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FOOD STANDARDS AGENCY

Mr Andreas Klepsch
European Commission
By email

30th June 2005 Reference: NFU 482

Dear Mr Klepsch,

INITIAL OPINION: LYCOPENE-RICH OLEORESIN FROM TOMATO

On 7 September 2004, the UK Competent Authority accepted an application from Berry Ottaway & Associates Ltd (UK) on behalf of LycoRed (Israel) for a lycopene-rich oleoresin derived from tomato as a novel food ingredient (Lyc-O-Mato®), in accordance with Article 4 of regulation (EC) 258/97. The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached. I apologise for the delay in submitting this opinion as the ACNFP's evaluation was extended while we obtained additional information from the applicant.

In view of the ACNFP's opinion, the UK Competent Authority considers that this lycopene-rich oleoresin from tomato meets the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97.

I am copying this letter and the ACNFP's opinion to the applicant.

Yours sincerely,

Annie-Laure Robin
For the UK Competent Authority

INVESTOR IN PEOPLE

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POSITIVE ABOUT DISABLED PEOPLE

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

APPLICATION FOR THE APPROVAL OF LYCOPENE-RICH OLEORESIN FROM TOMATO

UK OPINION

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR LYCOPENE-RICH OLEORESIN FROM TOMATO AS A FOOD INGREDIENT

Applicant:	**LycoRed**
Responsible person:	**Peter Berry Ottaway**
Novel Food ingredient:	**Lycopene-rich oleoresin from tomato**
EC Classification:	**2.1**

INTRODUCTION

1. An application was submitted by Berry Ottaway & Associates Ltd (UK) on behalf of LycoRed (Israel) for the authorisation of a lycopene-rich oleoresin derived from tomato as a novel food ingredient (Lyc-O-Mato®), on 7 September 2004. A copy of the application dossier was placed on the FSA web-site for public consultation.

2. Lycopene is a carotenoid with antioxidant properties. Carotenoids are lipid-soluble photosynthetic pigments, which are made up of isoprene units. The term "oleoresin" describes a naturally occurring mixture of a resin and an essential oil obtained from certain plants. LycoRed describes “tomato oleoresin” as a natural extract of tomato lipids which contains various important phytonutrients dissolved and dispersed in its natural oil.

3. LycoRed seeks approval to market its lycopene-rich oleoresin as an ingredient in a range of food products. The same extract is currently used in the EU in food supplements at a dose of 5-15mg of lycopene, which is equivalent to 83-250mg of Lyc-O-Mato 6%. The lycopene extract is also used in more concentrated form as a food colour (E160d). Council Directive 94/36/EC[1] permits the use of the extract as a colour in a range of foodstuffs at levels up to 500mg/kg (expressed as lycopene) but this approval does not extend to the use of lycopene as a food ingredient. The use of the extract as a source of lycopene in food products is therefore subject to the terms and conditions of the Novel Foods Regulation (EC) 258/97.

4. The application for authorisation of this oleoresin was prepared pursuant to Commission Recommendation (97/618/EC) of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients. The lycopene-rich oleoresin has been classified as a complex novel food ingredient from non-GM source having a history of consumption

[1] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs, Official Journal L 237 , 10/09/1994 p.13 -29

in the Community (class 2.1). The information presented in the dossier is structured and considered below, under the schemes outlined in this Commission Recommendation.

I. Specification of the novel food

Application dossier p.6-18

5. The novel food ingredient (NI) consists of a lycopene-rich oleoresin produced from the pulp of ripe tomatoes, also called "LycoRed LRT". These are a non-GM, hybrid variety of tomatoes (*Lycopersicon lycopersicum* L. Karst. *ex* Farw) which have been naturally selected for their high lycopene content (150-220ppm).

6. The NI consists of lycopene (5-15%) together with a number of other constituents that occur naturally in tomato. These are fatty acids and acylglycerols (69-74%), unsaponifiable matter (14-19%), water soluble matter (2.7-4.7%), water (0.48-0.86%), phosphorus compounds (0.35-0.52%), phospholipids (8.9-14%), nitrogen (0.16-0.31) and ash (0.7-0.8%). The active ingredient of the NI is lycopene consisting of 90-95% (all-trans)-lycopene. Cis isomers are also likely to be present at small quantities in a number of different forms.

7. The applicant notes that, as the composition of the tomatoes is subject to natural fluctuations, the percentage of lycopene in the oleoresin can vary between 5 and 15%. The analysis of 25 commercial batches of the NI produced between 1995 and 2003 showed the range of lycopene levels (5.8%-15.6%) and total carotenoids levels (7.0%-16.5%) found in these products.

8. The levels of solvent residues, pesticides, microbiological contamination and heavy metals are assessed and any batches that do not meet the specifications for these criteria, as detailed in table 2 of the application dossier, are destroyed.

9. The applicant has evaluated the stability of the NI using nine batches of the NI. This showed no relevant changes in storage at 4°C and room temperature for up to 37 months. These data indicate that the product is stable at both temperatures.

Discussion: *The Committee was satisfied that the compositional analyses carried out on the NI show the chemical safety and the stability of the NI.*

II. Effect of the production process applied to the novel food

Application dossier p.16-23 *CONFIDENTIAL*

10. The production of the NI is identical to the production of the additive E160d, although E160d is subject to an additional concentration step to obtain an oleoresin that contains 60-70% lycopene.

11. The starting material for the production of the NI is tomato pulp. The tomatoes used to produce the NI are naturally selected, non-GM, hybrid, high lycopene content (150-220ppm) variety of tomato (*Lycopersicon lycopersicum*[2] L. Karst. *ex* Farw). The tomatoes have been specifically selected for their high lycopene content.

12. The production of tomato oleoresin is a two-step process:

    i. The first step involves tomato pulp production. During this stage, the tomato is washed, crushed and screened. The juice is then heated using a heat exchanger at 80 to 90°C and centrifuged to produce the tomato pulp, which is analysed to confirm that the lycopene content is above 1,200ppm. The pulp is cooled, packed into laminate bags under vacuum and then placed into drums and stored at -18°C. The applicant has stated that this process introduces no exogenous substance and protects the tomato phytonutrients from oxidation, assuring that the subsequent extraction is conducted on unchanged and undeteriorated raw material.

    ii. The second step involves the extraction of lycopene from the tomato pulp. The pulp is crushed and extracted with ethyl acetate in a three-stage extraction process. The solvent is removed from the extract under vacuum at 40 to 60°C and the resulting oleoresin is analysed for lycopene content. Levels of solvent residues, pesticides, microbiological contamination and heavy metals are also analysed at this stage.

13. Batches that do not meet the NI specification on total lycopene level are reprocessed or blended with other batches to achieve the desired lycopene content. Lycopene levels can be increased by the partial removal of the tomato oil, which consists mainly of triglycerides without the dispersed lycopene crystals, by physical separation such as decanting or centrifugation. Lycopene is only slightly soluble in oil and therefore when the extraction solvent (ethyl acetate) is evaporated, lycopene precipitates forming a suspension of crystals in the tomato oil. No carrier oil or additives are added.

14. The production of the NI is carried out in accordance with the principles of Food Good Manufacturing Practices using the Institute of Food Science and Technology Guidelines in Europe. The applicant has therefore stated that the production process is fully controlled to avoid the presence of relevant levels of toxicants and pathogens and allows traceability from the

[2] *Lycopersicon lycopersicum* and *Lycopersicon esculentum* are synonyms for the tomato plant and come from different taxonomic schemes. They are used interchangeably in the literature.

seeds through cultivation in the field to the finished product. Any products, which do not meet the standards, are rejected.

15. The final product consists of an oleoresin, which is packed in 1, 10 and 25kg bags under nitrogen in aluminium, high density polyethylene or plastic coated metal containers and stored at 4°C.

Discussion: *The Committee was satisfied that the production process of the oleoresin is the same as the production process of the approved food colour E160d, with omission of the final concentration step. Members also noted that appropriate controls were put in place on the production of the LRT tomatoes and throughout the production process of the oleoresin to ensure the safety of the final product.*

III. History of the organism used as a source of the novel food

Application dossier p.24

16. As mentioned in paragraph 4 above, high lycopene content tomatoes are used to produce the NI. This variety is not consumed *per se*, but is used for the manufacture of tomato paste in Israel and the USA (1000 tonnes of tomato paste is yearly produced in the USA from LycoRed LRT tomatoes). The applicant also states that "*traditional and conventional breeding methods utilising the natural gene pool of the genus Lycopersicon have been applied in order to create a tomato plant with a high content of lycopene*". This particular variety is not consumed directly but is used in production of tomato products.

Discussion: *The Committee was content with the information provided on the history of use of the lycopene-rich tomatoes used to produce the NI.*

IX. Anticipated intake/extent of use of the novel food

Application dossier p.25-26 and Appendix A p.3-12

17. The food categories to which the applicant wishes to add the NI are listed below. Given that the levels of lycopene in the NI vary (see paragraph 6), the actual quantity would be adjusted to achieve the desired lycopene concentration.

18. The applicant notes that the levels of incorporation are significantly lower than those permitted for use of lycopene as a food colour (E160d) (see table below).

Summary of LycoRed's proposed food uses and The recommend levels of use from tomato oleoresin in the EU				
Food category	**Proposed food use**	**Added lycopene (mg per portion)**	**Added lycopene (mg/kg)**	**Tomato oleoresin (g/kg)** (a)
Dairy Products	Yoghurts	5 (125g)	40	0.7
	Desserts/Custard	5 (125g)	40	0.7
	Cheese	5 (40g)	125 (b)	2.1
	Ice cream	5 (80ml)	62.5	1.0
Bread and baked goods	Bread	5 (30g)	167	2.8
	Biscuits	3 (20g)	150	2.5
	Fruit cakes/cake	5 (60g)	83	1.4
	Crispbreads	5 (50g)	100	1.7
Meat products	Sausages	5 (120g)	42 (c)	0.7
	Pates	3 (33g)	91 (c)	1.7
	Meat substitutes	5 (100g)	50	0.8
Juices	Fruit and Vegetable juices	5 (250g)	20	0.3
	Tomato juice	10 (120g)	83	1.4
Non-alcoholic flavoured drinks		5 (220ml)	23	0.4
Soups and sauces	Soup (other than tomato)	5 (220g)	23	0.4
	Tomato soup	10 (220g)	45	0.7
Cereal and cereal products	Breakfast cereals	5 (30g)	167	2.8
	Cereal bar	5 (25g)	200	3.3
Snack foods		2.2 (25g)	88	1.4
Pasta products (not canned)		5 (30g)	167 (c)	2.8
Fats spread	Margarine	3 (10g)	300 (c)	5.0
	Other spread	3 (10g)	300 (c)	5.0
Canned products	Baked beans	2.5 (150g)	17	0.3
	Canned pasta	5 (200g)	25	0.4

Notes:
(a) Assuming a lycopene content of 6%. (The product as proposed could contain 5-15% lycopene and the level of addition would be adjusted accordingly)
(b) Exceeds the limits set for use as a food colour
(c) Lycopene is not permitted to be added to this food category for colouring purposes

19. The applicant estimates that the total intake of the NI will vary between 6 to 45 mg of lycopene per day due to the variable use of supplements and fortified products in addition to the background intake from natural sources. Assuming a lycopene content of 6%, this is equivalent to 100-750 mg/day of the NI. Further information on dietary lycopene intake and bioavailablity is given in section 1 of Appendix A of the application.

Discussion: *Members are aware that the authorisation for the use of lycopene in the EU as a food additive was given on the basis of advice from the former Scientific Committee on Food in its 1975, 1983 and 1987 reports on the use of 'natural' food colours. The SCF did not have sufficient data to be able to set an ADI for the use of tomato lycopene as a colour and noted in 1987 that, as with other natural colours, "acceptance is limited to situations under which the use of colouring matters extracted from foods would not be*

expected to result in ingestion differing substantially from the amounts likely to be ingested from the normal consumption of foods in which they appear."

Additionally, the Committee drew attention to the possible over-consumption of the oleoresin by children as a result of its presence in products such as ice cream, cakes and biscuits and highlighted the lack of data regarding the potential intake by infants (<1 year old) and young children (1-3 years old). The applicant has responded that it is not the intention of the company to target infants and young children in any of the food uses. The Committee therefore recommended that the labels of products containing the NI should indicate that they may not suitable for consumption by infants and children under the age of 3 years.

Concern was also raised by a member of the public on the consumption of the NI by male teenagers. The applicant has calculated that the margin of safety for individuals weighing 15kg or more was 90, based on results obtained from the 13-week oral toxicity study in rats which indicated a NOAEL of 4500 mg/kg bw/day. The Committee considered that the consumption of the NI by male teenagers did not raise any specific concerns.

X. Information from previous human exposure to the novel food or its source

Application dossier p.27-28 and Appendix A p.3-12

20. The applicant has used dietary composition studies from the Netherlands, Sweden, Finland, the USA and the UK to estimate the current consumption of lycopene naturally present in food such as tomato paste or sauces.

21. The applicant has indicated that intake from natural sources in the Netherlands shows an average lycopene intake of 1.05 – 1.56mg/day in men (max 26.1 mg/day) and 1.33 – 1.88mg/day in women (max 18.6mg/day) (Goldbohm *et al*, 1998). The Nordic Council of Ministers reported lower estimated lycopene intakes for Sweden and Finland of 0.34 and 0.26mg/day (Strube and Dragsted, 1999). An earlier study carried out by the Finnish Mobile Clinic Health Examination Survey gave a mean intake of 0.7 and 0.9 mg/day for men and women respectively (Jarvinen, 1995). Forman *et al* (1993) has estimated that daily intakes of lycopene in the US are in the order of 3.7mg. However, depending on the food products and supplements consumed in combination, intake can be as high as 15-30mg/day. A British study by Scott *et al* (1996) estimated that the mean daily consumption of lycopene-rich food gave about 1.1mg/day of lycopene.

22. The applicant notes that the dietary intake of lycopene as a food additive (E160d) is difficult to estimate because there are no dietary survey studies that look at the consumption of food additives in the normal diet. The use of existing dietary surveys is not possible because there are no available data on the amount of colour added to individual foods.

23. In addition to tomato and tomato products, the applicant has identified a number of other natural sources of lycopene that are minor components of the UK diet. Such foods are watermelon, red palm oil, guava and red grapefruit. Whilst these data indicate a range of different levels of intake, the use of lycopene in the EU, either as a food supplement or a food colour (E160d) is currently only permitted when it is obtained from a tomato source. It is therefore reasonable to assume that the background levels described by the applicant would have a similar compositional profile to the NI. The same data will also be indicative of the intake of other components present in the NI. A dose of 1mg of lycopene is equivalent to 7-20 mg of the oleoresin.

24. In order to estimate the background intake of tomato oleoresin arising from consumption of tomatoes and tomato products, the Secretariat has examined National Diet and Nutrition Survey data from 2001, covering British adults aged 16-64. The 97.5th percentile consumption of tomatoes – including the contribution of foods containing tomatoes and tomato products – was found to be 105 g/person/day. The lycopene content of the NI is 5-15%, and it is derived from LycoRed LRT tomatoes containing 150-250 mg/kg lycopene (see paragraph 5 above). The yield of the tomato oleoresin can therefore be estimated to fall within the range 0.1-0.5%, assuming complete recovery of lycopene. On this basis, high level tomato consumption of 105g/day is equivalent to 105-525 mg of tomato oleoresin.

Discussion: *Initially, the Committee queried why the application dossier had only provided information on previous human exposure to tomatoes and tomato products, but not the oleoresin. The applicant responded that over 400 tonnes of the NI were used in food supplements sold in Europe, the US and the Far East between 1995 and 2004. The applicant also noted that during this period, no adverse events related to the consumption of these food supplements were reported to LycoRed. The Committee was content with this additional information.*

XI. Nutritional information on the novel food

Application dossier p.29-32 of the application dossier and Appendix A p13-23

25. The applicant states that, whilst the lycopene component of the NI can be considered to be nutritionally equivalent to conventional tomatoes, tomato products and the additive E160d, small variations in the levels of other carotenoids and plant ingredients may occur due to the difference in the tomato varieties used and/or effects of the production process. The applicant is of the opinion that the addition of the NI to foodstuffs will not significantly affect their overall nutrient levels.

26. The potential health benefits of the introduction of lycopene into human diet are detailed in the application dossier. The findings of these studies do not have any bearing on the safety evaluation of the tomato preparation. They indicate that lycopene is an efficient oxygen quencher and has antioxidant properties which are reported to be associated with

the inhibition of LDL oxidation/cholesterol synthesis. Finally, lycopene has been reported to enhance UV protection of the skin.

Discussion: *The Committee was content with the nutritional information provided for the NI and did not consider the perceived benefits attributed to the consumption of lycopene.*

XII. Microbiological information on the novel food

Application dossier p.33

27. The production of the NI is controlled throughout and the final product is analysed in order to ensure its microbiological safety. The microbiological analyses carried out on the NI are listed in the application. The applicant has specified that the NI is produced without the aid of any microbiological processes.

Discussion: *The Committee was satisfied that the applicant has demonstrated the microbiological safety of the NI.*

XIII. Toxicological information on the novel food

Application dossier p.34-42 and Appendix B

28. The applicant considers that the NI should not present any additional toxicological risks than those currently associated with tomato and tomato products. The applicant has not provided any information demonstrating the absence of tomatine, a toxic component found in unripe tomatoes, but concluded that the ripe tomatoes used to produce the NI would not contain tomatine. In response to a request for additional information from Members, the applicant highlighted that numerous scientific publications have shown that tomatine level declines during tomato ripening, whilst the lycopene content increases. The applicant will ensure that only red tomatoes are selected for the production of the NI. Finally, as tomatine is a polar molecule, it is unlikely to be extracted with the NI and would remain in the water phase. Two batches of the NI (containing 6% and 7% lycopene) were tested and tomatine was not detected at a limit of detection of 1ppm.

29. The applicant has provided a toxicokinetic evaluation of lycopene, using information obtained on [^{14}C]-lycopene from secondary literature sources and not based on the evaluation of original papers or study reports. No differences in the toxicokinetic properties of lycopene between humans and rats have been observed. The applicant acknowledges that this information may not be representative of the toxicokinetic behaviour of lycopene in the NI.

30. A number of other toxicological studies, including acute toxicity (with irritation, skin sensitisation), semi-chronic toxicity and mutagenicity studies have been performed on the NI containing 5% or 6% lycopene. All these studies are detailed in Appendix B of the dossier and are outlined below.

31. **Acute toxicity, eye and skin irritation and skin sensitisation studies** – The acute oral and dermal toxicity of the NI at 5% on rats was found to be low with the LD50 levels greater than 5000mg/kg bw. The NI containing 6% lycopene was not found to be irritating to skin when tested on rabbits. However, results obtained in 1994 by Dreher, using 4 different batches of the NI containing 5% lycopene, showed that 2 batches out of 4 were irritating the skin of rabbits. Dreher used again these two batches for a sensitisation studies on guinea pig's skin and found one positive result. Although no analytical data were available on these two batches, the applicant explained that a problem with the lactic fermentation of the lycopene-rich tomato pulp, from which these two batches may have been derived, occurred in 1994 and could have induced these positive results. LycoRed has since changed their production process to prevent this fermentation problem, which was caused by the contamination with lactic acid bacteria, by introducing two analytical parameters in the control quality schedule. The applicant also states that the NI containing 5% or 6% lycopene did not irritate the eyes of rabbits.

32. **Semi-chronic toxicity** - A 13-week oral toxicity studying rats using daily doses by gavage of 0, 45, 450 or 4500 mg of the NI (containing 5% lycopene) per kg body weight (bw) was conducted. The staining of the tails detected on some rats was not considered to be relevant as this was attributed to accidental transfer of the NI during dosing. An increase in lung weight observed in female rats in the two upper dose groups was not accompanied by histopathological changes and was not considered to be an adverse effect. It was therefore concluded that the no-observed-adverse-effect-level (NOAEL) for this study was 4500 mg/kg bw/day[3]. This indicates a safety factor of 300, compared with the anticipated maximum intake of 45 mg added lycopene/day (see paragraph 19 above) for an adult of 60 kg (45mg of lycopene is equivalent to 900mg of the NI containing 5% lycopene, or 15 mg/kg bw)

33. **Mutagenicity studies** – The NI (5%) was negative in an Ames test, which used four batches of *Salmonella* and one batch of *E.coli*. Other mutagenicity studies of purified lycopene carried out by Collins (1998) and Riso (1999) did not show that lycopene had any mutagenic effects on human DNA. Although the applicant recognises that these studies are insufficient to assess the potential genotoxicity of the NI, which contains other components in addition to lycopene, they consider that there is no indication for genotoxicity.

[3] This figure is misquoted as 24500 in Appendix B (p.28) of the application dossier.

34. Although it was not mentioned in the application dossier, a study conducted by Guttenplan et al (2001)[4] reported a pro-mutagenic effect of a lycopene-rich tomato extract when given to animals pre-treated with benzo[a]pyrene, a known carcinogen. The applicant suggested that this study has to be viewed in the context of a number of other studies showing that lycopene preparations protect animals against tumour induction. The applicant also expresses doubt about the identity of the test substance used in this study. In particular, the material has a very much higher beta-carotene content than could be expected from lycopene-rich tomato oleoresin. The applicant noted that the test substance has the trade name 'Betatene', which has been used for some years for carotenoid mixtures derived from micro-algal sources. The applicant suggests that the material used for this study may have been a blend of tomato lycopene and algal carotenoid-rich extract.

35. No data on reproductive/developmental toxicity and teratogenicity of the NI were submitted in this application.

Discussion: *The Committee was specifically concerns about the following aspects of the toxicological assessment of the NI:*

(i) ***Skin sensitisation study*** *- Members were concerned that results obtained on two out of 4 batches of Lyc-O-Mato® 5% were positive in the skin irritation test. The applicant suggested that this issue had been resolved by changes to the production process to prevent the lactic fermentation of the lycopene-rich tomato pulps. However, Members recommended that this hypothesis should be tested by repeating the study with more recent batches of the product. The applicant consulted an expert for advice, who confirmed that the positive results obtained on the 2 batches produced in 1994 was due to the fermentation problem causing high acidity (pH 3.1-3.5) from the high citric acid level (2.5-3.6%). This manufacturing process was revised in 1995 which resulted in oleoresin batches with higher pH (4.5-4.7) and lower citric acid level (0.3-0.5%). Batches from 1995 were tested on rabbits and guinea pigs and it was found that neither skin irritation nor contact hypersensitivity were induced by the NI. The Committee accepted this additional confirmation and concluded that the NI did not cause skin sensitisation.*

(ii) ***Semi-chronic toxicity study*** *– in their initial consideration, the Committee requested that detailed histopathological data be provided by the applicant to clarify the significance of the increase in lung weights that was observed for female rats in the upper dose groups. The applicant provided some additional information and the Committee requested that a toxicologist with expertise in animal pathology be contacted in order to assess the significance of the findings. The nominated expert confirmed that the observed increased absolute lung weights was not indicative of a target organ toxic effect and related to the body weight increases for rat females, caused by treatment. The Committee agreed with the advice and*

[4] Guttenplan J. B., Chen M., Kosinska W., Thompson S., Zhao Z., Cohen L. A. (2001) Effects of a lycopene-rich diet on spontaneous and benzo[a]pyrene-induced mutagenesis in prostate, colon and lungs of the *LacZ* mouse. Cancer letters 164 (2001), 1 – 6

concluded that the 4,500 mg/kg bw/day exposure level could be taken as the NOAEL in this study.

(iii) ***Mutagenicity studies*** *- the Committee was satisfied that the NI is not genotoxic. The Committee asked that initial statements made by the applicant regarding the absence of tomatine should be backed up by additional data and was satisfied with the additional information provided by the applicant on this point.*

Allergenicity and labelling

Application dossier p39-40

36. In their dossier, the applicant accepts that whilst there is little information available on tomato allergens, some individuals are known to be allergic to tomatoes. A study by Westphal *et al* (2004) concluded that tomato profilin is a minor allergen and can induce immunological reaction in tomato-allergic individuals.

37. The applicant originally indicated that due to the nature of the oleoresin, they were unable to accurately quantify the level of proteins in the NI. The applicant therefore suggested that, as the NI originates from tomatoes, the NI would be described as a "tomato extract containing lycopene", which will alert any consumers who seek to avoid eating tomato products. Members requested that the applicant investigated alternative methods of protein analysis. The applicant provided results obtained using a SDS-PAGE method followed by silver staining.

Discussion: *There were technical problems associated with the measurement of proteins in the NI and with the SDS-PAGE analysis. Whilst the latter gave some reassurance, the Committee was of the view that the protein analysis did not categorically demonstrate that the NI was free from allergens. In view of the low level of tomato allergy in the population, Members were content that the provision of clear labelling offered adequate protection for consumers who are sensitive to tomato allergens.*

OVERALL DISCUSSION

38. The applicant has provided details on the specification of the proposed novel food ingredient, which has a lycopene content of between 5 and 15%. This variation is due to the composition of its tomato source, which is subject to natural variation. The production process is essentially the same as that for the approved food colour E160d.

39. The information supplied by the applicant offers sufficient reassurance that consumption of the NI does not give rise to any toxicological or allergenic concerns.

40. The applicant has demonstrated that the NI is stable at ambient and refrigerated temperatures. The applicant has also demonstrated that this NI is microbiologically safe by applying a quality control system throughout its production process.

41. Regarding the labelling of the product, the applicant needs to comply with the Food Labelling Regulations 1996 (as amended). They should also ensure that the labelling and presentation of the products does adequately inform the consumer, particularly in relation to its consumption by infants and children under the age of 3 years.

CONCLUSION

42. The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by LycoRed that the range of uses for its lycopene-rich oleoresin is acceptable, subject to the applicant's adherence to the proposed specification and the production parameters described above. The Committee also wishes to note that any foods containing the NI should be labelled in accordance with existing legislation and should not make claims that are likely to mislead consumers. The labelling should also indicate that these products may not be suitable for infants or young children under the age of 3 years.

30th June 2005