

SUBSTANTIAL EQUIVALENCE OPINION

Coriander Seed Oil

The Food Safety Authority of Ireland (FSAI) received an application in March of 2017 from Ovalie Innovation of France for an opinion on the substantial equivalence of its coriander seed oil. The novel ingredient is compared with the same ingredient already authorised in 2014 to Nestec (Commission Implementing Decision 2014/155/EU).

The novel coriander seed oil is produced from the seeds of the coriander plant *Coriandrum sativum* L.. The manufacturing process involves cold pressing the coriander seed followed by centrifugation of the crude oil to remove particulate matter. Collection, storage, marketing and shipping of seeds follow ISO 9001:2001 standards, and the production facility has a Hazard Analysis Critical Control Point (HACCP) system in place. The novel coriander seed oil is intended for use in food supplements to be consumed at levels of 600 mg per day.

The applicant considers the ingredient to be novel and fall within the category of “*foods and food ingredients consisting of or isolated from plants and food 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 use,*” as set out in Article 1.2(e) of the novel food Regulation EC No. 258/97.

Composition

Coriander seed oil (CAS No. 8008-52-4) is a triglyceride which is light yellow in colour and consists of at least 70% petroselinic acid by weight, a mono-unsaturated fatty acid which is easily oxidized. It is virtually free from protein and carbohydrate and batch analyses demonstrate that the novel ingredient is similar to the authorised comparator in terms of composition and purity as outlined in the Annex of Commission Implementing Decision 2014/155/EU. A few minor differences are evident but these do not impact on the safety or quality of the product.

The stability of the oil (refined or not) was established at 18 months when the oil is stored in dry, light protected conditions at a temperature not exceeding 20°C.

Purity	Ovalie Innovation Coriander seed oil	Commission Decision 2014/155/EU
Refractive index (at 20°C)	1.466 to 1.474	1.466 to 1.474
Acid value	Max. 2.5 mg KOH/g	Max. 0.6 mg KOH/g
Peroxide value	Max. 5 meqO ₂ /kg	Max. 5 meqO ₂ /kg
Iodine value	Max. 110 units	88 to 102 units
Saponification value	Max. 200 mg KOH/g	186 to 198 mg KOH/g
Unsaponifiable matter	Max. 15 g/kg	Max. 15 g/kg
Fatty acid composition		
Palmitic acid	2 – 5%	2 – 5%
Stearic acid	<1.5%	<1.5%
Petroselenic acid	60 – 75%	60 – 75%
Oleic acid	8 – 15%	8 – 15%
Linoleic acid	12 – 19%	12 – 19%
α-Linolenic acid	<1%	<1%
Trans fatty acids	≤1%	≤1%

Nutritional value and Metabolism

The source and composition of the Ovalie Innovation coriander seed oil is similar to the authorised comparator and therefore it is to be expected that the nutritional value and metabolism will also be similar.

Intended uses

The applicant intends to place the novel coriander seed oil on the EU market in food supplements at a maximum dose of 600 mg/day, which is the same for the comparator as set out in Commission Implementing Decision 2014/155/EU.

Level of undesirable substances

Before and during pressing, operating parameters such as seed moisture content, processing temperature and duration are controlled to ensure that the efficiency of the oil production process is reproducible. The manufacturing steps employed are designed to ensure that the risk of microorganism growth is minimised. Batch analyses demonstrate that heavy metals (arsenic cadmium, lead and mercury) and microbiological contaminants such as *Salmonella*,

Enterobacteria, coliforms, *Escherichia coli*, yeasts and moulds are controlled to within regulatory or safety limits. Checks for other potential contaminants included dioxins, PCB's, polycyclic aromatic hydrocarbons, pesticide residues and mycotoxins among others, with no concerns identified.

Conclusion

The FSAI is satisfied from the information provided by Ovalie Innovation that their coriander seed oil is substantially equivalent to coriander seed oil previously authorised for the EU market by Commission Implementing Decision 2014/155/EU. The novel ingredient will be used in food supplements with a maximum dose of 600mg/day, without prejudice to the specific provisions of Directive 2002/46/EC. The designation of the novel ingredient in foods containing it will be “coriander seed oil” in accordance with *Article 2* of Commission Implementing Decision 2014/155/EU.