

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

75th Meeting of ACAF on 15 February 2018

Discussion paper

Update on Formaldehyde

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REGULATORY POSITION OF FORMALDEHYDE IN ANIMAL FEED

Purpose

1. This paper advises on the authorisation status of formaldehyde as a feed additive, providing background context to the recently voted denial of authorisation. Members are invited to provide comments.

Background

2. The use of formaldehyde as a preservative in animal feed previously fell under the Biocidal Products Directive (98/8/EC). This Directive set out classifications of biocides based on key functional groups (product-types) defined in Annex V, with formaldehyde falling under Product-type 20 (PT-20) covering '*Preservatives for food or feedstock*'. This Directive was superseded by the [Biocidal Products Regulation \(EU\) 528/2012](#) with the omission of this PT-20 classification in recognition that such entries should be covered by Regulations (EC) [1333/2008](#) and [1831/2003](#) for food and feed additives, respectively. Whilst formaldehyde was not used as a food additive preservative, a transition period was established for formaldehyde at EU level under [Commission Decision 2013/204/EU](#) until 1 July 2015 when it was anticipated the authorisation into animal feed legislation would be concluded.
3. In 2014, EFSA published two Opinions (Nos. [3561](#), [3562](#)) on formaldehyde as a feed additive, each assessing separate holder authorisation applications. A follow-up Opinion on the safety and efficacy of formaldehyde (EFSA 2014, [No.3790](#)) reiterated former conclusions on the safety of formaldehyde as a feed additive, although no safe level for pigs and poultry could be established, and concerns over worker safety were raised. These concerns were based on the carcinogenic potential from exposure to formaldehyde vapours, being classified as a carcinogen 1B (i.e. evidenced in animal models, not determined from data relating to humans).
4. SCoPAFF discussions over 2014-15 focused on the ten-year authorisation of formaldehyde and the creation of a new functional group '*Hygiene condition enhancers*' to accommodate its function as a feed decontaminant. The most significant issue surrounded the carcinogenic potential of formaldehyde and implementing worker safety practices such as the use of closed production systems and worker monitoring requirements. Further restrictive criteria were established, confining the use of formaldehyde to pig and poultry feed only, which had been positively identified as contaminated with *Salmonella*. With no prospect of this authorisation being concluded prior to the expiry of [Commission Decision 2013/204/EU](#) on 1 July 2015, a minority of Member States implemented national derogations for the continued use of formaldehyde. The [UK derogation](#) permitted the use of formaldehyde until conclusion of this authorisation process within SCoPAFF-Animal Nutrition Section; where upon, the new legislation would take precedence.

5. The vote on the new functional group '*Hygiene condition enhancers*' was finalised and voted in favour at the July 2015 meeting and subsequently entered into force on the 9 December 2015 under [Regulation \(EU\) 2015/2294](#).
6. Following this EU level prohibition of formaldehyde, support for authorisation lessened; and in late 2015, an urgent authorisation (five-year term) was proposed, whilst a denial of authorisation was also first raised. With an ongoing impasse; in early 2016, a three-year urgent authorisation was recommended and indications showed a small shortfall in a qualified majority vote (QMV) in favour. However, support continued to decline throughout the year and in December 2016 Commission proceeded with a denial of authorisation. A request for an urgent authorisation of one year was initially rejected in early 2017 and little discussion held for several months.
7. The first draft Regulation on the denial of authorisation of formaldehyde (i.e. prohibition of use) was first presented at the July 2017 meeting, which included provision to permit a one year temporary authorisation. At the September meeting, the Commission deleted this provision as this was viewed as incompatible with the denial of authorisation within the same Regulation. The denial of authorisation concerned the existing use of formaldehyde as a preservative in skimmed milk for piglets and for the proposed authorisation as a '*Hygiene condition enhancer*' to decontaminate *Salmonella* in feed.
8. During the October 2017 meeting, the Commission confirmed that a temporary authorisation would not be progressed under a separate Regulation. The Commission also stated that due to the potential impact on the loss of formaldehyde as a feed additive, the draft Regulation for the denial of authorisation would be subject to a one month [EC public consultation](#) (21 November – 19 December 2017). Following this deadline, nearly one hundred citizen submissions had been posted; originating from 12 Member States and a number of 3rd Countries, largely in support for the continued use of formaldehyde. Citizen feedback fell into key areas concerning (*inter alia*) the high efficacy of formaldehyde as a microbiological decontaminant, safety of the feed and food-chains, misapplication of the precautionary principle and inconsistencies in formaldehyde use compared to other economic sectors. Conclusion of this consultation coincided with the December SCoPAFF meeting and on the 20 December this Regulation was prepared for vote.
9. Prior to vote, the Commission provided a detailed summary on the rationale to proceed to vote and counter arguments presented within the EU consultation in support of the continued use of formaldehyde. The denial of authorisation of formaldehyde was voted by a qualified majority vote (QMV) in favour by 26/28 Member States.

Next Steps

10. Under the requirements of this voted EU Regulation, the use of formaldehyde as a feed additive will be prohibited twenty days following the publication of the Regulation in the Open Journal of the European Union ([OJEU](#)). At the time of this paper going to press, the final Regulation had not been published and whilst

accurate timelines cannot be provided; in the absence of legal barriers, this publication may be anticipated within the first quarter of 2018. It must be emphasised that this Regulation concerns the denial of use for formaldehyde as a feed additive only. Other uses of formaldehyde, such as decontamination of feedmill environments remain unaffected, being regulated under Biocidal Products Regulation

Discussion

11. The Committee are invited to note the contents of this paper and to provide any comments they care to make.

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