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EUROPEAN COMMISSION

Brussels, 1.9.2010  
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2010/0239 (NLE)

Proposal for a

**COUNCIL DECISION**

**concerning the non-inclusion of 1,3-dichloropropene in Annex I to Council Directive  
91/414/EEC**

**(Text with EEA relevance)**

## EXPLANATORY MEMORANDUM

The attached draft proposal for a Council Decision concerns the non-inclusion of 1,3-dichloropropene as active substance in the positive list (Annex I) of Council Directive 91/414/EEC. The proposal for a non-inclusion is based on a number of concerns identified during the second evaluation of this active substance, which is not approved since September 2007.

Directive 91/414/EEC concerning the placing of plant protection products on the market sets up a harmonised framework for the authorisation and placing on the market of plant protection products. Article 8(2) of this Directive provides a programme to be carried out over a period of 12 years for the gradual examination of the active substances contained in the pesticides, which are on the market for the inclusion in Annex I of the Directive. Regulation (EC) No 451/2000 and Regulation (EC) No 1490/2002 lay down the detailed rules for the implementation of the second and third stages of the above mentioned programme of work.

1,3-dichloropropene is one of the active substances covered by the second stage of this work programme. It had been non-included in Annex I of Directive 91/414/EEC by Commission Decision 2007/619/EC, in particular due to the release in the environment of large amounts of known and unknown polychlorinated impurities, for which no information on persistency, toxicological behaviour, uptake from crops, accumulation, metabolic fate and residue level were available, as well as to the inconclusive nature of the consumer risk assessment and to the risk of groundwater potential contamination, for birds, mammals, aquatic organisms and other non target organism.

In June 2008, the notifier of the active substance re-submitted a new dossier according to the accelerated procedure provided for in Regulation (EC) No 33/2008. This dossier has been evaluated by the designated rapporteur Member State (Spain) and by the European Food Safety Authority (EFSA), which delivered on 30 September 2009 its conclusions on the risk assessment for 1,3-dichloropropene.

However, the additional data and information provided by the notifier did not permit to eliminate all the specific concerns that led to the first non-inclusion. Therefore, on 9 July 2010, the Commission submitted to the Standing Committee on the Food Chain and Animal Health a draft Commission Decision concerning the non-inclusion of 1,3-dichloropropene in Annex I to Council Directive 91/414/EEC.

The Committee delivered no opinion and the results of the vote were the following:

- 14 Member States voted in favour (150 votes)
- 11 Member States voted against (154 votes)
- 2 Member States abstained (41 votes)

Consequently, pursuant to article 19 of Directive 91/414/EEC and in accordance with Article 5 of Council Decision 1999/468/EC the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority.

The draft Decision is not subject to the right of scrutiny of the European Parliament (Article 8 of Council Decision 1999/468/EC).

Proposal for a

**COUNCIL DECISION**

**concerning the non-inclusion of 1,3-dichloropropene in Annex I to Council Directive 91/414/EEC**

**(Text with EEA relevance)**

THE COUNCIL OF THE EUROPEAN UNION,

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<sup>1</sup>, and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) By Commission Decision 2007/619/EC<sup>2</sup> it was decided not to include the active substance 1,3-dichloropropene in Annex I to Directive 91/414/EEC. That Decision was taken within the framework of the second stage of the programme of work provided for in Commission Regulations (EC) No 451/2000<sup>3</sup> and (EC) No 703/2001<sup>4</sup> which lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and which establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC.
- (2) The original notifier submitted a new application pursuant to Article 6(2) of Directive 91/414/EEC and Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I<sup>5</sup>. It requested the application of the accelerated procedure pursuant to Chapter III of Regulation (EC) No 33/2008 and submitted an updated dossier. The application was submitted to Spain, which had been designated rapporteur Member State by Regulation (EC) No 451/2000.
- (3) That application complies with the substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008 and was submitted within the time period provided for in the second sentence of Article 13 of that Regulation.

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<sup>1</sup> OJ L 230, 19.8.1991, p. 1.

<sup>2</sup> OJ L 249, 25.9.2007, p. 11.

<sup>3</sup> OJ L 55, 29.2.2000, p. 25.

<sup>4</sup> OJ L 98, 7.4.2001, p. 6.

<sup>5</sup> OJ L 15, 18.1.2008, p. 5.

- (4) Spain evaluated the new information and data submitted by the notifier and prepared an additional report on 15 April 2009.
- (5) The additional report was peer reviewed by the Member States and the European Food Safety Authority, hereinafter 'EFSA', and presented to the Commission on 30 September 2009 in the format of the EFSA Conclusion for 1,3-dichloropropene<sup>6</sup>. 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 9 July 2010 in the format of the Commission review report for 1,3-dichloropropene.
- (6) The new assessment by the rapporteur Member State and the new conclusion by the EFSA concentrated on the concerns that lead to the non-inclusion, which were due to the release in the environment of large amounts of known and unknown polychlorinated impurities, for which no information on persistency, toxicological behaviour, uptake from crops, accumulation, metabolic fate and residue level were available, as well as to the inconclusive nature of the consumer risk assessment and to the risk of groundwater potential contamination, for birds, mammals, aquatic organisms and other non target organism.
- (7) New data and information were submitted by the notifier in the updated dossier to address the concerns which lead to the non-inclusion, in particular as regards the identity of a number of impurities, the level of residues expected in crops, the risk to groundwater contamination and the risk to birds, mammals, aquatic organisms and non-target organisms. A new assessment was performed, as included in the additional report and in the EFSA Conclusion for 1,3-dichloropropene.
- (8) However, the additional data and information provided by the notifier did not permit to eliminate all the specific concerns that led to the non-inclusion.
- (9) In particular, there is a concern for the consumer exposure in relation to eleven unidentified manufacturing impurities. Furthermore, the potential contamination of groundwater in relation to 1,3-dichloropropene, its relevant toxic breakdown product (*EZ*)-3-chloroacrylic acid and eleven unidentified manufacturing impurities were not adequately addressed and there is a potential for long-range transport through the atmosphere of ten manufacturing impurities. In addition, the risk to non-target organisms was not demonstrated to be acceptable.
- (10) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. Furthermore, in accordance with Article 21(1) of Regulation (EC) No 33/2008, the Commission invited the notifier to submit comments on the draft review report. The notifier submitted its comments, which have been carefully examined.
- (11) However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection

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<sup>6</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance (*EZ*)-1,3-dichloropropene on request from the European Commission. EFSA Journal 2009; 7(10):1341. [102 pp.]. doi:10.2903/j.efsa.2009.1341. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu).

products containing 1,3-dichloropropene satisfy in general the conditions laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

- (12) 1,3-dichloropropene should therefore not be included in Annex I to Directive 91/414/EEC.
- (13) Decision 2007/619/EC should be repealed.
- (14) This Decision does not prejudice the submission of a further application for 1,3-dichloropropene pursuant to Article 6(2) of Directive 91/414/EEC and Chapter II of Regulation (EC) No 33/2008.
- (15) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman,

HAS ADOPTED THIS DECISION:

*Article 1*

1,3-dichloropropene shall not be included as active substance in Annex I to Directive 91/414/EEC.

*Article 2*

Decision 2007/619/EC is repealed.

*Article 3*

This Decision is addressed to the Member States.

Done at Brussels,

*For the Council  
The President*