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Safety of erythrosine for ornamental fish

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety of erythrosine for ornamental fish. Erythrosine is a sensory additive belonging to the functional group colourants. In 2015, the FEEDAP Panel calculated the safe concentration in complete feed of ornamental fish to be 59 mg/kg complete feed. Considering that erythrosine contains 56.5% iodine, the safe level in feed of ornamental fish was recalculated taking into account the currently authorised maximum content of total iodine in complete feed and resulted to be 35 mg erythrosine/kg complete feed. The applicant submitted a new tolerance study in rainbow trout to demonstrate the safety of erythrosine for ornamental fish at doses higher than 59 mg/kg complete feed. The FEEDAP Panel noted that the study shows several limitations: (i) blood biochemistry was not measured, although required according to the guidance on the assessment of the safety of feed additives for the target species (ii) a low number of replicates (3 per treatment) which does not permit to obtain a reliable estimate and may not be sufficient to evidence differences between the groups (with no indication on the *a priori* power of the study design), and (iii) the use level group was not included in the study design. Owing to these three limitations, the FEEDAP Panel is not in the position to change its previous conclusions that the safe level of erythrosine in ornamental fish is 59 mg/kg complete feed. This safe level is reduced to 35 mg erythrosine/kg complete feed, when considering the iodine content of erythrosine and the currently authorised maximum content of total iodine in complete feed for fish.

Keywords: sensory additive, colourant, erythrosine, tolerance, ornamental fish

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003 establishes rules governing the Community authorisation of additives for animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Roha EUROPE S.L.U., is seeking a Community authorisation of Erythrosine (E 127) (Roha) as a feed additive to be used as colourants: i-substances that add or restore colour in feedingstuffs for ornamental fish, cats and dogs (Table 1).

Table 1: Description of the substances

Category of additive	Colourants: i-substances that add or restore colour in feedingstuffs
Description	Erythrosine (E 127) (Roha)
Target animal category	Ornamental fish, cats and dogs
Applicant	Roha EUROPE S.L.U.
Type of request	New opinion

On 8 September 2015, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ('Authority'), in its opinion on the safety of the product, concluded the following on the safety of Erythrosine (E 127) (Roha) in ornamental fish, cats and dogs: 'The highest safe concentration of erythrosine was calculated to be 16 ppm for dogs, 13 ppm for cats and 59 ppm for ornamental fish in complete feed'.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of Authority's opinion for the safety of ornamental fish. The new data have been received on 29 November 2018.

In view of the above, the Commission asks the Authority to deliver a new opinion on the safety of erythrosine (E 127) (Roha) as a feed additive for ornamental fish based on the additional data submitted by the applicant.

1.2. Additional information

Erythrosine (E 127) is a colourant feed additive. It is included in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 and it is authorised for cats, dogs, ornamental fish and reptiles.[1]

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered two opinions on erythrosine.

The first one was the re-evaluation of the safety and efficacy of erythrosine when used as a colourant additive in feed for cats and dogs, ornamental fish and reptiles (EFSA FEEDAP Panel, 2011). In this opinion, it was concluded that the maximum use level indicated by the applicant (500 mg/kg complete feed) was not safe for cats and ornamental fish; no conclusion could be drawn on the safety of erythrosine for reptiles.

The second opinion was an update of the first one and was adopted by the FEEDAP Panel in 2015 (EFSA FEEDAP Panel, 2015). The applicant provided, among other data, a feeding study in fish with 10 colourants, including erythrosine (fed at a nominal concentration of 1920 mg/kg feed). This study was not considered in the assessment because of a number of limitations. The maximum safe concentration in complete feed for ornamental fish was calculated from a no observed adverse effect level (NOAEL) observed in a 60-day rat study (30 mg erythrosine/kg body weight (bw) per day based on perturbation of thyroid function) and applying an uncertainty factor of 100. The maximum safe concentration in feed for ornamental fish resulted to be 59 mg erythrosine/kg complete feed. Since erythrosine contains 56.5% iodine, the contribution of iodine to the diet was considered. The maximum safe concentration of erythrosine established for ornamental fish (59 mg erythrosine/kg complete feed) results in 33 mg iodine per kg feed which is above the limit of 20 mg/kg, the currently authorised maximum content of

[1] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs, OJ L 270, 14.12.70, p.1 and List of the authorised additives in feedingstuffs published in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in feedingstuffs. OJ C 50, 25.2.2004, p. 1.

total iodine in complete feed for fish.[2] Consequently, the safe level in feed of ornamental fish was recalculated considering the iodine content of erythrosine and resulted to be 35 mg erythrosine/kg complete feed.

The applicant has now submitted additional data (a tolerance study in rainbow trout (*Oncorhynchus mykiss*)) on the safety of erythrosine for ornamental fish.

2. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information[3] following previous applications on the same product.[4]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of erythrosine for ornamental fish is in line with the principles laid down in Regulation (EC) No 429/2008[5] and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017).

3. Assessment

Erythrosine is a colourant feed additive. The applicant originally indicated 500 mg/kg feed as the highest supplementation level for all target animals, including ornamental fish (EFSA FEEDAP Panel, 2011). In 2015, the applicant modified the proposed former maximum content for ornamental fish to 3,000 mg erythrosine/kg (EFSA FEEDAP Panel, 2015).

In order to demonstrate the safety of erythrosine for ornamental fish at doses higher than 59 mg/kg complete feed, a tolerance study in rainbow trout (*O. mykiss*) was submitted. The study consisted of a control group, a group fed 1,923.9 mg erythrosine/kg feed (0.64 times the highest supplementation level of 3,000 mg erythrosine/kg), and a group fed 19,446.0 mg erythrosine/kg (6.48 times the highest supplementation level of 3,000 mg erythrosine/kg). Animals were fed the diets for 90 days and the parameters measured during the trial included mortality, behaviour, length and body weight, specific growth rate and feed to gain ratio. Samples were collected at the end of the study for haematological and histological measurements. No clinical chemistry was performed.

The FEEDAP Panel assessed the study and noted that it shows several limitations: (i) blood biochemistry was not measured, although required according to the guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017) (ii) a low number of replicates (3 per treatment) which does not permit to obtain a reliable estimate and may not be sufficient to evidence differences between the groups (with no indication on the *a priori* power of the study design), and (iii) the use level group was not included in the study design. Owing to these three limitations, the FEEDAP Panel did not consider further this study in the assessment.

Considering the above, the FEEDAP Panel is not in the position to change its previous conclusions that the safe level of erythrosine in ornamental fish is 59 mg/kg complete feed. Considering that erythrosine contains 56.5% iodine, the safe level in feed of ornamental fish was recalculated taking into account the currently authorised maximum content of total iodine in complete feed[2] and resulted to be 35 mg/kg complete feed.

4. Conclusions

The FEEDAP Panel, based on the new tolerance study submitted, is not in the position to change its previous conclusions that the safe level of erythrosine in ornamental fish is 59 mg/kg complete feed. This safe level corresponds to 35 mg erythrosine/kg complete feed when considering the iodine

[2] COMMISSION IMPLEMENTING REGULATION (EU) 2015/861 of 3 June 2015 concerning the authorisation of potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous as feed additives for all animal species. OJ L 137, 4.6.2015, p.1.

[3] Dossier reference: FAD-2018-0095.

[4] Dossier reference: FAD-2010-0382 and FAD-2012-0020.

[5] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

content of erythrosine and the currently authorised maximum content of total iodine in complete feed for fish.

Documentation provided to EFSA/Chronology

Date	Event
18/12/2018	Reception mandate and additional data from the European Commission submitted by Roha EUROPE S.L.U on Erythrosine: Fish Feeding Study with Rainbow Trout (*Oncorhynchus mykiss*)
3/4/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

bw	body weight
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
NOAEL	no observed adverse effect level