REGULATED PRODUCTS SAFETY ASSESSMENT

Safety Assessment on Product E 401 (Sodium Alginate) Used as a Surface Treatment in Entire Fruits and Vegetables (RP290)

Food Standards Agency[1], Food Standards Scotland[2]

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FSA Research and Evidence

An application was submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) in February 2021 from Bio Natural Solutions – BNS S.A.C. ('the Applicant') for the modification of the conditions of use of sodium alginate (CAS: 9005-38-3), which is an already authorised food additive (E 401), to the surface of entire fresh fruit and vegetables, as a coating to preserve them.

The Applicant intends to extend the use of the sodium alginate (E 401) as a coating material within the food category: 4.1.1 'Entire fresh fruit and vegetables to include citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates' at the level of *quantum satis*.

To support the FSA and FSS in evaluating the dossier the Joint Expert Group on Additives, Enzymes and other regulated products (AEJEG) were asked to review the dossier and the supplementary information from the Applicant. The AEJEG concluded that no risk to health would be presented from this extension of use of E 401 on the basis that the additive was considered of low toxicological concern, as indicated by the European Food Standards Agency's (EFSA) decision that a numerical ADI was not required. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) also reviewed the AEJEG safety assessment agreeing with the conclusions of the AEJEG.

The views of the AEJEG and COT have been taken into account in this safety assessment which represents the opinion of the FSA and FSS on the extension of use of the sodium alginate (E 401) as a coating material in entire fresh fruit and vegetables.

1. Introduction

The FSA and FSS have undertaken a safety assessment for the extension of use of sodium alginate (E 401) as a coating material in entire fresh fruit and vegetables under the common authorisation procedure for food additives,

food enzymes and food flavourings legislation, assimilated Regulation 1331/2008. To support the safety assessment by FSA and FSS, the Joint Expert Group on Additives, Enzymes and other regulated products (AEJEG) provided risk assessment advice to the FSA and FSS outlined in this safety advice document.

The dossier was evaluated in line with Article 3 of assimilated Regulation 1331/2008, and has considered the aspects of the food additive and its modification of use. This, and the guidance put in place by EFSA for food additive applications, has formed the basis and structure for the assessment (EFSA, 2012). This assessment has considered the extension of use of the food additive.

With thanks to the members of the AEJEG who provided advice during the course of the assessment who were: Dr Allain Bueno, Dr Claude Lambré, Dr Martin Rose, Dr Olwenn Martin, Professor Qasim Chaudhry and Dr Claire Stephenson.

Information regarding the identity of the substance including existing and proposed specifications were provided. In addition, information on the manufacturing process, stability of the substance, fate in food, existing authorisations and risk assessments, and biological and toxicological data were provided. This information was considered satisfactory. The Applicant did not provide a dietary exposure assessment for E 401 as they stated that it is 'not expected that sodium alginate would migrate to the internal edible part of the peel, and that due to the specific foods they have listed as part of the application (citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates) the additive would still very unlikely be consumed directly from the peel.'

It was concluded that sufficient information had been provided to allow for an evaluation of the proposal for modification of the conditions of use of sodium alginate to the surface of entire fresh fruit and vegetables, as a coating to preserve them.

Following the final review by the AEJEG in July 2022, the AEJEG advised that no risk to health will be presented from this extension of use of E 401 on the basis that the additive is considered of low toxicological concern, as indicated by EFSA's decision that a numerical ADI was not required.

This document outlines the conclusions of the AEJEG assessment on the safety of the extension of use of the sodium alginate (E 401) as a coating material in entire fresh fruit and vegetables (citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates) at *quantum satis*. Products included in this assessment are shown in Table 1. This assessment was reviewed by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in June 2024.

Table 1. Products included in this assessment

Title	Product type	Intended use/s	Intended dose/ intake
Sodium alginate (E 401)	Surface treatment	Entire fresh fruit and vegetables, specifically citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, and pomegranates	*quantum satis*

2. Assessment

2.1. Identity and characterisation

In nature, alginates are hydrocolloids, occurring as salts that form part of the cell wall of brown algae. These compounds, in calcium, magnesium or sodium salt forms, can represent up to 40% of the dry weight of these organisms (Avendaño-Romero et al., 2013). Alginate occurs as an anionic polyelectrolyte with a backbone of (1–4) linked β-D-mannuronic acid (M units) and α-L-guluronic acid (G units). It can form irregular patterns of GG, MG, and MM blocks. Among the organic salts of alginic acid, sodium alginate has been widely researched as a coating material to preserve fruit and vegetable products and has proven to be effective and safe (Guo et al., 2020; Nair et al., 2020; Senturk Parreidt et al., 2018).

The Applicant has provided information on the main identifiers of monomeric sodium alginate as well as its physiochemical properties (Tables 2 and 3).

Table 2. Sodium alginate main identifiers and descriptors

Identifier	Description
Chemical name (IUPAC)	Sodium 3,4,5,6-tetrahydroxyoxane-2-carboxylat
Chemical structure (monomer)	Image of sodium alginate molecular structure (Figure 1)
Molecular formula	(Monomer) $C_6H_9NaO_7$
Molecular weight	(Monomer) 216.12 g/mol
Synonyms	AI3-19772, Algiline, Algin ,Algin (Laminaria spp. and other kelps), Algin (polysaccharide), Alginate KMF, Alginic acid, sodium salt, Algipon L-1168, Amnucol, Antimigrant C 45, Cecalgine TBV, Cohasal-IH, Darid QH, Dariloid, QH, Duckalgin, FEMA No. 2014, Halltex, HSDB 1909, Kelco Gel LV, Kelcosol, Kelgin, Kelgin F, Kelgin HV, Kelgin LV, Kelgin XL, Kelgum, Kelset, Kelsize, Keltex, Keltone, L'-Algiline, Lamitex, Manucol, Manucol DM, Manucol KMF, Manucol SS/LD2, Manugel F 331, Manutex, Manutex F, Manutex RS 1, Manutex RS-5, Manutex rS1, Manutex SA/KP, Manutex SH/LH, Meypralgin R/LV, Minus, Mosanon, Nouralgine, OG 1, Pectalgine, Proctin, Protacell 8, Protanal, Protatek, Snow algin H, Snow algin L, Snow algin M, Sodium alginate, Sodium polymannuronate, Stipine, Tagat, Tragaya, UNII- C269C4G2ZQ
Raman spectra	An image of the Raman spectra is available from Wiley. *Align Raman Spectrum.* [Online] SpectraBase. Available at: Algin – Optional [Raman] - Spectrum - SpectraBase
CAS Registry Number	9005-38-3

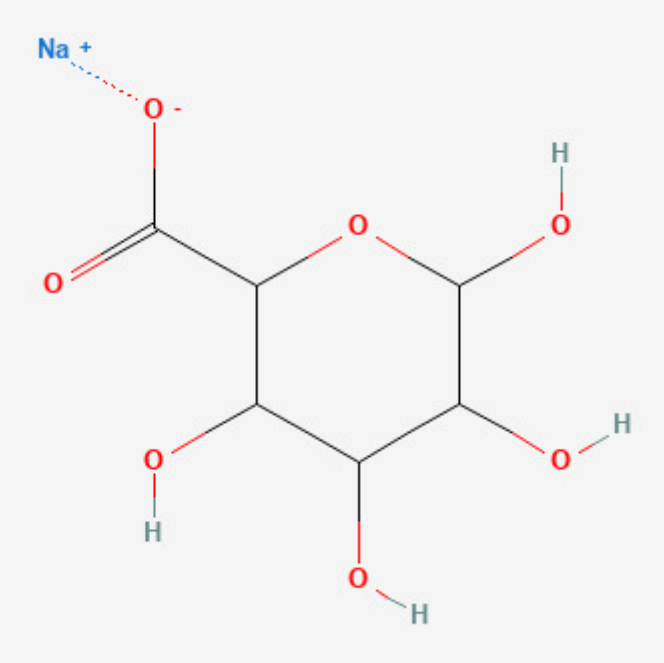

Figure 1. Chemical structure of sodium alginate (monomer).

Source: National Center for Biotechnology Information (2021)

Identifier	Description
E number	E 401
EINECS number	618-415-6

Source: ChemIDPlus, National Library of Medicine

Table 3. Sodium alginate main physicochemical properties

Property	Description
Appearance	Nearly odourless, white to yellowish fibrous or granular powder
Melting point	>300°C
pH	5.5-7.5; 1% aq. sol. (20°C)
Solubility	Dissolves slowly in water, forming a viscous solution; insoluble in ethanol and ether

2.2. Specifications

The specifications for sodium alginate (E 401) are defined in the assimilated Regulation 231/2012 and in the JECFA Combined Compendium of Food Additive Specifications (Joint FAO/WHO expert Committee on Food Additives, 2006).

2.3. Manufacturing process

The Applicant stated that the process of obtaining sodium alginate involves extraction from natural raw material (brown algae) to synthesis using chemical methods. The process begins with the extraction of the alginate salts in the algae with a hot solution of sodium carbonate (alkali). From the

previous extraction process, an aqueous substance that contains cellulose results. This solution is diluted, and diatomaceous earth is added to facilitate cellulose separation by filtration. The next step is precipitation of alginic acid or calcium alginate by adding an acid or calcium chloride. Both precipitates are used for the synthesis of sodium alginate by adding sodium carbonate (FAO, 2021).

With regards to the additive relative to this application, the Applicant stated that manufacture of the consumed additive is carried out by a 'world-renowned company such as Kimica Corporation' (Japan origin – Global Kimica website). The Applicant provided the technical specifications for the AEJEGs consideration.

They further stated that the additive is purchased through a distribution following quality protocols, by the company Bio Natural Solutions SAC with manufacture of coatings in Peru and with R&D headquarters in the United Kingdom as BNS Worldwide LTD. The production of the coating complies with all the protocols of Good Manufacturing Practices through physical processes of mixing the sodium alginate in water and subsequent homogenisation with the other declared inputs, in a single line for this purpose.

The AEJEG was satisfied that the specifications of E 401 relevant to the current application were compliant with assimilated Regulation 231/2012.

The Committee on Toxicity noted that commercial sodium alginate is a polymer, with a typical average molecular weight of 10,000 - 600,000 (JECFA, 2006)).

2.4. Methods of analysis in food

The Applicant stated that HPLC is commonly used when developing methods for the analysis of sodium alginate in food. Kim *et al*. (2006) describes an HPLC method using an MCI gel column and deionised water as mobile phase. Separation of sodium alginate was achieved within 15 minutes. Correlation for the standard curve was higher than 0.999 in the 0.1%-2% range, with a limit of detection of 0.005%. This methodology was successfully used in sodium alginate analysis of cereals, chocolate and kelp.

2.5. Composition of the coating mixture

The Applicant provided confidential information regarding the composition of the coating. The AEJEG were satisfied with the information received on the composition of the natural coating mixture used.

2.6. Mode of application of the coating

The form of application in fresh fruits is by spraying a dose of 1 litre of coating per tonne of fruit, that is 1 ml of coating for each kg of fruit treated.

2.7. Case of need

The Applicant provided an overview of the technological need for the use of sodium alginate (E 401) as a coating agent in certain fruits and vegetables. They stated that the additive acts as a film-forming agent that is applied to the surface of fruits and vegetables, which acts as a physical barrier to oxygen and moisture, reducing transpiration and respiration of those fruits and vegetables. As a result, physiological degradation reactions are reduced, which helps to preserve the post-harvest and nutritional quality of fruits and vegetables. Therefore, the edible film allows a better and more durable preservation of those fruits and vegetables and ultimately reduces food waste. The use of sodium alginate (E 401) as a covering agent helps to maintain quality of fresh fruit and vegetables post-harvest prior to consumption by increasing the shelf-life, thus facilitating the availability and increasing the access to market of fresh fruit and vegetables.

2.8. Research on sodium alginate-based coatings for fruits and vegetables

The Applicant listed a number of studies where surface treatment with sodium alginate has been used, as a matrix to apply active ingredients, in order to prevent phytopathogens, preserve the organoleptic properties of foods (e.g. in cinnamon), protect bioactive compounds and prevent water loss in sweet cherries, mangoes, strawberries and cantaloupes and also as a 'suitable material for nanotechnology applied to postharvest horticultural products'. In these studies, sodium alginate had been used either alone or in a mixture at levels ranging from 1% to 5%.

Based on the data presented in this section, the Applicant noted that 'Scientific literature shows the viability of sodium alginate as an effective, ecological and innocuous material for the post-harvest treatment of horticultural products. Formulations with the best effects contain a concentration between 1%-3% sodium alginate, commonly added with another active compound of natural origin. For this reason, the coating made from sodium alginate is intended for external treatment as a surface protector for citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranate because it is not expected to migrate to the internal edible part of the fruit. The treatment on fruits of which the peels are usually not consumed is not likely to have an effect on human health.'

Finally, the Applicant noted that the coating would improve the conservation conditions of fruits by improving the quality of imported agricultural products, lead to food loss reduction and that natural products such as sodium alginate from a renewable source are encouraged.

2.9. Existing Authorisations and Risk Assessments

Sodium alginate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1993) with an acceptable daily intake (ADI) 'not specified'. Following an evaluation of sodium alginate in 1994 by the Scientific Committee for Food (SCF, 1994) they adopted the JECFA provision for an unspecified ADI (section 3.3 in SCF (1994)). This was based on the fact that sodium alginate and its salts were found to be not digested, staying intact, and therefore not absorbed. No adverse effects were observed in a subchronic study in rodents at 13,500 mg/kg bw/d of sodium alginate (no further details on species/duration of study were provided by the Applicant) and there were no concerns over the genotoxicity or carcinogenicity of sodium alginate (tested up to 37,500 mg/kg bw/d in mice) (SCF, 1994).

In 2017, the EFSA ANS Panel re-evaluated alginic acid and its sodium, potassium, ammonium and calcium salts (E 400–E 404) when used as food additives. The Panel concluded that there was no need for a numerical ADI for alginic acid and its salts (E 400, E 401, E 402, E 403 and E 404), and that there was no safety concern at the level of the refined exposure assessment for the reported uses of alginic acid and its salts (E 400, E 401, E 402, E 403 and E 404) as food additives (EFSA ANS Panel, 2017).

The FEEDAP panel (EFSA panel on additives and products or substances used in animal feed) also concluded that there was no need for an ADI for alginic acid and its salts (EFSA FEEDAP Panel, 2017).

Alginates are currently listed as 'allowed synthetics' in section 205.605 (b) in the USDA organic regulations (USDA National Organic Program, 2014). Alginates do not appear in the Organic Food Production Act.

Other approvals include:

The Canadian Organic Regime (alginates (alginic acid, sodium alginate, and potassium alginate)) in the section titled 'Non-Organic Ingredients Classified as Food Additives', of the Systems Allowed Substances List. of organic production (Canadian General Standards Board, 2011).

- Codex Alimentarius Commission (2014): Only potassium (E 402) and sodium (E 401) alginates are listed as permitted food additives in Table 3.1 as an ingredient of non-agricultural origin in the Commission's Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.
- EC No 834/2007 and 889/2008: Alginates (E 401-E 405) are included in the list of food additives allowed for use as thickeners and stabilizers (E 400 –E 499). Alginates are classified as non-agricultural in the EU Organic Regulations (assimilated Regulation No 889/2008). Sodium alginate (E 401) is listed as an approved food additive for use in certain raw fruits and vegetables in an amendment to Annex II of Commission Regulation (EC) No 969/ 2014.
- The Japan Agricultural Standard (JAS) for organic processed foods identifies sodium alginate as a limited permitted food additive for use only in processed foods of plant origin, INS number 401 (The Japanese Organic Standard, 2005).
- The International Federation of Organic Agriculture Movements recognises sodium and potassium alginate as approved additives for use in processed organic products without annotation (IFOAM, 2014).

2.10. Proposed Use Levels

Currently, sodium alginate (E 401) is approved for use in food in a number of food categories. The Applicant has provided information on the current authorisations and the Maximum Permitted Levels (MPLs), per assimilated Regulation 1333/2008 shown in Table 4:

Table 4. MPLs of sodium alginate (E 401) in foods

Foodstuff	Individual restriction(s)
(1.6.1) Unflavoured pasteurised cream (excluding reduced fat creams)	*quantum satis*
(4.1.2) Peeled, cut and shredded fruit and vegetables	ML = 2400mg/kg, only pre-packaged refrigerated unprocessed fruit and vegetables ready for consumption, to be sold to the final consumer
(8.2) Meat preparations	*quantum satis*, only preparations in which ingredients have been injected; meat preparations composed of meat parts that have been handled differently: minced, sliced or processed and that are combined together
(13.1.3) Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	ML = 500 mg/kg, only desserts and puddings
(13.1.5.1) Dietary foods for infants for special medical purposes and special formulae for infants	ML = 1000 mg/kg, from four months onwards in special food products with adapted composition, required for metabolic disorders and for general tube-feeding

Foodstuff	Individual restriction(s)
(13.1.5.2) Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	

ML: maximum permitted level.

The Applicant noted that when used as a coating material for an edible surface treatment of fresh fruit, E 401 prevents moisture loss, which in turn protects the quality, extends the shelf life and ultimately reduced food waste.

Additional current authorisations and the Maximum Permitted Levels (MPLs), per assimilated law Regulation (EC) No 1333/2008 have been presented below in Table 5.

Table 5. Authorised MPLs of sodium alginate (E 401) in foods according to the Annex II to assimilated law Regulation (EC) No 1333/2008

Foodstuff	Individual restriction(s)
(1.3) Unflavoured fermented milk products, heat-treated after fermentation	*quantum satis*
(1.4) Flavoured fermented milk products including heat-treated products	*quantum satis*
(1.6.3) Other creams	*quantum satis*
(1.7.1) Unripened cheese excluding products falling in category 16	Except mozzarella *quantum satis*
(1.7.5) Processed cheese	*quantum satis*
(1.7.6) Cheese products (excluding products falling in category 16)	*quantum satis*
(1.8) Dairy analogues, including beverage whiteners	*quantum satis*
(2.2.2) Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/ 2007 and liquid emulsions	*quantum satis*
(2.3) Vegetable oil pan spray	*quantum satis*
(3) Edible ices	*quantum satis*
(4.2.1) Dried fruit and vegetables	*quantum satis*
(4.2.2) Fruit and vegetables in vinegar, oil, or brine	*quantum satis*
(4.2.4.1) Fruit and vegetable preparations excluding compote	*quantum satis*
(4.2.5.2) Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC	ML = 10,000 mg/kg, Maximum individually or in combination with E 400–E 404, E 406, E 407, E 410, E 412, E 415 and E 418

Foodstuff	Individual restriction(s)
(4.2.5.3) Other similar fruit or vegetable spreads	ML = 10,000 mg/kg, Maximum individually or in combination with E 400–E 404, E 406, E 407, E 410, E 412, E 415 and E 418
(4.2.5.4) Nut butters and nut spreads	*quantum satis*
(4.2.6) Processed potato products	*quantum satis*
(5.1) Cocoa and chocolate products as covered by Directive 2000/36/EC	Only energy reduced or with no added sugar. *quantum satis*
(5.2) Other confectionery including breath-freshening microsweets	E 401 may not be used in jelly mini-cups, defined, for the purpose of this Regulation, as jelly confectionery of a firm consistence, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cups or mini-capsule to project the confectionery into the mouth. *quantum satis*
(5.3) Chewing gum	*quantum satis*
(5.4) Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	*quantum satis*
(6.2.2) Starches	*quantum satis*
(6.3) Breakfast cereals	*quantum satis*
(6.4.2) Dry pasta	Only gluten-free pasta and/or pasta intended for hypoproteic diets in accordance with Directive2009/39/EC *quantum satis*
(6.4.4) Potato gnocchi	Except fresh refrigerated potato gnocchi *quantum satis*
(6.4.5) Fillings of stuffed pasta (ravioli and similar)	*quantum satis*
(6.5) Noodles	*quantum satis*
(6.6) Batters	*quantum satis*
(6.7) Pre-cooked or processed cereals	*quantum satis*
(7.1) Bread and rolls	Except products in 7.1.1 and 7.1.2 *quantum satis*
(7.2) Fine bakery wares	*quantum satis*
(8.3.1) Non-heat-treated meat products	*quantum satis*
(8.3.2) Heat-treated meat products	Except *foie gras, foie gras entier, blocs de foie gras*[(b)], *Libamáj, libamáj egészben, libamáj tömbbe*[(c)] *quantum satis*
(8.3.3) Casings and coatings and decorations for meat	*quantum satis*
(9.2) Processed fish and fishery products including molluscs and crustaceans	*quantum satis*
(9.3) Fish roe	Only processed fish roe *quantum satis*
(10.2) Processed eggs and egg products	*quantum satis*
(11.2) Other sugars and syrups	*quantum satis*
(12.1.2) Salt substitutes	*quantum satis*

Foodstuff	Individual restriction(s)
(12.2.2) Seasonings and condiments	*quantum satis*
(12.3) Vinegars	*quantum satis*
(12.4) Mustard	*quantum satis*
(12.5) Soups and broths	*quantum satis*
(12.6) Sauces	*quantum satis*
(12.7) Salads and savoury-based sandwich spreads	*quantum satis*
(12.8) Yeast and yeast products	*quantum satis*
(12.9) Protein products, excluding products covered in category1.8	*quantum satis*
(13.2) Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	*quantum satis*
(13.3) Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	*quantum satis*
(13.4) Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	Including dry pasta *quantum satis*
(14.1.2) Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Only vegetable juices *quantum satis*
(14.1.3) Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Only vegetable nectars *quantum satis*
(14.1.4) Flavoured drinks	*quantum satis*
(14.1.5.2) Other	Excluding unflavoured leaf tea; including flavoured instant coffee *quantum satis*
(14.2.3) Cider and perry	*quantum satis*
(14.2.4) Fruit wine and made wine	*quantum satis*
(14.2.5) Mead	*quantum satis*
(14.2.6) Spirit drinks as defined in Regulation (EC) No 110/2008	Except whisky or whiskey *quantum satis*
(14.2.7.1) Aromatised wines	*quantum satis*
(14.2.7.2) Aromatised wine-based drinks	*quantum satis*
(14.2.7.3) Aromatised wine-product cocktails	*quantum satis*
(14.2.8) Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits	*quantum satis*

Foodstuff	Individual restriction(s)
with less than 15% of alcohol	
(15.1) Potato-, cereal-, flour- or starch-based snacks	*quantum satis*
(15.2) Processed nuts	*quantum satis*
(16) Desserts excluding products covered in category 1, 3 and 4	*quantum satis*
(17.1) [(a)] Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	*quantum satis*
(17.2) [(a)] Food supplements supplied in a liquid form	*quantum satis*
(17.3) [(a)] Food supplements supplied in a syrup-type or chewable form	*quantum satis*
(18) Processed foods not covered by categories 1–17, excluding foods for infants and young children	*quantum satis*

ML: maximum permitted level.
(a): FCS 17 refers to food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children.
(b): French to English translation: Duck or Goose liver, duck or goose liver whole, duck or goose liver in blocks
(c): Hungarian to English translation: Goose liver, goose liver whole, goose liver in blocks

The Applicant requested the extension of use of sodium alginate (E 401) to the category of food category 4.1.1 (entire fresh fruits and vegetables) and specifically on: citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates at levels of *quantum satis.*

2.11. Dietary exposure assessment

The Applicant did not provide an exposure assessment. They stated that it was 'not expected that sodium alginate would migrate to the internal edible part of the peel, and that due to the specific foods they have listed as part of the application (citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates) the additive would still very unlikely be consumed directly from the peel.'

For context, the AEJEG considered the evidence presented in the EFSA 2017 Opinion on the level of exposure from food: 'In the maximum level exposure assessment scenario, mean exposure from alginic acid and its salts (E 400–E 404) from their use as food additives ranged from 35.1 mg/kg bw per day in the elderly to 300.3 mg/kg bw per day in toddlers. The 95th percentile of exposure from alginic acid and its salts (E 400–E 404) ranged from 66.1 mg/kg bw per day in elderly to 388.6 mg/kg bw per day in children. In the refined estimated exposure scenarios, in the brand-loyal scenario, mean exposure from alginic acid and its salts (E 400–E 404) from

their use as food additives ranged from 11.1 mg/kg bw per day in infants to 192.0 mg/kg bw per day in toddlers. The high 95th percentile exposure from alginic acid and its salts (E 400–E 404) ranged from 31.2 mg/kg bw per day in elderly to 276.7 mg/kg bw per day in infants.'

The AEJEG also considered the evidence presented in the EFSA 2017 Opinion on the level of exposure from other sources: 'Alginic acid and its salts are used as active ingredients or excipients in pharmaceutical products (e.g. Martindale, 2014). As active ingredients alginic acid, magnesium alginate and sodium alginate are given, sometimes formulated in combination with carbonates and other antacids (aluminium hydroxide), in the management of gastroesophageal reflux disease (GERD). Alginic acid or its salts react with gastric acid to form a viscous gel acting as mechanical barrier to reduce reflux of gastric content (Kapadia & Mane, 2007; Mandel et al., 2000; Martindale, 2014; Reimer et al., 2016). In medicinal products, the adult single dosages for sodium alginate is 500–1000 mg, given up to four times daily and for alginic acid it is 300 mg, given up to six times daily. Alginic acids and its salts are used as excipients such as suspending and thickening agents, stabilisers for oil-in-water emulsions and as binding and disintegrating agents (Martindale, 2014).'

The AEJEG considered that both EFSA and JECFA concluded that there was no need for a numerical ADI for sodium alginate (E 401). Furthermore, the AEJEG considered the use of sodium alginate as a fruit coating as of low toxicological concern, and especially in categories of fruit where the peel would unlikely be consumed (or only consumed minimally in cases of use in food such as baking), and considering the information contained within the 2017 EFSA Opinion, on balance they did not find the lack of an exposure assessment problematic, as exposure from the proposed application would not contribute significantly to the existing exposures.

The COT noted that gastroesophageal reflux disease should be abbreviated to GORD and not GERD as used in the quoted EFSA Opinion above (EFSA ANS Panel, 2017).

2.12. Biological and Toxicological Data

2.12.1. Absorption, distribution, metabolism and excretion

The Applicant presented a study by Nakamura *et al*. (1988), studying the disposition of alginate salts and their effect on serum concentrations of Na, K and Ca. A single dose of alginate salt (Na, K or Ca) was administered orally to rats (at 90.4 mg/kg). No significant differences were observed in the faecal excretion or alginate content pattern in the gastrointestinal tract as a function of time as 72.7 to 79.3% of the administered alginates were excreted in the faeces in 3 days, alginates remained in the stomach for 2

hours, moving to the small intestine after 4 hours and eventually moving to the large intestine after 8 hours, remaining there after 24 hours. Finally, administration of the alginates did not affect Na, K and Ca serum levels.

The Applicant also presented a human study by Anderson *et al*. (1991). Five male volunteers were administered sodium alginate at 175 mg/kg bw per day for 7 days, followed by consumption of 200 mg of sodium alginate/ kg bw/d for 16 days. Sodium alginate acted as a faecal bulking agent in the volunteers, leading to a significant increase ($p<0.01$) in daily faecal wet weight, increase in water content and daily dry weight. No changes in faecal pH were observed and no significant effects on haematological indices, plasma biochemical parameters, urinalysis parameters, blood glucose and plasma insulin concentrations, or hydrogen concentrations in breath were observed. There were no allergic responses. Although the dietary transit time remained constant for two volunteers, it decreased for two and increased slightly for one, with little resulting change in the overall mean value.

Based on this information the Applicant concluded that the study indicates that ingesting sodium alginate at a high level for 23 days did not cause effects other than those normally associated with a polysaccharide bulking agent; in particular, enzyme indicators and other sensitive indicators of adverse toxicological effects were unchanged.

2.13. Applicant's overall conclusions on safety

The Applicant concluded that based on their own analytical data, external data and the current EU categorization of sodium alginate on peeled, cut and shredded fruit and vegetables, there will be no risk to human health with the inclusion of this additive to the proposed 'entire fresh fruit and vegetables' category as a surface treatment. Furthermore, due to the specific foods they have listed as a part of this application, they considered it very unlikely the additive will be directly consumed from the peel.

2.14. AEJEG Conclusions

The AEJEG has considered the application using the key information presented above.

The AEJEG acknowledged the lack of an exposure assessment related to this application, however they considered that the use of sodium alginate as a coating for fruit was of low toxicological concern, and especially in categories of fruit where the peel would unlikely be consumed (or only consumed minimally in cases of use in food such as baking), on balance they did not find the lack of an exposure assessment problematic.

Overall, the AEJEG recognised the safe history of use of E 401 within the EU and other countries. The AEJEG recognised that a number of scientific bodies, including JEFCA and EFSA have established an ADI not specified for the additive E 401, due to lack of toxicological concerns. The AEJEG concurred with this and considered the extension of use of sodium alginate for the surface coating of fruits and vegetables (specifically fresh citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates) as described in this Application to be safe under the proposed conditions of use and to be of low toxicological concern.

3. Conclusions

To support the FSA and FSS in evaluating the dossier, the AEJEG were asked to review the dossier submitted by the Applicant and the subsequent additional information requested and advise the FSA and FSS.

The COT also reviewed the AEJEG advice and agreed with their conclusions.

The FSA and FSS agreed on the conclusions of the AEJEG in that the extension of use of the sodium alginate (E 401) as a coating material in entire fresh fruit and vegetables (citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates) at *quantum satis* is safe under the proposed conditions of use.

The AEJEG advised the FSA and FSS that sufficient information had been provided to allow for an evaluation of the proposal for the modification of the conditions of use of sodium alginate to the surface of entire fresh fruit and vegetables as a coating to preserve them, there were no concerns over safety of the proposed extension of use.

The FSA and FSS therefore concluded in this assessment that the extension of use of the sodium alginate (E 401) as a coating material in entire fresh fruit and vegetables (citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, pomegranates) as described within this application would not pose a risk to health. Therefore, there were no concerns over safety of the proposed extension of use.

Abbreviations

AEJEG	Joint Expert Group on Additives, Enzymes and other Regulated Products
ADI	Acceptable daily intake
ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
Ca	Calcium
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

AEJEG	Joint Expert Group on Additives, Enzymes and other Regulated Products
EFSA	European Food Safety Authority
EFSA ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
EFSA FEEDAP	EFSA Panel on Additives and Products or Substances used in Animals Feed
EU	European Union
E 401	Sodium alginate
FSA	Food Standards Agency
FSS	Food Standards Scotland
G units	α-L-guluronic acid
GERD	gastroesophageal reflux disease
GORD	High Performance Liquid Chromatography
HPLC	High Performance Liquid Chromatography
JAS	Japan Agricultural Standard
JECFA	Joint FAO/WHO Expert Committee on Food Additives
K	Potassium
Kg	Kilogram
M units	β-D-mannuronic acid
MCI	Mitsubishi Chemical Ion
ML	Maximum Permitted Level
ml	Millilitre
mg	Milligram
mg/kg	Milligram per kilogram
mg/kg bw/d	Milligram per kilogram bodyweight per day
MPLs	Maximum Permitted Levels
Na	Sodium
SCF	Scientific Committee for Food

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