Dr. Elizabeth Lewis
2233 Argentia Road
Suite 308, Mississauga
ON L5N 2X7
Canada

September 13th, 2011

Dear Elizabeth,

I am contacting you in regard to the application by your client, CJ CheilJedang Corporation for an opinion under *Article 3.4.* of the novel food Regulation EC No. 258/97 on the substantial equivalence of D-tagatose to the same ingredient which was authorised for the EU market in 2005 by Arla Food Ingredients following a safety assessment by the UK Food Standards Agency.

Based on the information provided, the Food Safety Authority of Ireland (FSAI) concludes that D-tagatose produced by the CJ CheilJedang Corporation is substantially equivalent to that produced by Arla Food Ingredients with respect to its composition, nutritional value, metabolism, intended use and level of undesirable substances. Labelling and other stipulations attached to novel food authorisation of D-tagatose from Arla Food Ingredients will be respected in the marketing of D-tagatose by CJ CheilJedang Corporation.

A summary of the information considered and the FSAI opinion is included.

If you are satisfied with this opinion you should notify the European Commission, in accordance with *Article 5* of Regulation EC No. 258/97 prior to placing this product on the market.

Commission contact details:

Mr Andreas Klepsch
European Commission
DG SANCO, E6
Rue de la Loi 200
B-1049 Brussels, Belgium

Regards,

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Dr. Pat O'Mahony
Chief Specialist, Food Technology

SUBSTANTIAL EQUIVALENCE OPINION

D-Tagatose

The Food Safety Authority of Ireland (FSAI) received an application on July 29th, 2011 from CJ CheilJedang Corporation for an opinion on the substantial equivalence of D-Tagatose to the same ingredient previously authorised to Arla Food Ingredients. D-tagatose from Arla Food Ingredients was authorised in 2005 on the basis of a safety assessment carried out by the UK Food Standards Agency. Following a 60-day review by other Member States no reasoned objections were raised to the marketing of D-tagatose by Arla Food Ingredient. The UK authorities notified Arla Food Ingredients that D-tagatose complied with the criteria laid down in *Article 3(1)* of Regulation EC No. 258/97 and could be placed on the market in accordance with the conclusions of the safety assessment. The UK assessment concluded that:

I. D-tagatose shall comply with the purity criteria set out in the Annex to the notification letter
II. The designation D-Tagatose shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it
III. In a prominently displayed footnote related to the designation D-Tagatose by means of an asterisk (*) the words "excessive consumption may produce laxative effects" shall be displayed on the label of any product where the levels of D-Tagatose exceeds 15g per serving and all beverages containing greater than 1% D-Tagatose (as consumed). The words shall have a typeface of at least the same size as the list of ingredients itself.

Composition

The specification of the novel ingredient from both sources was shown to be almost identical, and the D-tagatose from CJ CheilJedang Corporation was consistently produced to a minimum specified purity of 98% dry weight with no more than 1% of D-galactose.

Comparison of the Specifications of D-Tagatose		
Parameter	**CJ D CheilJedang Corporation**	**Arla Food Ingredients**
Description	White crystals	Virtually odourless, white or almost white crystals
Assay	Not less than 98% on dry weight basis	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	[135~138]	133-137°C

Nutritional Value and Metabolism

As the composition of the 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. Since D-tagatose is derived from lactose which in turn is derived from milk, the label must refer to milk as the source of D-tagatose to be in compliance with Annex IIIa of Directive 2000/13/EC as amended.

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 D-tagatose from Arla Food Ingredients.

Level of Undesirable Substances

The close similarity of the production processes and the use of food-grade lactose as starting material mean that the levels of undesirable substances would be similar for the D-tagatose from both sources. The levels of heavy metals (arsenic, cadmium, mercury and lead) and microbial content in D-tagatose from both sources are equivalent.

Manufacture of D-Tagatose

The production methods employed by CJ CheilJedang Corporation and Arla Food Ingredients are based on the same key principles; hydrolysis of lactose to D-galactose and D-glucose, and isomerisation of D-galactose to D-tagatose. While some minor technical variations are evident in the processes, the isomerisation of D-galactose to D-tagatose is the only notable difference. Instead of the calcium hydroxide ($Ca(OH)_2$) isomerisation used by Arla Food Ingredients, the CJ CheilJedang Corporation converts D-galactose to D-tagatose using immobilised enzyme L-arabinose isomerase from *Thermotoga neapolitana* which is produced by a genetically modified bacterium. This enzyme is considered a processing aid and is not present in the final product and therefore EU GM authorisation or labelling requirements are not applicable. In addition, the applicant explains that this enzyme will be submitted for authorisation to be included in an EU positive list that is being developed under Regulation EC No. 1332/2008.

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 marketing by Arla Food Ingredients and already on the EU market since 2005. As well as the conditions for marketing set out in the 2005 authorisation letter from the UK authority, milk must be listed as the source of D-tagatose and so comply with food allergen labelling requirements set out in Annex IIIa of Directive 2000/13/EC as amended.