

## ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

## LYCOPENE

**Issue**

The Committee is asked to consider three recent EFSA opinions for lycopene and whether in the light of their publication, the UK conclusions regarding the safety of each of the novel food applications for lycopene require review.

**Background**

1. The Committee has considered four novel food applications for lycopene. These are
  - Lycopene from a fungal source, *Blakeslea trispora*;
  - Lycopene rich oleoresin from tomatoes;
  - Synthetic lycopene; and
  - Additional uses of the fungal product, in a cold water dispersible formulation.

Previous ACNFP opinions 2004-2007

2. The UK issued initial opinions for lycopene from the fungal source and the lycopene rich oleoresin, and commented on the initial opinion of the Dutch Competent Authority for synthetic lycopene. In addition, in October 2007 the Committee considered a cold water dispersible form of the fungal product and advised that, as there were no additional concerns regarding composition, this form should also be taken into account in the ongoing EFSA review of the various forms of lycopene.
3. The Committee's original opinion for fungal lycopene, issued in 2004, stated that the ingredient was acceptable subject to adherence with the specification and production parameters. The Committee noted that that lycopene was present in the diet both as an inherent constituent of foods (tomatoes, water melons), and as a tomato extract which can be used as a food colour and in dietary supplements (the tomato extract has a history of consumption in food supplements prior to 1997, which places this use outside the scope of the novel food regulation). Following concerns raised by other Member States (MS) this application was referred to EFSA, which accepted various food uses resulting in an intake of up to 2mg lycopene per day (a figure that could be exceeded by consuming a tomato rich diet.). The fungal oleoresin was subsequently authorised in October 2006 for a limited number of food categories, in line with EFSA's advice.
4. The Committee's 2005 opinion for lycopene rich oleoresin from tomatoes concluded broadly along similar lines, although in this case the Committee expressed concern

that the product should not be consumed by young children or infants due to concerns about possible over consumption, which were related to the proposed use of the ingredient in products such as ice cream and biscuits.

5. The applications for synthetic lycopene was initially assessed by the Dutch authorities, whose report was assessed by the ACNFP in 2007. The Committee highlighted a number of concerns, noting that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) had recently set an ADI of 0 - 0.5 mg/kg body weight, a figure that was significantly lower than the estimated intake resulting from the uses proposed by the applicant company.

#### EFSA Opinions 2008

6. Three EFSA opinions have been published in 2008, covering:
  - the use of lycopene as a food additive (for colouring purposes) – **Annex 1**
  - the use of lycopene from tomatoes as a novel food ingredient – **Annex 2**
  - the use of synthetic lycopene as a novel ingredient – **Annex 3**
7. The food additive opinion sets an ADI for lycopene of 0.5mg/kg body weight from all dietary sources, a figure that is consistent with the figure proposed by JECFA although the latter was expressed only in the context of the fungal and synthetic products.
8. The other two EFSA opinions conclude that the novel ingredients are as safe as other forms of lycopene but they also highlight that there is a possibility that, given the range of dietary sources of lycopene, some users could exceed the ADI. In the case of the synthetic lycopene, EFSA also raised a concern that a 20% formulation proposed by the applicant does not apparently contain an antioxidant and this formulation was not used in any of the toxicological tests.
9. The Secretariat notes that the intended food categories for the two novel food applications are broadly similar although there are differences in the proposed levels of incorporation. In addition the intake assessment of tomato lycopene, as reported by EFSA, does not give an indication of consumption levels for different groups of the population.

#### **Committee Action Required**

10. The ACNFP is asked whether, in the light of the new EFSA opinions, it wishes to revisit each of their earlier assessments, with particular regard as to whether the proposed use categories would lead the ADI to be routinely exceeded, whether in the population as a whole, or (more likely) in specific groups, notably children`

**Annexes attached:**

Annex 1 – EFSA Opinion on Use of Lycopene as a food colour

Annex 2 – EFSA Opinion on Safety of Lycopene oleoresin from tomatoes

Annex 3 – EFSA Opinion on Safety of Synthetic Lycopene