

Commission Directive 2006/41/EC of 7 July 2006 amending  
Council Directive 91/414/EEC to include clothianidin and  
pethoxamid as active substances (Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market<sup>(1)</sup>, and in particular Article 6(1) thereof,

Whereas:

- (1) Pursuant to Article 6(2) of Directive 91/414/EEC Belgium received, on 26 September 2001, an application from Sumitomo Chemical Takeda Agro Company Ltd, London, for the inclusion of the active substance clothianidin in Annex I to Directive 91/414/EEC. Commission Decision 2002/305/EC<sup>(2)</sup> 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) Germany received an application pursuant to Article 6(2) of Directive 91/414/EEC on 16 October 2000 from Stähler Agrochemie GmbH & Co., KG (now Stähler International GmbH & Co., KG) (on behalf of the Taskforce Stähler Agrochemie GmbH & Co. KG, Tokuyama Europe GmbH and Tomen France SA) for the inclusion of the active substance pethoxamid in Annex I to Directive 91/414/EEC. Commission Decision 2001/626/EC<sup>(3)</sup> 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.
- (3) For those 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 designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 4 June 2003 (clothianidin) and 27 August 2002 (pethoxamid), respectively.
- (4) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 27 January 2006 in the format of the Commission review reports for clothianidin and pethoxamid.

- (5) The review of clothianidin and pethoxamid did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or of the European Food Safety Authority which has taken over the role of that Committee.
- (6) It has appeared from the various examinations made that plant protection products containing the active substances concerned 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 reports. It is therefore appropriate to include clothianidin and pethoxamid in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.
- (7) 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 clothianidin or pethoxamid 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.
- (8) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (9) 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:

- (1) [OJ L 230, 19.8.1991, p. 1](#). Directive as last amended by Commission Directive 2006/45/EC ([OJ L 130, 18.5.2006, p. 27](#)).
- (2) [OJ L 104, 20.4.2002, p. 42](#).
- (3) [OJ L 217, 11.8.2001, p. 14](#).