Initial assessment

Synthetic Lycopene

Name of Applicant: DSM Nutritional Products.

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Novel Food Classification: 1.2(f)

A novel food application submitted by DSM Nutritional Products was formally accepted by the Food Safety Authority of Ireland (FSAI) on July 18, 2008. The application is for the approval of synthetic lycopene as an ingredient in food supplements and for food fortification under the novel food Regulation (EC No. 258/97).

Under normal circumstances, and in line with the novel food Regulation, the Food Safety Authority of Ireland (FSAI) would carry out a safety assessment of the ingredient and report back to the Commission within 90 days. However, the safety of lycopene (from synthetic and natural sources) has been evaluated by EFSA and JECFA in recent years. The EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food provided a favourable opinion on the production process used for this ingredient and its use as a food colourant (E160d). Therefore the Food Safety Authority of Ireland is of the opinion that the various safety evaluations carried out by EFSA and JECFA provide sufficient evidence of the safety of synthetic lycopene.

However, the potential intake of synthetic lycopene from food and food supplements as proposed by the applicant needs to be addressed in the context of overall lycopene intake from all possible sources. As this matter is currently being addressed at EU level, the FSAI is of the opinion that an additional assessment, as set out in *Article 6.3* is required in order to determine whether this product meets the criteria for acceptance as a novel food ingredient as set out in *Article 3.1* of the novel food Regulation.