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[...]

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

of **XXX**

concerning the provisional authorisation of a preparation of formaldehyde as a feed additive for chickens for fattening, laying hens, piglets (weaned) and pigs for fattening

(Text with EEA relevance)

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

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concerning the provisional authorisation of a preparation of formaldehyde as a feed additive for chickens for fattening, laying hens, piglets (weaned) and pigs for fattening

(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 15 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 such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of formaldehyde. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of formaldehyde as a feed additive for pigs and poultry, to be classified in the additive category “technological additives”.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 July 2014² that, under specific conditions of use and as regards the use for chickens for fattening, laying hens and piglets (weaned), the preparation of formaldehyde does not have an adverse effect on animal health, consumer safety or the environment, and that it has the potential to reduce bacterial growth in feed contaminated with *Salmonella* for the target species. The Authority could not conclude on the safety of other animal categories on the basis of the studies submitted by the applicant. It also concluded that, due to the respiratory risk deriving from the handling of formaldehyde, which is classified as carcinogenic (category 1b) by inhalation under Regulation (EC) No 1272/2008 of the European Parliament and of the Council³, strict measures are necessary to protect the safety of users. In particular, the Authority recommends 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 recommends that consideration should be

¹ OJ L 268, 18.10.2003, p. 29.

² *EFSA Journal* 2014;12(7):3790.

³ 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).

given to whether the strict protection measures, once established, would effectively protect users at the level of feed compounders and farmers. 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.

- (5) Due to the risk for users, including workers, posed by the handling of formaldehyde, it is considered necessary for feed business operators, in accordance with the objective of ensuring a high level of protection of human health and users' interests pursued by Regulation (EC) No 1831/2003, to search for alternative feed additives for reducing microbiological contamination of feed.
- (6) Such alternative feed additives, which could be authorised under the functional group "hygiene condition enhancers" and for which efficacy to reduce the contamination of feed with *Salmonella* could be demonstrated, are currently being developed.
- (7) 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 *Salmonella*, considering that such products fall within the scope of Regulation (EC) No 1831/2003. In accordance with Commission Decision 2013/204/EU⁷, biocidal products containing formaldehyde for use as feed preservatives may no longer be placed on the market since 1 July 2015. That date was set with the aim to provide the time necessary to allow the transition from the biocidal products regulatory regime to Regulation (EC) No 1831/2003.
- (8) The implementation of the hygienic requirements and good practices along the feed chain, as provided for in Regulation (EC) No 183/2005 of the European Parliament and of the Council⁸, contributes to the safety and quality of feed through a preventative approach. However, the objectives of that Regulation are made more difficult to achieve due to the current non-availability of the biocidal products mentioned in recital 7 and the lack of alternative products which prove both safe and efficacious for reducing the contamination of feed with *Salmonella*. In other respects, the establishment of specific microbiological criteria for feed at European Union level would set harmonised safety criteria on the acceptability of feed, in particular as regards the presence in feed of certain pathogenic bacteria such as *Salmonella*. However, those criteria have not yet been established in the context of Regulation (EC) No 183/2005, which may undermine a smooth and harmonised

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).

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. 17).

⁸ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

application by feed business operators of feed hygiene rules and practices, in particular for reducing contamination of feed with *Salmonella*.

- (9) This situation raises concerns for animal welfare, as it may therefore not be ensured that animals are fed a wholesome diet, maintaining them in good health, in accordance with the requirements of Council Directive 98/58/EC⁹. Feed contaminated with *Salmonella* may cause indeed unnecessary pain, suffering and injury to the animals concerned, and lead to mortality. In addition, *Salmonella* infection of animals through feed may require the adoption of drastic containment measures, such as the mass slaughtering of entire breeding flocks.
- (10) Despite the expiry of the authorisation with effect from 1 July 2015 of biocidal products containing formaldehyde for use as feed preservatives and the current lack of alternative products allowed for the same purpose, no authorisation of formaldehyde for reducing contamination of feed with *Salmonella* has been granted under Regulation (EC) No 1831/2003 as hygiene condition enhancer, resulting in a situation of regulatory gap for that specific use. Yet, the variety of sources of possible *Salmonella* contamination of feed and the frequency of potentially contagious contacts with feed require a continuous application of control measures to keep the feed safe. As a result, there is an urgent need to adopt measures in order to ensure animal welfare through a protection against *Salmonella* infection caused by contaminated feed.
- (11) Pending the authorisation of alternative feed additives under the conditions laid down in Regulation (EC) No 1831/2003 and the development of specifically adapted and efficient hygiene measures, a provisional authorisation of the preparation of formaldehyde as hygiene condition enhancer in feed is necessary to avoid any negative effects on animal welfare resulting from microbiological contamination of feed with *Salmonella*.
- (12) Due to the risks referred to in recital 4, the authorisation of that preparation should be restricted to a non-renewable period of three years and, as regards the conditions of use, only for feed where contamination by *Salmonella spp* has been detected.
- (13) In order to minimise the risks for users, including workers, it is appropriate to provide for effective and strict protective and risk mitigation measures and occupational exposure measurements of formaldehyde to be implemented by feed business operators for the handling of the additive and of feed or premixtures containing it, without prejudice to the protective measures to be taken in accordance with national provisions implementing European Union legislation on health and safety at work. In addition, it is appropriate to lay down post-market monitoring requirements in order to allow the evaluation, by the competent authorities of the Member States, of the application of the protective measures taken and the appropriateness of such measures.
- (14) In order to allow the Member States to properly control the application of this Regulation, in particular as regards protective measures for users and post-market monitoring requirements, it is appropriate to require that feed business operators using the additive formaldehyde and feed containing it notify this activity to the competent national authorities.
- (15) Therefore, that preparation should be provisionally authorised accordingly.

⁹ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).

- (16) 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
Provisional authorisation

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group "hygiene condition enhancers", is provisionally authorised as an additive in animal nutrition until *[three years after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*, subject to the conditions laid down in Articles 2 and 3 and those set out in the Annex.

Article 2
Protective measures for users

1. The incorporation in feed of the additive referred to in Article 1 and of premixtures containing it shall be done in a closed system, specifically adapted for that purpose, in order to ensure that it is carried out under appropriate conditions minimising any emission of liquid or gas into the environment.
2. For users of the additive referred to in Article 1, of premixtures and of other feed containing it, feed business operators shall establish safe operational procedures and appropriate organisational measures to address the risks caused by inhalation, eyes and dermal contact. Those products shall be used with appropriate personal protective equipment, including breathing protection, eyes protection, gloves and protective clothing, where exposure to any dust, mist or vapour generated by the use of formaldehyde occurs or may not be excluded.
3. Feed business operators shall perform regular campaigns of occupational exposure measurements for the handling of the additive referred to in Article 1, premixtures or other feed containing it. These monitoring campaigns shall take place at least annually and shall be based on relevant standard methodologies or protocols. They shall comprise both personal inhalation exposure sampling and biomonitoring sampling and be representative of the range of tasks with possible exposure to formaldehyde and of the total number of workers that are potentially exposed.

Article 3
Post-market monitoring reports

1. A feed business operator incorporating in feed the additive referred to in Article 1 or premixtures containing it shall carry out a post-market monitoring on the practical implementation of the measures provided for in Article 2 and send annually a report to the competent authorities of the Member State where it is established.
2. The post-market monitoring report shall include at least the following information:
 - (a) Name and address of the feed business operator responsible for the incorporation in feed of the additive or premixtures containing it;
 - (b) Location/address of the place where the additive or premixtures containing it have been incorporated in feed;

- (c) Frequency (record of dates) of the operations of incorporation in feed of the additive or premixtures containing it;
 - (d) Description of the facilities/working environment and system established for the operations of incorporation in feed of the additive or premixtures containing it;
 - (e) Description of the protective equipment, including technical characteristics thereof, used by staff involved in operations of incorporation in feed of the additive or premixtures containing it;
 - (f) Number of staff people, including the supervisory staff, involved in the operations of incorporation in feed of the additive or premixtures containing it and their respective skills/qualifications;
 - (g) Modalities of information of the staff on the measures protecting workers, the duties and procedures to be complied with for operations of incorporation in feed of the additive or premixtures containing it;
 - (h) Measures put in place in order to control and ensure the effective implementation of the measures protecting workers, the duties and procedures referred to in (g);
 - (i) Results of the measurements referred to in Article 2(3);
 - (j) Description of any incidents and of any difficulties occurred in complying with the obligations concerning the measures protecting workers, the duties and procedures referred to in (g);
 - (k) Description of any observed or reported adverse health effect suffered by staff involved in operations of incorporation in feed of the additive or premixtures containing it.
3. The first report shall be sent by [*one year after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] and thereafter once each calendar year until the end of the authorisation period.
4. Member States shall subsequently forward the post-market monitoring reports to the Commission as soon as they receive them.

Article 4 *Notification*

Feed business operators using the additive referred to in Article 1, premixtures and other feed containing it, shall notify in writing this activity to the competent authorities of the Member State where they are established. That notification shall be provided by [*2 months from the date of entry into force of this Regulation - Date to be inserted by the Service responsible for the publication*] or within 2 months from the date of the start of that activity, whichever is the later.

Article 5 *Entry into force*

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

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