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**Assessment** : Safety assessment  
of the application for butylated  
hydroxyanisole (BHA) as a feed  
additive for use in cats, from  
FEDIAF.

Reference Number RP 1198

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## 1.Executive summary

The FSA/FSS have undertaken an assessment of application RP 1198 for the use of butylated hydroxyanisole (BHA) (> 98.5%<sup>1</sup>) as a feed additive for use in cats from FEDIAF EuropeanPetFood, Avenue Louise 89, Brussels, Belgium (category: technological additives; functional group: antioxidants, to improve the stability of the final feed product).

A number of feed additive applications have been received by Great Britain (GB) where EFSA, prior to the end of the transition period, evaluated an application for the product. FSA/FSS have reviewed the EFSA opinion (EFSA Journal 2021;19(7):6714) and confirm that it is adequate and relevant for GB risk analysis and used this to form the basis of the GB opinion. A full risk assessment of this application was not considered necessary by FSA and FSS.

The FSA/FSS risk assessors concluded that the EFSA opinion is adequate and relevant for GB risk analysis. and therefore, the use of the BHA additive, as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use.

There are no specific conditions or restrictions in relation to handling, labelling, post-market monitoring requirements and use of this additive as described in this application. Maximum Residue Limits (MRLs) are not required for this additive.

## 2.Background and purpose of review

EFSA Journal 2021; 19(7): 6714,

**Question number:** EFSA-Q-2020-00809

In accordance with Retained EU Regulation 1831/2003 on feed additives, the application RP 1198 for the use of butylated hydroxyanisole (BHA) as a feed additive for cats from FEDIAF has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA/FSS has adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

However, a number of applications have been received by GB where EFSA, prior to the end of the transition period, evaluated an application for the product for which an application is now made to GB. FSA/FSS has decided to make use of the EFSA risk

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<sup>1</sup> Analytical determination was by reversed phase high performance liquid chromatography coupled with ultraviolet-diode array detection (HPLC-UV-DAD).

assessment, where this is appropriate, in forming its opinion. Therefore, FSA/FSS risk assessors have reviewed the EFSA opinion<sup>2</sup> for the application below in the context of intended GB use and have concluded that the intended uses are safe.

In reviewing the EFSA risk assessment opinion the reviewers have verified that the standard approach as outlined in the relevant guidance<sup>3</sup> has been followed and the arguments made are consistent with the data summarised in the opinion.

Consideration has been given to the processes undertaken to ensure the opinions are robust and whether there are any aspects that would require further review such as specific issues for the countries of the GB. The result of the assessment is that the EFSA scientific opinions are adequate also for GB risk analysis. Therefore, a full risk assessment has not been performed by FSA/FSS.

BHA is currently approved for use as a feed additive up to 150 mg/kg complete feed in all animal species except cats. It is also approved for use as a food additive.

### 3.Details of the EFSA assessment

#### Methodology applied in the EFSA opinion

EFSA FEEDAP guidance: Guidance on the assessment of the safety of feed additives for the target species (**2017a**), Guidance on the identity, characterisation and conditions of use of feed additives (**2017b**), Guidance on studies concerning the safety of use of the additive for users/workers (**2012**) and principles in Regulation (EC) No 429/2008.

#### 3.1 Characterisation

The additive BHA (> 98.5%) is a white, waxy solid mixture of 2-*tert*-butyl-4-hydroxyanisole and 3-*tert*-butyl-4-hydroxyanisole. It has a chemical formula of C<sub>11</sub>H<sub>16</sub>O<sub>2</sub> and CAS number of 25013-16-5. It is made up of at least 85% of the 3-*tert* isomer.

#### 3.2 Genetic modification step

Not applicable.

#### 3.3 Specification

Physicochemical properties, homogeneity data and stability data (as shelf life of the product rather than stability in feed) were not presented for the additive but were discussed in a previous EFSA opinion (EFSA FEEDAP Panel, 2018<sup>4</sup>). The additive is homogenous within a pre-mix (ten subsamples of one batch tested) and compound feed stuff (ten subsamples of three batches tested). Stability data for the additive for three batches in both a 2-year study and an accelerated 6-month study

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<sup>2</sup> EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2021. Scientific Opinion on the safety and efficacy of a feed additive consisting of butylated hydroxyanisole (BHA) for use in cats (FEDIAF). EFSA Journal 2021;19(7):6714, 10 pp. <https://doi.org/10.2903/j.efsa.2021.6714>

<sup>3</sup> See reference list for the full set of guidance applied.

<sup>4</sup> EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018. Scientific Opinion on the safety and efficacy of butylated hydroxyanisole (BHA) as a feed additive for all animal species. EFSA Journal 2018;16(3):5215, 18 pp. <https://doi.org/10.2903/j.efsa.2018.5215>

showed no losses over the time period. As an antioxidant BHA is considered unstable in both feed materials and compound feed and therefore the stability in these matrices was not evaluated.

Six batches of BHA were analysed for heavy metals (mercury, lead, cadmium and arsenic) and fluorine. No safety concerns were noted with results from the analyses.

This application requested the use in cat feed at a maximum concentration of 150 mg/kg complete feed.

#### 3.4 Exposure assessment for consumers

Not applicable as this application is for pet food.

#### 3.5 Toxicological data

This application is for the maximum inclusion of 150 mg BHA / kg complete cat feed. In a previous assessment for the use of BHA for all animal species (EFSA FEEDAP Panel, 2018) EFSA concluded that the inclusion up to 150 mg/kg complete feed was safe for all animal species but could not conclude on the safety for cats due to the lack of tolerance data. EFSA in 2018 could not conclude on safety for cats due to their 'known lower capacity for glucuronidation of phenolic compounds and for which no specific data were available.'

This application provided new data from a tolerance study conducted in healthy cats. In short, a mix of 60 male and female cats were administered BHA through their feed at concentrations of 0, 150, 450 and 750 mg / kg for 28 consecutive days, with 15 animals per dosing group. Parameters monitored throughout this study included general health condition and behaviour (twice daily), feed intake, body weight and condition and faecal consistency. Blood samples were taken prior to the study and at days 7, 14 and 28 which were analysed for haematology and biochemistry parameters. No mortalities were recorded during the study. There were some indications of reduced feed intake in the highest dose group. However, equivalence testing did not identify any significant differences in feed intakes across the study groups.

Overall, EFSA concluded that cats tolerated the highest concentration of BHA evaluated in this study and therefore the inclusion rate of 150 mg BHA / kg complete cat feed is safe.

## 4. EFSA assessment and conclusions

From the conclusions of the tolerance study in cats, concentrations of BHA up to 5 times the intended maximum inclusion rate of 150 mg/kg complete feed were tolerated in cats. Therefore, the addition of BHA at 150 mg/kg complete feed is safe for cats.

From the previous assessment in 2018 (EFSA FEEDAP Panel, 2018) it was concluded that the BHA additive should be considered a skin and eye irritant and a potential skin sensitiser. Due to a lack of dusting potential, it is not considered a risk to the user via inhalation.

From the previous assessment in 2018 (EFSA FEEDAP Panel, 2018) it was concluded that it is unlikely the BHA additive would pose a risk to the environment at the maximum inclusion rate proposed.

## **5. Caveats and uncertainties**

There are no caveats or uncertainties to highlight.

## **6. FSA Conclusion on reliability and applicability**

The application has been assessed in line with the applicable guidance and is partially based on considerations of detailed proprietary information available to the EFSA Panel. Whilst this is only briefly summarised this description is consistent with the conclusions.

### **6.1 Analytical Method Review**

FSA/FSS accepts the EURL analytical method evaluation report<sup>5</sup>. FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

## **7. Outcome of assessment**

FSA/FSS has reviewed the EFSA opinions and consider them adequate and relevant for GB risk analysis. Therefore, the opinions were used to form the basis of the GB opinion. A full risk assessment of this application was not considered necessary by FSA and FSS.

FSA/FSS had access to all supporting documentation that was provided to the EFSA Panel by the applicant, and subsequently used to form the EFSA opinion. FSA/FSS agree with the safety conclusions outlined in the EFSA opinions.

Following the principles outlined in the background for making use of the EFSA opinions, the FSA/FSS opinion is that the BHA additive, as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use.

## **8. References**

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<sup>5</sup> <https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-FAD-2010-0132.pdf>

EFSA ANS Panel (EFSA Panel on EFSA Panel on Food Additives and Nutrient Sources added to Food), 2011. Scientific Opinion on the re-evaluation of butylated hydroxyanisole – BHA (E 320) as a food additive. EFSA Journal 2011;9(10):2392, 49pp. <https://doi.org/10.2903/j.efsa.2011.2392>

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. <https://doi.org/10.2903/j.efsa.2012.2539>

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017a. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. <https://doi.org/10.2903/j.efsa.2017.5021>

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017b. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. <https://doi.org/10.2903/j.efsa.2017.5023>

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018. Scientific Opinion on the safety and efficacy of butylated hydroxyanisole (BHA) as a feed additive for all animal species. EFSA Journal 2018;16 (3):5215, 18 pp. <https://doi.org/10.2903/j.efsa.2018.5215>

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2019. Guidance on the assessment of the safety of feed additives for the environment. EFSA Journal 2019;17(4):5648, 78 pp. <https://doi.org/10.2903/j.efsa.2019.5648>

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2021. Scientific Opinion on the safety and efficacy of a feed additive consisting of butylated hydroxyanisole (BHA) for use in cats (FEDIAF). EFSA Journal 2021;19(7):6714, 10 pp. <https://doi.org/10.2903/j.efsa.2021.6714>