SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 14 March 2019

doi: 10.2903/j.efsa.2019.5658

Safety of betaine as a novel food pursuant to Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (EFSA NDA Panel), Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Marco Vinceti, Francesco Cubadda, Karl Heinz Engel, Thomas Frenzel, Marina Heinonen, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Henk van Loveren, Emanuela Turla and Helle Katrine Knutsen

Abstract

In 2017, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded that betaine as a novel food (NF) is safe to be used at a maximum intake level of 6 mg/kg body weight per day in addition to the intake from the background diet. Following the present request from the European Commission, the EFSA NDA Panel was asked to deliver a scientific opinion on betaine by carrying out the assessment for the revised uses and use levels of betaine as proposed by the applicant. Thus, EFSA performed an intake assessment based on individual data from the EFSA Comprehensive European Food Consumption Database and the new proposed uses of the NF for the general population. The resulting ranges for the mean and high-level estimated intakes of betaine for the general population do not exceed the safe level of intake previously established. The Panel concludes that the NF, betaine, is safe under the new proposed conditions of use.

Keywords: betaine, novel food, intake assessment

Requestor: European Commission following an application by DuPont Nutrition Biosciences ApS

Question number: EFSA-Q-2018-00997

Correspondence: nda@efsa.europa.eu

Panel members: Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Marco Vinceti.

Acknowledgements: The Panel wishes to thank Davide Arcella for the support provided to this scientific opinion.

Suggested citation: EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Engel KH, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Pöting A, Poulsen M, Sanz Y, Schlatter JR, van Loveren H, Turla E and Knutsen HK, 2019. Scientific Opinion on the safety of betaine as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal 2019;17(4):5658, 8 pp. https://doi.org/10.2903/j.efsa.2019.5658

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Table of contents

1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

On 2 November 2018, the company DuPont Nutritional Biosciences ApS, submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) No 2015/2283[1] to place on the EU market betaine as a novel food (NF).

This application follows the 2015 application by the same company to Finland to place betaine on the EU market as a NF ingredient under Article 4 of Regulation (EU) No 258/1997.[2]

Following the initial assessment of this application by Finland, and the reasoned objections raised by Member States, the Commission requested EFSA to assess the safety of betaine as a NF ingredient. In its opinion of 25 October 2017, EFSA concluded that betaine would pose no safety concerns if the total daily intake from all uses would not exceed 400 mg/day.

The application submitted on 2 November 2018 contains revised use and intake concentrations for betaine as a NF aligned with the maximum level of 400 mg/day deemed to be safe by EFSA.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion by carrying out the assessment for the revised uses and intakes of betaine when used as a NF.

In doing so, EFSA should take into account its 25 October 2017 opinion on betaine as a NF which established a maximum daily intake of 400 mg/day of betaine.

1.2. Interpretation of the Terms of Reference

The EFSA opinion adopted on 25 October 2017 has been amended to express the maximum safe intake level of 400 mg per day on a mg/kg body weight (bw) basis (i.e. 6 mg/kg bw per day).

Thus, in order to address the present mandate, EFSA carried out the assessment for the revised uses and use levels of betaine when used as a NF by considering the established maximum safe intake level of 6 mg/kg bw per day in addition to the intake from the background diet.

2. Data and methodologies

2.1. Data

The assessment of the safety of betaine at the new proposed uses and use levels is based on the new data provided by the applicant and the scientific opinion on the safety of betaine as a NF which was adopted by the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) in 2017 (EFSA NDA Panel, 2017).

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications[3] and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of the Commission Implementing Regulation (EU) 2017/2469.[4]

[1] Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (2013/0435 (COD). OJ L 327, 11.12.2015, p. 1–22.

[2] Regulation (EU) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–6.

[3] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle H, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tomé D, Vinceti M, Willatts P, Engel K-H, Marchelli R, Pöting A, Poulsen M, Salminen S, Schlatter J, Arcella D, Gelbmann W, de Sesmaisons-Lecarré A, Verhagen H and van Loveren H, 2016. Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4594, 24 pp. https://doi.org/10.2903/j.efsa.2016.4594

[4] Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

This assessment concerns only risk that might be associated with consumption of the NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3. Assessment

On 25 October 2017, the EFSA NDA Panel adopted the scientific opinion on the safety of betaine as a NF when added to a variety of foods (EFSA NDA Panel, 2017). In that scientific opinion, the Panel concluded that an amount up to 6 mg/kg bw per day of betaine in addition to the intake from the background diet is considered as safe.

In order to address the present mandate, the EFSA NDA Panel is asked to perform the assessment of the new uses and use levels of betaine as proposed by the applicant.

3.1. Target population

The target population proposed by the applicant is sportspeople above 10 years of age.

According to Article 5(6) of Regulation (EU) 2017/2469, where it cannot be excluded that a NF intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups. Thus, the Panel considers the general population as the target population.

3.2. Proposed uses and use levels

The new intended uses and use levels of betaine as proposed by the applicant are presented in Table 1.

Table 1: Uses and maximum use levels of the NF as proposed by the applicant

Proposed use	Maximum use level of the NF (mg/100 g)[(a)]
Drink powders targeted to athletes	60
Isotonic ready-to-drink beverages targeted to athletes	60
Protein and cereal bars targeted to athletes[(b)]	500
Meal replacements targeted to athletes	20
Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	500 (bar); 136 (soup); 188 (porridge); 60 (beverages)
Foods for Special Medical Purposes, defined by Regulation (EU) No 609/2013, excluding foods for infants and young children	400 mg/day[(c)]

(a): Use levels all expressed as consumed (i.e. as diluted).
(b): In order to increase the number of consumers (to increase statistical reliability of the results), all protein and cereals bars were included in the assessment.
(c): Not included in intake assessment as dose is per daily serving and provided under medical supervision. Products will be labelled to indicate maximum daily dose.

3.3. Anticipated intake

3.3.1. Intake from the proposed uses and use levels of the NF

The applicant provided an intake assessment of the NF based on the new proposed uses and use levels as indicated in Table 1 and the United Kingdom National Diet and Nutrition Survey (UK NDNS) dietary survey, years 1–6 (2008–2014) (Department of Health, 2014, 2016; NatCen Social Research/ MRC Elsie Widdowson Laboratory/University College London, Medical School, 2017).

To evaluate the intake of betaine, EFSA performed a refined intake assessment based on individual data from the EFSA Comprehensive European Food Consumption Database, which is based on EU dietary surveys (EFSA, 2011). As indicated in Section 3.1, the general population, which includes sportspeople, was considered by EFSA in its intake assessment. **Table** 2 presents the food categories according to the FoodEx2 classification system and the maximum use levels of the NF which were used for the refined intake assessment performed by EFSA (European Food Safety Authority, 2015). For the entry 'Protein and protein components for sports people', which include drink powders, EFSA used the maximum use level of the NF in powders prior to be reconstituted to a solution, as indicated by

the applicant. For the entry 'Food for sporting people' and 'Carbohydrate-rich energy food products for sports people', which mainly include bars, EFSA used the proposed maximum use levels for cereal bars. The uses as 'Meal replacements targeted to athletes' and 'Total diet replacement foods for weight control' were allocated to the FoodEx2 categories 'Food for weight reduction' and 'Single meal replacement for weight reduction'.

Table 3 presents the ranges of the estimated daily intake of betaine among the EU dietary surveys (all subjects) performed by EFSA on a mg/kg bw per day basis.

The Panel notes that the mean and high-level (95th percentile) estimated intakes of betaine for the general population do not exceed the safe level of intake as previously established by the NDA Panel, i.e. 6 mg/kg bw per day in addition to the intake from the background diet (EFSA NDA Panel, 2017).

The Panel notes the main source of intake of the NF from the new proposed uses: cereal bars in infants and toddlers; cereal bars and isotonic and sport drinks in other children; isotonic and sport drinks and energy drinks in adolescents; protein and protein components and food for weight reduction in adults; cereal bars and protein and protein components in elderly people. A detailed description of the contribution of each food category to the estimated intake of the NF for each population group from each EU dietary survey is available in the excel file annexed to this scientific opinion (under supporting information).

Table 2: Food categories according to FoodEx2 classification and maximum use levels of the NF used in the intake assessment performed with the EFSA Comprehensive European Food Consumption Database

FoodEx2 code	FoodEx2 category	Maximum use level of the NF (mg/100 g)
A03RX	Food for sporting people	500
A03RY	Carbohydrate-rich energy food products for sports people	500
A03RZ	Carbohydrate-electrolyte solutions for sports people	60[(a)]
A03SA	Protein and protein components for sports people	1,080[(b)]
A03FZ	Functional drinks	60[(a)]
A03GA	Energy drinks	60[(a)]
A03GB	Isotonic and sport drinks	60[(a)]
A00EY	Cereal bars	500
A00FA	Cereal bars mixed	500
A00EZ	Cereal bars plain	500
A03RS	Food for weight reduction	500
A03RV	Single meal replacement for weight reduction	500

(a): Maximum use level of the NF as consumed (i.e. as diluted).
(b): Maximum use level of the NF in powders (to be reconstituted to obtain a maximum use level of 60 mg/100 g in the final solution).

Table 3: Ranges among EU surveys of the estimated daily intake of the NF (mg/kg bw per day), based on the EFSA Comprehensive European Food Consumption Database

Population groups	Number of EU dietary surveys	Estimated intake of the NF–all subjects (mg/kg bw per day)	
		Range of means (minimum and maximum) across EU dietary surveys	Range of 95th percentile (minimum and maximum) across EU dietary surveys
Infants (4–11 months)	11	0.00–0.05	0.00–0.00[(a)]
Toddlers (12–35 months)	14	0.00–0.63	0.00–5.48
Other children (3–9 years)	19	0.00–0.41	0.00–2.76

Population groups	Number of EU dietary surveys	Estimated intake of the NF–all subjects (mg/kg bw per day)	
		Range of means (minimum and maximum) across EU dietary surveys	Range of 95th percentile (minimum and maximum) across EU dietary surveys
Adolescents (10–17 years)	18	0.00–0.65	0.00–3.52
Adults (18–64 years)	19	0.00–0.67	0.00–1.90
Elderly (≥65 years)	18	0.00–0.07	0.00–0.69

NF: novel food; bw: body weight.
(a): The value is 0 as less than 5% of individuals consumed the concerned foods

3.3.2. Intake from other sources

As reported in the previous opinion in 2017, betaine-containing food supplements (with serving size up to 1.5 g of betaine) are currently available in the EU market for sports people.

4. Discussion

In 2017, in its scientific opinion on betaine, the Panel concluded that an amount up to 6 mg/kg bw per day of betaine in addition to the intake from the background diet is considered safe (EFSA NDA Panel, 2017).

The intake assessment of betaine based on the new proposed uses and use levels indicated that the mean and high-level (95th percentile) estimated intakes of betaine for the general population do not exceed the safe level of intake as previously established by the NDA Panel. The Panel considers the NF as safe, at the new proposed uses and use levels in the general population.

Regarding 'Foods for Special Medical Purposes', the Panel considers that the proposed maximum daily intake of 400 mg/day is safe for adults only, as for individuals below 18 years of age the proposed maximum daily intake exceeds the safe level of 6 mg/kg bw.

The Panel also notes that the consumption of some of the food supplements containing betaine currently on the EU market could, on their own, result in intakes of betaine higher than those considered safe by the Panel.

5. Conclusions

The Panel concludes that the NF, betaine, is safe under the new proposed conditions of use. However, if used in conjunction with food supplements containing betaine, the Panel notes that the safe level of intake may be exceeded.

Documentation provided to EFSA

1) Letter from the European Commission to EFSA with the request to provide a scientific opinion on betaine by carrying out the assessment for the revised uses and intakes of betaine when used as a NF. Ref. Ares(2018)6550422, dated 19/12/2018.
2) On 19/12/2018, a valid application on betaine, which was submitted by DuPont Nutrition Biosciences ApS, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2018/0685) and the scientific evaluation procedure started.

References

Department of Health, 2014. National Diet and Nutrition Survey: results from years 1 to 4 (combined) of the Rolling Programme for 2008 and 2009 to 2011 and 2012. Department of Health/Food Standards Agency (FSA), London, UK. Available online: https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012 (Location of PDF documents; First published: 14 May 2014).

Department of Health, 2016. National Diet and Nutrition Survey: results from years 5 and 6 (combined) of the Rolling Programme (2012/2013 –2013/2014). Department of Health/Food Standards Agency (FSA), London, UK. Available online: https://www.gov.uk/government/statistics/ndns-results-from-years-5-and-6-combined (Location of PDF documents; First published: 9 September 2016).

EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle HJ, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tom_e D, Vinceti M, Willatts P, Engel K-H, Marchelli R, Pöting A, Poulsen M, Schlatter JR, Turla E and van Loveren H, 2017. Scientific opinion on the safety of betaine as a novel food pursuant to Regulation (EC) No 258/97. EFSA Journal 2017;15(11):5057, 28 pp. https://doi.org/10.2903/j.efsa.2017.5057

European Food Safety Authority, 2015. The food classification and description system FoodEx2 (revision 2). EFSA supporting publication 2015:EN-804. 90 pp.

NatCen Social Research/MRC Elsie Widdowson Laboratory/University College London, Medical School, 2017. National Diet and Nutrition Survey years 1-6, 2008/09-2013/14 [data collection], 8th edition. UK Data Service. SN: 6533. Available online: https://doi.org/10.5255/ukda-sn-6533-7 [Accessed 05 December 2017]

Abbreviations

Bw	body weight
NDA	Nutrition, Novel Foods and Food Allergens
NF	novel food
UK NDNS	United Kingdom National Diet and Nutrition Survey