

Maisons-Alfort, 6 January 2012

**OPINION**  
**of the French Agency for Food, Environmental and Occupational**  
**Health & Safety**

**on the initial assessment report by the Irish authorities concerning the**  
**placing on the market of the novel food ingredient coriander seed oil**

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*ANSES undertakes independent and pluralistic scientific expert assessments.*

*ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.*

*It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.*

*It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).*

*Its opinions are made public.*

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## **1. REVIEW OF THE REQUEST**

On 18 November 2011, the Directorate General for Competition, Consumer Affairs and Fraud Control requested that ANSES provide an opinion on the initial assessment report by the Irish authorities concerning the placing on the market of the novel food ingredient referred to by the applicant and in this Opinion as 'coriander seed oil', but which is in fact obtained from coriander fruits.

## **2. BACKGROUND AND PURPOSE OF THE REQUEST**

This request falls within the scope of Regulation (EC) No 258//97 concerning novel foods and novel food ingredients (NI). The product applied for belongs to class 2.1, i.e. a complex NI from non-genetically modified sources which has a history of food use in the Community.

According to Table II of Recommendation 97/618 EC, the information required for class 2.1 NIs is as follows:

- I. Specification of the NI
- II. Effect of the production process applied to the NI
- III. History of the organism used as the source of the NI
- IX. Anticipated intake/extent of use of the NI
- X. Information from previous human exposure to the NI or its source
- XI. Nutritional information on the NI
- XII. Microbiological information on the NI
- XIII. Toxicological information on the NI

### 3. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French standard NF X 50-110 "Quality in Expert Appraisals – General requirements of Competence for Expert Appraisals (May 2003)".

The expert assessment was carried out by the Expert Committees (CESs) on 'Human nutrition' (the lead CES) [hereinafter: CES NUT] and on 'Additives, flavourings and processing aids' [hereinafter: CES AAAT]. On 15 December 2011, the work, covering both scientific and methodological aspects, was presented to the CES on the basis of three expert assessment reports. This Opinion was adopted by the CES NUT and the CES AAAT by correspondence owing to the short response times imposed.

### 4. ANALYSIS AND CONCLUSIONS OF THE CES

#### ▪ Specification of the NI

The NI is an oil particularly rich in the mono-unsaturated fatty acid petroselinic acid (C18:1 n-12 or cis delta 6). In addition to petroselinic acid (60-75% m/m), it also contains small quantities of other fatty acids such as linoleic acid (12-19%), oleic acid (8-15%), palmitic acid (2-5%) and stearic acid (<1.5%). The applicant specifies that petroselinic acid is the cis $\Delta$ 6 isomer of octadecenoic acid and has structural similarities with oleic acid (14°C), which is the cis $\Delta$ 9 isomer of octadecenoic acid. It also indicates that the difference in the double bond position gives petroselinic acid a melting point (30°C) higher than that of oleic acid (14°C), which could make it suitable for industrial purposes or for use in food. The applicant thus suggests that oils rich in petroselinic acid could provide 'low-fat' alternatives to conventional vegetable oils, owing to their lower rate of assimilation.

The NI also has a phytosterol and phytostanol content of 2.4 to 3.7 g/kg. The predominant phytosterols are  $\beta$ -sitosterol, stigmasterol and campesterol.

Regarding the potential presence of substances such as heavy metals, dioxins/PCBs and pesticides, the applicant stipulates that the tests carried out on different batches of the NI reveal that the levels are lower than the maximum levels permitted under European legislation, or than the quantification limits for the analytical methods applied. Similarly, it is mentioned in the application file that the NI's protein content is lower than the quantification limits for the analytical methods applied (0.1 g/100 g).

The applicant states that the NI's shelf-life is 12 months maximum if stored in an airtight environment and protected from light at temperatures not exceeding 20°C. It mentions that acid and peroxide rates and the absence of solvent residues and other contaminants indicate the good oxidative stability of the coriander oil. However, since the storage conditions may affect the taste and nutritional value of the oil, additional analyses will be added to the dossier in 2012.

*The Irish authorities take the view that the applicant provides little information on the nutritional impact of 'coriander seed oil' and on petroselinic acid.*

***The CES NUT emphasises that, owing to its very high petroselinic acid content, coriander seed oil's composition is atypical and is not nutritionally equivalent to any commonly consumed oil.***

*Moreover, the applicant's suggestion that the NI could be a 'low fat' alternative to vegetable oils is not borne out by the data provided in the scientific literature. In particular, in vivo data on the bioavailability of fatty acids contradict this assertion.*

*The CES AAAT points out that there may be confusion between 'coriander seed oil' and 'coriander essential oil', which do not have the same composition, as the latter has a much higher linalol content (approx. 70% m/m). It should be clarified that the NI must not contain residues of essential oil.*

*Regarding the NI's stability, the CES NUT has not given a conclusive opinion, since some information has not been provided. However, it is likely that the fatty acid composition of the oil (75% to 80% of mono-unsaturated fatty acids) may make it relatively stable.*

▪ **Effect of the production process applied to the NI**

The manufacturing process of the NI involves mechanical pressing of coriander seeds followed by extraction with hexane. Hexane tests carried out on three different batches of the NI show that the residual concentration in this solvent is lower than the quantification limit for the analytical method (0.5 mg/kg). Hexane is a solvent authorised for use in food, provided that the residues in the finished product do not exceed 1 mg/kg. It is specified in the dossier that the hexane residues in the finished product will not exceed this amount. The raw oil is then refined and stabilised in accordance with standard practice.

*The Irish authorities have no particular comment to make on this point.*

*The CES AAAT has no particular comment to make on this point.*

*The CES NUT stresses that owing to the traces of essential oil in the raw oil, the applicant must ensure that the refining and stabilisation procedures allow the terpenes to be eliminated.*

▪ **History of the organism used as the source of the NI**

Non-genetically modified coriander seeds (*Coriandrum sativum* L.) are purchased in Bulgaria. Fruits and leaves of *Coriandrum sativum* L. have a history of consumption in the EU and distilled essential oil of coriander seed has been used for over a century as a fragrance and a food ingredient.

*The Irish authorities have no comment to make on this point.*

*The CES NUT and CES AAAT have no comments to make on this point.*

▪ **Anticipated intake/extent of use of the NI and information from previous human exposure to the NI or its source**

The applicant intends to market the novel ingredient in food supplements at levels of approximately 600 mg/day (3x200 mg per day), equivalent to 10 mg/kg bw/day for a person weighing 60 kg. It stresses that the supplements are not intended to replace another food and will be appropriately labelled in accordance with Directive 2002/46/EC. It points out that, although no population has been identified as at risk from consumption of the NI, food supplements containing the NI are not intended for children.

The applicant points out that coriander oil does not have a history of consumption in the EU but coriander has been cultivated in the EU for many years and whole and ground fruits are consumed alone or mixed with other spices in the form of seasoning and curry powders.

The applicant estimated the normal dietary consumption of coriander oil using British consumption data and taking into account that the oil represents 20.4% of the total weight of coriander seed.

Average consumption levels and those for the 97.5<sup>th</sup> percentile have been evaluated for the heaviest consumers of coriander seed and for the general population. It reports that within the population of coriander seed consumers, the average intakes are 20 mg of coriander oil per day in adults and 27 mg per day in adolescents. Intakes for the 97.5<sup>th</sup> percentile may reach 202 mg/day in adults and 230 mg/day in adolescents.

The applicant concludes on this basis that the estimated high intake from coriander oil accounts for a third of the anticipated intake of the NI from food supplements.

*The Irish authorities note that the proposed levels of consumption of the NI (600 mg/day) are around 20 times higher than the average basal consumption (28.4 mg/day) of coriander oil, but only three times higher than the highest intakes (230 mg/day). Thus, in an extreme scenario, the combined intakes from diet and food supplements are estimated at 830 mg/day.*

*The Irish authorities consider that, from a nutritional point of view, consumption of the NI at the doses proposed – which are three times higher than the highest intakes from the normal diet – does not give rise to any safety concerns.*

***The CES NUT considers that an intake of 600 mg/day of 'coriander seed oil' should not significantly alter the nutritional balance of essential fatty acids in the diet, even for the heaviest consumers of coriander seed. In contrast, the CES does question the validity of the estimated intakes of petroselinic acid from a normal diet. This estimate is based on the hypothesis that the absorption of this fatty acid is identical in coriander powder and in 'coriander seed oil', which is highly unlikely. Rather, it is likely that the quantities of petroselinic acid actually absorbed through the normal diet are much lower. The CES NUT therefore considers that it is not possible to infer that the NI is safe based on the history of consumption of coriander seed.***

***Moreover, the CES AAAT observes that curry containing coriander extracts is heavily consumed in England and the exposure to 'coriander seed oil' estimated on this basis by the applicant may therefore be considered extreme in relation to exposure in France, given the level of curry consumption anticipated in France.***

#### ▪ **Nutritional information on the NI**

'Coriander seed oil' is intended to be incorporated into food supplements to impart apparent benefits on skin and hair. The main constituent of 'coriander seed oil' is petroselinic acid, which is a monounsaturated fatty acid (60-75%). Smaller proportions of other fatty acids such as linoleic, oleic, palmitic and stearic acid are also present.

The applicant describes the uses of coriander in all its forms, including seed. It also states that petroselinic acid is present in caraway seed, parsley seed, fennel seed, and the berries of the Devil's Walkingstick (*Aralia spinosa* L.).

*The Irish authorities have no comment to make on this point.*

***The CES NUT and the CES AAAT have no comments to make on this point.***

#### ▪ **Microbiological information on the NI (XII)**

The applicant provided a summary of the microbiological specifications and the analyses of three batches of 'coriander seed oil' using standard methods.

*The Irish authorities consider that the microbiological status of the NI is satisfactory and that this is confirmed by the results of the tests on the batches.*

**The CES NUT and the CES AAAT have no comments to make on this point.**

▪ **Toxicological information on the NI**

The applicant points out that few studies have been published specifically on the safety of 'coriander seed oil' as opposed to the essential oil of coriander fruits, on which there are numerous publications. The safe consumption of the NI is based mainly on the history of consumption of coriander seeds. The applicant also refers to a 13-week oral toxicity study in rats using doses of up to 1000 mg/kg bw/day and a small number of subchronic toxicity studies using doses of up to 6000 mg/kg bw/day.

Absorption, tissular distribution, metabolism and excretion

The long-chain fatty acids which constitute the NI are readily absorbed from the gastrointestinal tract and metabolised. The results of some *in vitro* studies show that triglycerides containing petroselinic acid are hydrolysed at slower rates compared to other triglycerides, which could lead to the NI having a bioavailability different from that of other vegetable oils (Heimermann et al., 1973). However, a 10-week rat feeding study comparing the *in vivo* absorption of triglycerides from the NI with those from other oils e.g. sunflower and olive, shows that petroselinic acid was absorbed at similar rates to oleic acid but significantly higher levels of linoleic acid and lower levels of arachidonic acid were observed in tissue and blood lipids of animals fed the NI compared to those fed high-oleic sunflower oil, suggesting that petroselinic acid interferes with the synthesis of arachidonic acid from linoleic acid. The authors of this study suggest that petroselinic acid is metabolised in the liver via carbon chain elongation and/or beta oxidation (Weber et al., 1997).

Toxicity studies

The applicant points out that it has not identified any acute toxicity study for 'coriander seed oil'.

The applicant carried out a subchronic study in rats on the NI in accordance with the OECD principles of Good Laboratory Practice (GLP) and also presents two published subchronic toxicity studies in rats for 'coriander seed oil'.

*Study in rats on the NI (batches of oil provided by the applicant): 13-week oral toxicity study*

Four groups of Wistar Cri: WI (Han) rats (10 males + 10 females) received by gavage 0, 150, 400 or 1000 mg/kg bw/day of the NI for 91 and 92 days. In addition, two satellite groups of five control rats of each gender (1% carboxymethyl cellulose) and five rats of each gender fed 1000 mg/kg bw/day were formed for a two-week reversibility study. Standard clinical analyses (blood and urine) were conducted on all animals as well as ophthalmological tests. All the animals were subject to anatomopathological tests and all the major organs were histologically examined.

The results do not indicate any mortality nor any significant clinical signs linked to the treatment. Weight changes (reductions) were observed in males belonging to the 150 and 400 mg/kg bw/day groups but were not statistically significant. There was a slight but not statistically significant increase in food consumption in the males and females. The haematological examinations revealed statistically significant reversible modifications – not, however, linked to the dose – some of which were observed in only one gender and within the limits of the historical data. Besides an increase in the glucose rate in the males, which is statistically significant only at the highest dose tested (1000 mg/kg bw/day), the other clinical biology results did not reveal any significant effects. The average blood glucose levels in the males in this study were 7.5 mmol/L ( $\pm$  1.2) in the control rats, 7.6 $\pm$ 0.6 mmol/L in the group treated with 150 mg NI/kg bw/day, 8.0 $\pm$ 0.6 mmol/L in the group treated with 400 mg NI/kg bw/day and 10.0 $\pm$ 1.5 mmol/L in the group treated with 1000 mg NI/kg bw/day.

The blood glucose in the females remained unaltered, with plasma levels of  $5.4 \pm 0.6$  mmol/L,  $5.3 \pm 0.7$  mmol/L,  $5.4 \pm 0.5$  mmol/L and  $5.9 \pm 0.9$  mmol/L respectively in the control group and the groups treated with 150 mg NI/kg bw/day, 400 mg NI/kg bw/day and 1000 mg NI/kg bw/day. Moreover, the blood glucose of the (male and female) animals in the reversibility group remained unchanged, with values for the male control rats of  $6.0 \pm 0.9$  mmol/L and  $6.0 \pm 0.3$  mmol/L for those treated with 1000 mg NI/kg bw/day. In the females in the reversibility group, the respective values were 5.1 and 4.9 mmol/L. An increase in the relative weight of the thymus was reported in the males treated with the intermediate dose (400 mg/kg bw/day), but without any histological changes in this organ. In the females, a reduction in the absolute weight of the brain and heart were observed, but only at the end of the reversibility study. The anatomopathological results did not reveal any lesions in the organs examined.

The applicant proposes, on the basis of this 13-week (gavage) study, a dose with a No-Observed-Adverse-Effect-Level (NOAEL) of 1000 mg/kg bw/day (the highest dose tested).

*Studies in rats in scientific publications (using batches of coriander oil other than those produced by the applicant)*

#### 10-week oral toxicity study in rats

A group of 9 male Wistar rats received by gavage a diet containing 12% coriander oil, 72% petroselinic acid (corresponding to roughly 6000 mg/kg bw/day) and 2% corn oil for a period of 10 weeks. Four other groups of 10 rats were treated with equivalent quantities of either sunflower oil rich in oleic acid, or conventional sunflower oil, olive oil or rapeseed oil. Finally, one control group (5 rats) was administered a standard diet with 4% fat (Richter et al., 1996). All animals were subject to anatomopathological examinations and histological examinations of the liver, heart, aorta, stomach and spleen.

The results reveal fatty infiltration and an accumulation of fatty cysts in the liver tissue, accompanied by an increase in liver nuclei indicating hepatocyte stimulation. No such marked effect was noted in the animals treated with the other oils although fatty infiltrations were also observed. No other organ examined was affected by this kind of lesion. The authors suggested that the fatty infiltration of the hepatocytes could have resulted from the fact that there were insufficient hepatic lipases to metabolise the petroselinic acid (see metabolism section).

#### 10-week oral toxicity study in rats

Six groups of 10 male Wistar rats were administered by gavage a diet containing coriander oil (72% petroselinic acid), olive oil, high oleic acid sunflower oil, conventional sunflower oil or rapeseed oil at concentrations of 12% (roughly 6000 mg/kg bw/day), as well as 2% corn oil for a period of 10 weeks. The animals were subject to anatomopathological and histological examinations of the liver, heart, aorta, stomach and spleen (Weber et al., 1995).

The results do not reveal any mortality linked to the treatment, nor any significant clinical signs or effect on weight. The increases in liver weight in animals fed coriander oil were observed compared with animals treated with other sources of fat. No difference in the weight of the pancreas, kidneys, spleen and gonads was reported. The distribution of the fatty acids in the tissue of the animals in the group fed coriander oil showed a slight increase in petroselinic acid and oleic acid.

### In vitro genotoxicity studies

#### Bacterial reverse mutation

Study carried out in accordance with OECD Guidelines (No 471), Directive 2000/32/EC and ICH Guidelines (1995).

This is an Ames test with and without metabolic activation (S-9) on five strains of *Salmonella typhimurium*: TA-1535, TA-1537, TA-98, TA-100 and TA102. The assay encompasses positive and untreated control animals. The results reveal the absence of cytotoxicity in the concentrations tested of up to 16,000 µg/plate. This concentration is higher than the concentration of 5000 µg/plate recommended in the OECD Guidelines. Under these test conditions, the NI does not have any mutagenic effect on the five strains tested.

Mammalian cell mutation

This is a TK<sup>+/−</sup> test with and without metabolic activation (S-9) on mouse lymphoma cells L5178Y. It involves long-term exposure to the NI (24 hours) without metabolic activation and a short exposure (4 hours) with and without metabolic activation. The results reveal the absence of mutagenicity in the concentrations tested of up to 8000 µg/mL.

Conclusions on the toxicity and metabolism data

The applicant points out that the anticipated intake of the NI of 10 mg/kg bw/day, corresponding to a daily consumption of food supplements containing 600 mg of 'coriander seed oil' by an individual weighing 60 kg, gives a margin of safety of 100. If the NOAEL is compared with an intake of 830 mg from food supplements, combined with the 230 mg from the consumption of coriander seed oil by the heaviest adolescent consumers, the margin of safety is 72.

*The Irish authorities take the view that the minor biochemical and physiological changes observed at the NOAEL dose are not surprising given the long-term consumption of a high-fat diet and are not considered adverse effects of the NI itself. The margins of safety of 100 (if only consumption of the food supplement is considered) and 72 (if consumption of the food supplement together with coriander seed in a normal diet for the 97.5<sup>th</sup> percentile in adolescents is considered), calculated on the basis of the NOAEL of 1000 mg/kg bw/day, are adequate. The significant effect on lipid metabolism observed in response to the highest dose of the NI (6000 mg/kg bw/day) must be considered in the context that it represents 600 times the recommended dose in the food supplement.*

*The Irish authorities take the view that, although the toxicological information is limited owing to the absence of carcinogenicity, reproductive toxicity and clinical studies, in the light of the history of consumption of coriander-based products and the relevant margins of safety, it can reasonably be considered that the NI does not present a risk at the doses proposed.*

***The CES NUT emphasises that very little is known about petroselinic acid, which has not been the subject of many studies. It is metabolised without harm in rat liver: it is elongated to C20:1 n-12 and/or shortened to C16:1 n-12, and no problems relating to accumulation of this fatty acid in the liver have been noted. In spite of the structural similarities between petroselinic acid and oleic acid, these two fatty acids do not have any metabolic similarities. Triglycerides rich in petroselinic acid seem more resistant to pancreatic lipase than those rich in oleic acid (Heimermann et al., 1973). Petroselinic acid is also a better substrate for the acyltransferases involved in the biosynthesis of triglycerides (Weber et al., 1999). Moreover, the positions at which petroselinic acid is esterified onto phospholipids (only sn1) and triglycerides (sn1 and 3) differs from those for oleic acid (sn1, 2 and 3; Hoy et Holmer, 1981; Weber et al., 1995 and 1999). All these observations show that petroselinic acid is very well incorporated in the membranes and lipid storage of all tissues and organs (Weber et al., 1995 and 1999). It has even been linked, in rats fed a very high dose, to an increase in fatty infiltration and the appearance of fatty cysts in the liver (Weber et al., 1995; Richter et al., 1996). These observations suggest that petroselinic acid is a poor substrate for either beta-oxidation or hormono-sensitive lipase or hepatic lipase. More in-depth studies with isolipidic control diets would be needed to dispel the doubts in this regard.***

***Moreover, unlike oleic acid, petroselinic acid appears to inhibit the formation of arachidonic acid from linoleic acid, probably through its inhibitory effect on the A6-desaturase, although it is not competing with it (Weber et al., 1995). This is not prohibitive, as the metabolism process involves considerable competition between the substrates for Δ6-desaturase. To our knowledge, no clinical studies in humans have been carried out on this subject. It would, however, be advisable, as proposed by the applicant, to recommend that this oil not be given***

*to children, since they require considerable arachidonic acid synthesis to be maintained for the purpose of growth.*

*Lastly, the CES NUT stresses the absence of a human study on petroselinic acid or on 'coriander seed oil'.*

*The CES AAAT believes that the 13-week oral toxicological study in rats carried out in accordance with the recognised guidelines is acceptable and can be used to evaluate the safety of the NI. As regards the raised blood glucose in the males, the CES does not consider the raised blood glucose level in males as an effect to be included in the risk evaluation, since it is not statistically significant in the doses tested, except in the highest dose, it is limited in absolute value and it does not appear in the reversibility study. In general, the results of this study have not revealed any adverse effects and it was consequently possible to identify a NOAEL of 1000 mg/kg bw/day. This NOAEL corresponds to the highest dose tested in the assay.*

*The CES AAAT considers that the effects of lipid accumulation in the liver or the effects on the blood lipid profile of certain fatty acids reported in rats fed coriander oil containing 72% petroselinic acid (not produced by the applicant) may be partly explained by the fact that the animals ingested large amounts of the oil corresponding to 5000 and 6000 mg/kg bw/day. Indeed, the animals which consumed the same quantity of other vegetable oils also exhibited fatty infiltration, albeit to a lesser extent.*

*The CES AAAT also considers that the traditional in vitro tests submitted by the applicant are acceptable. The conclusions are clear and show the absence of an in vitro mutagenic effect associated with the NI in bacterial and mammalian cells. The CES observes that the recommended dose of the NI of 600 mg per day is equivalent to 10 mg/kg bw/day for a person weighing 60 kg. This dose is 500 and 600 times lower than the above-mentioned doses revealing lipid responses in rats. Moreover, a 100-fold margin of safety was identified between the maximum anticipated exposure to the NI (10 mg/kg bw/day) and the NOAEL identified in the 13-week toxicological study (1000 mg/kg bw/day) on the NI.*

*The CES AAAT therefore agrees with the Irish authorities that the doses proposed do not present any toxicological risk.*

#### ▪ Allergenicity

Allergenic symptoms, which are likely to be associated with specific plant proteins, have been reported for coriander. Since residual proteins are removed during the oil refining process, the applicant assumes that the NI does not present any risk of allergenicity. Nor has the applicant identified any reports of allergenicity or sensitivity to coriander seed oil in the literature.

*The CES NUT and the CES AAAT take the view that, since residual proteins are removed during the refining of the oil, the NI does not present any allergenic risk.*

#### ▪ Conclusion of the Irish authorities

*The Irish food safety authority has not identified any safety concerns as regards consumption of the NI containing 'coriander seed oil' at the proposed dose of 600 mg/day and therefore considers that the NI meets the criteria described in Article 3.1 of the Novel Foods Regulation.*

#### ▪ Conclusions of the CES NUT and CES AAAT

*The CES AAAT considers that the studies submitted by the applicant are sufficient to define a NOAEL of 1000 mg/kg bw/day. It emphasises that this dose is 500 to 600 times higher than the dose recommended by the applicant for addition to food supplements and around 100 times higher than the maximum anticipated exposure to the NI. It considers that these margins of safety are acceptable. The traditional in vitro tests submitted by the applicant are also acceptable. The conclusions are clear and reveal the absence of a mutagenic effect associated with the NI in bacterial and mammalian cells. Consequently, the CES AAAT agrees with the Irish authorities that the proposed doses do not present any toxicological risk.*

*The CES NUT stresses that, owing to its very high petroselinic acid content, 'coriander seed oil' has an atypical composition and is not nutritionally equivalent to any other commonly consumed oil. It considers that the bioavailability of petroselinic acid in the seed is in all likelihood lower than its bioavailability in the oil. Consequently, the intakes of bioavailable petroselinic acid from a normal diet are likely to have been overestimated by the applicant and it cannot be concluded that the novel ingredient is safe based on the history of consumption of coriander seed.*

*The CES NUT takes the view that little is known about the metabolism of petroselinic acid, and the medium- and long-term consequences of an intake of 600 mg/day have not been sufficiently evaluated. The CES is concerned about the following in particular:*

- the fact that petroselinic acid appears to be a poor substrate for beta-oxidation and for hepatic lipase or hormone-sensitive lipase. There are no in-depth studies involving isocaloric control diets to address doubts concerning the long-term impact of consumption of the novel ingredient on the accumulation of lipids in the liver;*
- the medium- and long-term impact of consuming 600 mg of coriander seed oil per day on the bioavailability of essential fatty acids, given the probable action of petroselinic acid on desaturases.*

*Therefore, additional specific studies on the hepatic metabolism of petroselinic acid appear to be necessary in order to demonstrate that the NI can be safely consumed in the long term. Moreover, in as far as the history of consumption is insufficient in Europe, post-marketing monitoring is required.*

## 5. CONCLUSION AND RECOMMENDATIONS OF THE AGENCY

ANSES adopts the conclusions of the CES NUT and the CES AAAT.

Director General

Marc MORTUREUX

**KEYWORDS**

*Petroselinic acid, novel ingredient, oil, coriander seed*

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