Safety Assessment of Paprika Extract EXS0570IND

Name of Applicant: Pharmanager Ingredients, France

Contact person(s): Céline Burgaud; Pharmanager Ingredients Céline Pozza, Pharmanager development

Novel Food Classification: *1.2 (e)*

Introduction

An application for the authorisation of Paprika Extract EXS0570IND was submitted to the Food Safety Authority of Ireland (FSAI) by Pharmanager Ingredients of France in accordance with *Article 4* of the novel food Regulation (EC) No. 258/97. The application was accepted by the FSAI on June 22nd of 2017.

Paprika extract is derived from the paprika fruit (*Capsicum annuum* L.) and is already authorised in the EU as a food colouring agent (E160c) in accordance with Regulation (EC) No 1333/2008. However, the applicant now wishes to extend its use to food supplements for the adult population as a source of β-carotene (vitamin A precursor). The safe use of Paprika extract as an additive (E160c) has previously been evaluated by EFSA, with a final opinion published in 2015 concluding an ADI of 24 mg/kg bw/day and an ADI for total carotenoids from E160c of 1.7 mg/kg bw/day. Paprika extract (E 160c) is permitted *quantum satis* (QS) in food except for meat preparations and processed meat, in which it is allowed up to 10 mg/kg product, and foodstuffs in which the use of colours is specifically prohibited. The novel food is to be marketed as Paprika Extract EXS0570IND will consist of 53-63.5% paprika extract as a source of , 35-45% sunflower oil (carrier) and 1.5-2% of rosemary leaf extract (E392).

The applicant categorises the novel food as "Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use" in line with in *Article 1.2(e)* of the novel food Regulation (EC) No 258/97. The application dossier was prepared pursuant to Commission Recommendation 97/618/EC and in order to assess wholesomeness, the novel food was considered in Class 2 "Complex novel food from non-GM sources" and sub section 2.1 "The source of the novel food (red peppers) has a history of food use in the EU"**.**

I. Specification of the novel food

Paprika extract is derived by extraction with a mix of hexane and acetone from pulverised dried red peppers (paprika fruit - *Capsicim annuum L.*). The novel food to be placed on the EU market is Paprika Extract EXS0570IND, a dark red viscous liquid which consists of paprika extract (53-63.5%), sunflower oil as a carrier (35-45%) and rosemary leaf extract (1.5-2%), an authorised additive. Both the paprika extract and rosemary leaf extract adhere to the respective additive specifications set out in Commission Regulation (EU) 231/2012.

Specifications for Paprika Extract EXS0570IND	
Appearance	Viscous liquid
Colour	Dark red
Paprika extract	53-63.5%
Sunflower oil	35-45%
Rosemary leaf extract	1.5-2%
Total carotenoids	≥ 7%
Capsanthin/Capsorubin	≥ 30% of total carotenoids
β-carotene	0.3-0.6%
Capsaicin	< 250 ppm
Residual solvent (hexane / acetone)	<50 ppm (combination of hexane/acetone)

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

The extraction process of Paprika Extract EXS0570IND uses a mix of two solvents (hexane and acetone) which are listed as authorized extraction solvents. All processes applied to this novel food ingredient are well established, with a significant history of safe use. The quality and manufacturing process are verified by quality controls in place to ensure adherence to product specifications.

III. History of the organism used for the novel food

The paprika extract in this application is produced from non-GM red peppers (*Capsicum annuum* L.) grown in India. However, red peppers have a significant history of consumption around the world. Paprika extract is authorised as a food additive (E160c) under EC Regulation 1333/2008 and is commonly used in foods for food colouring purposes in Europe.

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

Paprika Extract EXS0570IND consists of approximately 8.3% total carotenoids and will be added to food supplements targeting the adult population as an alternative source of β-carotene, a precursor of vitamin A. The use of Paprika Extract EXS0570IND will be governed by the applicant's desire to provide at least 15% of the Reference Intake (RI) level for vitamin A as set out in the Food Information for Consumers Regulation (800µg/day, equivalent to 4.8mg/day β-carotene) while respecting the lowest Maximum Daily Intakes (MDI) of vitamin A in food supplements set nationally by individual EU Member States at 800µg/day. The applicant intends that supplements containing the novel ingredient will provide at least 15% of the vitamin A Reference Intake (120µg/day vitamin A, equivalent to 720µg β-carotene). The applicant utilises exposure data from the 2015 EFSA assessment of paprika extract (E160c) expressed as total carotenoids from paprika. They also express the data as equivalent to paprika extract in E160c based on the total carotenoids specifications for E160c (7% total carotenoids) and the understanding that E160c is the primary contributor (99%) to the total dietary exposure of paprika extract.

The applicant estimates the daily intake of Paprika Extract EXS0570IND by adults from food supplements to be 240 to 800 mg/day, corresponding to 3.4285 – 11.4285 mg/kg bw/day of paprika extract for a 70kg adult. This equates to a total carotenoid intake of 19.9 - 66.4 mg/day (0.2845 – 0.9485 mg/kg bw/day for a 70kg adult). The proposed intake of paprika extract (8.3% total carotenoids) when added to the EFSA-calculated combined intakes of E160c and paprika from background dietary intake results in a relatively minor risk of exceeding the carotenoid ADI of 1.7 mg/kg bw/day at the upper intake extremes.

The applicant highlights the fact that the novel ingredient is the same as the EU-approved additive (E160c) which is permitted for use at *quantum satis* levels. The anticipated daily intakes from this novel food are unlikely to pose a significant risk under the conditions described.

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

The safe use of Paprika extract as an additive (E160c) has been evaluated by EFSA in 2015, with a final opinion concluding an ADI of 24 mg/kg bw/day and an ADI for total carotenoids of 1.7 mg/kg bw/day. Paprika extract (E160c) is permitted *quantum satis* (QS) in food except for meat preparations and processed meat, in which it is allowed up to 10 mg/kg product, and foodstuffs in which the use of colours is specifically prohibited.

X. Nutritional information on the novel food

Paprika Extract EXS0570IND contains β-carotene, a precursor of Vitamin A, but otherwise contributes minimally in terms of energy or micronutrient value. It is designed to replace other supplemental sources of vitamin A and provide at least 15% of the vitamin A Reference Intake and up to the lowest MDI established at 800µg/day. As for all β-carotene supplements, absorption depends on the amount of fat in the diet and the concentration of β-carotene consumed.

XI. Microbiological information on the novel food

Microbial contamination is not a significant concern due to the production process and this is confirmed by batch analyses which demonstrate that the product is within specified parameters.

Total Aerobic microorganisms	$\leq 2.10^4$ CFU/g
Moulds and Yeasts	$\leq 2.10^2$ CFU/g
Gram negative bili tolerant bacteria	≤ 100 CFU/g
Escherichia coli	Not detected in 1 g
Salmonella	Not detected in 25 g

XII. Toxicological information on the novel food

The specifications for Paprika Extract EXS0570IND generally comply with those for paprika extract used as a food additive (E160c). The novel ingredient contains less than 0.01% capsaicin which is within the limit of 250ppm (0.25%) set for E160c. For these reasons, the applicant uses the 2015 safety evaluation of paprika extract (E160c) by EFSA as a basis to conclude on the toxicological safety of the novel ingredient and does not provide any additional toxicological data.

Conclusions

This novel food application concerns the use in food supplements of Paprika Extract EXS0570IND as the novel ingredient co-formulated with sunflower oil as a carrier and rosemary leaf extract (E392). Paprika extract is already authorised for the EU market as a colouring agent (additive E160c) but the applicant wishes to market it as a source of β-

carotene for adults in the unspecified form of food supplements which requires authorisation in line with the novel food Regulation (EC) No 258/97. The applicant has provided data relating to rosemary leaf extract but as this is used in its authorised capacity as an additive (E392), any further assessment is not required.

The applicant contends that the supplement will primarily provide an alternative source of vitamin A on the EU market and therefore should not pose a significant risk of over exposure to either vitamin A or any of the other constituents. The toxicological safety assessment relies entirely on the 2015 assessment by EFSA which is reasonable, especially considering the *quantum satis* use of the additive E160c.

Adverse effects related to the consumption of high dose vitamin A supplements during pregnancy have been reported and in some EU member states pregnant women are cautioned to avoid such supplements during pregnancy unless advised by a physician. The advice for post-menopausal women and older men who are at risk of osteoporosis in some EU Member States is to avoid a combined intake of more than 1.5mg vitamin A per day from food and food supplements. This relates to some evidence of a possible increased risk of osteoporotic fracture following consumption of higher dose vitamin A supplements. For these reasons, it may be worth considering some consumption advice for potentially vulnerable population sub-groups.

Recommendation

The Food Safety Authority of Ireland has not identified any significant safety concerns associated with the use of Paprika Extract EXS0570IND as a source of vitamin A in food supplements. Therefore, the FSAI is of the opinion that it meets the criteria for novel food set out in *Article 3.1.* of the novel food Regulation (EC) No 258/97 but that consumption advice for certain population-sub-groups should be considered.