Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 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)

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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 nutrition[(1)], 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/EEC[(2)].

(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 6 months of age for use in skimmed milk by Commission Directive 83/466/EEC[(3)]. 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 1451/2007[(4)], 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 Council[(5)]. However, Regulation (EU) No 528/2012 of the European Parliament and of the Council[(6)], 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 *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/EU[(7)], 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 6 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 2014[(8)] and in its opinion of 1 July 2014[(9)] 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. The Authority concluded that, as regards the requested use in feed of the preparation of formaldehyde, 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 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 Council[10].

(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/EU[11] has, in its Recommendation of 30 June 2016[12], pronounced itself on a limit value for formaldehyde based on a mode-of-action assessment, which was then considered by the tripartite Advisory Committee on Safety and Health at Work[13] in accordance with the procedures for establishing occupational exposure limits.

(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 Council[14], 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 Council[15].

(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 enhancers[16], 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 authorised[17] 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