



EUROPEAN
COMMISSION

Brussels, **XXX**
SANCO/12443/2013 rev
1(POOL/E3/2013/12443/12443-EN.doc)
[...](2013) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of **XXX**

**withdrawing the approval of the active substance fenbutatin oxide, in accordance with
Regulation (EC) No 1107/2009 of the European Parliament and of the Council
concerning the placing of plant protection products on the market, and amending
Implementing Regulation (EU) No 540/2011**

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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/EEC¹, and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2011/30/EU² included fenbutatin oxide as active substance in Annex I to Council Directive 91/414/EEC³ with the condition that Member States concerned ensure that the applicant at whose request fenbutatin oxide has been included provides further confirmatory information on the genotoxicological potential and ecotoxicological relevance of the impurity SD 31723 and to the spectra, storage stability and methods of analysis in the formulation by 31 May 2013.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011⁴.
- (3) The applicant at whose request fenbutatin oxide had been approved did not submit the confirmatory information by the deadline of 31 May 2013. By mail of 27 June 2013 it confirmed to the Commission its intention not to submit such information.
- (4) Consequently, it is appropriate to withdraw the approval of fenbutatin oxide.
- (5) Commission Directive 2011/30/EU should therefore be repealed.
- (6) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

¹ OJ L 309, 24.11.2009, p. 1.

² *[this act is on bitartenol!]* Commission Directive 2011/30/EU of 7 March 2011 amending Council Directive 91/414/EEC to include fenbutatin oxide as active substance and amending Commission Decision 2008/934/EC (OJ L 61, 8.3.2011, p. 14.).

³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁴ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

- (7) Member States should be provided with time to withdraw authorisations for plant protection products containing fenbutatin oxide.
- (8) For plant protection products containing fenbutatin oxide, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should, at the latest, expire 18 months after entry into force of this Regulation.
- (9) 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
Withdrawal of approval

The approval of the active substance fenbutatin oxide is withdrawn.

Article 2
Repeal of Commission Directive 2011/30/EU

Commission Directive 2011/30/EU is repealed.

Article 3
Amendment to Implementing Regulation (EU) No 540/2011

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, row 331, fenbutatin oxide, is deleted.

Article 4
Transitional measures

Member States shall withdraw authorisations for plant protection products containing fenbutatin oxide as active substance by *[Office of Publications please insert date 6 months after entry into force]*.

Article 5
Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on *[Office of Publications please insert date 18 months after entry into force]* at the latest.

Article 6
Entry into force

This Regulation shall enter into force on the twentieth 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,

For the Commission
The President
José Manuel BARROSO