

SCIENTIFIC OPINION

Scientific Opinion on modification of the terms of authorisation of a red carotenoid-rich bacterium *Paracoccus carotinifaciens* (Panaferd-AX) as feed additive for salmon and trout¹

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on a modification to the terms of authorisation of a red carotenoid-rich bacterium *Paracoccus carotinifaciens* (Panaferd-AX) as feed additive for salmon and trout.

The red carotenoid-rich bacterium *Paracoccus carotinifaciens* is authorised as a sensory additive for use in salmon and trout with a maximum content of 100 mg, expressed as the sum of astaxanthin, adonirubin and canthaxanthin per kg complete feed. The current carotenoid composition of the product is specified as 3–5 g canthaxanthin, 10–15 g adonirubin and 20–23 g astaxanthin/kg. The applicant proposes to modify the ranges of canthaxanthin to 1–5 g, and that of adonirubin to 7–15 g/kg product, while maintaining the astaxanthin range.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concludes that adjusting the ranges for canthaxanthin and adonirubin to the values proposed by the applicant would not affect safety and efficacy of the product, considering that there are no changes in (i) the manufacturing of the product compared to the former application, and (ii) the conditions of use already authorised.

The applicant provided data of 70 batches to substantiate his proposal. Fourteen batches did not meet the specification for astaxanthin (below 20 g/kg product). The content of canthaxanthin and adonirubin of the remaining batches did not support the ranges as proposed by the applicant. However, reviewing the carotenoid composition, compliance with ranges of 2–5 g canthaxanthin/kg and 9–15 g adonirubin/kg product has been obtained.

The FEEDAP Panel noted that any extension of the range of the specified carotenoid contents would increase the uncertainties of the feed manufacturer when using the product.

¹ On request from the European Commission, Question No EFSA-Q-2009-00629, adopted on 9 December 2009.

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³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Colouring agents and Vitamins (subgroup on Panaferd-AX) for the preparation of this opinion.

KEY WORDS

sensory additive, Panaferd-AX, *Paracoccus carotinifaciens*, carotenoid, astaxanthin, canthaxanthin, adonirubin, salmonids

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BACKGROUND

Regulation (EC) No 1831/2003⁴ establishes rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a proposal from the company Nippon Oil Corporation⁵ for a modification of some of the terms of the current authorisation of the additive “2a(ii)167”, red carotenoid-rich bacterium *Paracoccus carotinifaciens* (Commission Regulation (EC) No 721/2008).⁶

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 13(3) (modification of an existing authorisation of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application.⁷ According to Article 8 of that Regulation, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. The particulars and documents in support of the application were considered valid by EFSA as of 6 October 2009.

The additive red carotenoid-rich bacterium *Paracoccus carotinifaciens* (Panaferd-AX) consists of sterilised dried cells of *Paracoccus carotinifaciens*. The product is authorised at Community level for salmon and trout until 15 August 2018.⁵

EFSA issued an opinion on the safety and efficacy of Panaferd-AX for salmon and trout (EFSA, 2007).

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animal(s), consumer, user and the environment and the efficacy of the product consisting of sterilised dried cells of the red carotenoid-rich bacterium *Paracoccus carotinifaciens* (NITE SD 00017) (Panaferd-AX) when used under the conditions described in Table 1.

⁴ OJ L 268, 18.10.2003, p.29

⁵ Nippon Oil Corporation. Nippon Oil (UK) Plc. 15, Eldon St., London EC2M 7LD, UK

⁶ OJ L 198, 26.7.2008, p.23

⁷ EFSA Dossier reference: FAD-2009-0018

Table 1: Description and conditions of use of the additive as proposed by the applicant

Additive	Red carotenoid-rich <i>Paracoccus carotinifaciens</i>
Registration number/EC No/No (if appropriate)	2a(ii)167
Category(-ies) of additive	Sensory additives.
Functional group(s) of additive	[A II]; COLOURANTS; SUBSTANCES WHICH WHEN FED TO ANIMALS ADD COLOURS TO FOOD OF ANIMAL ORIGIN

Description			
Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Preparation of dried killed cells of <i>Paracoccus carotinifaciens</i> (NITE SD 00017)	Astaxanthin (C ₄₀ H ₅₂ O ₄ , CAS: 472-61-7) Adonirubin (C ₄₀ H ₅₂ O ₃ , -3-Hydroxy-β,β-carotene-4,4'-dione, CAS: 511-23801) ⁸ Canthaxanthin (C ₄₀ H ₅₂ O ₂ , CAS: 514-78-3)	— 20–23 g/kg astaxanthin — 7–15 g/kg adonirubin — 1–5 g/kg canthaxanthin	Normal phase High Performance Liquid Chromatography (HPLC) coupled to UV/visible detection for determination of astaxanthin, adonirubin and canthaxanthin in feedingstuffs and fish tissue.

Trade name (if appropriate)	
Name of the holder of authorisation (if appropriate)	

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg/kg of complete feedingstuffs		
Salmon, trout	-	-	100	-

Other provisions and additional requirements for the labelling	
Specific conditions or restrictions for use (if appropriate)	<ol style="list-style-type: none"> The maximum content is expressed as the sum of astaxanthin, adonirubin and canthaxanthin. Use permitted from the age of 6 months onwards or weight of 50 g. The mixture of the additive with astaxanthin or canthaxanthin is allowed provided that the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin from other sources does not exceed 100 mg/kg in complete feedingstuff.
Specific conditions or restrictions for handling (if appropriate)	
Post-market monitoring (if appropriate)	
Specific conditions for use in complementary feedingstuffs (if appropriate)	

⁸ The FEEDAP Panel notes that the CAS number of Adonirubin is 4418-72-8

Maximum Residue Limit (MRL) (if appropriate)			
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
The sum of adonirubin and canthaxanthin/kg muscle (wet tissue)	Salmon / trout	Muscle	10 / 8

ASSESSMENT

1. Introduction

The product (Panaferd-AX) is a feed additive (sensory; colourant which, when fed to animals, add colours to food of animal origin) consisting of dried sterilised cells of a red carotenoid-rich bacterium (*Paracoccus carotinifaciens* NITE SD 00017). Its use in salmon and trout is authorised in the EU with a maximum content of 100 mg, expressed as the sum of astaxanthin, adonirubin and canthaxanthin, per kg complete feed (Commission Regulation (EC) No 721/2008)⁹.

The applicant proposed a modification of the terms of the authorisation, to widen the ranges for adonirubin (from 10–15 to 7–15 g/kg) and canthaxanthin (from 3–5 to 1–5 g/kg), while maintaining the astaxanthin specification (20–23 g/kg product).

The FEEDAP Panel assessed the safety and efficacy of Panaferd-AX in a previous opinion (EFSA, 2007) and considers that the proposed modification would not affect the previous assessment. Therefore, the current opinion focuses only on the characterisation of the product.

2. Characterisation of the product

2.1. Red carotenoids in the additive

The applicant provided data of 70 Panaferd-AX batches (45 from one plant and 25 from another plant, manufactured between 2003 and 2009) on the content of astaxanthin, adonirubin and canthaxanthin.¹⁰ The ranges were for astaxanthin 16.2 to 24.0 g/kg, for canthaxanthin 1.6 to 6.1 g/kg, and for adonirubin 7.6 to 16.6 g/kg product.

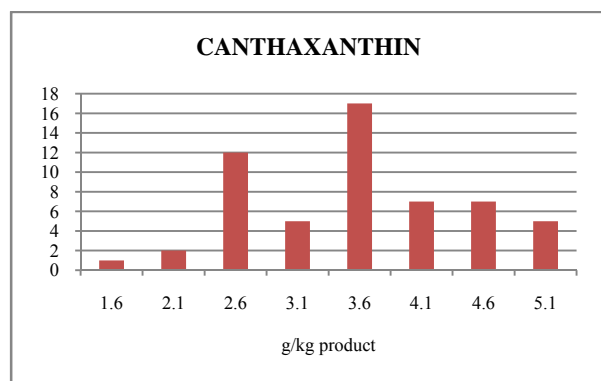


Figure 1. Frequency distribution (classes with 0.5 g/kg intervals) of the canthaxanthin content of 56 batches of Panaferd-AX

Among the 70 batches, 14 did not meet the specification for astaxanthin (20–23 g/kg) being below 20 g astaxanthin/kg product; therefore they will not be further considered. The remaining 56 batches showed mean values \pm SD for canthaxanthin of 3.3 ± 0.9 , for adonirubin of 11.2 ± 1.8 , and for astaxanthin of 21.8 ± 0.8 g/kg. The frequency distribution (classes with 0.5 g intervals) of the individual values is given in Figures 1 and 2 for canthaxanthin and adonirubin, respectively.

Figure 1 shows only one batch in the range of 1.2–1.6 g canthaxanthin/kg product. The frequency distribution does not support the proposal of the applicant to widen the specification to 1–5 g canthaxanthin/kg product, allowing only a modification from the existing range of 3–5 to 2–5 g/kg.

⁹ OJ L 198, 26.7.2008, p.23

¹⁰ Technical Dossier, Section II

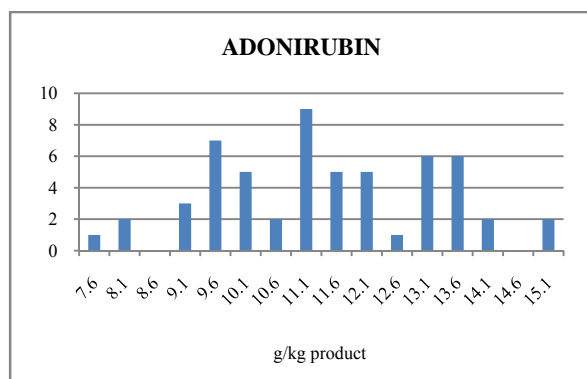


Figure 2. Frequency distribution (classes with 0.5 g/kg intervals) of the adonirubin content of 56 batches of Panaferd-AX

Figure 2 shows only one batch in the range of 7.2–7.6 g adonirubin/kg product. Although the data favours a widening of the specification, the frequency distribution does not support the proposal of the applicant to extend the specification to 7–15 g/kg. However, maintaining the existing minimum content of 10 g/kg would prevent about 20 % of the batches to be marketed. A modified range of 9–15 g adonirubin/kg product is proposed.

The authorised range for astaxanthin (20–23 g/kg) is confirmed by the frequency distribution of the astaxanthin content in Panaferd-AX for the 56 batches examined.

3. Safety and efficacy

Safety for target species, consumer, user and environment, as well as the efficacy of the product would not be affected by the proposed modification to the terms of authorisation, considering that there are no changes in (i) the manufacturing of the product compared to the former application, and (ii) the conditions of use as laid down in Commission Regulation (EC) No 721/2008.

CONCLUSIONS

A modification of the terms of authorisation of the red carotenoid-rich bacterium (*Paracoccus carotinifaciens*), consisting of an extension of the range of canthaxanthin and adonirubin contents (by lowering the lower bound), while maintaining that of astaxanthin, would not affect safety and efficacy of the product.

The data provided by the applicant does not support the proposed modifications. However, reviewing the carotenoid composition of 56 batches indicates compliance with ranges of 2–5 g canthaxanthin/kg and 9–15 g adonirubin/kg product.

REMARKS

Any extension of the range of the specified carotenoid content would increase the uncertainties of the feed manufacturer when using the product which could no longer be used on the basis of the characteristics given by the authorisation.

DOCUMENTATION PROVIDED TO EFSA

1. Panaferd-AX (sterilised cells of astaxanthin-rich *Paracoccus carotinifaciens*) dossier. June 2009. Submitted by Food Chemical Risk Analysis.
2. Comments from Member States received through the ScienceNet.

REFERENCES

- EFSA (European Food Safety Authority), 2007. Safety and efficacy of Panaferd-AX (red carotenoid-rich bacterium *Paracoccus carotinifaciens*) as feed additive for salmon and trout - Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed. *The EFSA Journal* (2007) 546, 27-30.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178650355146.htm