SCIENTIFIC OPINION

Scientific opinion on the safety and efficacy of Brilliant Blue FCF (E133) as a feed additive for cats and dogs[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Brilliant Blue FCF, an authorised food colourant, is intended to be used as a feed additive for dogs and cats without a maximum content. The applicant reported a typical inclusion level in feed for the target species. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) considered Brilliant Blue FCF as safe for cats and dogs up to a maximum concentration of 278 and 334 mg/kg complete feed, respectively. Considering the large discrepancy between reported use and safe dietary levels of Brilliant Blue FCF, the FEEDAP Panel recommended the introduction of a maximum content of 300 mg/kg complete feed for cats and dogs. Brilliant Blue FCF should be regarded as an inhalation hazard. In the absence of data on skin and eye irritancy, it would be prudent to regard Brilliant Blue FCF as being potentially irritating to skin and/or eyes. Skin exposure of workers to Brilliant Blue FCF is not expected to cause skin sensitisation or local neoplasias. The FEEDAP Panel also considered Brilliant Blue FCF as effective in colouring feed for the target species.

KEY WORDS

Brilliant Blue FCF, sensory additive, colourant, cats, dogs, safety

[1] On request from the European Commission, Question No EFSA-Q-2012-00333, adopted on 19 June 2013.

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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 Brilliant Blue FCF (E133) in feed for cats and dogs.

Brilliant Blue FCF, an authorised food colourant, is intended to be used as a feed additive for dogs and cats without a maximum content. The applicant reported a typical inclusion level in feed for the target species.

The FEEDAP Panel considered Brilliant Blue FCF as safe for cats and dogs up to a maximum concentration of 278 and 334 mg/kg complete feed, respectively.

Brilliant Blue FCF should be regarded as an inhalation hazard. In the absence of data on skin and eye irritancy, it would be prudent to regard Brilliant Blue FCF as being potentially irritating to skin and/or eyes. Skin exposure of workers to Brilliant Blue FCF is not expected to cause skin sensitisation or local neoplasias.

The Panel also concluded that Brilliant Blue FCF is effective in colouring feed.

Considering the large discrepancy between reported use and safe dietary levels of Brilliant Blue FCF, the FEEDAP Panel recommended a maximum content of 300 mg/kg complete feed for cats and dogs.

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BACKGROUND

Regulation (EC) No 1831/2003[4] 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 time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company Sensient Colors UK Ltd (on behalf of Feed Additives Synthetic Colours Group)[5] for re-evaluation of the product Brilliant Blue FCF (E 133), when used as a feed additive for cats and dogs (category: 2. sensory additive; functional group: (a) colourants/substances that add or restore colour in feedingstuff) under the conditions mentioned in Table 1.

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 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive).[6] 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 13 September 2012.

Brilliant Blue FCF (E133) is included in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. It is authorised without a time limit in application of Article 9t (b) of Council Directive 70/524/EEC[8] concerning additives in feedingstuffs (2004/C 50/01) for its use in cats and dogs as colourant additive (colouring agents authorised for colouring foodstuffs by Community rules). The additive is also authorised for all species or categories of animals with the exception of cats and dogs for 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.

Brilliant Blue FCF is an approved food colourant in the EU and it is listed in Annex I of Directive 94/36/EC9 of 30 June 1994. According to the same Directive Brilliant Blue FCF is an allowed synthetic food colouring substance in the EU with a maximal allowed use level of 20-500 mg/kg food for various foodstuffs. Brilliant Blue FCF is also allowed in beverages at levels up to 200 mg/L.

The specific purity criteria concerning the use of Brilliant Blue FCF in foodstuffs are included in Commission Regulation (EU) No 231/2012.[10]

[4] 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.
[5] Sensient Colors UK Ltd. on behalf of Feed Additives Synthetic Colours Group, Oldmedow Road, PE30 4LA, Kings Lynn, UK.
[6] Although in the forwarded sheet for this application the European Commission included a new use (Article 4) for all animal species, the original request of the applicant was restricted to cats and dogs. Therefore the current assessment is restricted to the use of Brilliant Blue FCF for cats and dogs.
[7] EFSA Dossier reference: FAD-2010-0351.
[8] Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs. OJ L 270, 14.12.1970, p. 1.
[9] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.09.1994, p. 13.
[10] 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.

Brilliant Blue FCF has been evaluated previously by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1970 (JECFA, 1970) and the Scientific Committee for Food (SCF) in 1975 and 1984 (EC, 1975; EC, 1984). In 2010 the European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted an opinion on the re-evaluation of Brilliant Blue FCF (E 133) as food additive (EFSA, 2010).

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 animals, user, environment and the efficacy of the product Brilliant Blue FCF, when used under the conditions described in Table 1.

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

Additive	Brilliant Blue FCF
Registration number/EC No/No (if appropriate)	E 133
Category(-ies) of additive	2 (Sensory)
Functional group(s) of additive	A (Colourants)

Description			
Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Disodium α-(4-(N-ethyl-3-sulfonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulfonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulfonate; Reddish-blue powder or granules	$C_{37}H_{34}N_2Na_2O_9S_3$	Colour (Blue); Spectrometry (630 nm); Assay (Minimum 85% total colouring matters calculated as sodium salt)	Annex II Methods of Analysis Relating to the Criteria of Purity of Food Additives Commission Directive 81/712/EEC

Trade name (if appropriate)	Brilliant Blue FCF
Name of the holder of authorisation (if appropriate)	Not relevant

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg/kg of complete feedingstuffs		
Cats and dogs	Not relevant	Not relevant	Not relevant	Not relevant

Other provisions and additional requirements for the labelling	
Specific conditions or restrictions for use (if appropriate)	Not relevant
Specific conditions or restrictions for handling (if appropriate)	Not relevant
Post-market monitoring (if appropriate)	Not relevant
Specific conditions for use in complementary feedingstuffs (if appropriate)	Not relevant

Maximum Residue Limit (MRL) (if appropriate)			
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
Not relevant	Not relevant	Not relevant	Not relevant

ASSESSMENT

1. Introduction

The current application is for re-evaluation of the use of Brilliant Blue FCF (E133) as a feed additive for cats and dogs.

Brilliant Blue FCF is included in the European Union (EU) Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. It is authorised without time limit in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in feedingstuffs[11] for use in cats and dogs as a colourant additive (colouring agents authorised for colouring foodstuffs by Community rules). The additive is also authorised for all species or categories of animals with the exception of cats and dogs for animal feedingstuffs only in products processed from (i) waste products of foodstuffs or (ii) other base substances, with the exception of cereals and manioc flour, denatured by means of these agents or coloured during technical preparation to ensure the necessary identification during manufacture. No maximum levels of Brilliant Blue FCF in feeds are established in the EU.

Brilliant Blue FCF is an approved food colourant in the EU and it is listed in Annex I of Directive 94/36/EC[12] of 30 June 1994. According to the same Directive, Brilliant Blue FCF is an allowed synthetic food colouring substance in the EU with a maximum allowed use level of 20–500 mg/kg food for various foodstuffs. Brilliant Blue FCF is also allowed in beverages at levels up to 200 mg/L. The specific purity criteria concerning the use of Brilliant Blue FCF in foodstuffs are included in Commission Regulation (EU) No 231/2012.[13]

Brilliant Blue FCF has been evaluated previously by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1970 (JECFA, 1970) and the Scientific Committee for Food (SCF) in 1975 and 1984 (EC, 1975, 1984). In 2010, the European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted an opinion on the re-evaluation of Brilliant Blue FCF (E133) as a food additive (EFSA, 2010).

2. Characterisation

The additive under application, Brilliant Blue FCF (E133, CI Food Blue 2, FD&C Blue No 1), is identical to the active substance.

Brilliant Blue FCF is formed by the oxidation of a leuco base, which is formed by coupling one part 2-, 3- and 4-formyl benzene sulphonic acid with two parts 3-((ethyl)(4-sulphophenyl) amino) methyl benzene sulphonic acid. Material safety data sheets of the raw materials used in the synthesis are provided in the dossier.

Brilliant Blue FCF consists essentially of disodium α-(4-(*N*-ethyl-3-sulphonatobenzylamino) phenyl)-α-(4-*N*-ethyl-3-sulphonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulphonate and its isomers (chemical formula $C_{37}H_{34}N_2Na_2O_9S_3$, Chemical Abstracts Service (CAS) number 3844-45-9, molecular weight 792.84). It also contains subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.

Brilliant Blue FCF is described as the sodium salt; however, the calcium and the potassium salts are also permitted as food additives (Commission Regulation (EU) No 231/2012).[14] The FEEDAP Panel notes that food legislation also permits the use of aluminium lakes (Commission Regulation (EU) No

[11] Commission 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.
[12] OJ L 237, 10.09.1994, p. 13.
[13] OJ L 83, 22.3.2012, p. 1.
[14] OJ L 83, 22.3.2012, p. 1.

231/2012[15]) of this colour; however, the current application does not mention these forms of the colour. Consequently, aluminium lakes of Brilliant Blue FCF were not assessed.

The structural formula of Brilliant Blue FCF is given in Figure 1. Brilliant Blue FCF is water soluble. It is produced as a fine powder of reddish-blue colour or as a granular product (mainly for liquid application).

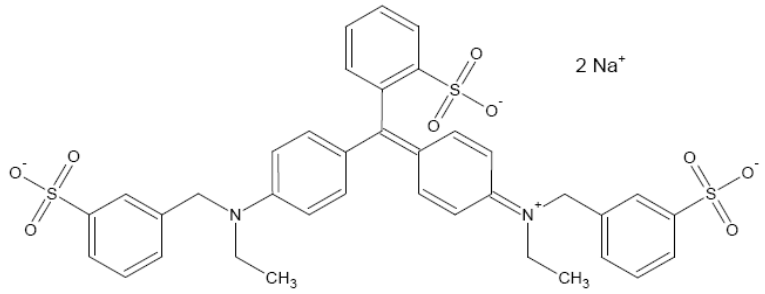

Figure 1: Structural formula of Brilliant Blue FCF

The specifications for Brilliant Blue FCF when used as a feed additive are identical to those for Brilliant Blue FCF when used as a food additive laid down in Commission Regulation (EU) No 231/2012,[16] except those for lead, which follow the previous legislation (Commission Directive 2008/128/EC).[17]

Brilliant Blue FCF is specified to contain a minimum content of 85 % total colouring matter, calculated as the sodium salt. This is confirmed by analytical data from five batches (93.6–94.5 %).[18] Subsidiary colouring matter (1.04–3.95 %), leuco base (< 0.3–0.49 %), sum of 2-, 3- and 4-formyl benzene sulphonic acids (0.14–0.31 %), 3-((ethyl)(4-sulphophenyl) amino)methyl benzene sulphonic acid (≤ 0.1 %) and unsulphonated primary aromatic amines (< 0.01 %), analysed in five batches, comply with the specifications. Heavy metals (lead, cadmium and mercury) and arsenic also met the specifications.[19]

The particle size distribution in the fine powder was determined by laser diffraction/scattering analysis of three batches.[20] The volume-based percentage of particles < 10 μm diameter was between 20.6 and 30.8, that of particles < 50 μm diameter was between 72.3 and 84.4 and that of particles < 100 μm diameter was between 91.5 and 98. Data on dusting potential were not provided. No data were provided for the granular product.

2.1. Stability and homogeneity

No data were submitted. The applicant reported a shelf-life of four to six years for Brilliant Blue 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. Moreover, the applicant made reference to a control review[21] made by the United States Office of Cosmetics and Colours (OCAC) of its procedures for the Colour Certification Program (between 1989 and 1993). A total of 175 samples representing food colours,

[15] OJ L 83, 22.3.2012, p. 1.
[16] OJ L 83, 22.3.2012, p. 1.
[17] Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs. OJ L 6, 10.1.2009, p. 20.
[18] Technical dossier/Section II/Annex 1.
[19] Technical dossier/Section II/Annex 1.
[20] Technical dossier/Section II/Annex 2.
[21] Technical dossier/Section II/Annex 4.

including Brilliant Blue FCF certified between 1963 and 1992, were analysed. The data generally confirm a long shelf-life of the colours (at least some years) and emphasise the need for dry storage.

The applicant noted that the conditions of use for Brilliant Blue FCF in foods are well established. Any substance which interacts with or alters the conjugated unsaturated bonds of the molecule will affect the colour. Brilliant Blue FCF will generally be unstable in the presence of oxidising or reducing agents (e.g. sugars and acids).

No data on the potential of the additive to homogenously distribute in different feedingstuffs have been submitted. The applicant noted that, owing to its solubility, Brilliant Blue FCF will generally be distributed in the aqueous medium of the feedingstuff regardless of its route of application (either added directly as a solid to the feedingstuff, in the presence of water or by addition of an aqueous solution).

2.2. Conditions of use

Brilliant Blue FCF is intended to be used in complete and complementary feedingstuffs for dogs and cats without a maximum content. Inclusion rates will depend on various factors including the colour of the base formulation, the blend of colours being used and the desired properties of the finished feed, e.g. browner to resemble cooked meats or brightly coloured. The applicant reported a typical inclusion level in feed for the target species.[22]

2.3. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

EFSA has verified the EURL report as it relates to the methods used for the control of the active substance in the feed additive. The Executive Summary of the EURL report can be found in the appendix.

3. Safety

Brilliant Blue FCF has been evaluated previously by JECFA in 1970 (JECFA, 1970) and by the SCF in 1975 and 1984 (EC, 1975, 1984). JECFA established an acceptable daily intake (ADI) of 12.5 mg/kg body weight (bw) by applying a safety factor of 200 to a no observed adverse effect level (NOAEL) of 5 % in the diet (2 500 mg/kg bw/day), which was the highest dose tested in a rat chronic toxicity study. The SCF initially confirmed this ADI. However, in 1984, the SCF revised the ADI to 10 mg/kg bw/day, based on new long-term studies in mice and rats, from which a NOAEL of 2 % in the diet (1 318 mg/kg bw/day) was identified for decreased terminal body weight in female rats. In 2010, the EFSA ANS Panel set a new ADI of 6 mg/kg bw based on the reinterpretation of the chronic toxicity study that the SCF used to derive its ADI, wherein a NOAEL of 1 % in the diet (631 mg/kg bw/day) was identified for decreases in survival and terminal body weight in female rats. Based on the available data, the ANS Panel considers that Brilliant Blue FCF is not genotoxic. The FEEDAP endorses this view.

3.1. Safety for the target species

In a toxicity study that was not conducted to modern standards (Hansen et al., 1966), Beagle dogs were given Brilliant Blue FCF (disodium salt) at dietary concentrations of 0, 1 or 2 % for one year. A group of four males and two females was given 2 %; two males and two females were given 1 %; and one male and one female were kept as controls. Body weights were measured weekly (but only the initial and final results were reported). Blood was taken for haematology at unspecified times. All dogs were autopsied and histopathology was performed. One male dog in the 2 % group died of an infection thought to be distemper. One male in the 1 % group died of an undiagnosed infection, showing degenerative changes of the pancreas and congestion and inflammatory cell infiltration in a moderately fatty liver. There were no treatment-related clinical signs in any of the dogs. Initial and

[22] Supplementary information/April 2013.

final body weights showed no clear treatment-related effect, but group sizes were too small to allow statistical testing. Haematological results were reported to be unremarkable for all dogs (including those with infections), although detailed results were not given. No treatment-related gross or microscopic lesions were seen in dogs that survived until the end of the study. The authors considered that the NOAEL for this study was the highest dose given—2 %, equivalent to 500 mg/kg bw per day—but the FEEDAP Panel considered the reporting and conduct of this study to be of poor quality and could therefore not use this NOAEL to identify the safe use level in dogs.

Since no specific data on tolerance of cats were available and considering the limitation of the available dog study, the FEEDAP Panel set a maximum dietary safe level for cats and dogs using the lowest NOAEL (631 mg/kg bw/day) already taken for deriving an ADI as described in the FEEDAP Panel guidance for additives which are authorised for use in food (EFSA, 2012). The FEEDAP Panel applied a safety factor of 100 (Table 2).

Table 2: Maximum safe dietary level of Brilliant Blue FCF in complete feed for cats and dogs

Species	Body weight (kg)	Safe intake (mg/day)	Feed intake (g dry matter/day)	Maximum safe dietary level	
				(mg/kg dry matter)	(mg/kg complete feed)
Cat	3	19	60	316	278
Dog	15	95	250	379	334

The maximum safe dietary level which could be derived from the available data is 334 mg/kg complete feed for dogs and 278 mg/kg complete feed for cats.

3.2. Safety for the user/owner

3.2.1. Effects on the respiratory system

Particle size distribution analysis of a fine powder formulation of Brilliant Blue FCF showed it to contain a large proportion of particles of respirable size. In the absence of information on dusting potential and of any information on the granulated form, it would be prudent to regard users as being at risk of inhalation exposure to dust from the additive. In the absence of information on the inhalation toxicity of Brilliant Blue FCF, such exposure is regarded as hazardous.

3.2.2. Effects on eyes and skin

3.2.2.1. Allergy and skin irritancy/sensitisation

It was reported by the Scientific Committee on Cosmetic Products and non-food Products intended for Consumers (SCCNFP, 2004) that Brilliant Blue FCF did not show skin sensitisation potential when tested in a local lymph node assay, but details of the study were not available.

Twenty-four urticaria patients, whose condition had worsened when treated with antihistamines, were tested for allergy to a variety of drug excipients using a patch test (Shah, 2010). Two were sensitive to Brilliant Blue FCF.

No local reactions (irritation or sensitisation) were seen in 207 human volunteers tested with daily skin applications of 5 % aqueous Brilliant Blue FCF or its aluminium lake. An induction phase of applications three times per week for three weeks was followed 12 days later by a challenge application (BIBRA, 1996).

3.2.2.2. Eye irritancy

Brilliant Blue FCF (disodium salt) and its insoluble aluminium lake were tested for eye irritancy as 3 % (mass/volume) suspensions in aqueous media (Gettings et al., 1992). Groups of 12 New Zealand White rabbits received daily applications to one eye of 30 µL of each test material or a vehicle control

solution for 21 days. Ophthalmic examination of the rabbits showed no treatment-related changes to the eyes.

Burnett and Opdyke (1971) tested various colouring agents, including Brilliant Blue FCF and its aluminium lake, for eye irritancy at 10 % aqueous solutions or suspensions. Groups of six or more albino rabbits received 0.2 mL of the test solution in one eye twice daily, five times per week, for four weeks. One hour after each treatment, the eyes were examined for signs of irritation or staining. Three days after the last application, two rabbits from each group were killed and their eyes and optic nerve trunks were examined grossly and microscopic examination of the upper eyelids was performed. Brilliant Blue FCF aluminium lakes caused marked staining of the eyes, whereas Brilliant Blue FCF caused less intense staining. Neither substance caused any eye irritation when examined prior to application on days 2, 5 10 and 20 of treatment and three days after the end of the treatment. Only mild irritation (Draize score 2) was seen one hour after application on day 5. Three days after the end of treatment, all eyes appeared normal. Eyes, optic nerve trunks and eyelids appeared normal.

3.2.2.3. Skin cancer

Brilliant Blue FCF was one of several colouring agents tested for carcinogenicity in a skin painting study in mice (Carson, 1984). Fifty Swiss Webster mice of each sex were treated with a 1 % aqueous suspension of Brilliant Blue FCF (0.1 mL applied twice weekly to 6 cm^2 of clipped skin for 18 months), whereas other groups acted as untreated controls, vehicle controls or positive controls (3,4-benzpyrene in acetone). The positive controls reacted as expected. The treatment with Brilliant Blue FCF did not increase the incidence of neoplasias compared with untreated or vehicle-treated controls. It was concluded that repeated dermal exposure to Brilliant Blue FCF is unlikely to cause skin cancer.

3.2.3. Conclusions on user safety

Brilliant Blue FCF should be regarded as an inhalation hazard.

Although testing of diluted solutions/suspensions of Brilliant Blue FCF in human volunteers showed no evidence of skin irritation, the irritancy of undiluted material has not been tested. In the absence of evidence to the contrary, it would be prudent to regard Brilliant Blue FCF as being potentially irritant to skin.

Although testing of diluted solutions/suspensions of Brilliant Blue FCF in rabbits showed only mild transient eye irritation, the irritancy of undiluted material has not been tested. In the absence of evidence to the contrary, it would be prudent to regard Brilliant Blue FCF as being potentially irritant to eyes.

Skin exposure of workers to Brilliant Blue FCF is not expected to cause skin sensitisation or local neoplasias.

3.3. Safety for the environment

Following the provision of the guidance on environmental risk assessment (EFSA, 2008), there is no requirement for the assessment of the environmental impact of the use of a feed additive when used in pets. This is the case for Brilliant Blue FCF.

4. Efficacy

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).[23] However, considering the wide variety of feedingstuffs used in complete and complementary feed for cats and dogs and the uncertainty which

[23] 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.

concentration of Brilliant Blue FCF would result in a visible effect, a demonstration of dose–effect in a typical complementary feedingstuff was provided.[24]

Samples of standard biscuits were prepared containing wholemeal flour, milk powder and vegetable oil. Brilliant Blue FCF was added at 0, 50 and 500 mg/kg feed. The colour of the samples was measured by reflectance spectrophotometry. By the addition of brilliant Blue FCF, the *a** value decreased from 7 (blank sample) to −14 (50 mg Brilliant Blue FCF/kg) and −21 (500 mg Brilliant Blue FCF/kg). The *L** value decreased accordingly (from 61 to 49 (50 mg Brilliant Blue FCF/kg) and 37 (500 mg Brilliant Blue FCF/kg)) and the *b** value decreased from 22 to 9 and −9, respectively. [25]

The data demonstrated that Brilliant Blue FCF is effective in colouring a typical complementary feed for target species at the minimum dose tested.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Brilliant Blue FCF is safe for cats and dogs up to a maximum concentration of 278 and 334 mg/kg complete feed, respectively.

Brilliant Blue FCF should be regarded as an inhalation hazard. In the absence of data on skin and eye irritancy, it would be prudent to regard Brilliant Blue FCF as being potentially irritating to skin and/or eyes. Skin exposure of workers to Brilliant Blue FCF is not expected to cause skin sensitisation or local neoplasias.

Brilliant Blue FCF is effective in colouring feed.

RECOMMENDATIONS

Considering the large discrepancy between reported use and safe dietary levels of Brilliant Blue FCF, the FEEDAP Panel recommends a maximum content of 300 mg/kg complete feed for cats and dogs.

DOCUMENTATION PROVIDED TO EFSA

1. Brilliant Blue FCF. November 2010. Sensient Colors UK Ltd.
2. Brilliant Blue FCF. Supplementary information. November 2012. Submitted by Sensient Colors UK Ltd.
3. Brilliant Blue FCF. Supplementary information. April 2013. Submitted by Sensient Colors UK Ltd.
4. Evaluation report of the European Union Reference Laboratory for Feed Additives on the methods(s) of analysis for Brilliant Blue FCF.
5. Comments from Member States received through the ScienceNet.

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[24] Technical dossier/Section IV/Annex 1.

[25] Colour quantification standardised by the Commission International de l'Eclairage. *L* (lightness, black to white reflectance, 1–100), *a* (red = positive, green = negative), *b* (yellow, blue).

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APPENDIX

Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Brilliant Blue FCF

In the current application authorisation is sought under articles 4(1) and 10(2) for *Brilliant Blue FCF* under the category/functional group 2(a)i "sensory additives"/"colourants - substances that add or restore colour in feedingstuffs", according to the classification system of Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for cats and dogs.

Brilliant Blue FCF is a synthetic reddish-blue powder or granules, consisting of a minimum of 85 % of total colouring matters content calculated as sodium salt. The Applicant states that the purity criteria set in the Commission Directive 2008/128/EC for the food additive apply to the requirement for the *feed additive*.

Brilliant Blue FCF is intended to be incorporated directly in *feedingstuffs* as a solution in *water* (either added directly as a solid to the *feedingstuffs* in the presence of water or by addition of an aqueous solution), with no recommended minimum or maximum levels. However, a typical maximum concentration of 500 mg/kg *feedingstuffs* is suggested by the Applicant.

For the determination of total colouring matters content of *Brilliant Blue FCF* in the *feed additive*, the Applicant proposed the internationally recognised FAO JECFA monographs for food additives (recommended by Commission Directive 2008/128/EC) where identification of *Brilliant Blue FCF* is based on (i) spectrophotometry at 630 nm in aqueous solution and (ii) Thin Layer Chromatography (TLC) with Retention factors (R_f) determined using several chromatographic conditions for confirmation, while quantification of total colouring matters content of *Brilliant Blue FCF* is based on i) spectrophotometry at 630 nm in aqueous solution and ii) titration with Titanous chloride. Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods recommended by Commission Directive 2008/128/EC and described in the FAO JECFA monographs for the determination of *Brilliant Blue FCF* in the *feed additive*.

The Applicant did not provide any experimental method or data for the determination of *Brilliant Blue FCF* in *premixtures* and *feedingstuffs*. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Brilliant Blue FCF* in *premixtures* and *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) is not considered necessary.