

SCIENTIFIC OPINION

Statement on the use of feed additives authorised/applied for use in feed when supplied via water¹

EFSA Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP) to produce a statement on the assessment of safety and efficacy of feed additives when used in water.

In the view of the FEEDAP Panel, there is no need to separately assess the safety and efficacy of an additive administered via water when an application for its use in feed is submitted or an authorisation exists, provided that the exposure of the animals is essentially the same.

The FEEDAP Panel made some recommendations.

KEY WORDS

Feed additives, additives used in water

¹ On request from EFSA, Question No EFSA-Q-2010-01272, adopted on 7 December 2010.

² Panel members : Gabriele Aquilina, Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Albert Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Reinhard Kroker, Lubomir Leng, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Derek Renshaw and Maria Saarela. Correspondence: FEEDAP@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Guidance for the preparatory work on this scientific opinion.

TABLE OF CONTENTS

Summary	1
Table of contents	2
Background as provided by EFSA	3
Terms of reference as provided by EFSA	3
Statement	4
1. Introduction	4
2. Additive administration via feed and water	4
Conclusions	4
Recommendations	5

BACKGROUND AS PROVIDED BY EFSA

Regulation (EC) No 1831/2003⁴ establishes the rules governing the Community authorisation of additives for use in animal nutrition. Moreover, Regulation (EC) No 429/2008⁵ provides detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.

Regulation (EC) No 1831/2003 foresees that, for the first time, feed additives can be used in water. However, no specific provisions have been included in Regulation (EC) 429/2008 for the assessment of safety and efficacy of additive when used in water.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The FEEDAP Panel is requested to produce a statement on the assessment of safety and efficacy of feed additives when used in water.

⁴ OJ L 268, 18.10.2003, p. 29.

⁵ OJ L 133, 22.5.2008, p. 1.

STATEMENT

1. Introduction

Regulation (EC) No 1831/2003, Article 2, 2(a) defines 'feed additives' as *substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3)*.

In addition, Regulation (EC) No 429/2008, Annex II, 2.5, outlines under proposed use in animal nutrition that the applicant shall define the proposed use of the additive in feed or water: *Details of the proposed method of administration and level of inclusion must be provided for [...] water for drinking*.

Regarding the nature of the applications submitted for the re-evaluation of additives, EFSA has received an increasing number of applications for use of additives in feed and/or water. In most applications, the concentration in water is derived from that in feed. However, there are applications proposing a dosing regime in water for drinking which would lead to an animals' exposure different from that resulting from feed.

The terms 'use in water', 'use via water' and 'use through water' are considered synonymous.

2. Additive administration via feed and water

With respect to the physiological background of intestinal absorption, distribution, metabolism and excretion, oral administration routes of additives via feed or water are considered, in principle, as bioequivalent.

In consequence, for an additive for which data is already available allowing a minimum effective dose to be established in feed, the corresponding concentration in water can be derived from feed intake. For additives without a minimum effective dose, the water concentration should be derived from practical use level in feed, usually that recommended by applicants.

For poultry, pigs and rabbits, the water intake would be 2–3 times higher than feed intake and the concentration in water reduced accordingly.

In ruminants (and horses), the concentrations of an additive cannot be consistently extrapolated from feed to water using a fixed ratio of feed to water intake. However, concentrations in feed for ruminants can be quantified also in terms of a daily dose, which can then be equally administered via feed or water. The conversion of feed concentration to water concentration should be made on the basis of the daily ration (amount of the additive per head and day).

For fish, it is not possible to convert dietary levels to bioequivalent concentrations in water.

CONCLUSIONS

In the view of the FEEDAP Panel, there is no need to separately assess the safety and efficacy of an additive administered via water when an application for its use in feed is submitted or an authorisation exists, provided that the exposure of the animals is essentially the same.

The FEEDAP Panel considers water as water for drinking, and consequently does not view the application of an additive in a feed which is delivered in a liquid form as an application in water.

RECOMMENDATIONS

If an application concerns the use in water of an additive which the use in feed has been applied for or is authorised, then the applicant shall state either that (i) the daily exposure of the animal to the additive from feed or water is essentially the same or (ii) the daily exposure of the animal to the additive from feed or water is different. In the first case, no further assessment is necessary. In the second case, an assessment of the consequences resulting from the proposed change of exposure will be required.

The FEEDAP Panel has principle doubts on the rationale of the use of certain additives in water:

- Technological additives which exert their effects directly on feed;
- Additives for which a maximum content in feed is set by authorisation (i.e. at present, vitamins A and D, carotenoids, coccidiostats);
- Additives for fish.

The FEEDAP Panel recommends therefore that the use of such additives in water should not be authorised in those cases.