DECISIONS

COMMISSION IMPLEMENTING DECISION

of 18 January 2013

allowing Member States to extend provisional authorisations granted for the new active substances emamectin and maltodextrin

(notified under document C(2013) 51)

(Text with EEA relevance)

(2013/38/EU)

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 the fourth subparagraph of Article 8(1) thereof,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2], and in particular Article 80(1)(a) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Directive 91/414/EEC shall continue to apply to active substances for which a decision has been adopted in accordance with Article 6(3) of Directive 91/414/EEC before 14 June 2011.

(2) In accordance with Article 6(2) of Directive 91/414/EEC, in June 2006 the Netherlands received an application from Syngenta Ltd for the inclusion of the active substance emamectin in Annex I to Directive 91/414/EEC. Commission Decision 2007/669/EC [3] confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.

(3) In accordance with Article 6(2) of Directive 91/414/EEC, in July 2008 France received an application from Biological Crop Protection Ltd for the inclusion of the active substance maltodextrin in Annex I to Directive 91/414/EEC. Commission Decision 2008/20/EC [4] confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.

(4) Confirmation of the completeness of the dossiers was necessary in order to allow them to be examined in detail and to allow Member States the possibility of granting provisional authorisations, for periods of up to three years, for plant protection products containing the active substances concerned, while complying with the conditions laid down in Article 8(1) of Directive 91/414/EEC and, in particular, the conditions relating to the detailed assessment of the active substances and the plant protection products in the light of the requirements laid down by that Directive.

(5) For these active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The rapporteur Member States submitted the draft assessment reports to the Commission on 6 March 2008 (emamectin) and on 10 December 2009 (maltodextrin), respectively.

(6) Following submission of the draft assessment reports by the rapporteur Member States, it has been found to be necessary to request further information from the applicants and to have the rapporteur Member States examine that information and submit their assessment. Therefore, the examination of the dossiers is still ongoing and it will not be possible to complete the evaluation within the time-frame provided for in Directive 91/414/EEC.

(7) As the evaluation so far has not identified any reason for immediate concern, Member States should be given the possibility of prolonging provisional authorisations granted for plant protection products containing the active substances concerned for a period of 24 months in accordance with the provisions of Article 8 of Directive 91/414/EEC so as to enable the examination of the dossiers to continue. It is expected that the evaluation and decision-making process with respect to a decision on a possible approval in accordance with Article 13(2) of Regulation (EC) No 1107/2009 for emamectin and maltodextrin will have been completed within 24 months.

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

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 309, 24.11.2009, p. 1.
[3] OJ L 274, 18.10.2007, p. 15.
[4] OJ L 1, 4.1.2008, p. 5.

HAS ADOPTED THIS DECISION:

Article 1

Member States may extend provisional authorisations for plant protection products containing emamectin or maltodextrin for a period ending on 31 January 2015 at the latest.

Article 2

This Decision shall expire on 31 January 2015.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 18 January 2013.

For the Commission

Tonio BORG

Member of the Commission