



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 21 January 2013**

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**COVER NOTE**

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Subject: Commission Decision of XXX concerning the non-inclusion of formaldehyde for product-type 20 in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

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Delegations will find attached Commission document D024574/01.

Encl.: D024574/01



Brussels, **XXX**  
D024574/01 CA-Dec12-Doc.3.10  
[...] (2012) **XXX** draft

## COMMISSION DECISION

of **XXX**

**concerning the non-inclusion of formaldehyde for product-type 20 in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market**

(Text with EEA relevance)

## COMMISSION DECISION

of **XXX**

**concerning the non-inclusion of formaldehyde for product-type 20 in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market<sup>1</sup>, and in particular Article 16(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market<sup>2</sup> establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC.
- (2) Formaldehyde (EC No 200-001-8, CAS No 50-00-0) is included in that list for use in, *inter alia*, product-type 20, preservatives for food or feedstocks, as defined in Annex V to Directive 98/8/EC.
- (3) Two companies ('the applicants') submitted a dossier to Germany for the evaluation of formaldehyde for use in product-type 20 by 31 October 2008 in accordance with Article 9 of Regulation (EC) No 1451/2007. Pursuant to Article 11 of Directive 98/8/EC, the dossiers made reference to two products containing formaldehyde (the 'reference products').
- (4) In a series of meetings and letters, the Commission informed the applicants and Member States that it considered the reference products to be included in the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>3</sup>, and hence excluded from the scope of Directive 98/8/EC by virtue of Article 1(2)(o) of that Directive. The Commission stated that it would not decide to include formaldehyde for product-type

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<sup>1</sup> OJ L 123, 24.4.1998, p. 1.

<sup>2</sup> OJ L 325, 11.12.2007, p. 3.

<sup>3</sup> OJ L 268, 18.10.2003, p. 29.

20 in Annex I, IA or IB to Directive 98/8/EC. It therefore invited the applicants to discontinue their participation in the review programme in accordance with Article 11(1) of Regulation (EC) No 1451/2007 and apply for authorisation of the reference products in accordance with Regulation (EC) No 1831/2003, for which it offered practical help, as well as its best efforts to avoid market disruption during the transition from one regulatory regime to the other.

- (5) Following the Commission's advice, one of the applicants informed the Commission of its intention to discontinue its participation in the review programme in accordance with Article 11(1) of Regulation (EC) No 1451/2007 on 10 September 2009. The other applicant chose to remain in the review programme despite the advice.
- (6) The Commission repeated its position in a letter of 25 May 2010 to Germany and the remaining applicant. By letter of 17 August 2010, Germany replied that the remaining applicant declined to discontinue its participation in the review programme, which gave Germany no other option but to continue the evaluation.
- (7) As confirmed by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products,<sup>4</sup> products used for the preservation of food or feed are covered by Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives<sup>5</sup>. Therefore, such products are excluded from the scope of Directive 98/8/EC by virtue of Article 1(2)(o) of that Directive. Therefore, in the interest on legal certainty, it should be decided that formaldehyde will not be included in Annex I, IA or IB to the Directive for product-type 20.
- (8) Formaldehyde is not known to be used as a food additive, and not approved for such use in accordance with Regulation (EC) No 1333/2008.
- (9) Two applications for authorisation of formaldehyde as a feed additive in accordance with Regulation (EC) No 1831/2003 are currently under assessment. The phase-out period for products containing formaldehyde and used for the preservation of feed and placed on the market as biocidal products should take into account the time necessary to regulate such products in accordance with Regulation (EC) No 1831/2003.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on biocidal products,

HAS ADOPTED THIS DECISION:

#### *Article 1*

Formaldehyde (EC No 200-001-8, CAS No 50-00-0) shall not be included in Annex I, IA or IB to Directive 98/8/EC for product-type 20.

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<sup>4</sup> OJ L 167, 27.6.2012, p. 1.

<sup>5</sup> OJ L 354, 31.12.2008, p. 16.

*Article 2*

Products placed on the market as biocidal products for use as feed preservatives and containing formaldehyde shall no longer be placed on the market with effect from 1 July 2015.

*Article 3*

This Decision is addressed to the Member States.

Done at Brussels,

*For the Commission*  
*Janez POTOČNIK*  
*Member of the Commission*