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Safety and efficacy of a feed additive consisting of Sunset Yellow FCF for cats and dogs, ornamental fish, grain-eating ornamental birds and small rodents (Sensient Colours Europe GmbH)

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Sunset Yellow FCF for cats, dogs, ornamental fish, grain-eating ornamental birds and small rodents when used as an additive that adds or restores colour in feedingstuffs. Sunset Yellow FCF is considered safe for the target species at the following concentrations in complete feed: 165 mg/kg for cats, 198 mg/kg for dogs, 733 mg/kg for ornamental fish, 24 mg/kg for grain-eating ornamental birds and 750 mg/kg for small rodents. In the absence of adequate information, the FEEDAP Panel cannot conclude neither on the eyes and skin irritation potential of Sunset yellow FCF, nor on its skin sensitisation potential. Exposure by inhalation is considered to be unlikely. The FEEDAP Panel cannot conclude on the efficacy of the additive.

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Keywords: Sunset Yellow FCF, colourant, pets, safety, efficacy

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC. In particular, Article 10(2) of that Regulation specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, within a maximum of seven years after the entry into force of this Regulation.

The European Commission received a request from Sensient Colors Europe GmbH,² for re-evaluation of the product Sunset Yellow FCF, when used as a feed additive for cats and dogs, ornamental fish, grain-eating ornamental birds and small rodents (category: sensory additives; functional group: (a) colourants: (i) substances that add or restore colour in feedingstuffs).

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 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 7 February 2020.

According to Article 8 of Regulation (EC) No 1831/2003, 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. EFSA shall deliver an opinion on the safety for the target animals and user and on the efficacy of Sunset Yellow FCF, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

Sunset Yellow FCF is authorised without a time limit under Council Directive 70/524/EEC³ as a feed additive that adds or restores colour in feedingstuffs for cats and dogs and ornamental fish without maximum levels. Under the same regulation, it is authorised without a time limit for all species or categories of animals, with the exception of cats and dogs, in animal feedingstuffs only in products processed from: (i) waste products of foodstuffs, (ii) other base substances, with the exception of cereals and manioc flour, denaturated by means of these agents or coloured during technical preparation to ensure the necessary identification during manufacture. Sunset Yellow FCF is also authorised for grain-eating ornamental birds and for small rodents without a time limit and with maximum levels of 150 mg/kg complete feedingstuffs under Regulation (EC) No 358/2005⁴.

Currently, Sunset Yellow FCF is authorised as a food additive in the European Union (EU) in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives⁵ and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012⁶.

Sunset Yellow FCF has been evaluated previously by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1982 and 2011 (JECFA, 1982, 2011) and the EU Scientific Committee for Food (SCF) in 1983 (EC, 1984) and in 2002 by the Nordic Working Group on Food Toxicology and Risk Assessment (NNT, 2002). In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted an opinion on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive (EFSA, 2009) and in 2014 an opinion on the reconsideration of the temporary acceptable daily intake (ADI) and refined exposure assessment for Sunset Yellow FCF (E 110) (EFSA ANS Panel, 2014).

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Sensient Colors Europe GmbH, Geesthachter Strasse 103, 21502, Geesthacht, Germany.

³ List of the authorised additives in feedingstuffs (1) published in application of Article 9 t (b) of Council Directive 70/524/EEC concerning additives in feedingstuffs. OJ C 50, 25.2.2004, p.1.

⁴ Commission Regulation (EC) No 358/2005 of 2 March 2005 concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs. OJ L 57, 3.3.2005, p. 3.

⁵ REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16

⁶ Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p.1.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁷ in support of the authorisation request for the use of Sunset Yellow FCF as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.⁸

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Sunset Yellow FCF is in line with the principles laid down in Regulation (EC) No 429/2008⁹ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012); Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a); Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a).

3. Assessment

Sunset Yellow FCF is a mono-azo colourant, intended to be used as a sensory additive, (functional group: colourants/substances that add or restore colour in feedingstuffs) in feed for cats, dogs, ornamental fish, grain-eating ornamental birds and small rodents.

3.1. Characterisation

The additive under assessment, Sunset Yellow FCF (E 124, Food Yellow No. 5, and FD&C Yellow No. 6) is identical to the active substance.

Sunset Yellow FCF is a sulfonated mono azo dye comprising primarily disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate (chemical formula $C_{16}H_{10}N_2Na_2O_7S_2$, CAS number 2783-94-0, molecular weight 452.37 g/mol) and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. Sunset Yellow FCF is described as the sodium salt. The calcium and the potassium salts are also permitted as food additives by Commission Regulation (EU) No 231/2012⁶. The structural formula of Sunset Yellow FCF is given in Figure 1. The solubility of the additive in water at 25°C is 190 g/L.

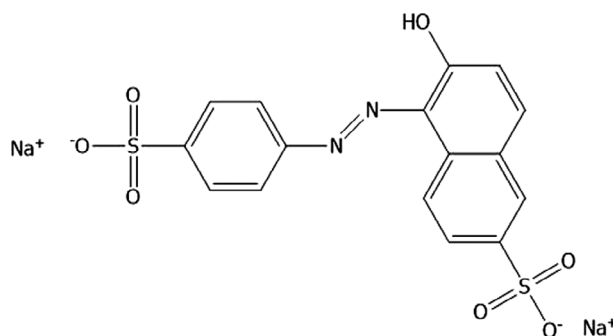


Figure 1: Structural formula of Sunset Yellow FCF

⁷ FEED dossier reference: FAD-2010-0366.

⁸ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0366>

⁹ 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.

The specifications for Sunset Yellow FCF when used as a feed additive are identical to those for Sunset Yellow FCF when used as a food additive and laid down in Commission Regulation (EU) No 231/2012¹⁰. The thresholds are set for total colouring matters calculated as the sodium salt ($\geq 85\%$), water insoluble matter ($\leq 0.2\%$), subsidiary colouring matter ($\leq 5\%$), 1-(phenylazo)-2-naphthalenol (Sudan I) (≤ 0.5 mg/kg), organic compounds other than colouring matters ($\leq 0.5\%$), unsulfonated primary aromatic amines (calculated as aniline) ($\leq 0.01\%$), ether extractable matter ($\leq 0.2\%$ under neutral conditions), arsenic (≤ 3 mg/kg), lead (≤ 2 mg/kg) and mercury and cadmium (≤ 1 mg/kg) each).

The results from five production batches were provided.¹¹ The certificate of analysis reported data on total colouring matters calculated as the sodium salt (90.0–91.0%), water insoluble matter ($< 0.07\%$ in all batches), subsidiary colouring matter ($< 5\%$ in all batches), 1-(phenylazo)-2-naphthalenol (Sudan I) (< 0.2 mg/kg in all batches),¹² organic compounds other than colouring matters ($< 0.17\%$ in all batches),¹³ unsulfonated primary aromatic amines¹⁴ (26–29 ppb), arsenic¹⁵ (9 ppm in all batches), lead¹⁵ (8 ppm in all batches) and mercury¹⁵ (7 ppm in all batches). Data on ether extractable matter and cadmium were not provided; instead, the applicant provided a statement of compliance with the specifications.¹⁶ The FEEDAP Panel noted that arsenic and lead content were above the specifications.

The additive is an orange-red powder or granules. It is produced in a number of different granulation sizes, depending on the intended use. Fine powders are used when the additive is added directly to feedingstuffs while a granular product is used for liquid application.

The dusting potential of six batches of the additive (only fine powder)¹⁷ was determined using the Stauber-Heubach method

The particle size distribution of the dust of the same six batches was analysed by laser diffraction

The FEEDAP Panel notes that during dust generation, a fraction of small particles is present in the dust. However, as the solubility of the additive in water is 190 g/L, there is no need to further characterise the fraction of small particles potentially present in the additive in line with EFSA Scientific Committee guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021).

3.1.1. Manufacturing process

Sunset Yellow FCF is manufactured by diazotising 4-aminobenzenesulphonic acid using hydrochloric acid and sodium nitrite, or sulfuric acid and sodium nitrite. The diazo compound is then coupled with 6-hydroxy-2-naphthalene-sulfonic acid. Sunset Yellow FCF is isolated as the sodium salt and dried.¹⁰

3.1.2. Stability and homogeneity

The applicant reported a shelf-life of 4–6 years for Sunset Yellow FCF stored in a dry, cool and ventilated place based on its own experience from the use of the product in food, cosmetics and other applications. However, no data supporting this claim was submitted.

Sunset Yellow FCF will generally be unstable in the presence of oxidising or reducing agents (e.g. sugars and acids).¹⁹

No homogeneity data are required for colourings which add or restore colour to feed.

¹⁰ COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, p. 1, 22.3.2012.

¹¹ Technical dossier/Section II/Annex II-1 and Supplementary Information November 2020.

¹² LOD=0.4 mg/kg

¹³ Sum of six compounds in line with Commission Regulation (EU) No 231/2012; LOD of the method not provided.

¹⁴ Aniline (LOD=3 ng/g, LOQ=5 ng/g), benzidine (LOD=0.1 ng/g, LOQ=0.25 ng/g), 4-aminobiphenyl (LOD=0.3 ng/g, LOQ=1 ng/g), 4-aminoazobenzene (LOD=0.1 ng/g, LOQ=0.25 ng/g), azobenzene (LOD and LOQ not provided) and 1,3-diphenyltriazene (LOD and LOQ not provided) were analysed.

¹⁵ LOD=5 mg/kg

¹⁶ Technical dossier/Section II/Sect_II_Identity

¹⁷ Analytical data on the dusting potential of the granular product were not obtained since the granular product has a larger particle size and further processed to produce the fine powder.

¹⁸ Technical dossier/Supplementary information November 2020/Dust Particle.

¹⁹ Technical dossier/Section II.

3.1.3. Conditions of use

Sunset Yellow FCF is intended to be used in complementary and complete feed for dogs, cats, ornamental fish, grain-eating ornamental birds and small rodents. No maximum content is proposed for dogs, cats and ornamental fish. For grain-eating ornamental birds and small rodents, the applicant proposed a maximum content of 150 mg/kg complete feedingstuffs.

The applicant provided data from pet food manufacturers indicating that typical use levels in feed for these target species is approximately 100 mg Sunset Yellow FCF/kg feed when used alone and 75 mg Sunset yellow FCF/kg feed when used in combination with other colouring substances.²⁰

The additive may be added to feed directly or via an intermediary step by dissolving it in water. The additive is not intended to be added to water for drinking.

3.2. Safety

3.2.1. Toxicological studies

Sunset Yellow FCF was evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1982 and 2011 (JECFA, 1982, 2011), by the EU Scientific Committee for Food (SCF) in 1984 (EC, 1984) and in 2002 by the Nordic Working Group on Food Toxicology and Risk Assessment (NNT, 2002). In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted an opinion on the re-evaluation of Sunset Yellow FCF as a food additive (EFSA, 2009) and in 2014 an opinion on the reconsideration of the temporary ADI and refined exposure assessment for Sunset Yellow FCF (E 110) (EFSA ANS Panel, 2014).

The applicant made reference to the evaluations mentioned above (including the most recent evaluation by the ANS Panel in 2014) and conducted two literature searches, the first one up to 2010 and the second one 2010–2020.

The first one was aimed at identifying other potential information related to the safety of the additive up to 2010 (when the dossier was submitted),²¹ the second one (covering the period 2010 up to November 2020) addressed mainly the different aspects of toxicology (including genotoxicity).²⁰ The FEEDAP Panel noted that for the second literature search, the search strategy was described in the dossier; however, relevant details (e.g. keywords and databases consulted) were not given. From the second search, a total of 88 articles were retrieved and evaluated, and from these 12 papers were selected for the review of the full text. The FEEDAP Panel assessed the outcome of the literature review, and the relevant papers are described below.

3.2.1.1. Genotoxicity

The genotoxicity of Sunset Yellow FCF was first assessed in 2009 by the EFSA ANS Panel (2009) and later in the ANS Panel statement on Allura Red and other sulfonated mono azo dyes, authorised as food and feed additives, including Sunset Yellow FCF (EFSA ANS Panel, 2013). In this latter statement, it was concluded that further investigation on the *in vivo* genotoxicity of the sulfonated mono azo dyes, including Sunset Yellow FCF, using an internationally validated experimental protocol for Comet assay is recommended.

For the current evaluation, the applicant submitted the same studies that were evaluated in the ANS Panel opinion in 2009²² and an updated literature search.²⁰ None of the four papers found in the literature was relevant for the assessment due to the unclear nature of the test item used. Therefore, in line with the recommendation in the statement on Allura Red and other sulfonated mono azo dyes, authorised as food and feed additives, including Sunset Yellow FCF (EFSA ANS Panel, 2013), the applicant was requested to submit an *in vivo* Comet assay performed with Sunset Yellow FCF. As a response to this request, the applicant proposed to infer the *in vivo* Comet assay outcome of Sunset Yellow FCF by reading across the negative results of the three analogue sulfonated mono azo dyes (Allura Red AC, Tartrazine and Ponceau 4R) evaluated in other EFSA FEEDAP Panel opinions

²⁰ Technical dossier/Supplementary information November 2020.

²¹ Databases searched: Medline, Biosis Previews, Agricola, Allied & Complementary Medicine, Mantis, Foodline: Science, CAB Abstracts, Federal Register, Elsevier Biobase, Foodline: Market, Embase, Diogenes, FDA News Mar., Adis Clinical Trials Insight, and BCC Market Research. The databases were searched using keywords/search terms related to Sunset Yellow FCF, including synonyms and CAS number.

²² Technical dossier/Section III/ Annex III_9, Annex III_14, Annex III_20, Annex III_25, Annex III_42, Annex III_55, Annex III_61, Annex III_73, Annex III_74.

(EFSA FEEDAP Panel, 2015, 2016, 2018b).²³ Based on the negative results of these *in vivo* Comet assays, the FEEDAP Panel concluded that Allura Red AC, Tartrazine and Ponceau 4R have no *in vivo* genotoxic potential. The original reports of the *in vivo* Comet assays performed with Allura Red AC, Tartrazine and Ponceau 4R were provided in the dossier.²⁴

The FEEDAP Panel noted that whereas the general toxicological properties of sulfonated mono azo dyes provide the mechanistic background, the read across prediction of *in vivo* Comet assay data for Sunset Yellow FCF uses Allura Red AC as source chemical, because of its closest structural similarity. The similarity is also reflected by the high Tanimoto coefficient (0.9), reported by the applicant.

By metabolic cleavage, Sunset Yellow FCF gives two sulfonated aromatic amines: 1-amino-2-naphthol-6-sulfonic acid, and 4-aminobenzene-1-sulfonic acid. 1-Amino-2-naphthol-6-sulfonic acid is identical for both Allura Red AC and Sunset Yellow FCF. The only difference between these substances is the presence of a methyl group and a methoxy group on the benzene sulfonic acid moiety in Allura Red AC. These substituents are not known to have special toxifying or detoxifying effects, thus, based on structural similarity, the toxicological profile of Sunset Yellow FCF and Allura Red AC is expected to be the same.

Based on the above, the FEEDAP Panel considers that the outcome of the *in vivo* Comet assay of Allura Red AC is applicable to Sunset yellow FCF. Therefore, the FEEDAP Panel concludes that Sunset Yellow FCF has no *in vivo* genotoxic potential.

3.2.1.2. General toxicology

Toxicity studies relevant for the safety evaluation of Sunset Yellow FCF have been evaluated by the JECFA, SCF and EFSA (JECFA, 1982, 2011; EC, 1984; EFSA, 2009; EFSA ANS Panel, 2014).

For the current assessment, the applicant submitted the original reports of the relevant studies already assessed in the evaluations mentioned above. Although some of these studies were performed according to standards appropriate to that time, some of them were not in accordance either with good laboratory practice (GLP) or with previous and current OECD guidelines. However, the FEEDAP Panel considered the number and quality of the studies sufficient for the assessment.

The FEEDAP Panel reviewed the evaluation made previously by other assessment bodies and checked the relevant studies submitted also for the current application. An overview of the main results and conclusions is given below.

Based on the results of acute toxicity studies in mice and rats,²⁵ Sunset Yellow FCF was shown to be of low toxicity. Short-term and subchronic toxicity of Sunset Yellow FCF was evaluated in studies performed in rats,²⁶ dogs²⁷ and pigs²⁸ (JECFA, 1982, 2011; EC, 1984; EFSA, 2009). The studies assessed in these evaluations indicated that the major adverse effects observed after oral administration of Sunset Yellow FCF were enlargement of the caecum and increased testes weight (not accompanied by histopathological changes) at doses higher than 500 mg/kg body weight (bw) per day in rats in a 90-day study.²⁹ In the other studies,³⁰ described in the ANS opinion in 2009 (EFSA, 2009), significant effects were reported on the testes and lipid profiles of rats receiving doses of 250 and 1,000 mg Sunset Yellow FCF/kg bw per day for 90 days. The ANS Panel noted that the Sunset Yellow FCF material used in these studies was obtained at a local market in India, and that the specifications and purity of this preparation were not defined. The effects on the testes seen in the studies mentioned above were overruled based on the results of a 28-day oral toxicity study in rats, specifically designed to study the effects on the testes (EFSA ANS Panel, 2014). This study was also made available for the current application.²⁰

The ANS Panel (2009) summarised and evaluated 11 chronic toxicity and carcinogenicity studies with Sunset Yellow FCF in mice,³¹ rats³² and dogs,²⁷ already included in the JECFA evaluation of 1982 and concluded that there was no evidence for carcinogenicity of this substance. In its opinion on the

²³ Technical dossier/Supplementary information August 2021/Annex 1.

²⁴ Technical dossier/Supplementary information January 2022.

²⁵ Technical dossier/Supplementary information November 2020/Annex III_21, Annex_II_41, Annex_III_61.

²⁶ Technical dossier/Supplementary information November 2020/Annex III_21, Annex_III_29, Annex_III_43, Annex_III_45, Annex_III_46, Annex_III_48.

²⁷ Technical dossier/Supplementary information November 2020/Annex III_71.

²⁸ Technical dossier/Supplementary information November 2020/Annex III_22.

²⁹ Technical dossier/Supplementary information November 2020/Annex III_21.

³⁰ Technical dossier/Supplementary information November 2020/Annex III_45, Annex_III_46.

³¹ Technical dossier/Supplementary information November 2020/Annex III_7, Annex_III_23, Annex_III_71, Annex_III_51

³² Technical dossier/Supplementary information November 2020/Annex III_44, Annex_III_76, Annex_III_51, Annex_III_36, Annex_III_71, Annex_II_38.

reconsideration of the temporary ADI and refined exposure assessment for Sunset Yellow FCF (EFSA ANS Panel, 2014), the ANS Panel also evaluated one unpublished long-term feeding study in mice and two studies in rats provided by the United States Food and Drug Administration (FDA). These studies were also evaluated by JECFA in 2011 and were also made available for the current evaluation.²⁰ Based on the results of these studies, it was concluded that Sunset Yellow FCF, when added to the diet of laboratory animals, does not induce carcinogenic activity in the kidneys or any other site.

The reproduction toxicity studies in mice,³³ rats³⁴ and rabbits³⁵ of Sunset Yellow FCF evaluated by the ANS Panel in 2009 (EFSA, 2009) did not show adverse effects of Sunset Yellow FCF on reproductive parameters and physical and behaviour development of the offspring in the postnatal life. The lowest NOAEL of 0.6% Sunset Yellow FCF in the diet (corresponding to about 1,000 mg/kg bw per day) could be defined as the highest dose tested in a mice study.³⁶ In its opinion on the reconsideration of the temporary ADI and refined exposure assessment for Sunset Yellow FCF (EFSA ANS Panel, 2014), the ANS Panel also evaluated two long-term feeding studies in rats with *in utero* exposure to Sunset Yellow FCF. These studies were also evaluated by JECFA in 2011 and were also made available for the current evaluation.²⁰ The FEEDAP Panel assessed these studies and agreed with the JECFA and ANS Panel evaluations, concluding that the lowest NOAEL is 0.75% (equivalent to 375 mg/kg bw per day), based on the occurrence of the adverse effect on pup body weight gain observed in rats during the last part of lactation in the group fed 1.5% Sunset Yellow FCF in the diet.

Overall, the FEEDAP Panel agrees with the conclusions reached by the above-mentioned assessment bodies.

Eight papers on repeated dose toxicity studies were selected from the literature search (Hashem et al., 2011; Kushawaha and Bharti, 2013; Al Dahhan et al., 2014; Khiralla et al., 2015; Mahfouz and Moussa, 2015; Elhalem et al., 2016; Ismail, 2016; Khayyat et al., 2018). The FEEDAP Panel evaluated these studies and noted that some of them (Al Dahhan et al., 2014; Mahfouz and Moussa, 2015; Elhalem et al., 2016; Ismail 2016; Khayyat et al., 2018) displayed changes in kidneys, liver and testes, previously observed in other evaluations. However, due to the several shortcomings identified (e.g. lack of multiple dose groups, purity of the test item not given, inconsistencies between the studies in terms of reported effects at the doses evaluated, route of administration by gavage in seven out of the eight studies), the FEEDAP Panel agreed that the studies cannot be used for the current assessment.

3.2.1.3. Conclusions on toxicity

The FEEDAP Panel concluded that Sunset Yellow FCF has no *in vivo* genotoxic potential. Toxicological studies in laboratory animals showed no adverse effects that need to be taken into consideration when assessing target species safety. Sunset Yellow FCF was not carcinogenic and did not cause reproduction/developmental toxicity. The lowest NOAEL was 375 mg Sunset Yellow FCF/kg bw per day based on the long-term feeding study in rats.³⁷

3.2.2. Safety for the target species

To support the safety for dogs, grain-eating ornamental birds and small rodents, the applicant made reference to the results of the studies already mentioned in Section 3.2.1.2 or retrieved by a literature search.

Two studies performed in dogs were briefly reported by the applicant. However, as the study reports were not submitted, the FEEDAP Panel is not in a position to evaluate these studies.

The applicant submitted a study performed in canary birds (10 per group)³⁸ given ad libitum a diet containing Sunset Yellow FCF (purity \geq 85%) at 0 or 1,500 mg/kg diet (tenfold the authorised maximum content) for 14 days. No signs of intolerance were observed. However, the short study period prevents a full assessment of the results for target animal safety.

A number of subchronic and chronic feeding studies with Sunset Yellow FCF in mice and rats have been previously described and assessed (EFSA ANS Panel, 2009, 2014; JECFA, 2011) and mentioned in Section 3.2.1.2. The identified NOAEL from these studies was 7,500 mg Sunset Yellow FCF/kg feed

³³ Technical dossier/ Supplementary information November 2020/Annex_III_68.

³⁴ Technical dossier/ Supplementary information November 2020/Annex_III_32, Annex III_54.

³⁵ Technical dossier/ Supplementary information November 2020/Annex_III_33

³⁶ Technical dossier/ Supplementary information November 2020/Annex III_68.

³⁷ An ADI for Sunset Yellow FCF of 4 mg/kg bw was established in EFSA ANS Panel opinion in 2014 (EFSA ANS Panel, 2014) applying an uncertainty factor to the lowest NOAEL of 375 mg/kg bw per day from the long-term feeding study in rats.

³⁸ Technical dossier/Section III/Annex 26.

(corresponding to 375 mg/kg bw per day). Considering a level of 7,500 mg/kg feed and an uncertainty factor (UF) of 10 for intra-species variability, the FEEDAP Panel concludes that 750 mg Sunset Yellow FCF/kg complete feed is considered safe for small rodents.

Since no specific tolerance studies on cats, dogs and ornamental fish were available, and considering the limitations of the studies in canary birds, the safe levels in feed for these species were calculated following the procedure described in the Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b). The NOAEL used in the calculation was 375 mg/kg bw per day and an UF of 100 was applied (Table 1).

Table 1: Calculated maximum safe dietary levels of Sunset Yellow FCF in complete feeds for cats, dogs and ornamental fish and birds

Species	Body weight (kg)	Feed intake (g dry matter/day)	Maximum safe dietary level (mg/kg complete feed) ⁽¹⁾
Cat	3	60	165
Dog	15	250	198
Ornamental fish	0.012	0.054	733
Grain-eating ornamental birds	0.025	3.4	24

(1): Complete feed containing 88% DM.

3.2.2.1. Conclusions on safety for the target species

Sunset Yellow FCF is considered safe for the target species at the following concentrations in complete feed: 165 mg/kg for cats, 198 mg/kg for dogs, 733 mg/kg for ornamental fish, 24 mg/kg for grain-eating ornamental birds and 750 mg/kg for small rodents.

No data were provided that would allow the FEEDAP Panel to assess the safe level of Sunset yellow FCF when used in combination with other colouring substances.

3.2.3. Safety for the user

No data on inhalation toxicity were provided. The powder form of Sunset Yellow FCF has a dusting potential in the average of 4.1 g/m³ which makes exposure of users by inhalation likely.

No studies were provided on the irritancy of Sunset Yellow FCF to skin or eyes.

A number of papers/studies were submitted in the dossier to address the skin sensitisation potential of Sunset Yellow FCF which were considered by the FEEDAP Panel not relevant for the current assessment due to some limitations (e.g. no information on the purity of the test item used was given, the studies were not aimed at studying the skin sensitisation potential of Sunset Yellow FCF).

In the absence of adequate information, the FEEDAP Panel cannot conclude on the eyes and skin irritation potential of Sunset Yellow FCF, or on its skin sensitisation potential. Exposure by inhalation is considered to be likely.

3.3. Efficacy

Sunset Yellow FCF is intended to be used to colour the food for small non-food-producing mammals and grain-eating ornamental birds. Where the function requested for feed is the same as that used in food, no further demonstration of efficacy might be necessary (Regulation (EC) No 429/2008).¹⁸ However, considering the wide variety of feedingstuffs used in complete and complementary feed for the target species object of the application, and the uncertainty on the concentration of Sunset Yellow FCF needed to result in a visible effect, an effect demonstration is required (EFSA FEEDAP Panel, 2018a,b).

The applicant provided pictures of two feed samples (one not containing Sunset Yellow FCF, one containing Sunset Yellow FCF at 100 mg/kg feed and another one in which Sunset Yellow FCF at 75 mg/kg feed is blended with other colourants – no indication is given on the type of animal feed used) which provided visual demonstration of the efficacy of Sunset Yellow FCF to colour feed.²⁰

The FEEDAP Panel noted that the change in colour of feed was not measured using appropriate methodologies and that the use of Sunset Yellow FCF in combination with other colouring would not allow to establish the contribution of the additive in colouring the feed; two more studies would be needed to cover a representative range of feeds to which the additive will be applied in line with the requirements of the FEEDAP Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a,b).

Therefore, in the absence of adequate evidence, the FEEDAP Panel cannot conclude on the efficacy of Sunset Yellow FCF as a colourant when used in feed for cats, dogs, ornamental fish, grain-eating ornamental birds and small rodents.

4. Conclusions

Sunset Yellow FCF is considered safe for the target species at the following concentrations in complete feed: 165 mg/kg for cats, 198 mg/kg for dogs, 733 mg/kg for ornamental fish, 24 mg/kg for grain-eating ornamental birds and 750 mg/kg for small rodents.

In the absence of adequate information, the FEEDAP Panel cannot conclude on the eyes and skin irritation potential of Sunset yellow FCF, and on its skin sensitisation potential. Exposure by inhalation is considered to be likely.

The FEEDAP Panel cannot conclude on the efficacy of the additive.

5. Documentation provided to EFSA/Chronology

Date	Event
08/11/2010	Dossier received by EFSA. Sunset Yellow FCF for cats, dogs, grain-eating ornamental birds, ornamental fish and small rodents. Submitted by Sensient Colours Europe GmbH
17/12/2019	Reception mandate from the European Commission
07/02/2020	Application validated by EFSA – Start of the scientific assessment
28/04/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation/toxicological studies/safety for the user/efficacy</i>
27/11/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
07/05/2020	Comments received from Member States
20/04/2020	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
25/02/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: safety</i>
20/08/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
08/12/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: safety</i>
06/01/2022	Reception of supplementary information from the applicant - Scientific assessment re-started
24/03/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ADI	acceptable daily intake
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
CAS	Chemical Abstracts Service
DM	dry matter
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
GLP	good laboratory practice
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
NOAEL	no observed adverse effect level
NNT	Nordic Working Group on Food Toxicology and Risk Assessment
SCF	Scientific Committee on Food
UF	uncertainty factor
WHO	World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of the Analysis for Sunset Yellow

In the current application, an authorisation is sought under Article 10(2) for Sunset Yellow FCF under the category/functional group 2(a) 'sensory additives'/^colourants', according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the feed additive for cats and dogs, ornamental fish, grain-eating ornamental birds and small rodents.

The feed additive is a synthetic orange–red powder or granules soluble in water, consisting of a minimum of 85% (w/w) of 'total colouring matters content' calculated as sodium salt of 6-hydroxy-5-[(sulfophenyl)azo]-2-naphthalene sulfonate (Sunset Yellow FCF). The applicant states that the purity criteria for Sunset Yellow FCF as a food additive set in the Commission Directive 2008/128/EC (superseded by the Commission Regulation (EU) 2012/231) are applicable also for the current feed additive.

Sunset Yellow FCF is intended to be incorporated directly in feedingstuffs or as a solution in water. The applicant proposed a maximum content of 150 mg/kg complete feedingstuffs only for grain-eating ornamental birds and small rodents.

For the determination of the 'total colouring matters content' in the feed additive, the Applicant submitted the internationally recognised FAO JECFA monographs for food additives (recommended by Commission Regulation (EU) 2012/231), where the determination of the total colouring matters content of Sunset Yellow FCF is based on (i) spectrophotometry and (ii) titration with titanous chloride.

The EURL recommends for official control the above-mentioned methods recommended by Commission Regulation (EU) 2012/231 and described in the FAO JECFA monographs for the determination of Sunset Yellow FCF in the feed additive.

For the determination of Sunset Yellow FCF in feedingstuffs, the Applicant submitted a single-laboratory validated and further verified method based on high-performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS).

The following performance characteristics were obtained in the frame of the validation and verification studies for the determination of Sunset Yellow FCF in feedingstuffs with the mass fractions ranging from 1 to 100 mg/kg: a relative standard deviation for repeatability (RSDr) ranging from 2.0% to 7.6%, a relative standard deviation for intermediate precision (RSDip) ranging from 2.8% to 16.4%, a recovery rate (RRec) ranging from 83 to 101% and a limit of quantification (LOQ) of 1 mg for Sunset Yellow FCF /kg feedingstuffs.

In addition, samples of a few commercial pet feed products (kibbles) have been analysed using the above-mentioned method and acceptable precision was demonstrated. However, a significantly lower mass fraction of Sunset Yellow FCF compared to the expected value was measured in one of the samples.

The applicant has attributed the lower mass fraction observed in the sample to a lack of homogeneity of the samples and/or the adverse impact of specific production conditions of the kibbles. It is therefore recommended that additional measures are taken for checking the documentation related to the specific characteristics of the production process of the complete feedingstuffs in case when significantly lower mass fractions of the colourant in comparison to the ones indicated on the labels are obtained during the official control of pet feed samples.

The applicant did not provide to the EURL a method for the determination of the above mentioned colourant in premixtures, as the feed additives (in the form of powder or as the solutions in water) are supposed to be added directly into feedingstuffs.

Based on the performance characteristics available, the EURL recommends for official control a single laboratory validated and verified LC-MS/MS method for the determination of Sunset Yellow FCF in feedingstuffs.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.