 192, 31.7.2003, p. 40.

The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within sixty days after the receipt of the additional information.

In that case, the six months period for the adoption of the conclusion by the Authority, as provided for in paragraph 1, shall be extended by a period which shall cease at the moment when the assessment of the additional information is received by the Authority.

3. The Commission and the Authority shall agree on a schedule for the delivery of the conclusions in order to facilitate the planning of the work. The Commission and the Authority shall agree on the format in which the conclusions of the Authority are submitted.'

*Article 2*

**Transitional provisions**

Article 10 of Regulation (EC) No 33/2008 shall continue to apply, as unamended, to active substances for which the draft assessment report by the rapporteur Member State was submitted to the Commission, as provided for in Article 8(1) of Regulation (EC) No 33/2008, before the entry into force of this Regulation.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the 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, 27 January 2010.

*For the Commission*
*The President*
José Manuel BARROSO