SUBSTANTIAL EQUIVALENCE OPINION

D-Tagatose

The Food Safety Authority of Ireland (FSAI) received an application in November of 2016 from CJ CheilJedang Corporation of South Korea for an opinion on the substantial equivalence of D-Tagatose. In 2011, the CJ CheilJedang Corporation successfully demonstrated the substantial equivalence of its D-Tagatose manufactured from lactose to D-Tagatose also derived from lactose and authorised in 2005 by the UK authorities as a novel food ingredient for the EU market to Arla Food Ingredients of Denmark. The CJ CheilJedang Corporation now wishes to place D-Tagatose manufactured from fructose on the EU market.

The applicant considers that the novel ingredient falls within the category of "*foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for food and food ingredients obtained by traditional propagating breeding practices and having a history of safe use"* as described in *Article 1 (e)* of the novel food Regulation EC No 258/97.

Composition

The specifications of the novel D-tagatose are almost identical to those of the D-tagatose authorised to Arla Food Ingredients in 2005. Quantitative data demonstrates reproducible results, with a D-tagatose purity of not less than 98%.

Comparison of the Specifications of D-Tagatose		
Parameter	**CJ CheilJedang Corporation**	**Arla Food Ingredients**
Description	White crystals	Virtually odourless, white or almost white crystals
Assay	Not less than 98% - dry weight	Not less than 98% on a dry weight basis
Loss on drying	Not more than 0.5%	Not more than 0.5%
Total ash	Not more than 0.1%	Not more than 0.1%
Lead	Less than 0.5 mg/kg	Not more than 1 mg/kg
Specific Rotation	$[\alpha]^{20}_{D}$ -5.22 to -6.1° (20% aqueous solution)]	$[\alpha]^{20}_{D}$ -4 to -5.6° (1% aqueous solution)
Melting range	135~138ºC	133-137°C

Nutritional Value and Metabolism

As the composition of the novel D-Tagatose from CJ CheilJedang Corporation and Arla Food Ingredients are very similar, it is reasonable to assume that the nutritional value and metabolism will also be equivalent. EU legislation requires that foods or food ingredients produced from "milk and products thereof (including lactose)" should indicate the use of the allergen "milk" as an ingredient. However; the novel D-Tagatose produced by CJ CheilJedang Corporation is derived from fructose rather than lactose and therefore this requirement does not apply.

Intended Uses

D-Tagatose from CJ CheilJedang Corporation will be used primarily as a bulk sweetener, but also as a humectant, stabiliser or texturiser in the same food groups and at the same maximum use-levels as the authorised comparator. Foods in which the novel ingredient will be used include ready-to-eat cereals, baked goods, health bars and diet soft candies, diet soft drinks and diet teas, coffee-based beverages and coffee drinks, low/non-fat ice cream and frozen yogurt, other flavoured yogurt, hard and soft candy, milk chocolate, smoothies, icings, formula diets for meal replacements, dietary supplements, table top sweeteners and chewing gum.

Level of Undesirable Substances

The applicant has demonstrated that the levels of undesirable substances for the novel ingredient and its authorised counterpart are similar in terms of heavy metals (arsenic, cadmium, mercury and lead) and microbiological contaminants including *Salmonella*, *Staphylococcus aureus*, coliforms and total aerobic count.

Manufacture of D-Tagatose

The manufacturing methods applied by CJ CheilJedang Corporation and Arla Food Ingredients are based on the same key principles, with some slight variations. The process used by CJ CheilJedang begins with the enzyme epimerisation of D-fructose to D-Tagatose and D-fructose, whereas the process for the authorised comparator begins with the enzymatic hydrolysis of lactose to D-galactose and D-glucose, followed by calcium ($Ca(OH)_2$) isomerisation to D- Tagatose. For the CJ CheilJedang product, epimerisation is achieved using an immobilised enzyme (D-fructose 4-epimerase) which is produced by *Corynebacterium glutamicum* that has been genetically modified to contain a gene from

Thermotoga neapolitana. The enzyme used is not present in the final product and is considered a processing aid. Therefore, GM authorisation or labelling requirements are not applicable. In addition, the applicant explains that a food enzyme application for the use of this enzyme in the manufacture of D-Tagatose has been made to the European Commission for inclusion in the EU Union list under development.

Conclusions

The FSAI is satisfied from the information provided by the applicant that D-Tagatose produced by the CJ CheilJedang Corporation is substantially equivalent to D-Tagatose authorised for the EU market since 2005. In accordance with the 2005 authorisation letter, a footnote must be associated with the designation D-Tagatose by means of an asterisk (*) stating "excessive consumption may produce laxative effects" on the label of all products containing more than 15g of the ingredient per serving and all beverages where levels exceed 1% D-Tagatose. The footnote statement must have a typeface of at least the same size as the list of ingredients itself.