

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

**LYCOPENE- RICH OLEORESIN FROM TOMATO**

**ISSUE**

Members are invited to consider the answer provided by LycoRed to the comments raised at their November meeting, and whether it provides sufficient information for the Committee to conclude its evaluation.

**Background**

2. At the November meeting, Members requested further information on an application for authorisation of an oleoresin derived from lycopene-rich tomatoes as a novel food ingredient (Lyc-O-Mato®), under the novel foods regulation (EC) 258/97 (ACNFP/69/2).
3. A letter detailing the ACNFP's comments on this application was sent to the applicant on 20 December 2004 and sought additional information on several points (Annex A):
  - (i) previous human exposure, especially for children;
  - (ii) proposed uses such as ice-cream, cakes or biscuits;
  - (iii) toxicity data: studies on skin irritation (to repeat), skin sensitisation (further information) and semi-chronic toxicity (histopathological data).
  - (iv) tomatine level;
  - (v) protein content;
  - (vi) potential intake by male teenager and
  - (vii) consumption on a per kilogram body weight basis (
  - (viii) concern for infants and children).
4. Berry Ottoway and Associates Ltd responded to this letter on 17 January 2005 (see Annex B).

## **Committee Action required**

5. The Committee is asked whether the applicant's response provides sufficient information and adequately addresses their concerns.
6. If so, the Secretariat proposes to draft an opinion incorporating the ACNFP's comments on LycoRed's application which would be circulated to Members, by post, for their consideration.
7. If not, the Committee is asked to indicate what additional information would be required.

**Secretariat  
January 2005**

## **Annexes attached**

- ANNEX A** Letter of 20/12/04 to the applicant with ACNFP comments
- ANNEX B** Response from the applicant of 17/01/05
- ANNEX C** Report No. 96/LYN002/0274 on acute dermal irritation
- ANNEX D** Report No. 96/LYN001/0523 on delayed contact hypersensitivity
- ANNEX E** Tables extracted from semi-chronic 13-week rat dietary study mentioned in Annex1 of the applicant's response:
- tables 9a and 9b,
  - page 359 (animal #154 of group 4F),
  - page 364 (animal #159 of group 4F).

Non-confidential annexes are available on request from the ACNFP Secretariat ([acnfp@foodstandards.gsi.gov.uk](mailto:acnfp@foodstandards.gsi.gov.uk)).