REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment of the Novel Food D-tagatose for a Change to the Conditions of Use (RP1652)

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

[1] Regulated Products Risk Assessment, Food Standards Agency, UK, [2] Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application from Bonumose, Inc., U.S.A ("the applicant") for a change to the conditions of use of D-tagatose as a novel food to each nation of Great Britain in July 2022.

D-tagatose was first authorised in 2005 following an application pursuant to Regulation (EC) No. 258/97 Article 4.2 applicable to the UK (and EU) and is currently authorised as a novel food in Great Britain (GB) under assimilated Commission Regulation (EU) 2017/2470. The novel food is an epimer of fructose and a sugar monosaccharide, with 75-92% the sweetness of sucrose "table sugar". D-tagatose is produced via enzymatic conversion followed by purification to obtain a dried crystalline product. This application seeks to modify the conditions of use to permit a new novel food source, maltodextrin, and a modified enzymatic conversion production method. The applicant seeks to amend the specifications and include additional labelling options to use "tagatose" as a name of the novel food in the specified labelling for its authorisation.

The FSA and FSS in their evaluation of the application reviewed the safety dossier and supplementary information provided by the applicant. The FSA and FSS did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the change in the conditions of use to extend the food is safe, and not putting consumers at a nutritional disadvantage.

The FSA and FSS concluded that the applicant had provided sufficient information to assure that the change in the conditions of use for D-tagatose in its production is safe under the intended conditions of use.

The safety assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.

1. Introduction

The FSA and FSS have undertaken the safety assessment of the change to the condition of use for D-tagatose under the novel foods legislation, assimilated Regulation (EU) 2015/2283.

D-tagatose is an authorised novel food in the UK under assimilated Commission Regulation (EU) 2017/2470. It was originally authorised in December 2005, following an application pursuant to Regulation (EC) No. 258/97 Article 4.2 from Bioresco Ltd, on behalf of Arla Food Ingredients (Denmark). An opinion by the UK Competent Authority Member State produced by the Advisory Committee for Novel Foods and Processes (ACNFP) was adopted without objections from the European Commission (EC) and its EU Member States (FSA, ACNFP 2005).

In accordance with the assimilated List of Novel Foods, D-tagatose is authorised for production by isomerisation of galactose (chemical or enzymatic conversion) or by epimerisation of fructose. The original 2005 application from Bioresco Ltd, on behalf of Arla Food Ingredients (Denmark) had specified intended uses in several food and drinks categories, including as a tabletop sweetener for the general population (> 2 years of age). These uses, use levels and estimated intakes were assessed by the ACNFP (FSA, ACNFP 2005). However, the EU/UK authorisation, did not adopt specified use categories, use levels or a target population.

Two substantial equivalence authorisations from a separate applicant (CJ CheilJedang Corporation of South Korea) resulted in an update to the UK and EU applicable authorisation for D-tagatose for the production process for D-tagatose in 2011 and in 2017. This followed an opinion by the Food Safety Authority of Ireland (FSAI) (FSAI, 2011, 2017). This further permitted an additional novel food source (fructose) and the production methods for enzymatic conversion of galactose and epimerisation of fructose.

The evaluation by the FSA and FSS assessed the food safety risks of the novel food and its production, in line with Article 11 of assimilated Regulation (EU) 2015/2283 and Article 7 of assimilated Commission

Implementing Regulation (EU) 2017/2469. The basis and structure of the assessment was conducted in accordance with the relevant technical guidance put in place by the European Food Safety Authority (EFSA) for full novel food applications (EFSA NDA Panel, 2016) which the FSA and FSS considers is relevant and should be applied to this novel food application owing to similarities in the regulatory regimes.

Under Article 3(4) of assimilated Commission Implementing Regulation (EU) 2017/2469, it may not be necessary for the applicant to provide all the data required under Article 5 of this Regulation when a novel food application seeks to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food. Verifiable justification explaining that the intended changes do not affect the results of the existing safety assessment is provided by the applicant. Given that the novel food is identical to the D-tagatose reviewed in the previous assessment, this new safety assessment has focused on the impact of the intended changes to the conditions of use for D-tagatose.

The information set out in this FSA-FSS opinion concerning the identity of the novel food, the production process, the compositional information, stability, specification, history of use, and allergenicity was provided by the applicant in the change to conditions of use novel food application. The opinion is focused with respect to the areas that were applicable to safety assessment of the proposed changes.

This assessment outlines the conclusions of the FSA and FSS on the change in the conditions of use for D-tagatose to include maltodextrin as a new novel food source, use of a modified enzymatic conversion production method and to update the specified labelling to include “tagatose” in its authorisation.

This represents the opinion of the FSA and FSS.

2. Assessment

2.1. Identity of the novel food

D-tagatose is a six-carbon monosaccharide ketohexose carbohydrate. Synonyms include tagatose, D-lyxo-hexulose, α-D-tagatose and it is often referred to as a rare sugar. The novel food (see Figure 1) is a C-4 epimer of D-fructose and isomer of D-galactose; it is water soluble and of a white or an almost white crystalline structure.

D-tagatose has a novel food classification as a chemical substance and is characterised by the following information:

- IUPAC name:
  (3S,4S,5R)-2-(hydroxymethyl)oxane-2,3,4,5-tetrol
- Chemical Formula: $C_6H_{12}O_6$
- CAS number: 87-81-0
- Molecular weight: 180.16 g/mol

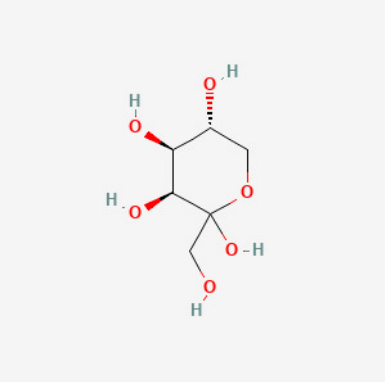

Figure 1. The structural formula of D-tagatose (NCBI, 2024)

The structure and identity of the novel food was confirmed using five batches of the high purity dry crystalline product, against a published monograph reference standard using FT-IR spectroscopy (Fourier transform infrared).

High-performance liquid chromatography - refractive index detector (HPLC-RID) was used to categorise the D-tagatose monosaccharides (and remaining trace D-fructose components) in five batches of the novel food.

This application proposes that D-tagatose is to be produced from maltodextrin as a new novel food source. The applicant had provided sufficient information in accordance with the novel food classification "food consisting of, isolated from or produced from plants or their parts" to characterise the identity of the raw maltodextrin ingredient plant source. These sources include maize, potato and pea.

There is no change to the identity of the novel food as currently defined in the List of Novel Foods (assimilated Commission Implementing Regulation (EU) 2017/2470).

2.1.1. Production process

The amended production process involves the synthesis of D-tagatose from maltodextrin via an enzymatic reaction with a series of purification steps and final drying to produce a crystalline product.

The first stage of the production process involves solubilisation of powdered food grade maltodextrin into a syrup which undergoes pasteurisation, flocculation, and UV treatment. Biotransformation of maltodextrin into D-tagatose takes place using a cascade of 7 immobilised enzymes. Details on these enzymes were provided by the applicant which included characterisation, purity and production. This included sufficient information in line with EFSA's Guidance on the risk assessment of genetically modified organisms and their products intended for food and feed use (EFSA Panel on Genetically Modified Organisms (GMO), 2011). The 6 out of 7 enzymes are produced from a food safe genetically modified microorganism (GMM) strain which is non-pathogenic. The seventh enzyme is not a product of genetic modification. No new hazards were identified from the use of these specified enzymes in the production of D-tagatose.

The following stages of the production process involves a series of purification steps in addition to final drying into crystalline form. Purification involves removing contaminants such as minerals, ions, salts, microbes, potential residual enzyme or residual DNA from the enzyme source, and as well as any saccharide impurities. These steps include ultrafiltration, ion exchange, simulated moving bed chromatography and UV treatment.

D-tagatose is currently permitted for production using the raw materials fructose or galactose for enzymatic conversion. The enzymatic conversion methods in previous applications are similar to the current application. The current application seeks a comparable production method but utilising maltodextrin and differences in the processing steps involved, such as a different mix of immobilised enzymes.

Information on the acceptance criteria for the raw materials and processing aids was provided.

The novel food is produced in line with Hazard Analysis and Critical Control Point (HACCP) principles. The manufacturing facility complies with GMP (Good Manufacturing Practice).

The production process has characterised the potential hazards and the corresponding control measures are appropriate. The compositional data detailed below further demonstrated that these measures are effective. The changes to the production process did not raise safety concerns.

2.1.2. Compositional information

The novel food is produced by enzymatic conversion of maltodextrin resulting in a purified dried crystalline of ≥99.3% purity with a trace amount of D-fructose as the remaining component. Commercial scale data for crystalline D-tagatose was provided (Tables 1-11). The results are grouped according to the independent batches tested.

Table 1. Compositional analysis of D-tagatose: purity, proximate analysis, particle size and colour

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
D-tagatose purity (dry matter) (%) - HPLC	≥98	99.3	99.3	99.4	99.5	99.5
Moisture (%)	--	0.057	0.035	0.049	0.07	0.134
Ash (%)	--	0.01	0.00	0.00	0.00	0.00
Particle size (µm)	--	237	414	491	382	439
Colour (ICUMSA units)	--	40	5	8	20	12
Test parameter	**Specification**	**Batch 6**	**Batch 7**	**Batch 8**	**Batch 9**	**Batch 10**
Protein (µg/mL) - Bradford	--	0	0	0	0	0
Test parameter	**Specification**	**Batch 11**	**Batch 12**	**Batch 13**	**Batch 14**	**Batch 15**
Loss on drying (%) 102°C, 2 hours	≤0.5	0.10	0.11	0.14	0.31	0.29

ICUMSA = International Commission for Uniform Methods of Sugar Analysis; HPLC= High-performance liquid chromatography.

As shown in Table 1, the purity of the novel food (99.4% mean value) complies with the specifications (≥98%) and demonstrates a high purity product. With regards to the proximate analysis, the loss on drying is within specifications and there is no detectable protein in the novel food. The particle size analysis confirms that the novel food is non-nano.

Table 2. Compositional analysis of D-tagatose: D-fructose impurity

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6
D-fructose (ppm)	--	16.18	5.03	9.01	10.56	3.35	7.68

ppm = parts per million.

It was noted that the current authorisation permits galactose or fructose as the starting ingredient which may result in either D-galactose or D-fructose saccharide impurities in trace amounts. The compositional data in Table 2 shows that a trace level of D-fructose (≤16.18 ppm) can be expected in the novel food.

Table 3. Compositional analysis of D-tagatose: physicochemical (specific rotation, & melting range)

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6	Batch 7
Melting range (°C)	128-137	129.5	129.7	130.4	131.6	130.6	NT	NT
Test parameter	**Specification**	**Batch 8**	**Batch 9**	**Batch 10**	**Batch 11**	**Batch 12**	**Batch 13**	**Batch 14**
Optical (specific) rotation [α]D 20 (°) 1 % aqueous solution (1)	– 4 to – 5.6	-4.5	-5.4	-5.382	-5.012	-4.930	-5.272	-5.236

NT= not tested.

As shown in Table 3, the melting range was below the current specification (133-137°C) ranging between 129.7 and 131.6°C. The change was attributed to the change in production method starting material resulting in a minor increase to the level of D-fructose as a trace component of the novel food (mean value 8.67 ppm). The applicant subsequently sought an amendment to the specification as detailed in the specifications section below.

Table 4. Compositional analysis of D-tagatose: solubility

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Water solubility (g/L)	--	>1000	>1000	>1000	>1000	>1000
Ethanol solubility (g/L)	--	<1	<1	<1	<1	<1

As shown in Table 4, D-tagatose is highly soluble in water and has low solubility in ethanol.

Table 5. Compositional analysis of D-tagatose: heavy metals

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Arsenic (mg/kg)	--	0.0194	0.0178	0.100	0.00912	0.100
Lead (mg/kg) (AOAC 2013.06 modified, ICP-MS) –	≤1.0	0.0194	0.0178	0.100	0.01824	0.100

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Cadmium (mg/kg)	--	0.0194	0.0178	0.100	0.01824	0.100
Mercury (mg/kg)	--	0.00972	0.00888	0.050	0.01824	0.500
Test Parameter	**Specification**	**Batch 6**	**Batch 7**	**Batch 8**	**Batch 9**	**Batch 10**
Lead (mg/kg) (USP 233, ICP-MS)	≤1.0	0.015	0.018	0.013	0.041	0.015

AOAC = Association of Official Analytical Chemists; ICP-MS= Inductively coupled plasma-mass spectrometry; USP = US Pharmacopeia.

The heavy metal analysis confirmed that the levels are within limits and do not pose a safety concern (Table 5). The List of Novel Foods authorisation (retained under assimilated regulation 2017/2470) specifies that the determination of lead should utilise an appropriate atomic absorption technique. The applicant had provided justification for two separate ICP-MS methods and had indicated that the atomic absorption spectrophotometric graphite furnace method as indicated in in the Food Chemicals Codex (FCC) monograph for lead was no longer available. The FSA and FSS were satisfied that the chosen ICP-MS methods are appropriate for the determination of lead impurities.

Table 6. Compositional analysis of D-tagatose: microbiological

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Coliforms (cfu/g)	--	<10	<10	<10	<10	<10
Salmonella (cfu/25 g)	--	Not detected	Not detected	Not detected	Not detected	Not detected
Total aerobic plate count (cfu/g)	--	<10	<10	<30	<10	<10
Yeast (cfu/g)	--	<10	<10	<10	<10	<10
Mould (cfu/g)	--	<10	<10	<10	<10	<10
Escherichia coli (cfu/1g)	--	Not detected	Not detected	Not detected	Not detected	Not detected

Cfu = colony forming unit.

Table 7. Compositional analysis of D-tagatose: microbiological (*Escherichia coli*)

Test parameter	Specification	Batch 1	Batch 2	Batch 3
Escherichia coli (cfu/g)	--	Not detected	Not detected	Not detected

Cfu = colony forming unit.

Table 8. Compositional analysis of D-tagatose: microbiological (endotoxins)

Test parameter	Specification	Batch 1	Batch 2	Batch 3
Endotoxin units (EU/g)	--	<0.2	0.278	<0.2

EU = Endotoxin unit.

As shown in Tables 6, 7 and 8, the microbiological levels in the novel food are very low. There is no detectable contamination from *Escherichia coli* in the end product which demonstrates that the production enzymes do not contaminate the end product and that the process is sufficiently controlled.

Table 9. Compositional analysis of D-tagatose: antimicrobial activity and antimicrobial resistance (Kanamycin)

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Kanamycin activity	--	Not detected	Not detected	Not detected	Not detected	Not detected
Residual Kanamycin DNA (*Kan* nptII gene)	--	Not detected	Not detected	Not detected	Not detected	Not detected

nptII - Neomycin phosphotransferase II; DNA = deoxyribonucleic acid.

The applicant stated that the antimicrobial assay (Table 9) was conducted to determine the antimicrobial behaviour of the novel food and its components. The assay was conducted to determine whether D-tagatose had a similar antimicrobial behaviour to kanamycin. No antimicrobial kanamycin activity was detected. The second test was to determine whether there was any residual DNA (*Kan* nptII gene) which is the gene that specifically confers kanamycin resistance to microorganisms. This gene was not detected in the novel food.

Table 10. Compositional analysis of D-tagatose: food grade antimicrobial preservative

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Food-grade anti-microbial preservative (ppm)	--	<1	<1	1.743	1.477	<1

Ppm = parts per million.

The food grade anti-microbial preservative (Table 10), used during the production process as a raw material, was not detected above the limits of detection in three out of five batches. The highest-level present in one batch was 1.743 ppm. Sufficient information had been provided by the applicant to demonstrate its safe use in the production of D-tagatose. These levels were not considered to pose a human safety risk.

Table 11. Compositional analysis of D-tagatose: sulphite

Test parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6	Batch 7
Sulphite (mg/kg)	--	<10	<10	<10	<10	<10	<10	<10

The levels of sulphite, a component of a raw material used during the production process, were not detected above the limits of detection (Table 11).

Collectively, the results across all batches tested (Tables 1-11) demonstrate that the novel food has been appropriately characterised. No new safety concerns were identified due to the changes in the production method. The change to the melting ranges did not require further review. The novel food otherwise remains the same as authorised previously. The batch analysis does not raise safety concerns.

2.1.3. Stability

Results from a 2-year normal storage conditions stability study (21-24 °C; 42-61 % Relative Humidity) was provided on four batches of D-tagatose produced at pilot scale. The pilot production method had minor differences in the current proposed production process including differences in the crystallisation steps, purification steps and the commercial production introduced use of a food-grade antimicrobial preservative. Due to the differences between pilot and commercial scale production the shelf life could not be validated by the FSA and FSS for the assessment. The FSA and FSS were satisfied that the applicant had proposed to conduct stability studies of commercially produced D-tagatose to confirm the shelf life and physiochemical, biochemical and microbiological stability.

The available results for D-tagatose produced product at pilot scale, showed that no appreciable degradation had taken place over the two-year time period. Purity, moisture and ash parameters remained stable and within limits. Three samples were also investigated for microbial contamination (*Escherichia coli*) and this was not-detected in each 1 g sample per batch tested (under detection limits).

Information on the production process, composition, stability and the specification of the novel food does not raise safety concerns.

2.1.4. Specification

The current specification for the novel food (Table 13) is defined in the List of Novel Foods (assimilated Regulation (EU) 2017/2470).

Table 13. Specification for the novel food reproduced from the List of Novel Foods (assimilated Regulation (EU) 2017/2470)

Parameter	Specification
Purity: Assay (%) on a dry weight basis	≥98
Loss on drying (%) 102°C, 2 hours	≤0.5
Specific Rotation $[\alpha]_D^{20}$ (°) 1 % aqueous solution (1)	– 4 to – 5.6
Melting range (°C)	133-137
Heavy metal: lead (mg/kg)*	≤1.0

* = Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5. 'Instrumental methods'(1).
(1) = Food and nutrition paper 5 Rev 2 – Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 307 p.; English – ISBN 92-5-102991-1.

The applicant proposed updated specifications (Table 14) to include a wider melting range specification parameter to allow for the lowered melting ranges of their novel food product. The remaining parameters are unchanged. The specification parameters are supported by the analytical data.

Table 14. Proposed amendment to the specifications for the novel food

Parameter	Specification
Purity: Assay (%) on a dry weight basis	≥98
Loss on drying (%) 102°C, 2 hours	≤0.5
Specific Rotation $[\alpha]_D^{20}$ (°) 1 % aqueous solution (1)	– 4 to – 5.6
Melting range (°C)	128-137
Heavy metal: lead (mg/kg)*	≤1.0

* = Determined using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5. 'Instrumental methods'(1).
(1) = Food and nutrition paper 5 Rev 2 – Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 307 p.; English – ISBN 92-5-102991-1.

The FSA and FSS were satisfied that the composition of D-tagatose otherwise complies with the selected parameters set out in the specifications in the List of Novel Foods under assimilated Regulation (EU) 2017/2470 and that the amendment for the GB authorisation does not pose a safety concern.

2.1.5. History of Use

2.1.5.1. History of use of the source

Maltodextrin, the newly proposed source of the novel food in the production of D-tagatose, is a carbohydrate derived from plant starches. It has a significant history of use in in the GB food industry in a wide variety of food and beverage applications. Outside of GB, maltodextrin has been certified GRAS (Generally Recognised As Safe) since 1983 (Hofman et al., 2016; U.S. Food and Drug Administration, 1983). This GRAS notification means that maltodextrin is not subject to premarket approval in the U.S based on a safety review conducted by the FDA. Maltodextrin as a new novel food source for D-tagatose does not raise safety concerns.

2.1.5.2. History of use of D-tagatose

D-tagatose is naturally occurring in only trace levels in foods such as heat-treated dairy products and fruits such as apples and oranges (Ortiz et al., 2024). As such it is considered a novel food in the UK and EU.

In accordance with the assimilated List of Novel Foods, D-tagatose is authorised as a novel food in the UK (assimilated Regulation (EU) 2017/2470) and was introduced to the EU and UK markets by a separate applicant following a 2005 authorisation and opinion by the ACNFP and FSA, whilst it was a member of the EU (FSA 2005; FSA, ACNFP 2005). This permitted the chemical conversion of galactose into D-tagatose.

Two subsequent substantial equivalence authorisations in 2011 and in 2017 applicable to the EU and UK by another applicant (CJ CheilJedang Corporation of South Korea) resulted in further authorisations for D-tagatose produced by enzymatic conversion of galactose and also epimerisation of fructose (FSAI, 2011, 2017).

The EU/UK authorisations informed the current assessment for D-tagatose and the review of the changes to the conditions of use sought.

2.1.6. Intended Use and Maximum Use Levels

The List of Novel Foods (assimilated Regulation (EU) 2017/2470) for GB does not specify authorised uses or maximum use levels and none have been newly proposed in this change to the conditions of use application.

The current labelling per the current authorisation is show in Table 15. The intended specific labelling and proposed update to the authorisation is show in Table 16.

Table 15. Current authorised uses, maximum use levels and specific labelling requirements of the novel food reproduced from the List of Novel Foods (assimilated Commission Implementing Regulation (EU) 2017/2470)

Specified Food Category	Maximum Use Levels	Specific labelling requirement
Not specified	Not specified	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'D-Tagatose'. 2. The labelling of any product where the level of D-tagatose exceeds 15 g per serving and all beverages containing greater than 1 % D-tagatose (as consumed) shall bear a statement 'excessive consumption may produce laxative effects'.

Table 16. The proposed specific labelling requirement for D-tagatose

Specified Food Category	Maximum Use Levels	Specific labelling requirement
Not specified	Not specified	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'D-Tagatose' or 'Tagatose'. 2. The labelling of any product where the level of D-tagatose exceeds 15 g per serving and all beverages containing greater than 1 % D-tagatose (as consumed) shall bear a statement 'excessive consumption may produce laxative effects'.

The applicant has proposed a change to the additional specific labelling requirements to include 'Tagatose' in the labelling for consumers in addition to 'D-Tagatose'. As stated by the applicant, the rationale was to allow for a common name rather than a scientific name for consumers. The assessment has not reviewed the impact on risk of the proposed change.

2.1.7. Absorption, Distribution, Metabolism and Excretion (ADME)

ADME has not changed as a result of the proposed change to the conditions of use. The changes in production process does not alter the identity of the novel food and therefore this aspect was not reviewed further.

2.1.8. Nutritional Information

Information concerning the nutritional profile of the novel food was assessed by ACNFP in the original 2005 assessment (FSA, ANCFP 2005). D-tagatose is incompletely absorbed and fermented by gut bacteria in the large intestine. This leads to an increase in short chain fatty acids. Due to laxative effects in larger doses, a tolerable single dose of no more than 15 g D-tagatose per serving was agreed for the EU and UK authorisation.

The ACNFP noted during the original evaluation in 2005, that the indicated energy value for D-tagatose was 1.5 kcal/g. Subsequently, in November 2016, the European Food Safety Authority (EFSA) provided an opinion on the energy conversion factor for D-tagatose for labelling purposes and concluded that the energy value for D-tagatose is 3 kcal/g (EFSA, 2016). Whilst outside of the scope of the safety assessment, it was noted that nutrition labelling for novel sweeteners must be compliant with Regulation (EU) No. 1169/2011 on the provision of food information to consumers.

The FSA and FSS note that the nutritional profile is comparable despite use of a different novel food source, maltodextrin, in the production process; the purity remains within the compositional specifications of the novel food. D-tagatose remains the major constituent at ≥98 %. However, the current authorisation permits galactose or fructose as the starting ingredient which may result in either D-galactose or D-fructose saccharide impurities in trace amounts. The current application shows that a trace level of D-fructose (≤16.18 ppm) can be expected in the novel food. As such, the change to the conditions of use does not pose a nutritional disadvantage.

2.1.9. Toxicological Information

New toxicological information was not required for the safety assessment of D-tagatose. The novel food remains unchanged, and the production process does not introduce new hazards. The changes in the production process are therefore unlikely to impact the toxicological behaviour of the novel food and as such does not raise any concerns that would require further review. The toxicological assessment from the previous assessment remains valid and applicable to this application.

2.1.10. Allergenicity

Batch data on the protein content of D-tagatose when produced by a different production method, demonstrates that protein in the novel food is not detected (0 µg/mL) by Bradford assay. Additionally, there was no detectable bacterial contamination in the novel food from *Escherichia coli* (USP 62 method) or from the enzymes used in the production method.

Batch data on the sulphite content demonstrated that sulphite is below the limit of quantification (<10 ppm).

The changes in the production process does not introduce new hazards. The likelihood of allergenic reactions to D-tagatose remains low.

3. Discussion

This application seeks to change the conditions of use for D-tagatose as a novel food to permit a change to the enzymatic production process and a new novel food source (maltodextrin). Additionally, this application seeks to amend the specifications and amend the specific labelling requirements to include 'Tagatose' in the labelling for consumers in addition to 'D-tagatose'. No other changes were requested.

The production process utilises a specific series of crystallisation steps and purification steps for the conversion of maltodextrin. The enzyme cascade step employs 7 immobilised enzymes to generate the resultant D-tagatose novel food. The potential hazards and the corresponding control measures were appropriately characterised and did not raise safety concerns.

The composition of the novel food (≥99.3 purity) was appropriately characterised. The melting ranges had ranged between 129.7 and 131.6°C which closely aligned with the current authorisation for D-tagatose (133-137°C by specification) although it was noted that this didn't meet the current specification. An amendment to the specification is proposed to take account of this. However, no safety concerns were raised and the values in this case were deemed comparable.

The FSA and FSS were otherwise satisfied that D-tagatose under the proposed changes met the current specifications for the novel food. The trace quantities of D-fructose in the novel food demonstrated by the analyses, can be expected for D-tagatose under the existing authorisation as a trace component.

The microbiological analyses and protein content (0 µg/mL) of D-tagatose demonstrated that the enzymes are effectively removed during production and no residual DNA from their sources are present in the final product. The composition and specifications with the exception of the melting point remain unchanged from the current authorised product.

The FSA and FSS are satisfied that the proposed changes to the conditions for the novel food does not pose a human safety risk.

4. Conclusions

The FSA and FSS have undertaken the assessment of the change to the conditions of use of D-tagatose and concluded that the novel food is safe and does not pose a safety risk to human health. The change in production method does not raise safety concerns or result in a nutritional disadvantage. The FSA and FSS agree that the change to the specific labelling would not mislead consumers.

These conclusions were based on the information in the novel food dossier and the supplementary information submitted by the applicant.

Abbreviations

Abbreviation	Definition
ACNFP	Advisory Committee on Novel Foods and Processes
ADME	Absorption, Distribution, Metabolism and Excretion
AOAC	Association of Official Analytical Chemists
CAS	Chemical Abstracts Service
CFU	Colony forming unit
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
EFSA NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
EC	European Commission
EU	European Union
EU	Endotoxin unit
FDA	Food and Drug Administration
FCC	Food Chemicals Codex
FSA	Food Standards Agency
FSS	Food Standards Scotland
FSAI	Food Safety Authority of Ireland
FT-IR	Fourier transform infrared
GB	Great Britain
GMM	Genetically modified microorganism
GMO	Genetically modified organism
GMP	Good Manufacturing Practice
GRAS	Generally Recognized As Safe
HPLC	High-performance liquid chromatography
HPLC-RID	High-performance liquid chromatography - refractive index detector
HACCP	Hazard Analysis and Critical Control Point
ICP-MS	Inductively coupled plasma-mass spectrometry
ICUMSA	International Commission for Uniform Methods of Sugar Analysis
IUPAC	International Union of Pure and Applied Chemistry
NCBI	National Center for Biotechnology Information
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
nptII	Neomycin phosphotransferase II
Ppm	Parts per million
USP	US Pharmacopeia
UV	Ultraviolet

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