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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the denial of authorisation of formaldehyde as a feed additive belonging to
the functional groups of preservatives and hygiene condition enhancers**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) Formaldehyde was authorised for an unlimited period in accordance with Directive 70/524/EEC as a feed additive belonging to the group of preservatives for pigs up to six months of age for use in skimmed milk by Commission Directive 83/466/EEC³. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) Formaldehyde (EC No 200-001-8, CAS No 50-00-0) was included in the list, established by Commission Regulation (EC) No 1451/2007⁴, of active substances to be assessed with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council⁵. However, Regulation (EU) No 528/2012 of the European Parliament and of the Council⁶, replacing Directive 98/8/EC, does not cover products used for the preservation of feed by controlling harmful organisms, in particular for reducing the contamination of feed with

¹ OJ L 268, 18.10.2003, p. 29.

² Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

³ Forty-third Commission Directive 83/466/EEC of 28 July 1983 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ L 255, 15.9.1983, p. 28). The chemical description of the additive was made more precise by Commission Directive 85/429/EEC of 8 July 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ L 245, 12.9.1985, p. 1).

⁴ 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 (OJ L 325, 11.12.2007, p. 3).

⁵ 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 (OJ L 123, 24.4.1998, p. 1).

⁶ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market of biocidal products (OJ L 167, 27.6.2012, p. 1).

Salmonella, considering that such products fall within the scope of Regulation (EC) No 1831/2003. Since 1 July 2015, in accordance with Commission Decision 2013/204/EU⁷, biocidal products for use as feed preservatives and containing formaldehyde are not to be placed on the market. That date was set with the aim to provide the time necessary to allow the transition from the biocidal products regulatory regime to the feed additives regime under Regulation (EC) No 1831/2003.

- (4) In accordance with Article 7 of Regulation (EC) No 1831/2003, two applications were submitted for the authorisation of a preparation of formaldehyde as a feed additive for all animal species, requesting the additive to be classified in the additive category "technological additives" and in the functional group "preservatives". Both applications include the use in skimmed milk for pigs up to the age of six months, as an existing product, in accordance with Article 10(2) of Regulation (EC) No 1831/2003. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) In addition, in accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of formaldehyde as a feed additive for pigs and poultry, requesting the additive to be classified in the additive category "technological additives" and in the functional group "hygiene condition enhancers". This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (6) The European Food Safety Authority ('the Authority') concluded in its two opinions of 28 January 2014⁸ and in its opinion of 1 July 2014⁹ that, as regards the target species, the preparation of formaldehyde would be safe at specific concentration levels for chickens for fattening, laying hens, Japanese quail and piglets (weaned) but that no safe level for all animal species and categories, including all poultry and pigs, could be determined. In addition, a formaldehyde concentration level that would be safe for reproduction for the target species could not be derived from the available studies. The Authority also concluded that the preparation of formaldehyde had the potential to be effective as preservative and, as hygiene condition enhancer, in reducing microbial growth in feed contaminated with *Salmonella*. In those three opinions, the Authority further concluded that formaldehyde raised concerns for the safety of the users. Formaldehyde is a toxic substance, a strong irritant, a potent skin and respiratory sensitiser (including occupational asthma) and causes eye damage. In its opinions, the Authority mentioned that, while local irritation is expected to strongly promote carcinogenesis, lower local concentrations of formaldehyde are known to produce DNA adducts and that therefore it deemed it prudent not to consider the exposure to non-irritant concentration as totally risk free. The Authority concluded that moreover, on the basis of the present knowledge, a causal association between formaldehyde exposure and leukaemia could not be ruled out. Consequently, the Authority concluded that no safe level of exposure of the skin, eyes or the respiratory system to formaldehyde could be identified. Therefore, the Authority recommended that measures should be taken to ensure that the respiratory tract, as well as the skin and eyes, of any person handling the product are not exposed to any dust, mist or vapour generated by the use of formaldehyde. In addition, the Authority recommended that

⁷ Commission Decision 2013/204/EU of 25 April 2013 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 (OJ L 117, 27.4.2013, p. 18).

⁸ *EFSA Journal* 2014;12(2):3561 and *EFSA Journal* 2014;12(2)3562.

⁹ *EFSA Journal* 2014;12(7):3790.

consideration should be given to whether the strict protection measures, once established, would effectively protect users. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (7) Formaldehyde is classified as carcinogenic (category 1B) by inhalation and germ cell mutagenic (category 2) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹⁰.
- (8) In the framework of Union legislation on health and safety at work, occupational exposure limits are being developed for formaldehyde. The Scientific Committee on Occupational Exposure Limits established by Commission Decision 2014/113/EU¹¹ has, in its Recommendation of 30 June 2016¹², pronounced itself on a limit value for formaldehyde based on a mode-of-action assessment.
- (9) In accordance with Article 9 of Regulation (EC) No 1831/2003, the measure on the authorisation of an additive is to take into account the requirements of paragraphs 2 and 3 of Article 5 of that Regulation, as well as Community law and other legitimate factors relevant to the matter under consideration. The risk management decision concerning the authorisation of formaldehyde as a feed additive should therefore be based on all the information available regarding the risks at stake, in particular on the one hand the risks posed by the handling of formaldehyde to users, in particular workers, and on the other hand the risks to animals or to consumers of the animal products concerned that could derive from not using formaldehyde as a feed additive.
- (10) In accordance with Union legislation on health and safety at work, and in particular with Article 4 of Directive 2004/37/EC of the European Parliament and of the Council¹³, the employer is to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous for workers' health or safety.
- (11) Due to the serious risks for users posed by the handling of formaldehyde, such approach based on replacement is also appropriate for that additive, taking into account the objective of ensuring a high level of protection of human health and users' interests pursued by Regulation (EC) No 1831/2003 and the precautionary principle provided for in Regulation (EC) No 178/2002 of the European Parliament and of the Council¹⁴.

¹⁰ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

¹¹ Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014).

¹² SCOEL/REC/125. Available at the following address: <https://publications.europa.eu/en/publication-detail/-/publication/7a7ae0c9-c03d-11e6-a6db-01aa75ed71a1>

¹³ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

¹⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (12) As regards possible alternative products to formaldehyde as an additive belonging to the functional group of preservatives, a series of additives are currently authorised in the Union under the same functional group.
- (13) As regards possible alternative products to formaldehyde as an additive belonging to the functional group of hygiene condition enhancers¹⁵, research is currently being conducted to develop additives which would prove both safe and efficacious in reducing microbiological contamination in feed. An additive has already been authorised¹⁶ under that functional group and is therefore considered as an alternative, although with a different mechanism of action, in order to reduce the number of bacterial pathogens, including *Salmonella* spp, in feed, without causing the concerns over users' safety raised by the use of formaldehyde. Several applications for authorisation of other additives under that functional group have been submitted and are being assessed in accordance with Regulation (EC) No 1831/2003. In addition, other authorised feed additives may, as zootechnical additives, improve the quality of animal products through a reduction of contamination with enteropathogens such as *Salmonella* spp.
- (14) In addition to the possibility of using alternative products to formaldehyde for the envisaged purposes in feed, the implementation of the hygiene requirements and good practices along the feed chain, as provided for in Regulation (EC) No 1831/2003 of the European Parliament and of the Council¹⁷, contributes to the safety and quality of feed through a preventive approach. In particular, specific hygiene measures are provided for under that framework for the control, prevention and treatment of feed contaminated with *Salmonella*.
- (15) It follows from the above elements that, taking into account the adverse effects of formaldehyde on the health of users handling the substance, in conjunction with the application of the precautionary principle in the protection of workers' health and with the fact that some products and measures, which do not present the same human safety concerns, are available as alternatives to the envisaged uses of formaldehyde in feed, the advantages of formaldehyde do not compensate the health risks. Therefore, the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied and accordingly, the authorisation of formaldehyde as a feed additive for use as preservative and hygiene condition enhancer should be denied.
- (16) Since further use of formaldehyde may cause a risk to human health, the feed additive belonging to the functional group of "preservatives" for use in skimmed milk for pigs up to the age of six months, and premixtures containing it, should be withdrawn from the market as soon as possible. For practical reasons however, a limited period should be allowed for the withdrawal from the market of the existing stocks of those products in order to enable operators to comply properly with the withdrawal obligation. As a result, this Regulation should not apply immediately as regards skimmed milk containing the additive or the premixtures, and compound feed containing such

¹⁵ This functional group has been established as a result of technological and scientific development by Commission Regulation (EU) 2015/2294 of 9 December 2015 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives (OJ L 324, 10.12.2015, p. 3).

¹⁶ Commission Implementing Regulation (EU) 2017/940 of 1 June 2017 concerning the authorisation of formic acid as a feed additive for all animal species (OJ L 142, 2.6.2017, p. 40).

¹⁷ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 12 January 2003 laying down requirements for feed hygiene (OJ L 35, 8.2.2003, p. 1).

skimmed milk, that have been produced up to three months after this Regulation enters into force, in order to take into account the use of those products in the feed chain.

- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Denial of authorisation

The authorisation of formaldehyde as an additive in animal nutrition, belonging to the additive category "technological additives" and to the functional groups "preservatives" and "hygiene condition enhancers", is denied.

Article 2

Withdrawal from the market

Existing stocks of formaldehyde as an additive belonging to the additive category "technological additives" and to the functional group "preservatives" for use in skimmed milk for pigs up to the age of six months, and of premixtures containing that additive, shall be withdrawn from the market as soon as possible and at the latest by *[3 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

As regards skimmed milk containing the additive or skimmed milk containing the premixtures referred to in Article 2, and compound feed containing such skimmed milk, which have been produced before *[3 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*, it shall apply from *[6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission

The President

Jean-Claude JUNCKER