SCIENTIFIC OPINION

Scientific opinion on the safety and efficacy of CAROPHYLL® Red 10% (preparation of canthaxanthin) for all poultry for breeding purposes (chickens, turkeys and other poultry)\(^1\)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)\(^2, 3\)
European Food Safety Authority (EFSA), Parma, Italy

The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver an opinion on the safety and efficacy of CAROPHYLL® Red 10% (preparation of canthaxanthin) for all poultry for breeding purposes (chickens, turkeys and other poultry). Canthaxanthin is a naturally occurring red carotenoid (β-Carotene-4,4’-dione).

Canthaxanthin from CAROPHYLL® Red 10% was safe for breeder hens at the proposed dose of 6 mg/kg complete feed with a margin of safety of at least four. Safety of the canthaxanthin use level can be extrapolated to minor poultry breeder hens.

The maximum proposed canthaxanthin concentration in feed for breeder hens (6 mg/kg) does not exceed that already authorised for pigmenting eggs of the same animal category (8 mg/kg). Consequently, the intake of edible tissues and products from canthaxanthin treated poultry does not exceed the acceptable daily intake when respecting the established MRLs for poultry tissues. Eggs produced for breeding purposes are normally not consumed. Even given the unlikely case that all eggs for breeding would be consumed as table eggs, no concerns regarding consumer safety would arise from the use of canthaxanthin from CAROPHYLL® Red 10% in breeding poultry at the dose of 6 mg/kg complete feed.

The FEEDAP Panel considered the use of lignosulphonate as a carrier in CAROPHYLL® Red 10% to be safe for the consumer.

Canthaxanthin is not an irritant to skin and eyes and unlikely to be a skin sensitizer. CAROPHYLL® Red 10% was not tested for irritancy or sensitisation potential. In the absence of any information on lignosulphonate, the major constituent of the additive, it would be prudent to consider the additive as an irritant to skin and eyes and a

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\(^1\) On request from the European Commission, Question No EFSA-Q-2011-00083, adopted on 12 December 2012.
\(^2\) Panel members: Gabriele Aquilina, Alex Bach, Vasileios Bampidis, Maria De Lourdes Bastos, Gerhard Flachowsky, Josep Gasa-Gasó, Mikolaj Antoni Gralak, Christo Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Derek Renshaw, Guido Rychen, Maria Saarela, Kristen Sejrsen, Patrick Van Beelen, Robert John Wallace and Johannes Westendorf. Correspondence: FEEDAP@efsa.europa.
\(^3\) Acknowledgement: The Panel wishes to thank the members of the Working Group on Colouring agents, including Georges Bories, Jürgen Gropp, Anne-Katrine-Haldorsen and Annette Schuhmacher, for the preparatory work on this scientific opinion.

skin sensitiser. The exposure by inhalation of users, when handling CAROPHYLL® Red 10%, was expected to be minimal. Consequently, the risk of inhalation toxicity is low.

Considering the oxidative susceptibility of carotenoids, the use of CAROPHYLL® Red 10% at the proposed maximum concentration of 6 mg canthaxanthin/kg complete feed for breeder hens will not result in a substantial increase in the canthaxanthin concentration in the environment and consequently does not pose a risk to the environment.

Canthaxanthin from CAROPHYLL® Red 10% at a concentration of 6 mg/kg complete feed has the potential to stabilise the reproductive performance of breeder hens as measured by hatchability and related parameters after incubation of eggs, particularly in phases of reduced hatchability of eggs from breeder hens fed canthaxanthin-free diets. An extrapolation of this conclusion to other breeder poultry species was not possible owing to inconsistencies in the timing of the effects observed and the absence of a scientifically sound theory on the mode of action.