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Safety evaluation of buffered vinegar as a food additive

EFSA Panel on Food Additives and Flavourings (FAF),
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Abstract

The EFSA Panel on Food Additives and Flavourings (FAF) provides a scientific opinion on the safety of buffered vinegar as a new food additive. Buffered vinegar is a liquid or dried product prepared by adding sodium/potassium hydroxides (E 524 to E 525) and sodium/potassium carbonates (E 500 to E 501) to vinegar, compliant with European Standard EN 13188:2000 and exclusively obtained from an agricultural source origin (except wood/cellulose). The primary constituents of buffered vinegar are acetic acid and its salts. No biological or toxicological data obtained with the proposed food additive were submitted by the applicant as part of the dossier as, following oral ingestion, buffered vinegar dissociates into the acetic anion a natural constituent of the diet, and of the human body for which extensive data on their biological effects exist and for which EFSA in 2013 has previously concluded that the establishment of an acceptable daily intake (ADI) is not considered necessary. At the proposed maximum/typical use levels, the mean exposure to buffered vinegar from its use as a food additive expressed as acetic acid equivalents ranged from 8.9 mg/kg body weight (bw) per day in infants to 280.3 mg/kg bw per day in children. The 95th percentile of exposure to buffered vinegar ranged from 27.9 mg/kg bw per day in infants to 1,078 mg/kg bw per day in toddlers. The Panel concluded that there is no safety concern for the use of buffered vinegar as a food additive at the proposed maximum/typical use levels. The Panel could not conclude on the safety for the proposed uses at *quantum satis* as Group I food additive since the resulting exposure could not be estimated.

Keywords: acetic acid, buffered vinegar, food additive

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Summary

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Panel on Food Additives and Flavourings (FAF) was asked to provide a scientific opinion on the safety of buffered vinegar (expressed as acetic acid equivalents) proposed as a preservative food additive in a variety of food categories in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

The present evaluation is based on the data on buffered vinegar in a newly submitted dossier by the applicant and additional information submitted by the applicant during the assessment process in response to a request by EFSA.

The proposed food additive is a liquid or dried mixture prepared by adding buffering agents (hydroxides and/or carbonates) to vinegar exclusively obtained by biological fermentation from an agricultural source (except wood/cellulose). The primary constituents of buffered vinegar are acetic acid and its salts.

Liquid buffered vinegar is a colourless to brown viscous liquid and the powder form is a white to creamish-white crystalline powder. The pH for the liquid buffered vinegar is 4.75–7.5 and for the powder form (as a 10% aqueous solution) is 4.75–6.75. Water solubility was determined to be > 1,000 g/L for liquid buffered vinegar and 200–1,000 g/L for powdered buffered vinegar.

Buffered vinegar is produced by blending vinegar (from biological fermentation from an agricultural source) with buffering agents (i.e. sodium and potassium hydroxides (E 524–525) and/or carbonates (E 500–501) authorised as food additives according to Regulation (EC) No 1333/2008) and water. Optionally citric acid (E 330) may be used to standardise the pH prior to spray drying. The resulting blend gives liquid buffered vinegar, which may be dried to form powdered buffered vinegar. The starting material vinegar was declared by the applicant as being 'food-grade' and compliant with European Standard EN 13188:2000 (CEN, 2000).[1]

The stability of the proposed food additive and the fate in food in one of the intended food categories have been demonstrated by the applicant.

No biological or toxicological data obtained with the proposed food additive were submitted by the applicant as part of the dossier. The Panel agreed with the justification provided by the applicant for not complying with the Tier 1 requirements of the 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) by stating that, following oral ingestion, buffered vinegar dissociates into the acetic anion, a natural constituent of the diet and of the human body for which extensive data on their biological effects exist and for which EFSA has previously concluded that the establishment of an acceptable daily intake (ADI) is not considered necessary (EFSA, 2013).

To assess the dietary exposure to buffered vinegar, expressed as acetic acid equivalents, the exposure was calculated based on the typical and maximum use levels proposed by the applicant.

At the proposed maximum/typical use levels, the mean exposure to buffered vinegar from its use as a food additive expressed as acetic acid equivalents ranged from 8.9 mg/kg bw per day in infants to 280.3 mg/kg bw per day in children. The 95th percentile of exposure to buffered vinegar ranged from 27.9 mg/kg bw per day in infants to 1,078 mg/kg bw per day in toddlers.

The Panel noted that the proposed food additive buffered vinegar may contain up to 30% sodium and this could lead to an additional exposure to sodium from the proposed uses in food.

The Panel noted that the highest exposure estimates for all six age groups are coming from a single dietary survey with estimates, at the mean and p95, respectively, up to threefold and fivefold higher than the estimates from other surveys. These high estimates were mainly driven by the consumption of the food category 'soups and broth' (contributing up to 63% at the mean exposure for the whole population and up to 94% for the high consumers). The highest consumption values were especially prominent in infants, toddlers and children.

The Panel concluded that there is no safety concern for the use of buffered vinegar as a food additive at the proposed maximum/typical use levels.

The Panel could not conclude on the safety for the proposed uses at *quantum satis* as Group I food additive since the resulting exposure could not be estimated.

[1] EN 13188:2000. Vinegar. Product made from liquids of agricultural origin. Definitions, requirements, marking.

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1. Introduction

The present scientific opinion deals with the safety evaluation of buffered vinegar proposed as a food additive in a variety of food categories.

1.1. Background and terms of reference as provided by the European Commission

1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008[2] on food additives. Only food additives that are included in the Union list, in particular Annex II to that regulation, may be placed on the market and used in foods under conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012[3].

An application has been introduced for the authorisation of the use of a product called 'buffered vinegar' as a preservative in several food categories of Annex II to Regulation (EC) No 1333/2008.

1.1.2. Terms of Reference

The European Commission requests the European Food Safety Authority to perform a risk assessment to provide a scientific opinion on the safety of the proposed use of buffered vinegar as a food additive, in accordance with Regulation (EC) No 1331/2008[4] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

1.2. Information on existing evaluations and authorisations

There are no existing authorisations or risk assessments for buffered vinegar in the EU. In the EU, acetic acid and its salts (E 260–263) are all authorised as Group I food additives in accordance with Regulation (EC) No 1333/2008 on food additives and specifications are defined in Commission Regulation (EU) No 231/2012. The re-evaluation of these food additives under Regulation (EU) No 257/2010[5] is still ongoing.[6] The authorisations for these food additives were based on the risk assessment by the Scientific Committee on Foods (SCF) in 1990, where an acceptable daily intake (ADI) of 'not specified' was established for the group of food additives (SCF, 1991).

Based on an anticipated exposure to acetic acid from the use of calcium acetate added for nutritional purposes to food supplements, an equivalent exposure to acetic acid of 2.4 g/person per day was reported by the ANS Panel (EFSA ANS Panel, 2009).

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted two opinions on the safety and efficacy of acetic acid, as a technological additive for all animal species (EFSA FEEDAP Panel, 2012) and as a feed flavouring (EFSA FEEDAP Panel, 2013). In 2021, a third opinion was adopted by the FEEDAP Panel, covering a new manufacturing process for acetic acid (EFSA FEEDAP Panel, 2021). The FEEDAP Panel concluded that there were no safety concerns for the target species, consumers or the environment.

In the conclusion on the peer review of the pesticide risk assessment of the active substance acetic acid, the following considerations were noted: '*The adverse effects described in the available human data are all related to the irritating properties of concentrated acetic acid by oral, dermal or inhalation exposure. Based on the widespread presence of acetic acid in human foods, together with the fact that it is a normal metabolite in humans and animals, the establishment of an Acceptable Daily Intake*

[2] 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. 16–33.

[3] 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, 22.3.2012, p. 1–295.

[4] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, p. 1–6.

[5] Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

[6] See https://open.efsa.europa.eu, EFSA Question numbers: EFSA-Q-2011-00592; EFSA-Q-2011-00593; EFSA-Q-2011-00594; EFSA-Q-2011-00595.

(ADI) and Acute Reference Dose (ARfD) for oral intake of acetic acid by consumers is not considered necessary' (EFSA, 2013).

With respect to the safety of acetic acid solutions (with concentrations from 2% to 4%) used during processing to reduce microbial surface contamination on pork carcasses and cuts, the CEP Panel had assessed exposure to acetic acid from its proposed uses into context with acetic acid intake obtained via the typical diet. The intake of acetic acid (assuming a content of 6% w/v) from consumption of vinegar as reported in the Comprehensive Database ranged from 0 to 123 mg/person per day at the mean and from 0 to 480 mg/person per day at the 95th percentile. Based on these results, the CEP Panel concluded that no safety concerns were foreseen, provided that the substances used comply with the EU specifications for food additives (EFSA CEP Panel, 2018).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a group ADI of 'not limited' for acetic acid and its potassium and sodium salts at their 17th meeting in 1973 (JECFA, 1974), and this was maintained at the 49th JECFA in 1997 (JECFA, 1998).

Health Canada's Food Directorate proposed adding buffered vinegar (termed 'modified vinegar' by Health Canada) to Part 2 of the *List of Permitted Preservatives* (Health Canada, 2020).

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier to support the safety evaluation of the present application on buffered vinegar proposed as a preservative food additive in a variety of food categories (Documentation provided to EFSA n.1).

Following the request for additional data sent by EFSA on 1 October 2021, the applicant provided additional data on 01 December 2021 (Documentation provided to EFSA n.2).

Following a further request for additional data sent by EFSA on 15 March 2022, the applicant provided additional data on 13 April 2022 (Documentation provided to EFSA n.3).

2.2. Methodologies

This opinion was formulated following the principles described in the EFSA Guidance of the Scientific Committee on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidance documents from the EFSA Scientific Committee.

The current '*Guidance for submission for food additive evaluation*' (EFSA ANS Panel, 2012) has been followed by the FAF Panel for evaluating the present application.

3. Assessment

3.1. Technical data

3.1.1. Identity of the proposed food additive

The proposed food additive, named as buffered vinegar, is a liquid or dried mixture of different constituents prepared by adding buffering agents to vinegar exclusively obtained by biological fermentation from an agricultural source (except wood/cellulose). Based on the information provided by the applicant, acetic acid and its salts are the primary constituents of buffered vinegar.

The buffering agents used in the production of buffered vinegar are the sodium and potassium hydroxides (E 524–525) and/or carbonates (E 500–501) authorised as food additives according to Regulation (EC) No 1333/2008. Citric acid (E 330) can also be optionally used as buffering/neutralising agent (Documentation provided to EFSA n. 1–3).

Information on the chemical composition for both buffered vinegar (liquid) and buffered vinegar (dried powder) were provided by the applicant:

- Buffered vinegar (liquid): 15–40% (w/w) acetic acid equivalents (i.e. content of acetic acid and its salts, expressed as acetic acid); 2–20% (w/w) free acetic acid; 3–30% total cations (not more than (NMT) 10% sodium; NMT 30% potassium);
- Buffered vinegar (dried powder): 55–75% (w/w) acetic acid equivalents (see explanation above), 2–20% (w/w) free acetic acid, 20–40% total cations (NMT 30% sodium; NMT 40% potassium) and NMT 18% water content.

The compositional equivalence of two batches of liquid buffered vinegar with traditional household vinegar (4% acetic acid) and the vinegar starting material (22% acetic acid) used for production of buffered vinegar was explored by gas chromatography coupled to mass spectroscopy (GC–MS) and by liquid chromatography coupled to high resolution mass spectrometry (LC-HRMS) (Documentation provided to EFSA n. 1). The GC–MS fingerprinting used headspace gas and liquid injection as the sample introduction techniques. Acetic acid, ethanol, ethyl acetate and acetaldehyde were detected in all four samples and methyl acetate was detected in the vinegar starting material. The LC-HRMS fingerprinting used both negative ionisation (ESI-) and positive ionisation (ESI+) modes. The LC-HRMS ion chromatograms obtained were weak and indistinctive. Acetic acid was the only peak that was identified and it was present in all of the four samples. The Panel noted that the fingerprinting techniques (GC–MS and LC-HRMS) fall far short of a comprehensive analysis since, as applied, they identified only the four or five most prominent constituents of the samples analysed. However, taking into account the source materials used and the method of production of the proposed food additive, the Panel concluded that no further data in regard to composition was needed.

The reported pH for the liquid buffered vinegar is 4.75–7.5, and for the powder form (as a 10% aqueous solution), the pH is reported to be 4.75–6.75 (Documentation provided to EFSA n. 1).

According to the applicant, liquid buffered vinegar is described as a colourless to brown viscous liquid and the powder form as a white to creamish-white crystalline powder (Documentation provided to EFSA n. 1).

Water solubility of liquid and powder buffered vinegar was determined according to the OECD TG 105 (OECD, 1995) and it resulted > 1,000 g/L for liquid buffered vinegar and 200–1,000 g/L for powdered buffered vinegar. Also, the applicant provided information on the water solubility of the main constituents of the proposed food additive, namely for acetic acid (602.9 g/L), sodium acetate (1,250 g/L) and potassium acetate (2,530 g/L) (ECHA, 2021a,b,c) (Documentation provided to EFSA n. 1).

Regarding buffered vinegar (powder form), the Panel considered that at its specified water solubility (200–1,000 g/L), the proposed food additive is expected to be fully solubilised either in the food matrix or in the gastrointestinal tract, even up to the highest proposed use levels. Therefore, consumers will not be exposed to the material in particle form. Additionally, the Panel noted that the water solubility of the proposed food additive and its constituents is substantially higher than the threshold of 33.3 g/L indicated in the EFSA SC Guidance on technical requirement for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021) below which assessment of the fraction of small particles is needed. Based on these considerations of solubility, the Panel concluded that the conventional risk assessment according to the EFSA ANS Panel Guidance for submission for food additive evaluation (EFSA ANS Panel, 2012) can be followed.

3.1.2. Proposed specifications

The buffered vinegar specifications, as proposed by the applicant, for both the liquid and powdered form are presented in Table 1.

Table 1: Specifications for buffered vinegar, as proposed by the applicant (Documentation provided to EFSA n. 3)

Synonyms	**Buffered vinegar (liquid); buffered vinegar (powder)**	
Definition	Buffered vinegar is a liquid or dried product prepared by adding buffering agents to vinegar. The buffering agents used are sodium/potassium hydroxides (E 524 to E 525) and sodium/potassium carbonates (E 500 to E 501). The vinegar is compliant with the European Standard EN 13188:2000 and is exclusively obtained from an agricultural source origin (except wood/cellulose). The primary constituents of buffered vinegar are acetic acid and its salts.	
Assay	Liquid: 15–40% (w/w) acetic acid equivalents[(a)]	HPLC
	Powder: 55–75% (w/w) acetic acid equivalents[(a)]	
	2 to 20% (w/w) free acetic acid	JECFA (2006)
Description	Liquid: colourless to brown viscous liquid	Internal method
	Powder: white to creamish-white crystalline powder	

Synonyms	Buffered vinegar (liquid); buffered vinegar (powder)	
Identification	Liquid: pH 4.75–7.5	Internal method
	Powder: pH 4.75–6.75 (10% aqueous solution)	
Purity		
Total cations	Liquid: 3–30% total cations (NMT 10% sodium; NMT 30% potassium)	ICP
	Powder: 20–40% total cations (NMT 30% sodium; NMT 40% potassium)	
Water content	Powder: NMT 18%	Karl-Fischer method
Ethanol	NMT 0.5% (w/w)	HS-GC–MS
Arsenic	NMT 1 mg/kg	ICP
Lead	NMT 0.5 mg/kg	ICP
Mercury	NMT 0.5 mg/kg	ICP
Cadmium	NMT 0.5 mg/kg	ICP

HS-GC–MS: Headspace–gas chromatography–mass spectrometry; ICP: Inductively coupled plasma; NMT: no more than.
(a): Acetic acid equivalents refer to the content of acetic acid and its salts, expressed as acetic acid.

The Panel noted that according to the definition given in the Standard EN 13188:2000, vinegar is '*produced exclusively by the biological process of double fermentation, alcoholic and acetous, from liquids or other substances of agricultural origin*'.

According to the applicant, '*Citric acid (E330) is used in the manufacturing process of buffered vinegar purely as an optional pH regulator prior to spray drying*'. The Panel would recommend that this optional use of citric acid (E330) should be included in the definition of the proposed food additive.

The Panel noted that analytical data from the analysis of five independent batches of both liquid and powdered buffered vinegar were provided showing that the proposed food additive is manufactured in compliance with the proposed specifications as given in Table 1 (Documentation provided to EFSA n. 1).

Regarding the toxic elements, the applicant provided analytical data developed by inductively coupled plasma mass spectrometry (ICP-MS), according to USP 233 method, on five independent representative batches of buffered vinegar, both in liquid and in powder form, for levels of arsenic (As), lead (Pb), cadmium (Cd) and mercury (Hg). For the five batches of buffered vinegar (liquid) the acetic acid equivalence was in the range of [redacted] and the levels of As, Pb and Hg were reported to be < 0.005 mg/kg of each element for four of the five batches and < 0.01 mg/kg of each element for the fifth batch. Only one of the five batches of buffered vinegar (liquid) was analysed for Cd and this was reported to be < 0.01 mg/kg. For the five batches of buffered vinegar (powder), the acetic acid equivalence was in the range of [redacted] and the level of As reported for the five batches was 0.005, 0.006, 0.007, 0.007 and < 0.01 mg/kg. The levels of Pb and Hg were < 0.005 of each element for four batches and < 0.01 mg/kg for the fifth batch. Only one of the five batches of buffered vinegar powder was analysed for Cd and this was reported to be < 0.01 mg/kg. (Documentation provided to EFSA n.1).

The applicant stated that the proposed maximum limits for such toxic elements (see Table 1) have been established based on the lowest technologically achievable levels and that they are supported by the data obtained during piloting and scale-up of buffered vinegar production. The Panel noted that there is a wide discrepancy between the reported data, being all less than 0.01 mg/kg, and these proposed maximum limits which are ca. 50–100 times higher than the reported concentrations. The anticipated impact of the proposed specifications and of the reported analytical data on the potential exposure to these toxic elements is described in Section 3.3.3 (Tables 7 and 8).

3.1.3. Manufacturing process

Buffered vinegar is produced by blending vinegar (from biological fermentation from an agricultural source) with buffering agents (i.e. sodium and potassium hydroxides (E 524–525) and/or carbonates (E 500–501) authorised as food additives according to Regulation (EC) No 1333/2008) and water. The resulting blend gives liquid buffered vinegar, which may be dried to form powdered buffered vinegar. Optionally citric acid (E 330) may be used to standardise the pH prior to spray drying.

The starting material vinegar was declared by the applicant as being 'food-grade' and compliant with European Standard EN 13188:2000 (CEN, 2000) defining vinegar as a '*product produced*

exclusively by the biological process of double fermentation, alcoholic and acetous, from liquids or other substances of agricultural origin' (Documentation provided to EFSA n. 1–3).

3.1.4. Methods of analysis in food

The applicant indicated a number of publications from the scientific literature reporting several HPLC- and GC-based analytical methods for the determination of acetic acid in different types of food matrices (Documentation provided to EFSA n. 1).

The Panel noted that the reported methods refer to the determination of acetic acid, but they are not specific to the proposed food additive.

3.1.5. Stability, reaction and fate in foods of the proposed food additive

Storage stability of one batch each of liquid and powder buffered vinegar was investigated at 25°C, 65% of relative humidity (RH) for 36 months and 24 months, respectively. Samples of the proposed food additive were analysed (at time points 1, 2, 3, 6, 9, 12 and 24 months for powder buffered vinegar and at time points 0, 3, 6, 9, 12, 18, 24 and 36 months for liquid buffered vinegar) for free and total acidity, moisture content, appearance, pH, toxic elements (As, Pb, Cd, Hg) and microbiological parameters (total aerobic microbial count (TAMC) and Total Yeast & Mould Count (TYMC)). Compliance with the respective limits set for the analysed parameters was maintained for the full duration of the testing period, both for the liquid and powder buffered vinegar, thus demonstrating that the proposed food additive is stable under the tested conditions (Documentation provided to EFSA n. 1).

In addition, the applicant analysed 11 batches of liquid buffered vinegar and seven batches of powder buffered vinegar, stored at room temperature and for up to 20 months (liquid) and 24 months (powder), for toxic elements content (Pb, As, Hg and Cd) and microbiological stability (TAMC and TYMC). The content of toxic elements and microbiological contamination 'remained negligible' (not detected or well below the respective limits set) during storage for liquid and powder buffered vinegar (Documentation provided to EFSA n. 1).

The applicant also tested the stability of buffered vinegar liquid and buffered vinegar powder added at 1.5% and 0.5% w/w, respectively, to minced beef (one of the intended uses for buffered vinegar), refrigerated at 4°C and protected from light, over a period of 15 days. It was noted that colour deterioration and off-flavours were perceived at day 8 of storage and the microbial limit was exceeded at day 12 and 15. However, the recovered acetic acid levels for samples prepared with liquid or powder buffered vinegar remained relatively stable, within the proposed specification for acetic acid equivalent (see Table 1) throughout the assessment period (Documentation provided to EFSA n. 1). According to the applicant, these results demonstrate the stability of buffered vinegar in foods to which it is intended to be added.

The Panel agreed that the stability of the proposed food additive and the fate in food in one of the intended food categories have been demonstrated by the applicant. The Panel considered that given the nature of the main constituents of the proposed food additive, being acetic acid and its simple salts, stability in the other food categories proposed is to be expected.

3.2. Proposed uses and use levels

Through the current application, an authorisation is sought with regard to the food categories listed in Table 2.

The Panel noted that the applicant has submitted proposed maximum use levels of buffered vinegar in mg/kg for a variety of food categories, expressed as acetic acid equivalents according to food additives categories in Part D of Annex II of Regulation (EC) No 1333/2008. The Panel also noted that according to the applicant, the proposed maximum use levels are considered to be the same as the typical use levels. Notwithstanding this, the applicant has also proposed inclusion of buffered vinegar as a Group I additive at a specific maximum level of *quantum satis*. The Panel noted that according to the 2012 EFSA ANS Panel Guidance, an exposure assessment from proposed uses at *quantum satis* cannot be calculated.

Table 2: Proposed uses and maximum/typical use levels of buffered vinegar expressed as acetic acid equivalents (mg/kg)

Food category number	Food category name	Restrictions/exceptions	Proposed maximum/typical use levels (expressed as acetic acid equivalents) (mg/kg)
01.7.1	Unripened cheese excluding products falling in category 16		7,500
01.7.4	Whey cheese		7,500
01.7.5	Processed cheese		7,500
01.8	Dairy analogues, including beverage whiteners		3,000
02.2	Fat and oil emulsions mainly of type water-in-oil		7,500
04.1.2	Peeled, cut and shredded fruits and vegetables	Legume fresh seeds only	3,000
04.2	Processed fruits and vegetables	Excluding dehydrated potato products and processed fruit products other than fruit preparations for fillings and/or flavouring	3,000
04.2	Processed fruits and vegetables	Only relishes[(a)]	7,500
04.2.5.4	Nut butters and nut spreads		3,000
06.4	Pasta	Excluding 6.4.2 Dry pasta	7,500
07.1	Bread and rolls		7,500
07.2	Fine bakery wares		7,500
08.2	Meat preparations as defined by Regulation (EC) No 853/2004		7,500
08.3	Meat products, including processed meat[(b)]		7,500
09.2	Processed fish and fishery products including molluscs and crustaceans		7,500
09.3	Fish roe		7,500
10.2	Processed eggs and egg products		3,000
12.2	Herbs, spices, seasonings		30,000
12.5	Soups and broth		7,500
12.6	Sauces		7,500
12.7	Salads and savoury-based sandwich spreads		7,500
12.9	Protein products		7,500
15.1	Potato-, cereal-, flour- or starch-based snacks		3,000
15.2	Processed nuts		3,000
18	Processed foods not covered by categories 1–17 excluding foods for infants and young children		7,500

(a): The Panel noted that for the proposed use in 'relishes', the most appropriate corresponding food category in Regulation (EC) No 1333/2008 would be '04.2.2. Fruit and vegetables in vinegar, oil, or brine'. The latter has been used for the exposure estimate performed by the Panel.
(b): The Panel noted that the food category corresponding to the code 8.3 in Regulation (EC) No 1333/2008 is 'Meat products'.

The Panel noted that according to Annex II to Regulation (EC) No 1333/2008, acetic acid and its salts (E 260 to E 263) are Group I additives permitted at a maximum level of *quantum satis*.

3.3. Exposure data

3.3.1. Food consumption data used for exposure assessment

EFSA comprehensive European food consumption database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011). The version of the Comprehensive database taken into account in this assessment was published in July 2021.[7]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons may not be appropriate. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from infants, toddlers, children, adolescents, adults and the elderly were used in the exposure assessment. For the present assessment, food consumption data were available from 42 different dietary surveys carried out in 22 European countries (Table 3).

Table 3: Population groups considered for the exposure estimates of buffered vinegar

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Portugal, Slovenia
Toddlers[(a)]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain
Children[(a)]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
The elderly[(b)]	From 65 years of age and older	Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013 (Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No f953/2009. OJ L 181, 29.6.2013, p. 35–56.).

(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in Comprehensive Database (EFSA, 2011).

Consumption records were codified according to the FoodEx2 classification system (EFSA, 2015). Nomenclature from the FoodEx2 classification system was linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform the exposure assessments. In practice, the FoodEx2 food codes were matched to the FCS food categories.

[7] Available online: https://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

Food categories considered for the exposure assessment of buffered vinegar

The food categories in which the use of buffered vinegar (expressed in acetic acid equivalents) is proposed were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (up to FoodEx2 Level 7) (EFSA, 2015).

Considering that the food category 18 (Processed foods not covered by categories 1–17, excluding foods for infants and young children) is extremely unspecific (e.g. composite foods), processed foods, prepared or composite dishes belonging to the food category 18 were reclassified under food categories in accordance to their main component. Therefore, food category 18 is not taken into account as contributor to the total exposure estimates.

In the FAIM tool (Food Additives Intake Model),[8] it is not possible to distinguish relishes within the food category 04.2.2, and therefore, the whole food category 04.2.2 is considered at the level of 7,500 mg/kg (proposed maximum/typical level for relishes). The remaining food categories of processed fruits and vegetables (FC 04.2) were considered at the level of 3,000 mg/kg (proposed maximum/typical level for the food category 04.2). Moreover, food category 04.1.2 as proposed by the applicant (i.e. legumes fresh seeds only) is considered by taking into account the food category 04.1 in FAIM tool at the maximum/typical use level provided by the applicant.

The restrictions/exceptions proposed by the applicant for the FC 04.1.2, FC 04.2 and FC 06.4 were considered in the refined estimates performed by the Panel (calculated with SAS Enterprise Guide Version 8.2.5).

3.3.2. Exposure to buffered vinegar from its proposed use as food additive

The Panel noted that the applicant has provided estimates of exposure to the proposed food additive: an estimate of exposure based on the FAIM template (Documentation provided to EFSA n.1 and n.3) and a more refined exposure estimate based on the EFSA Comprehensive Database combining consumption data with maximum/typical use levels detailed at FoodEx2 Level 5 (Documentation provided to EFSA n.2 and n.3).

Estimate of exposure based on the food additives intake model (FAIM) template

The applicant has provided an estimate of exposure to buffered vinegar expressed as acetic acid equivalents based on the output obtained using the FAIM model at the proposed maximum/typical use levels submitted (Documentation provided to EFSA n.1 and n.3). The Panel further noted that the applicant provided an estimation of the exposure to buffered vinegar using a version of the FAIM tool which includes UK surveys. However, the Panel considered it inappropriate to include UK surveys since the UK is no longer a member state of the European Union.[9]

Knowing that from the dossier, it was not possible to distinguish the UK estimates in the range of the exposure results, the Panel performed an updated estimation using the FAIM tool (version 2.1, which is without UK data) presented in Table 4.

Table 4: Summary of dietary exposure to buffered vinegar from its proposed maximum/typical use levels as a food additive in six population groups, estimated with FAIM (minimum–maximum across the dietary surveys in mg/kg bw per day expressed as acetic acid equivalents)

	Infants (12 weeks-11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Proposed maximum/typical use level exposure assessment scenario						
Mean*	32.1–214.9	85.7–323.2	91.5–336.2	39.2–165.3	36.1–98.0	36.4–73.4
95th percentile	100.7–629.2	147.0–1,142.7	154.7–1,044.3	66.8–520.8	63.8–347.0	60.5–261.0

*: Mean values considered for the safety assessment of the proposed food additive.

[8] FAIM tool version 2.1.
[9] https://www.efsa.europa.eu/sites/default/files/2021-06/22nd-plenary-meeting-faf-panel-minutes.pdf

Since the proposed use levels used in these calculations for estimation of exposure are expressed as acetic acid equivalents (Table 2), then these estimates of exposure to the proposed food additive are similarly in units of mg AAEs/kg bw per day.

At the proposed maximum/typical use levels, the mean exposure to buffered vinegar from its use as a food additive expressed as acetic acid equivalents ranged from 32.1 mg/kg bw per day in infants to 336.2 mg/kg bw per day in children. The 95th percentile of exposure to buffered vinegar ranged from 60.5 mg/kg bw per day in the elderly to 1,143 mg/kg bw per day in toddlers.

Refined estimate of dietary exposure to buffered vinegar

In addition to the estimates obtain with FAIM, the Panel considered it appropriate to perform a refined exposure assessment in six population groups. This allowed to consider the restriction in food categories proposed to contain buffered vinegar as indicated by the applicant (Table 2). It also permitted to better understand the main food categories contributing for the high consumers population.

Table 5 summarises the estimated exposure to buffered vinegar from its use as a food additive in six population groups (Table 3) according to the maximum/typical level exposure scenarios. Detailed results per population group and survey are presented in Appendix A.

Table 5: Summary of dietary exposure to buffered vinegar from its use as a food additive in the proposed maximum/typical level exposure assessment scenario, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks-11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Proposed maximum/typical level exposure assessment scenario						
Mean	8.9–145.9	31.8–263.4	57.2–280.3	22.8–138.1	22.5–81.4	18.8–59.9
95th percentile	27.9–450.5	86.9–1,078.2	109.2–951.9	42.2–499.6	43.0–333.9	36.0–253.1

Since the proposed use levels used in these calculations for estimation of exposure are expressed as acetic acid equivalents (Table 2), then these estimates of exposure to the proposed food additive are similarly in units of mg AAEs/kg bw per day.

At the proposed maximum/typical use levels, the mean exposure to buffered vinegar from its use as a food additive expressed as acetic acid equivalents ranged from 8.9 mg/kg bw per day in infants to 280.3 mg/kg bw per day in children. The 95th percentile of exposure to buffered vinegar ranged from 27.9 mg/kg bw per day in infants to 1,078 mg/kg bw per day in toddlers.

The Panel noted that the highest exposure estimates for all six age groups are coming from a single national dietary survey with estimates, at the mean and p95, respectively, up to threefold and fivefold higher than the estimates from the other surveys. These high estimates were mainly driven by the consumption of the food category 'soups and broth' (contributing up to 63% at the mean exposure for the whole population and up to 94% for the high consumers). The highest consumption values were especially prominent in infants, toddlers and children (see Appendix A for detailed exposure estimates).

The Panel queried the reported large difference related to the high level of consumption of these food categories but considered that there was no reason to disregard the data from the single survey. However, in order to have consumption values representative of the wider EU population, the Panel decided to base its considerations on the safety of the proposed food additive, including the proposed limits for toxic elements in the specifications, using mean estimates of exposure rather than p95 values. The Panel noted that the mean values including all the surveys are very similar to the p95 values when the highest values from the single survey are excluded.

Main food categories contributing to exposure to buffered vinegar

From the proposed maximum/typical level exposure assessment scenario, the main contributing food categories to the total mean exposure estimates were:

- FC 12.5 Soups and broths for all population groups (up to 63.5% to the total mean).
- FC 07.1 Bread and rolls for all the population groups (up to 55.3% to the total mean).

- FC 01.7.1 Unripened cheese and FC 07.2 fine bakery wares for infants were also important contributing food categories (respectively, up to 67.6% and 41.7%).

Appendix B indicates all the contributing food categories by population groups.

Uncertainty analysis

In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 6.

Table 6: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[(a)]
Consumption data: different methodologies/representativeness/underreporting/misreporting/ no portion size standard	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Correspondence of proposed use levels to the food items in the EFSA Comprehensive Database: uncertainties to which types of food the levels refer to	+/–
Uncertainty in possible national differences in use levels of food categories	+/–
Concentration data: Proposed maximum/typical use levels considered applicable to all foods within the entire food category, whereas most probably not all food belonging to a proposed food categories will contain buffered vinegar as a food additive	+

(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Buffered vinegar (expressed in acetic acid equivalents) is requested to be authorised in 24 food categories. For all food categories considered, it was assumed that 100% of the foods belonging to these food categories will contain buffered vinegar at the maximum/typical proposed use levels. Therefore, overall, the Panel considered that the uncertainties identified resulted in an overestimation of the exposure to buffered vinegar at the maximum/typical proposed use levels in European countries considered in the EFSA Comprehensive database.

3.3.3. Anticipated exposure to toxic elements from proposed specifications

The applicant provided lowest technologically achievable levels for As (1.0 mg/kg), Pb (0.5 mg/kg), Cd (0.5 mg/kg) and Hg (0.5 mg/kg) in the proposed food additive (Documentation provided to EFSA N. 2) for the purpose of defining appropriate specifications (Table 1). As noted already, the actual data provided for batches of the proposed food additive were much lower, being < 0.01 mg/kg for each of these four elements. On the basis of the data provided and using a modulation factor of 5, to provide some 'headroom' (to account for representativeness, homogeneity and analytical measurement uncertainty), limit values of 0.05 mg/kg for each element would seem to be more realistic.

The level of the toxic elements in the proposed food additive combined with the estimated intakes presented in Table 5 could result in an exposure which can be compared with the following reference points (RP) or health-based guidance values (HBGV) (Table 7) for the toxic elements.

Table 7: Reference points/health-based guidance value for toxic elements potentially present in the proposed food additive

Element/HBGV/RP (μg/kg bw/d or/w)	Basis
Arsenic (As) 0.3–8 ($BMDL_{01}$)	The reference point is based on a range of benchmark dose lower confidence limit ($BMDL_{01}$) values between 0.3 and 8 μg/kg bw per day identified for cancers of the lung, skin and bladder, as well as skin lesions. In general, the MOE should be at least 10,000 if the reference point is based on carcinogenicity in animal studies. However, as the BMDL for As is derived from human studies, an interspecies extrapolation factor (i.e. 10) is not needed (EFSA CONTAM Panel, 2009a; EFSA Scientific Committee, 2012).

Element/HBGV/RP (μg/kg bw/d or/w)	Basis
Lead (Pb) 0.5 ($BMDL_{01}$)	The reference point is based on a study demonstrating perturbation of intellectual development in children with the critical response size of 1-point reduction in IQ. The EFSA CONTAM Panel mentioned that a 1-point reduction in IQ is related to a 4.5% increase in the risk of failure to graduate from high school and that a 1-point reduction in IQ in children can be associated with a decrease of later productivity of about 2%. A risk cannot be excluded if the exposure exceeds the $BMDL_{01}$ (MOE lower than 1) (EFSA CONTAM Panel, 2010).
Cadmium (Cd) 2.5 (TWI)	The derivation of the reference point is based on a meta-analysis to evaluate the dose–response relationship between selected urinary cadmium and urinary beta-2-microglobulin (B2M) as the biomarker of tubular damage recognised as the most useful biomarker in relation to tubular effects. A group-based $BMDL_5$ of 4 μg Cd/g creatinine for humans was derived. A chemical-specific adjustment factor of 3.9 was applied to account for human variability in urinary cadmium within each dose-subgroup in the analysis resulting in a reference point of 1.0 μg Cd/g creatinine in urine in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 μg Cd/kg bw, corresponding to a weekly dietary intake of 2.5 μg Cd/kg bw (EFSA CONTAM Panel, 2009b).
Mercury (Hg) 4 (TWI)	The HBGV was set using kidney weight changes in male rats as the pivotal effect. Based on the $BMDL_{10}$ of 0.06 mg/kg bw per day, expressed as mercury, and an uncertainty factor of 100 to account for inter and intra species differences, with conversion to a weekly basis and rounding to one significant figure, a TWI for inorganic mercury of 4 μg/kg bw, expressed as mercury was established (EFSA CONTAM Panel, 2012).

Using the lowest technologically achievable levels claimed by the applicant (As = 1, Pb = 0.5, Cd = 0.5 and Hg = 0.5 mg/kg) or the values derived by the Panel based on the analytical data provided and a modulation factor of 5 (each element = 0.05 mg/kg) as input, the potential exposure to the toxic elements from the use of the proposed food additive can be estimated by calculation pro-rata to the estimates of exposure to the proposed food additive itself (Table 5).

For this exercise, it must be noted that the proposed specifications for these four elements (Table 1) do not take into account the physical form (liquid or powder) or the acetic acid equivalence (AAE) value of the proposed food additive. Similarly, the analytical data provided for these elements in the five batches of liquid form and the five batches of powder form were for the samples 'as such' and the results were not corrected or normalised for acetic acid equivalency values, which were [redacted] for the liquid form and [redacted] for the powder form. Since the proposed maximum/typical use levels are expressed in terms of acetic acid equivalents (Table 2), and consequently, the estimates of exposure to the proposed food additive (Table 5) are also expressed in AAEs, the form of the additive has to be taken into account for the further calculations here. The worst case would be the additive in liquid form since a higher amount of liquid form would need to be added to achieve the same AAE value in the food compared to adding the powdered form. For example, taking the maximum/typical use level for the first row of Table 2, to achieve a level of 7,500 mg/kg AAEs in the food, the level of addition of liquid form (assuming 17.7% AAEs) would be 42.37 mg/kg whilst the level of addition of powder form (assuming 66.2% AAEs) would be lower at 11.33 mg/kg.

The risk assessment of the undesirable impurities helps inform whether there could be a possible health concern if these impurities would be present at the limit values in the food additive as proposed by the applicant (Table 8) or if the limits were established based on the reported data (Table 9). The Panel emphasised that the choice of the maximum limits for toxic elements in the specifications is in the remit of the risk management. The numbers used here were merely taken to support the risk assessment of these toxic elements as presented below.

Table 8: Risk assessment for toxic elements using the specifications proposed by the applicant based on their lowest technologically achievable levels (documentation provided to EFSA n. 3)

Exposure to proposed additive (mg/kg bw per day)	MOE for As at 1.0 mg/kg	MOE for Pb at 0.5 mg/kg	% of the TWI for Cd at 0.5 mg/kg	% of the TWI for Hg at 0.5 mg/kg
280.3/1,583.6[(a)]	0.189–5.1	0.63	221.7%	138.6%

(a): Highest mean exposure from the proposed maximum/typical use level exposure assessment scenario (children population), being 280.3 mg/kg expressed as AAEs (using results from Table 5 calculated with SAS) and this corresponding to 1583.6 mg/kg of the proposed food additive in liquid form assuming an AAE value of 17.7%.

Table 9: Risk assessment for toxic elements using the analytical data provided by the applicant (documentation provided to EFSA n. 1)

Exposure to proposed additive (mg/kg bw/day)	MOE for As at 0.05 mg/kg	MOE for Pb at 0.05 mg/kg	% of the TWI for Cd at 0.05 mg/kg	% of the TWI for Hg at 0.05 mg/kg
280.3/1,583.6[(a)]	3.789–101.0	6.31	22.2%	13.9%

(a): Highest mean exposure from the proposed maximum/typical use level exposure assessment scenario (children population), being 280.3 mg/kg expressed as AAEs (using results from Table 5 calculated with SAS) and this corresponding to 1,583.6 mg/kg of the proposed food additive in liquid form assuming an AAE value of 17.7%.

When the illustrative calculations assume toxic element levels proposed by the applicant as the lowest technologically achievable levels, the results indicate a safety concern for all four elements with insufficient MOE values for As and Pb and exhaustion of the respective TWI values for Cd and Hg (Table 8).

When the illustrative calculations assume toxic element levels based on the analytical data provided and a modulation factor of 5, the results indicate a safety concern for As that has an insufficient MOE value at the lower end of the calculated range (Table 9).

3.4. Biological and toxicological data

No biological or toxicological data obtained with the proposed food additive were submitted by the applicant as part of the dossier. The applicant provided a justification for not complying with the Tier 1 requirements of the 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) by stating that, following oral ingestion, buffered vinegar dissociates into the acetic anion, a natural constituent of the diet and of the human body for which extensive data on the biological effects exist and for which EFSA has previously concluded that the establishment of an acceptable daily intake (ADI) is not considered necessary (EFSA, 2013). The Panel agreed with the justification provided by the applicant for not undertaking further toxicological testing on buffered vinegar itself.

4. Discussion

In the present opinion, the Panel evaluated the safety of buffered vinegar, proposed for use as a food preservative additive in several food categories at maximum/typical use levels provided by the applicant in the range from 3,000 to 30,000 mg/kg (expressed as acetic acid equivalents). The Panel could not conclude on the safety for the proposed uses at *quantum satis* as Group I food additive since the resulting exposure could not be estimated.

The proposed food additive is a liquid or powder mixture of different constituents prepared by adding buffered agents (the food additives sodium and potassium hydroxides (E 524–525) and/or carbonates (E 500–510)), to vinegar that is compliant with the European Standard EN 13188:2000 and is exclusively obtained from an agricultural source origin (except wood/cellulose). Optionally, citric acid (E 330) may be used to standardise the pH prior to spray drying in the manufacturing of the powder form. The main constituents of the proposed food additive mixture are acetic acid and its salts, ranging from 15–40% w/w acetic acid equivalents in the liquid form to 55–75% w/w in the dried powder form.

The applicant provided analytical data on the content of impurities potentially present in the food additive and proposed limits for the toxic elements (As, Pb, Cd and Hg). The Panel noted that the limits proposed were considerably higher than the analytical data provided. The anticipated impact of the proposed specifications on the potential exposure to those elements would give rise to safety

concern (see Tables 8 and 9). The Panel emphasises that the choice of maximum limits for toxic elements in the specifications is in the remit of risk management.

The Panel performed an exposure assessment to buffered vinegar (expressed as acetic acid equivalents) from its proposed maximum/typical use levels which resulted in a mean dietary exposure ranging from 8.9 mg/kg bw per day in infants to 280.3 mg/kg bw per day in children (Table 5). At the 95th percentile, exposure to buffered vinegar ranged from 27.9 mg/kg bw per day in infants to 1078.2 mg/kg bw per day in toddlers.

The Panel noted that the proposed food additive buffered vinegar may contain up to 30% sodium and this could lead to an additional exposure to sodium from the proposed uses in food.

The main food categories contributing to the total mean exposure estimates were soups and broths (FC 12.5) and bread and rolls (FC 07.1) for all population groups. The Panel considered overall that the uncertainties identified resulted in an overestimation of the exposure to buffered vinegar from its proposed use as a food additive at the maximum/typical use levels. For the safety assessment, the Panel considered it appropriate to use the mean values, noting that there was a high uncertainty around the P95 estimates driven mainly by the results of a single dietary survey, possibly not representative of the entire EU population. Moreover, the Panel noted that the mean values including all the surveys are very similar to the P95 values when that particular single survey is excluded.

No newly generated biological or toxicological data with the proposed food additive buffered vinegar were submitted in support of the current application. The Panel considered that these were not needed in consideration of the nature of the food additive, the starting materials entering the manufacturing process and the fact that the main constituents of the food additive are acetic acid and its salts. In reaching its conclusions, the Panel referred to previous EFSA considerations on acetic acid (EFSA, 2013): '*Based on the widespread presence of acetic acid in human foods, together with the fact that it is a normal metabolite in humans and animals, the establishment of an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) for oral intake of acetic acid by consumers is not considered necessary*'.

Acetic acid is identical to a normal constituent in the body (acetate) and is a regular component of the diet (Bose et al., 2019) and the Panel considered it to be of low intrinsic toxicity.

5. Conclusions

The Panel concluded that there is no safety concern for the use of buffered vinegar as a food additive at the proposed maximum/typical use levels. The Panel could not conclude on the safety for the proposed uses at *quantum satis* as Group I food additive since the resulting exposure could not be estimated.

6. Documentation as provided to EFSA

1) Application for the authorisation of the use of a product called 'buffered vinegar' as a preservative in several food categories of Annex II to Regulation (EC) No 1333/2008. Technical dossier. March 2021. Submitted by Kemin Industries BV and Purac Biochem BV.
2) Additional information submitted by the Kemin Industries BV and Purac Biochem BV following a request from EFSA. November 2021.
3) Additional information submitted by the Kemin Industries BV and Purac Biochem BV following a request from EFSA. April 2022.

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Abbreviations

ADI	Acceptable daily intake
AFC	Panel on Food additives, Flavourings, Processing Aids and Materials in contact with Food
ANS	Panel on Food Additives and Nutrient Sources added to Food
ARfD	Acute Reference Dose
BMDL	Bench Mark Dose (lower confidence interval)
bw	Body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CONTAM	Panel on Contaminants in the Food Chain
ECHA	European Chemicals Agency
FAIM	Food Additives Intake Model
FC	Food category
FCS	Food categorisation system
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
GC	Gas Chromatography
HBGV	Health based guidance value
HPLC	High Pressure Liquid Chromatography
HS-GC	Headspace Gas Chromatography
ICP	Inductively coupled plasma
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LC-HRMS	Liquid Chromatography - High Resolution Mass Spectrometry
MOE	Margin of Safety
MS	Mass Spectometry
OECD	Organisation for Economic Co-operation and Development
qs	quantum satis
RH	Relative humidity
RP	Reference point
SCF	Scientific Committee on Food
TAMC	Total aerobic microbial count
TG	Test Guideline
TWI	Tolerable weekly intake
TYMC	Total yeast & mould count

Appendix A – Detailed exposure estimates

Appendix A can be found in the online version of this output (in the 'Supporting information' section): https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7351#support-information-section

Appendix B – Food categories by population groups

Appendix B can be found in the online version of this output (in the 'Supporting information' section): https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7351#support-information-section