DIRECTIVES

COMMISSION DIRECTIVE 2010/42/EU

of 28 June 2010

amending Council Directive 91/414/EEC to include FEN 560 (fenugreek seed powder) 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 24 June 2003 an application from Société occitane de fabrications et de technologie for the inclusion of the active substance FEN 560 (also called fenugreek or fenugreek seed powder) in Annex I to Directive 91/414/EEC. Commission Decision 2004/131/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 18 February 2005.

(3) The draft assessment report was peer reviewed by the Member States and the European Food Safety Authority (EFSA) in the format of the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance fenugreek seed powder (FEN 560) on 18 December 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 was finalised on 11 May 2010 in the format of the Commission review report for FEN 560 (fenugreek seed powder).

(4) It has appeared from the various examinations made that plant protection products containing FEN 560 (fenugreek seed powder) 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 FEN 560 (fenugreek seed powder) 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 FEN 560 (fenugreek seed powder) 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.

(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,

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[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 37, 10.2.2004, p. 34.
[3] *The EFSA Journal* (2010) 8(1):1448, Conclusion on the peer review of the pesticide risk assessment of the active substance fenugreek seed powder (FEN 560). doi:10.2903/j.efsa.2010.1448. Available online www.efsa.europa.eu

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 April 2011 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 May 2011.

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 FEN 560 (fenugreek seed powder) as active substance by 30 April 2011. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to FEN 560 (fenugreek seed powder) 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 FEN 560 (fenugreek seed powder) 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 October 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 FEN 560 (fenugreek seed powder). 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 FEN 560 (fenugreek seed powder) as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2012 at the latest; or

(b) in the case of a product containing FEN 560 (fenugreek seed powder) as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2012 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 November 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 28 June 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
'313	FEN 560 (also called fenugreek or fenugreek seed powder) CAS N° None CIPAC N° None The active substance is prepared from the seed powder of *Trigonella foenum-graecum* L. (fenugreek).	Not applicable	100 % fenugreek seed powder without any additive and no extraction; the seed being of human food grade quality.	1 November 2010	31 October 2020	PART A Only uses as elicitor of the crop's self-defence mechanisms may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on FEN 560 (fenugreek seed powder), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to the risk to operators, workers and bystanders. Conditions of authorisation shall include risk mitigation measures where appropriate.'

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