DIRECTIVES

COMMISSION DIRECTIVE 2010/14/EU

of 3 March 2010

amending Council Directive 91/414/EEC to include heptamaloxyloglucan as active substance

(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(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC France received on 9 May 2006 an application from Elicityl SA for the inclusion of the active substance heptamaloxyloglucan in Annex I to Directive 91/414/EEC. Commission Decision 2007/560/EC [2] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) For that active substance, 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 applicant. The designated rapporteur Member State submitted a draft assessment report on 26 July 2007.

(3) The assessment report was peer reviewed by the Member States and the EFSA and presented to the Commission in the format of the EFSA Scientific Report for heptamaloxyloglucan on 17 July 2009 [3]. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 27 November 2009 in the format of the Commission review report for heptamaloxyloglucan.

(4) It has appeared from the various examinations made that plant protection products containing heptamaloxyloglucan may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include heptamaloxyloglucan in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

(5) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing provisional authorisations of plant protection products containing heptamaloxyloglucan to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should transform existing provisional authorisations into full authorisations, amend them or withdraw them in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 213, 15.8.2007, p. 29.
[3] *EFSA Scientific Report* (2009) 334, 1-52, Conclusion regarding the peer review of the pesticide risk assessment of the active substance heptamaloxyloglucan (finalised: 17 July 2009).

(6) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 November 2010 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 December 2010.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing heptamaloxyloglucan as active substance by 30 November 2010. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to heptamaloxyloglucan are met, with the exception of those identified in part B of the entry concerning the active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13(2) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing heptamaloxyloglucan as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2010 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning heptamaloxyloglucan. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

(a) in the case of a product containing heptamaloxyloglucan as the only active substance, where necessary, amend or withdraw the authorisation by 30 November 2011 at the latest; or

(b) in the case of a product containing heptamaloxyloglucan as one of several active substances, where necessary, amend or withdraw the authorisation by 30 November 2011 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 June 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 3 March 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, the following entry is added at the end of the table:

No	Common name, Identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'304	Heptamaloxyloglucan CAS No 870721-81-6 CIPAC No Not available	Full IUPAC name in footnote (*) Xyl p: xylopyranosyl Glc p: glucopyranosyl Fuc p: fucopyranosyl Gal p: galactopyranosyl Glc-ol: glucitol	≥ 780 g/kg The impurity Patulin must not exceed 50 µg/kg in the technical material.	1 June 2010	31 May 2020	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on heptamaloxyloglucan, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009 shall be taken into account.

(*) $\{[\alpha - D - Xyl\,p - (1\text{-}6)] - \beta - D - Glc\,p - (1\text{-}4)\}\{[\alpha - L - Fuc\,p - (1\text{-}2) - \beta - D - Gal\,p - (1\text{-}2) - \alpha - D - Xyl\,p - (1\text{-}6)] - \beta - D - Glc\,p - (1\text{-}4)\} - D - Glc\text{-}ol$'

(1) Further details on identity and specification of active substances are provided in the review report.