Ursula Schliessner
McKenna Long & Aldridge LLP
2 Avenue de Tervueren
1040 Brussels, Belgium

May 17, 2011

Dear Ursula,

I am contacting you in regard to the application by your client Lycored Ltd. Israel for an opinion on substantial equivalence under *Article 5* of the novel food Regulation EC No. 258/97. The novel ingredient in question is a crystalline lycopene purified from a lycopene-enriched tomato oleoresin that was authorised as a novel food ingredient by Commission Decision 2009/355/EC. You compare the crystalline form of lycopene from tomato to authorised synthetic lycopene and a fungal lycopene in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances. The proposed uses and maximum content levels for the crystalline lycopene will not deviate from those specified for synthetic and fungal lycopenes as set out in Annex II of Commission Decisions 2009/348/EC and 2009/365/EC respectively. In addition, the post launch monitoring requirements for natural and synthetic lycopene products already on the EU market shall apply equally to crystalline lycopene from tomato. Based on the information provided, the Food Safety Authority of Ireland (FSAI) concludes that Lycored's crystalline lycopene from tomato is substantially equivalent to synthetic and fungal lycopene already on the EU market.

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

Crystalline lycopene from tomato

The Food Safety Authority of Ireland (FSAI) received an application on May 4th, 2011 from Lycored Ltd., Israel for an opinion on the substantial equivalence of crystalline lycopene from tomato to synthetic lycopene and a fungal lycopene already authorised for the EU market.

Lycored Ltd. received authorisation in 2009 to place lycopene oleoresin (5-15% lycopene) from tomatoes on the EU market through Commission Decision 2009/355/EC. A number of other products containing concentrated lycopene (≥95%) also received authorisation to market in the EU in 2009 (Commission Decisions 2009/348/EC, 2009/362/EC and 2009/365/EC). Lycored now wishes to market tomato lycopene in a more concentrated form, which will be labelled as lycopene, and include the fact that it is derived from ripe tomatoes, *Lycopersicon esculentum*.

The initial application, along with subsequent clarifications by the applicant, was reviewed by the FSAI to determine the substantial equivalence of this product in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.

Composition and Nutritional Value

Crystalline lycopene from tomato consists predominantly (≥96%) of all-trans-lycopene similar to that for synthetic and fungal (≥95%) lycopenes, with minor levels of other carotenoids. The applicant provided a summary comparison (Table 1) that demonstrates the compositional similarity between the synthetic and fungal lycopenes and concentrated lycopene from tomato. For this reason the nutritional value of the concentrated tomato lycopene is likely to be very similar to the fungal and synthetic lycopenes. The stability of the crystalline lycopene is facilitated by hermetic packaging immediately upon production, along with the natural presence of the antioxidant tocopherol. The applicant is committed to post launch monitoring of crystalline lycopene from tomato in line with that set out for synthetic and fungal lycopenes in Commission Decisions 2009/348/EC and 2009/365/EC respectively

Table 1.

Ingredient	Tomato Oleoresin	Crystalline Lycopene from Tomato	Synthetic Lycopene	*B. trispora* Lycopene
Lycopene	5-15%	≥95%	≥96%	>95%
Trans Lycopene	90-95%	94-96%	"all trans"	"predominantly"
Other Carotenoids	1.75%: Phytoene, phytofluene, b-carotene	Minor quantities	"Minor quantities"	"≤5% other isomers"
Tocopherol	1.5-3%	<4%		
Unsaponifiable Matter	13-20%			
Total Fatty Acids	60-75%			
Water	≤0.5%			
Marketed Product	Oleoresin in natural tomato fat	Water dispersible powder in a suitable matrix; Antioxidative protection by tocopherol	"Powder in suitable matrix or as oily dispersion"; "Antioxidative protection has to be assured"	"Powder in suitable matrix or as oily dispersion"; "Antioxidative protection has to be assured"

Metabolism

Due to their similarity, the metabolism of crystalline lycopene from tomato is not likely to be different to that for the synthetic and fungal lycopene products.

Intended Use

The applicant intends to supply food manufacturing clients with the crystalline form of tomato lycopene should they prefer it to the tomato oleoresin lycopene. The range of foods to which the crystalline lycopene will be added, and the maximum content levels will be consistent with those set out in Commission Decisions 2009/348/EC and 2009/365/EC authorising the synthetic and fungal lycopenes respectively.

Levels of Undesirable Substances

The results of chemical and physical analysis provided in the data sheet demonstrate an acceptable profile of crystalline lycopene in terms of possible undesirable substances in comparison with the synthetic and fungal forms.

Conclusions

The FSAI is satisfied that the information provided by the applicant demonstrates the substantial equivalence, under *Article 3.4* of the novel food Regulation (EC No. 258/97), of crystalline lycopene derived from tomato oleoresin when compared to synthetic lycopene and lycopene derived from a fungal source (*B. trispora*) already on the EU market.