# Raapzaadolie met fytosterolen en vitamine E

Tweede beoordeling van de veiligheid voor de consument, volgens de Europese verordening 258/97 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten

# Rapeseed oil with phytosterols and vitamin E

Second opinion regarding consumer safety, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients

Gezondheidsraad:
Commissie Veiligheidsbeoordeling nieuwe voedingsmiddelen (VNV)

Health Council of the Netherlands:
Committee on the Safety Assessment of Novel Foods

aan/to:

de Minister van Volksgezondheid, Welzijn en Sport/
the Minister of Health, Welfare and Sport

de Minister van Landbouw, Natuurbeheer en Visserij/
the Minister for Agriculture, Nature management and Fisheries

Nr 2002/02VNV, Den Haag, 16 mei 2002
No. 2002/02VNV, The Hague, May 16, 2002

De Gezondheidsraad, ingesteld in 1902, is een adviesorgaan met als taak de regering en het parlement “voor te lichten over de stand der wetenschap ten aanzien van vraagstukken op het gebied van de volksgezondheid”(art. 21 Gezondheidswet).

De Gezondheidsraad ontvangt de meeste adviesaanvragen van de bewindslieden van Volksgezondheid, Welzijn & Sport, Volkshuisvesting, Ruimtelijke Ordening & Milieubeheer, Sociale Zaken & Werkgelegenheid, en Landbouw, Natuurbeheer & Visserij. De Raad kan ook eigener beweging adviezen uitbrengen. Het gaat dan als regel om het signaleren van ontwikkelingen of trends die van belang kunnen zijn voor het overheidsbeleid.

De adviezen van de Gezondheidsraad zijn openbaar en worden in bijna alle gevallen opgesteld door multidisciplinair samengestelde commissies van — op persoonlijke titel benoemde — Nederlandse en soms buitenlandse deskundigen.

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Health Council of the Netherlands

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Welzijn en Sport

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Mevrouw de minister,

Dit schrijven dient ter beantwoording van de door u mede namens de Minister van Landbouw, Natuurbeheer en Visserij aan de Gezondheidsraad voorgelegde adviesaanvraag over de veiligheid van nieuwe voedingsmiddelen en nieuwe voedselingrediënten. Aan de orde is een zogenoemde tweede beoordeling, conform de Europese verordening 258/97, van een raapzaadolie met fytosterolen en rijk aan vitamine E. Het nieuwe product zal niet als spijsolie worden toegepast. Het kan direct worden geconsumeerd als voedingssupplement, of verwerkt worden in allerlei levensmiddelen. Deze beoordeling is verricht door de Commissie 'Veiligheidsbeoordeling nieuwe voedingsmiddelen' van de Gezondheidsraad (Commissie VNV).

De eerste beoordeling van de aanvraag voor markttoelating is verricht door het Franse voedselveiligheidsbureau '*Agence française de sécurité sanitaire des aliments*' (AFSSA). De AFSSA plaatst kritische kanttekeningen bij het innemen van vitamine E, bepaalde vetzuren en fytosterolen die in de olie aanwezig zijn. De AFSSA heeft de raapzaadolie beoordeeld als veilig, mits de dagelijkse consumptie niet meer is dan 1,5 g. Daarnaast concludeert de AFSSA dat gezondheidclaims die inspelen op het mogelijk cholesterolverlagend effect van fytosterolen niet zijn toegestaan. De bevoegde autoriteit, de Franse overheid, heeft dit advies integraal overgenomen.

De Commissie VNV baseert haar oordeel op het rapport van de eerste beoordeling door de AFSSA en op de informatie in het dossier. De Commissie VNV stemt slechts ten dele in met de Franse beoordeling en is op een aantal onderdelen kritischer. Ten opzichte van de traditionele raapzaadolie is, door een speciaal productieproces, het fytosterolgehalte en het vitamine E-gehalte (totaal tocoferolen) van de nieuwe olie 10 maal groter. Daar staat tegenover dat het totale vetzuurgehalte is afgenomen met ongeveer 9%. De vetzuursamenstelling is echter niet noemenswaardig gewijzigd. De kwaliteit van het productieproces lijkt gewaarborgd. De olie bevat

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geen ongewenste bestanddelen of microbiologische verontreinigingen. Het erucazuurgehalte van de nieuwe raapzaadolie is volgens de aanvrager ten hoogste 5% van het totaal aan vetzuren. De olie voldoet hiermee aan Richtlijn 76/621/EEG betreffende de vaststelling van het maximumgehalte aan erucazuur in oliën en vetten.

Aanvullend op de eerste beoordeling constateert de Commissie VNV dat de samenstellinggegevens niet eenduidig zijn weergegeven. Op meerdere plaatsen in het dossier worden gehalten van oliefracties vermeld die soms van elkaar verschillen. Bij de productspecificatie maakt de Commissie VNV er bezwaar tegen dat voor fytosterolen en vitamine E slechts een minimaal gehalte wordt vermeld. Zij concludeert dat de samenstelling duidelijker moet worden gespecificeerd waarbij de aanvrager ook bovengrenzen voor de bestanddelen moet aangeven.

De Commissie VNV brengt onder de aandacht dat er voor inneming van vitamine E geen Nederlandse of Europese bovengrens is vastgesteld. In de toelichting bij het Nederlandse warenwetbesluit 'Toevoeging micro-voedingsstoffen aan levensmiddelen' wordt gesteld, dat inneming van 4 à 5 maal de aanbevolen dagelijkse hoeveelheid van 10 mg vitamine E (α-tocoferol equivalenten) zeker geen schadelijk effect oplevert. Volgens dit warenwetbesluit mag de dagportie per verrijkt product ten hoogste de aanbevolen hoeveelheid vitamine E bevatten. De 7 mg α-tocoferol equivalenten die de consument binnenkrijgt bij inneming van 1,5 g van de nieuwe raapzaadolie valt hier nog onder. Recent is in de Verenigde Staten een veilige bovengrens vastgesteld van 1000 mg per dag.

Het fytosterolgehalte van de raapzaadolie (7%) is vergelijkbaar met dat van fytosterol-verrijkte smeerbare vetten (8%). De hoeveelheid dagelijks te consumeren olie die de aanvrager voorstelt is echter laag (1,5 g) en bevat ongeveer 0,1 g fytosterolen. Dit is ruwweg de helft van de hoeveelheid die de doorsnee consument via de gewone voeding binnenkrijgt. De Commissie VNV is daarom van mening dat een overmatige fytosterolinneming bij de voorgestelde dagelijkse consumptie van de raapzaadolie niet aan de orde is. Zij is het eens met de AFSSA dat deze fytosterolinneming onvoldoende groot is om een cholesterolverlagend effect te bewerkstelligen.

De belangrijkste kritiek die de Commissie VNV heeft is dat de aanvrager geen voorstel doet hoe hij wil voorkomen dat de voorgestelde olieconsumptie wordt overschreden. De Commissie VNV heeft daarom bezwaar tegen het op de markt brengen van het nieuwe product tenzij de aanvrager duidelijk aangeeft welke maatregelen hij wil treffen om er voor te zorgen dat de consumptie beperkt blijft tot de voorgestelde hoeveelheden, te weten 1,5 g raapzaadolie per dag.

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**Gezondheidsraad** Vice-voorzitter
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Dit is van belang om de inneming van fytosterolen en vitamine E te begrenzen. Voor de directe consumptie van deze olie dient informatie te worden verstrekt over de verpakkingsvorm en -grootte. Ook is de commissie van mening dat het assortiment levensmiddelen waarin de raapzaadolie verwerkt zal gaan worden, nader gespecificeerd moet worden.

Ik onderschrijf de conclusies en aanbevelingen van de commissie.

Hoogachtend,

prof. dr JGAJ Hautvast

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# Letter to the Dutch Minister of Health, Welfare and Sport

On May 16, 2002, professor JGAJ Hautvast, Vice-president of the Health Council of the Netherlands wrote as follows to the Minister of Health, Welfare and Sport:

This letter has been prepared in reply to your request for advice regarding the safety of novel foods and food ingredients, also made on behalf of the Minister of Agriculture, Nature Management and Fisheries. The subject in question is a so-called second opinion, in accordance with European Regulation 258/97, concerning a rapeseed oil with phytosterols and vitamin E. The new product will not be sold for traditional use as salad or cooking oil. It can be consumed as such (food supplement), or incorporated in a wide range of foodstuffs. This assessment has been carried out by the 'Committee on Safety Assessment of Novel Foods' (VNV Committee) of the Health Council of the Netherlands.

The first assessment of the application for market introduction was carried out by the French Food Safety Agency, 'Agence française de sécurité sanitaire des aliments' (AFSSA). The AFSSA expressed a critical view on consumption levels of vitamin E, certain fatty acids and phytosterols, all of which are present in the oil. After assessing the rapeseed oil, the AFSSA has concluded that it is safe, provided that daily consumption does not exceed 1.5 g. The AFSSA also concluded that no health claims will be permitted in relation to phytosterols' ability to reduce cholesterol levels. The French government, which is the competent authority in this case, has fully adopted this recommendation.

The VNV Committee based its views on the report of the initial assessment by the AFSSA, and on the information contained in the dossier. The VNV Committee agrees only in part with the French assessment. A special production process is used to increase phytosterol and vitamin E levels in the new oil. As a result, phytosterol levels and vitamin E levels (total tocopherols) are 10 times greater than those found in traditional rapeseed oil. Conversely, total fatty acid content has been reduced by approximately 9%, without considerable changes in fatty acid composition. The quality of the production process appears to be guaranteed. The oil contains neither undesirable components nor microbiological contaminants. According to the applicant, the erucic acid content of the new rapeseed oil does not exceed 5% of the total fatty acid content. As a result, the oil complies with Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats.

In addition to the first assessment, the VNV Committee notes that the composition data of the oil are not unequivocally indicated. Data on the levels of oil fractions are presented several times in the dossier, yet the values given are not always the same. With regard to the product specification, the VNV Committee objects to the fact that only a minimum level is indicated for phytosterols and vitamin E. It concludes that the composition should be specified more clearly, by requiring that the applicant also indicates maximum levels for the various components.

The VNV Committee would like to point out that both the Netherlands and the EU have not established upper intake levels for vitamin E. The explanatory notes of the Dutch Commodities Act Decree 'Addition of micro-nutrients to food' state that an intake of 4 to 5 times the recommended daily allowance of 10 mg vitamin E (á-tocopherol equivalents) definitely produces no harmful effects. According to this Commodities Act, the daily allowance of a fortified product must contain no more than the recommended amount of vitamin E. The 7 mg of á-tocopherol equivalents that consumers receive when they ingest 1.5 g of the new rapeseed oil is still below this limit. A safe upper intake level was recently established in the United States. This amounts to 1000 mg per day.

The phytosterol content of the rapeseed oil (7%) is comparable to that of fat spreads that have been fortified with phytosterols (8%). However, the daily oil consumption proposed by the applicant is quite low (1.5 g), and contains about 0.1 g of phytosterols. This is roughly half of the amount that the average consumer ingests as part of their normal diet. The VNV Committee therefore takes the view that limited consumption of rapeseed oil poses no threat of excessive phytosterol intake. It agrees with the AFSSA that the anticipated phytosterol intake is too low to effectively reduce blood cholesterol levels.

The applicant has not provided information how exceeding the proposed daily oil consumption should be prevented. This is the major criticism of the VNV Committee. It

therefore objects to authorisation of the new oil on the European market unless the applicant clearly indicates what measures the company will take to ensure that consumption is restricted to the proposed amounts, namely 1.5 g of rapeseed oil per day. This is important, in order to limit the intake of phytosterols and vitamin E. With regard to the direct consumption of this oil, information should be provided on the type and size of the packaging to be used. The Committee also concludes that the range of foodstuffs, into which the rapeseed oil is to be incorporated, should be specified more clearly.

I endorse the conclusions and recommendations of the Committee,

(signed) professor JGAJ Hautvast

# Literatuur/Literature


EC97 Regulation (EC) 258/97 (Verordening (EG) nr 258/97 van het Europees Parlement en de Raad van 27 januari 1997 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten. Publikatieblad van de Europese Gemeenschappen 1997; L43: 1-6)

EC97a Recommendation 97/618/EC (Aanbeveling nr 97/618/EG van de Commissie van 29 juli 1997 betreffende de wetenschappelijke aspecten en de presentatie van de informatie die nodig is om aanvragen voor het in de handel brengen van nieuwe voedingsmiddelen en nieuwe voedselingrediënten te ondersteunen alsmede het opstellen van de verslagen van de eerste beoordeling uit hoofde van Verordening (EG) nr 258/97 van het Europees Parlement en de Raad. Publicatieblad van de Europese Gemeenschappen 1997; L253: 1-36)

FAO96 Biotechnology and Food Safety. Report of a joint FAO/WHO Consultation. Rome, FAO 1996.

FAO01 Evaluation of allergenicity of genetically modified foods. Report of a joint FAO/WHO expert consultation on allergenicity of foods derived from biotechnology. Rome, FAO 2001.

HCN92 Commissie Toxicologische aspecten van biotechnologisch bereide producten. Productveiligheid bij nieuwe biotechnologie. The Hague, Health Council of the Netherlands 1992, publication number 1992/03.

OECD93 Safety evaluation of foods derived by modern biotechnology. Concepts and principles. Paris, OECD 1993.

OECD96 OECD Workshop on Food Safety Evaluation. Paris, OECD 1996.

OECD98 Report of the OECD workshop on the toxicological and nutritional testing of novel foods. Paris, OECD 1998.

OECD00 Report of the task force for the safety of novel foods and feeds. Paris, OECD 2000.

SCF99 Opinion concerning the scientific basis for determining whether food products, derived from genetically modified maize, could be included in a list of food products which do not require labelling because they do not contain (detectable) traces of DNA or protein. Brussels, Scientific Committee on Food of the EU 1999.

SSC99 Opinion of the Scientific Steering Committee on microbial resistance, Brussels, Scientific Steering Committee of the EU 1999.

WHO91 Strategies for assessing the safety of foods produced by biotechnology. Report of a joint FAO/WHO Consultation. Geneva, WHO 1991.

WHO00 Safety aspects of genetically modified foods of plant origin. Report of a joint FAO/WHO expert consultation on foods derived from biotechnology. Geneva, WHO 2000.

A De adviesaanvraag/Request for advice

B De commissie/The committee

C EU-procedure/EU-procedure

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Bijlage **A**

# De Adviesaanvraag/Request for advice

Op 18 augustus 1999 schreef de Minister van Volksgezondheid, Welzijn en Sport aan de Voorzitter van de Gezondheidsraad (brief kenmerk GZB/VVB 993428):

Sinds mei 1997 is in de Europese Unie de Verordening (EG) 258/97 van kracht inzake nieuwe voedingsmiddelen en nieuwe voedselingrediënten. Daarmee werd de veiligheidsbeoordeling onderdeel van een communautaire procedure.

Met u is reeds de mogelijkheid besproken de beoordeling door de Gezondheidsraad te laten uitvoeren. Ik verzoek u dan ook mede namens de Staatssecretaris van Landbouw, Natuurbeheer en Visserij, in deze eerste fase van uitvoering van de Europese Verordening (EG) 258/97 gedurende een aantal jaren, de veiligheidsbeoordeling gestalte te geven. Voor het onderbrengen bij de Gezondheidsraad pleit het experimentele karakter dat de beoordeling de eerste jaren zal hebben. Dit experimentele karakter komt voort uit het feit dat het een nieuw soort beoordeling betreft van deels nieuwe categorieën van voedingsmiddelen of voedselingrediënten. Het is namelijk een veiligheidsbeoordeling vóór het op de markt brengen van met name voedingsmiddelen van een genetisch gemodificeerde oorsprong en zogenaamd functional foods (nutriceutica). Daarnaast ga ik ervan uit dat de onafhankelijke wetenschappelijke advisering door de Gezondheidsraad het vertrouwen van de Europese Commissie en de andere lidstaten in het Nederlandse oordeel nog versterkt.

Mijn beleid is erop gericht een zo groot mogelijke openheid en transparantie te realiseren van de gevolgde procedure en de beoordeling om de consument vertrouwen te geven in de veiligheid van de nieuwe

voedingsmiddelen. Ik verzoek de Gezondheidsraad hieraan bij te dragen door bijvoorbeeld inzage te geven in de dossiers waarvoor een aanvraag wordt ingediend, waarbij uiteraard bedrijfsvertrouwelijke gegevens worden beschermd en door de criteria, waarop de veiligheid zal worden beoordeeld, te publiceren.

De Minister van Volksgezondheid, Welzijn en Sport,
w.g. dr E Borst-Eilers

## English translation

On 18 August 1999, the Minister of Health, Welfare and Sport wrote as follows to the President of the Health Council of the Netherlands (under reference GZB/VVB 993428):

Since May 1977, Regulation (EC) 258/97 concerning novel foods and novel food ingredients has been in force in the European Union. Under the Regulation, the safety of novel foods has to be assessed as part of a community procedure.

Following discussions regarding the possibility of the Health Council making such assessments, the State Secretary for Agriculture, Nature Management and Fisheries and I wish the Council to take responsibility for safety assessment for a period of several years during the fist phase of implementation of European Regulation (EC) 258/97. It is considered appropriate that the Health Council should initially take on this role because the assessment activities will be of an experimental nature, involving both a new form of assessment (i.e. pre-marketing assessment) and, in many cases, new categories of foodstuff (primarily foodstuffs with a genetically modified basis and functional foods or nutraceuticals). We also feel that if assessments are made by a body with the Council's independent scientific status, this will support the validity of the Netherlands'opinion in the eyes of the European Committee and other member states.

My wish is to make the procedure and the assessment as open and transparent as possible, so as to enhance consumer trust in the safety of novel foods. I would like the Health Council to support this objective by, for example, allowing perusal of applicants (insofar as consistent with the need to protect the confidentiality of commercially sensitive information) and publishing the criteria upon which safety assessments are made.

The Minister of Health, Welfare and Sport,
(signed) dr E Borst-Eilers

Bijlage **B**

# De commissie/The committee

- Prof. dr LM Schoonhoven, *voorzitter/chairman*
  emeritus hoogleraar entomologie; Wageningen Universiteit en Researchcentrum/ emeritus professor of entomology; Wageningen University and Research centre
- Prof. dr CAFM Bruijnzeel-Koomen
  hoogleraar dermatologie/allergologie; Academisch Ziekenhuis Utrecht/ professor of dermatology/allergology; Academic Hospital Utrecht
- Ir EJ Kok
  toxicoloog; RIKILT-DLO Wageningen/toxicologist; State Institute for Quality Control of Agricultural Products, Wageningen
- Dr CF van Kreijl
  moleculair-bioloog; RIVM Bilthoven/molecular biologist; National Institute of Public Health and the Environment, Bilthoven
- Prof. dr P van der Laan
  hoogleraar statistiek; Technische Universiteit Eindhoven/professor of statistics; Technical University Eindhoven
- Dr B Loos, *adviseur/advisor*
  COGEM, Den Haag/Committee on Genetic Modification, The Hague
- Dr F Nagengast
  gastro-enteroloog; Academisch Ziekenhuis Nijmegen/gastro enterologist; Academic Hospital Nijmegen

- Dr JMA van Raaij
  voedingsfysioloog; Wageningen Universiteit and Researchcentrum/food physiologist; Wageningen University and Research centre
- Prof. dr G Schaafsmahoogleraar voeding; TNO Voeding, Zeist/professor of nutrition; TNO Nutrition and Food Research, Zeist
- Prof. dr EG Schoutenhoogleraar epidemiologie; Wageningen Universiteit and Researchcentrum/professor of epidemiology; Wageningen University and Research centre
- Dr GJA Speijerstoxicoloog; RIVM Bilthoven/toxicologist; National Institute of Public Health and the Environment, Bilthoven
- Prof. dr WJ Stiekema
  hoogleraar bioinformatica; Wageningen Universiteit en Researchcentrum/professor of bioinformatics; Wageningen University and Research centre
- Ir R Top, *adviseur/advisor*
  Ministerie van VWS; Den Haag/Ministry of Health, Welfare and Sport; The Hague
- Prof. dr WM de Vos
  hoogleraar microbiologie; Wageningen Universiteit en Researchcentrum/professor of microbiology; Wageningen University and Research centre
- Dr RA Woutersen
  Toxicoloog; TNO Voeding, Zeist/toxicologist; TNO Nutrition and Food Research, Zeist
- Dr ir M Rutgers, *secretaris/scientific staff member*
  Gezondheidsraad, Den Haag/Health Council of the Netherlands, The Hague

Administratieve ondersteuning/Administrative assistance: AD Lugtenburg; Gezondheidsraad, Den Haag/Health Council of the Netherlands, The Hague.

Bijlage **C**

# EU-procedure/EU-procedure

Als een fabrikant een nieuw voedingsmiddel op de markt brengt, dient de veiligheid voor de consument gewaarborgd te zijn. In 1997 werd de Europese verordening van kracht waarin de procedure is geregeld voor de goedkeuring voor marktintroductie van een nieuw voedingsmiddel (EC97). Bij deze procedure zijn verschillende actoren betrokken. De aanvrager moet beoordelen of het product werkelijk 'nieuw' is, dat wil zeggen dat het nog niet eerder in de Europese Unie in substantiële mate voor menselijke voeding is gebruikt en ook niet wezenlijk gelijkwaardig is aan een bestaand product. (Voor een wezenlijk gelijkwaardig product kan worden volstaan met een kennisgeving van de marktintroductie.) Ook moet het niet gaan om een levensmiddelenadditief, aroma of extractiemiddel, omdat deze producten op een andere wijze worden beoordeeld. Voor een nieuw voedingsmiddel in de zin van de Europese verordening moet de aanvrager een veiligheidsdossier overleggen volgens aanbevelingen van de Europese Commissie (EC97a). Deze aanbevelingen zijn gebaseerd op rapporten van verschillende instanties die zich met het onderwerp nieuwe voedingsmiddelen bezighouden, te weten de OECD (OECD93, OECD96) en de FAO/WHO (FAO96, WHO91). Ook de Gezondheidsraad heeft zich al eerder over dit onderwerp gebogen (HCN92). Sinds het verschijnen van de aanbevelingen van de EU wordt in internationaal verband (FAO01, OECD98, OECD00, SCF99, SSC99, WHO00) gewerkt aan explicitering en aanpassing aan de stand van de wetenschap.

De fabrikant levert het volgens de richtlijnen samengestelde dossier in bij het land waar het product het eerst op de markt zal komen. Daarop komt de nationale veiligheidsbeoordelingsautoriteit in actie. In Nederland is dat de Minister van Volksgezond-

heid, Welzijn en Sport. Zij heeft de Gezondheidsraad verzocht haar van advies te dienen. De Voorzitter van de Gezondheidsraad heeft hiertoe de commissie Veiligheidsbeoordeling nieuwe voedingsmiddelen (commissie VNV) ingesteld.

De commissie beoordeelt op basis van de huidige stand van de wetenschap of de door de fabrikant geleverde gegevens juist en volledig zijn en of zij het eens is met diens conclusies. Zij maakt een verslag van haar bevindingen — ook volgens de Europese aanbevelingen (EC97a, deel III) — en biedt dat de minister aan. De minister formuleert het Nederlandse oordeel over een voedingsmiddel en brengt dat in bij het Europese overleg in het Permanent Comité voor levensmiddelen. Alle Europese lidstaten worden uitgenodigd hun oordeel (de zogeheten tweede beoordeling) te geven over het dossier en over de eerste beoordeling alvorens genoemd Comité een eindoordeel velt. Als een dossier veel vragen oproept, gaat er een adviesvraag van de Europese Commissie naar het Wetenschappelijk Comité voor de menselijke voeding. Komt men dan nog niet tot overeenstemming dan beslist de Europese Ministerraad.

## English translation

When manufacturers bring novel foodstuffs onto the market, consumer safety has to be assured. In 1997, a European Regulation (EC97) came into force, laying down the procedure for approving the market introduction of novel foodstuffs. The procedure recognizes various actors. The applicant must decide whether a product is a novel foodstuff, i.e. a substance that has not previously been available for human consumption to any substantial extent within the European Union and is not substantially equivalent to any existing product. (If a foodstuff is substantially equivalent to any existing product, it is sufficient to inform the authorities of its market introduction). Food additives, aromas and extracts are excluded from the provisions of the directive, since they fall within the scope of an established assessment regime. Before marketing a novel foodstuff, the applicant must compile a safety dossier that complies with the Recommendations of the European Commission (EC97a). These Recommendations are based on reports by a number of bodies that have studied the issue of novel foodstuffs, in particular the OECD (OECD93, OECD96) and the FAO/WHO (FAO96, WHO91). The Health Council of the Netherlands has also considered the question earlier (HCN92). Since publication of the EU recommendations, international efforts have been made to clarify and adapt the latest scientific knowledge in the field (FAO01, OECD98, OECD00, SCF99, SSC99, WHO00).

Having compiled a dossier in line with the guidelines, the manufacturer has to submit it to the competent authority in the country where the product is to be marketed first. This dossier is assessed by the national safety assessment authority. In the Netherlands, this is the Minister of Health, Welfare and Sport, who is advised by the

Health Council. The President of the Health Council has created a Committee on the Safety Assessment of Novel Foods (VNV Committee) to advise the minister on behalf of the Council.

On the basis of the scientific state of the art, the committee has to decide whether the information provided by the manufacturer is accurate and complete and whether the manufacturer's conclusions are sound. The committee then draws up a report on its findings for the minister; this report must also comply with the European Recommendation (EC97a, part III). After considering the report, the minister formulates the Netherlands' opinion regarding the foodstuff in question, which is discussed at European level in the Standing Committee on Foodstuffs. All other European member states are invited to express a 'second opinion' regarding the dossier and the first opinion. The Standing Committee then arrives at a final judgement. If a dossier is particularly contentious, the European Commission calls upon the Scientific Committee on Food for advice. If consensus still cannot be reached, the issue is referred to the European Council of Ministers

Bijlage **D**

# Samenvatting van het dossier/ Executive summary of the dossier

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# RESUME

## « HUILE DE COLZA CONCENTRÉE EN INSAPONIFIABLE »

Ce présent document a été rédigé suivant les recommandations de la Commission des Communautés européennes du 29 juillet 1997 concernant les aspects scientifiques relatifs à la présentation des informations requises pour étayer des demandes d'autorisation de mise sur le marché de nouveaux aliments et de nouveaux ingrédients alimentaires au titre du règlement (CE) n° 258/97 du Parlement Européen et du Conseil.

# PLAN DU DOSSIER

# RESUME

Ce présent document a pour objectif de démontrer l'innocuité d'un nouvel ingrédient appelé « **huile de colza concentrée en insaponifiable** », dans le but d'obtenir l'autorisation de mise sur le marché de ce nouvel aliment au sein de la Communauté européenne.

Le nouvel aliment est obtenu par concentration de la fraction insaponifiable de l'huile de colza alimentaire (non érucique). Le procédé physique de séparation retenu pour cet enrichissement est la **distillation moléculaire.** Cette technique évite la dégradation thermique de la fraction insaponifiable, ne modifie pas la répartition en acides gras de la fraction triglycéridique et préserve les fractions triglycéridiques fortement insaturées.

**L'huile de colza concentrée en insaponifiable** se compose en moyenne de 91 % d'acide gras sous la forme de triglycérides, de **9 % d'insaponifiable** dont **7 % de phytostérols** et **1 % de tocophérols**.

De par sa composition chimique, le nouvel aliment se rapproche fortement de sa source. **L'huile de colza alimentaire (source) est exploitée comme équivalence substantielle.**

Sur le plan des contaminants de type aflatoxines et solvants, le nouvel aliment peut être comparé à une huile de colza alimentaire classique, qui doit être conforme aux spécifications en vigueur pour chaque classe de contaminant.
L'absence de micropolluants de type pesticides (résidus organochlorés et organophosphorés) et métaux lourds a été vérifiée dans huile de colza concentrée en insaponifiable.

Sur le plan microbiologique et allergisant le nouvel aliment peut être comparé à une huile de colza alimentaire classique.

Sur le plan toxicologique, le nouvel aliment a été classé dans la catégorie des préparations ne présentant pas un danger pour l'homme par ingestion. Le pouvoir mutagène du nouvel aliment a été démontré comme étant nul.

Le nouvel aliment, qui est une **huile de colza concentrée en insaponifiable,** ne présente donc **aucun danger d'ordre microbiologique, allergisant et toxicologique**.

Sur le plan nutritionnel, le nouvel aliment est équivalent substantiellement à l'huile de colza (source) pour les apports en acides essentiels linoléique (C18:2 n-6) et linolénique (C18:3 n-3) et en acide oléique (C18:1 n-9).

Le nouvel aliment est une source alimentaire concentrée en vitamine E, contribuant ou couvrant l'Apport Journalier Recommandé (A.J.R.). Le nouvel aliment présente aussi le bénéfice nutritionnel d'être une source privilégiée en phytostérols dont on connaît aujourd'hui le rôle hypocholestérolémiant.

**Une dose quotidienne de nouvel aliment fixée à 1,5 g apporte 7 mg de Vitamine E (7 mg α-T.E.) et 105 mg de phytostérols totaux .**

Le nouvel aliment est **une source supplémentaire d'apport en vitamine E et en phytostérols** ; il ne remplace en aucun cas un aliment existant. **Le nouvel aliment ne sera donc pas utilisé tel quel pour la consommation en « huile de table », ce n'est pas un aliment de grande consommation.**

- L'utilisation du nouvel aliment sera recommandée comme **ingrédient alimentaire**, à une dose journalière de **1,5 g par personne**, permettant un rééquilibrage au plan nutritionnel des **apports en vitamine E et en phytostérols** dans des **produits alimentaires** divers ou dans des **aliments fonctionnels**.

## SUMMARY

The purpose of this document is to demonstrate the safety of a novel ingredient "**rapeseed oil high in unsaponifiable matter**", with a view to obtaining the necessary authorisation to place this novel food on the market in the European Community.

This novel food is obtained via concentration of the unsaponifiable fraction of edible (non-erucic) rapeseed oil. The concentrate is derived via a physical separation process known as **molecular distillation**. This technique prevents thermal degradation of the unsaponifiable fraction, does not alter the distribution of fatty acids in the triglyceride fraction and keeps triglyceride fractions highly unsaturated.

**Rapeseed oil high in unsaponifiable matter** consists on average of 91% fatty acids, in the form of triglycerides, and **9% unsaponifiable matter**, which in turn consists of **7% phytosterols** and **1% tocopherols**.

The chemical composition of this novel food is very similar to that of its source. **Edible rapeseed oil (source) is used as a comparison for establishing substantial equivalence**.

In terms of aflatoxin and solvent contamination, the novel food is comparable to ordinary edible rapeseed oil, which must conform to the existing specifications for each class of contaminant.
Rapeseed oil high in unsaponifiable matter has been found to be free of pesticide micropollutants (organochlorine and organophosphorous residues) and heavy metals.

The microbiology and allergenicity of the new oil are also comparable to those of ordinary edible rapeseed oil.

From a toxicological point of view, the novel food has been categorised as a preparation which does not present a risk to man if ingested. Tests have proved that it is also non-mutagenic.

The novel food, **rapeseed oil high in unsaponifiable matter**, thus presents **no microbiological, allergenic or toxicological risks**.

From a nutritional point of view, the novel food is substantially equivalent to rapeseed oil (source) in terms of essential linoleic (C18:2 n-6) and linolenic (C18:3 n-3) acid content and oleic acid content (C18:1 n-9).

The novel food is a food source high in vitamin E, supplying all or part of the Recommended Daily Amount (RDA). It is also nutritionally beneficial in that it is a prime source of phytosterols, the hypocholesterolaemic effects of which are now well-known.

**The recommended dose of 1.5 g of the novel food per day will provide 7 mg of vitamin E (7 mg α-T.E.) and 105 mg of total phytosterols**.

The novel food is **a supplementary source of vitamin E and phytosterols**: it is not intended as a replacement for any existing foodstuff. **Consequently, the oil should not be used as a "salad oil"; it is not a product intended for consumption in large quantities**.

It is recommended that this novel food be used as a **food ingredient**. A dose of **1.5 g per person** per day **tops up vitamin E and phytosterol intake** from **everyday foodstuffs** and '**functional foods**'.

Bijlage **E**

# Eerste beoordeling/First assessment

# Initial assessment report concerning a request for an opinion on the use of rapeseed oil high in unsaponifiable matter as a food ingredient

Maisons-Alfort, 27 July 2001

**OPINION**

**of the French Food Safety Agency (*Agence française de sécurité sanitaire des aliments*) concerning the assessment of the use of rapeseed oil high in unsaponifiable matter as a food ingredient.**

Application submitted under Regulation (EC) No 258/97 on novel foods and novel food ingredients

Contents

# Chapter 1

## Introduction

A request for an assessment on the use of rapeseed oil high in unsaponifiable matter as a novel food ingredient under Regulation (EC) No 258/97 on novel foods and novel food ingredients was referred to the French Food Safety Agency by the Directorate-General for Consumer Affairs, Competition and Fraud Prevention on 10 December 1999.

After consulting the Specialised Committee of Experts on Human Nutrition on 18 December 2000 and 22 May 2001, the French Food Safety Agency issued an opinion on 12 June 2001.

In accordance with Article 6(2) of Regulation (EC) No 258/97 on novel foods and novel food ingredients, this initial assessment report has been drawn up to accompany the notification of the application to the European Commission.

# Chapter 2

## Presentation of the dossier

### 2.1 Administrative data

The application has been submitted by Laboratoires PHARMASCIENCE® / Division Industrie, 3 rue des Quatre Filles, 28230 EPERNON, France; the persons responsible for the dossier are P. Msika - Directeur du Centre de Recherche, 73 Boulevard de la Mission Marchand, BP 302 – 92402 COURBEVOIE CEDEX, France, and A. Piccirilli - Responsable du Département Lipochimie, 51 rue Saint-Denis, BP 34 A - 28231 Epernon, France.

### 2.2 General description of the product

The product is a non-erucic rapeseed oil, concentrated in its unsaponifiable fraction, proposed by the applicant as an ingredient for use as a supplementary source of vitamin E and phytosterols in foodstuffs. The unsaponifiable fraction is a combination of compounds with a molecular mass lower than that of triglycerides and obtained by a new process: molecular distillation.

### 2.3 Categorisation of the application

The application has been made under Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 on novel foods and novel food ingredients. The effect of the manufacturing process on the chemical and nutritional composition of the novel food places the novel food in **category f**, in accordance with Article 1(2) of Regulation (EC) No 258/97, which includes:
"*foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.*"

### 2.4 Scientific classification of novel food for the assessment of wholesomeness

In accordance with the Commission's Recommendation of 29 July 1997 (97/618/EC) concerning the scientific aspects of the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients, the novel food falls into **Class 6**. This class comprises "*foods and food ingredients which have been subjected to a process not currently used in food production. According to the scope of Regulation (EC) No 258/97, the resulting product is only considered to be a novel food if the process results in changes in the chemical composition or structure of the food or food ingredient, which affect its nutritional value, metabolism or level of undesirable substances.*"

## 2.5 Consultation of structured schemes for assessment of the novel food

As the novel food is in class 6, the following structured schemes must be followed in order to assess the safety and properties of the novel food:

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

# Chapter 3

## Assessment of the dossier

### 3.1 Structured Scheme I: Specification of the novel food

Non-erucic rapeseed oil is extracted from rapeseed (*Brassica napus L.* and *Brassica campestris L.*) during a process involving two stages, crushing and refining. Refined rapeseed oil used as the source of the novel food is an edible table oil which meets the requirements of the Codex Alimentarius. "Non-erucic" rapeseed oil must have an erucic acid content of less than 5 %. It consists mainly of triglycerides, containing 98 to 99 % of fatty acids and a small proportion of various substances (sterols, phytosterols), collectively termed the unsaponifiable fraction (0.7 to 1.8 %). Refined rapeseed oil is an oil low in saturated fatty acids (8 % of total fatty acids) and particularly high in monounsaturated fatty acid, oleic acid (60 - 65 % of total fatty acids), and has a good proportion of polyunsaturated essential fatty acids: linoleic acid (15 to 28% of linoleic acid : 18 : 2 n-6) / linolenic acid (6 to 14 % of alpha-linolenic acid : 18 : 3 n-3) is equal to 2. Rapeseed oil also contains 100 mg of tocopherols per 100 g, comprising 40 % α-tocopherol and 60 % γ-tocopherol.
The chemical compounds contained in the novel food are identical to those in the source material, except for the content of the unsaponifiable fraction.
The quality criteria of the novel food (appearance, water, impurities, state of oxidation, oxidative stability, metallic traces) have been assessed and are in accordance with the recommendations for edible oils contained in the Codex Alimentarius. The absence of organochlorine and organophosphorous pesticide residues and heavy metals has been verified.

***The Committee confirms that the novel food has the usual properties of ordinary rapeseed oil and that the content and composition of fatty acids, tocopherols, sterols and triterpenic alcohols are in accordance with the available data on that oil.***
***The Committee is of the opinion that the product has good oxidative stability, identical to that of the source product. Since the source oil complies with existing regulations, the results presented by the applicant make it possible to confirm that no organochlorine and organophosphorous pesticide residues are detected in the novel food after physical processing.***

### 3.2 Structured Scheme II: Effect of the production process applied to the novel food

Molecular distillation is the industrial process by which rapeseed oil high in unsaponifiable matter is produced from edible rapeseed oil. The principle of molecular distillation is very brief vaporisation (0.1 second) under high vacuum ($10^{-3}$ mm Hg) at high temperature (200-300 °C). This process makes it possible to carry out separation, purification, decolourisation and deodorisation operations. Applied to vegetable oils, molecular distillation makes it possible to extract predominantly the lightest compounds (unsaponifiable fraction). Under a high vacuum and at an adequate temperature, the unsaponifiable fraction is vaporised then recondensed, thus forming the distillate.
In the case of rapeseed oil distillation, the unsaponifiable fraction is concentrated by a factor of 10, according to the applicant. This increase in unsaponifiable matter is associated with the partial removal of triglycerides.

***The Committee confirms that the novel food contains approximately ten times more unsaponifiable matter than the source oil. Consequently, for the same amount of unsaponifiable matter, the novel food's calorific value is ten per cent less than that of the source oil. Apart from the concentration of the unsaponifiable fraction, the relative percentages of the various compounds other than the unsaponifiable fraction of the source oil are not altered significantly.***

### 3.3 Structured Scheme III: History of the organism used as the source of the novel food

The first edible rapeseed oil was produced in Canada but was considered unsafe to use for human consumption. The high level of erucic acid contained in rapeseed was in fact suspected of causing certain anti-nutritional effects, in particular myocardial lesions, digestive and growth problems during various experiments carried out on laboratory animals.

The applicant points out that varieties which produce an oil virtually free of erucic acid (< 5 %) are used for human consumption. In France the varieties Primor, followed by Jet Neuf pioneered the changeover to the production of rapeseed low in erucic acid from 1974.

Since 1995, rapeseed oil has been the main oil consumed in the European Union (25 %), ahead of sunflower oil (20 %) and soya oil (18 %). In 1997, 86 000 tonnes of rapeseed oil was consumed in France (40% being consumed directly and 60% by the agri-food industries), i.e. an average consumption of around 1.5 kg per year per inhabitant, equivalent to approximately 4 g of rapeseed oil per day per inhabitant.

The applicant adds that the source of the novel food is recognised as harmless to human health and is of particular interest from a nutritional point of view because it is high in linolenic acid and oleic acid.

***According to the Committee, it should be pointed out that, though the exact level is not stated, the novel food contains less than 5% erucic acid; this specification presents no risk to health, though it is relatively high in that the Primor variety, which is low in erucic acid, contains 0.2% of erucic acid. The Committee confirms that the novel food's fatty acid composition is in fact very good from a nutritional point of view, but points out that this is the composition of the source oil and that the novel food adds nothing more in this respect.***

### 3.4 Structured Scheme IX: Anticipated intake/extent of use of the novel food

The applicant recommends that rapeseed oil high in unsaponifiable matter be used as a food ingredient, and points out that the novel food will not replace any other foods in the diet and that its use will not be limited to a geographic area.
The applicant suggests that possible uses are food supplements and any food products requiring the addition of vitamin E and phytosterols ("functional foods"; supplemented foods such as margarines, composite edible oils, milk and milk products, seasonings and sauces, bakery and confectionery products, prepared and canned meals, prepared meat products, etc.).
On average, 100 g of rapeseed oil high in unsaponifiable matter contains 9 g of unsaponifiable matter, which in turn comprises 7 g of sterols, 1 g of tocopherols and 1 g of various constituents (squalene, hydrocarbons). The triglyceride fraction makes up 91 g of 100 g of the novel food.
The applicant recommends a daily intake of 1.5 to 5 g of the novel food, based on the equivalence with refined rapeseed oil Primor standard (source).

- 1.5 g of the novel food (13 kcal or 54 kJ) corresponds to 13 g (117 kcal or 489 kJ) or one tablespoon of rapeseed oil (source)
- 5 g of the novel food (45 kcal or 188 kJ) corresponds to 40 g (360 kcal or 1504 kJ) or three tablespoons of rapeseed oil (source).

***The Committee considers the principle of the novel food's equivalence with refined rapeseed oil, low in erucic acid, which is widely consumed in France and Europe, to be justified. It points out, however, that in order to complete the assessment of unsaponifiable content, it would be necessary to specify the range of contents obtained for the novel food (and the source oil), since the dossier referred only to the minimum content of unsaponifiable matter (0.7% for the source oil and 7% for the novel food).***

### 3.5 Structured Scheme X: Information from previous human exposure to the novel food or its source

The applicant states that refined rapeseed oil without erucic acid (source) is a product which is widely and commonly consumed in all European countries by all ages and sectors of the population. Furthermore, the rapeseed oil industrial production process is fully developed.
The applicant states that no information is available from previous human exposure to the novel food.
As regards its unsaponifiable content, the novel food (10% unsaponifiable fraction) is equivalent to other edible vegetable fats: shea-butter (7 to 10% unsaponifiable fraction) and avocado oil (1 to 12% unsaponifiable fraction).
With regard to the fatty acid content, the novel food is substantially equivalent to its source, rapeseed oil.
As regards its vitamin E content, the novel food is equivalent to a vegetable oil enriched with vitamin E (in the form of α-tocopherol).

***The Committee is of the opinion that the principle of equivalence with rapeseed oil, an oil for everyday consumption in France, is justified, with the exception of vitamin E and unsaponifiable matter.***

## 3.6 Structured Scheme XI: Nutritional information on the novel food

In view of its composition, the arguments put forward by the applicant to demonstrate the nutritional properties of the novel food are based on its fatty acid content, its vitamin E content and its phytosterol content.

- Fatty acid content:

Rapeseed oil (source) and, consequently, the novel food, contain on average less than 10% of saturated fatty acids, 60 % of oleic acid and 20 % of linoleic acid and 10 % of α-linolenic acid, with a linoleic acid/alpha-linolenic acid ratio equivalent to 2. The applicant points out that the quantity of fatty acids consumed for the same quantity of novel food or rapeseed oil is slightly lower for the novel food. Rapeseed oil is classed among the linolenic vegetable oils (α-linolenic acid content greater than 1%).

With regard to **oleic acid**, the applicant refers to recent nutritional studies carried out on olive oil which suggest that oleic acid leads to a decrease in LDL-cholesterol combined with an increase in HDL-cholesterol, thus helping to protect against cardiovascular diseases. The applicant adds that the novel food may likewise boost the intake of monounsaturated fatty acids via oleic acid, a dose of the novel food of between 1.5 and 5 g per day providing 0.7 to 3 g of oleic acid.

With regard to **linoleic acid**, which is an essential fatty acid, the applicant draws attention to the role of these fatty acids in the synthesis of eicosanoids (prostaglandins, thromboxanes and leukotrienes) via arachidonic acid. Eicosanoids act as oxygenated chemical messengers in the platelet aggregation mechanism, but are also involved in the control of renal function, inflammatory and immunity phenomena. The applicant adds that in addition to its metabolic role, linoleic acid plays a structural role and is included in the composition of acyl-ceramides. One dose of the novel food of between 1.5 and 5 g per day provides 0.2 to 1.25 g of linoleic acid, the recommended nutritional intake of linoleic acid being between 8 and 10 g per day in adults.

With regard to **α-linolenic acid**, an essential fatty acid, the applicant draws attention to the fact that this fatty acid is the precursor of the n-3 series of polyunsaturated fatty acids, which include eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). EPA competes with arachidonic acid for cyclooxygenase which begins their transformation into eicosanoids. DHA is a major component of membrane phospholipids. In addition to its structural role within nerve cells (brain) or nerve-related cells (retina), it is involved in the functions associated with such cells (cognitive properties, vision). One dose of the novel food of between 1.5 and 5 g per day provides 0.1 to 0.7 g of α-linolenic acid, the recommended nutritional intake of α-linolenic acid being between 1.5 and 2 g per day in adults.

***The Committee confirms that the linoleic acid / α-linolenic acid ratio of the novel food is close to the recommended ratio (which is 5, according to the literature). It concludes that 1.5 to 5 g per day of the novel food provides from 11% to 25% of the recommended nutritional intake of linoleic acid and 3.5% to 28% of that of α-linolenic acid. However, it points out that the saturated fatty acid content increases from 8 g / 100g in rapeseed oil to 9.5 g / 100 g in the novel food, i.e. an increase of 19%.***

- Vitamin E content:

The applicant gives a brief presentation of the biological roles of vitamin E (the α-tocopherol form, according to the applicant): it is an antioxidant which acts mainly on membranes and lipoproteins by trapping the free radicals. Reference is also made to vitamin E's other roles in preventing ischaemic cardiovascular diseases, preventing certain cancers, stimulating the immune response in the elderly, decreasing the risk of cataracts and slowing down the progression of degenerative diseases.
With regard to the intake of vitamin E, the applicant refers to several reference values, the advised nutritional intake being 12 mg per day of α-tocopherol equivalent (α-TE ) or (18 IU). The applicant stresses that in order to attain the advised nutritional intake, it is sufficient to consume approximately 3 g of the novel food or 5 g of wheat germ oil or 15 g of sunflower oil per day.
With regard to the risks of consuming too much vitamin E, taking into account the maximum safe intake adopted by the *Conseil Supérieur d'Hygiène Publique de France (CSHPF)* (French Public Health Board) of 40 mg per day of α-TE in addition to food intake, the applicant states that a daily dose of the novel food of between 1.5 and 5 g provides 3 to 20 mg of α-TE, thus avoiding the risk of consuming too much vitamin E.

***The Committee concludes that the 1.5 g and 5 g/day doses of the novel food provide on average 7 mg and 23 mg respectively of α-tocopherol (i.e. 58% and 191% of the advised nutritional intake). The intake of 23 mg/day represents 57.5% of the maximum safe intake adopted by the CSHPF. However, the Committee points out that there are at present no studies which show that such high intakes of vitamin E have a preventive effect (cardio-vascular diseases, cancers, cataracts) or stimulate the immune system in the elderly. However, this sector of the population, which has a low vitamin E intake, may be advised to increase their intake of vitamin E, while restricting their energy intake, which is what the novel food may enable them to do.***

- Phytosterol content:

Phytosterols are natural plant constituents and are present in vegetable oils at a proportion of between 0.1 and 0.5 %. They are mainly terpenic constituents of unsaponifiable plant matter with a molecular structure similar to cholesterol. This similarity is responsible for the inhibition of intestinal absorption of cholesterol. For this reason they are added to some margarines intended for hypercholesterolaemic patients.
The applicant points out that nutritional studies carried out on phytosterols show that a supplement of 0.8 to 3 g per day (depending on the population and the desired objectives) of phytosterols reduces total cholesterol and LDL-cholesterol, and adds that there are no significant harmful effects and no maximum safe intake has been set for phytosterols. A daily dose of the novel food of between 1.5 and 5 g provides 105 to 350 mg of total phytosterols.

***The Committee confirms that the hypocholesterolaemic role of phytosterols, in particular sitosterol, is currently well documented in scientific literature. A daily dose of the novel food of 1.5 to 5 g provides on average 105 mg to 350 mg of total sterols, respectively. According to the literature, the effective doses needed to achieve a 10-15% reduction in LDL cholesterol range from 750 mg to 3000 mg per day of sitosterol. The amounts provided by the novel food are on average only 50 to 175 mg of sitosterol, which is approximately one quarter of the lowest effective dose.***

### 3.7 Structured Scheme XII: Microbiological information on the novel food

The applicant states that on account of the lipophilic nature of the novel food, the lack of water and solid impurities it contains and the microbial purity of the source, the risks of bacterial proliferation are unlikely. Moreover, the temperature at which the novel food is processed (230 °C) eliminates any risk of microorganisms being present. The novel food is packed and stored away from light and under inert gas, which decreases both the risk of microbial proliferation and contamination.

***The Committee confirms that the process involving very brief vaporisation by heating (0.1 second) under high vacuum ($10^{-3}$ mm Hg) cannot present a risk of microbiological contamination.***

### 3.8 Structured Scheme XIII: Toxicological information on the novel food

The toxicological study of the novel food comprised:

- an assessment of acute oral toxicity in mice and rats:

The purpose of the tests was to give a qualitative and quantitative assessment of toxic phenomena and the time taken for them to appear following a single oral dose of the novel food at a dose of 10 ml/kg of body weight in mice, and 5000 mg/kg of body weight in rats. The results of the autopsy carried out 14 days after administration of the novel food showed that in these conditions, the novel food caused no deaths, caused no changes in the general state of health and caused no visible organic changes. These oral dose limit tests were carried out in accordance with OECD Guideline 401 (test limited to 10 animals) relating to the testing of chemicals.

- test for possible mutagenic potential using the Ames test:

The Ames test was carried out on five bacterial strains (*Salmonella typhimurium*) and showed that the novel food had no mutagenic potential.

***The Committee accepts the applicant's conclusions and points out that the novel food's quality criteria generally comply with the Codex Alimentarius recommendations.***

## Chapter 4

## Conclusions and recommendations:

*The French Food Safety Agency:*

- ***issues a favourable opinion on the use of rapeseed oil high in unsaponifiable matter as a food ingredient at a dose of 1.5 g per day;***
- ***is of the opinion that the intake proposed by the applicant of 5 g per day is unacceptable on account of the excessive vitamin E content, in the light of nutritional recommendations and the risks of over-consumption which might arise because it does not replace another product;***
- ***stresses that no nutritional claims may be made for phytosterols because the product does not contain the effective dose necessary to reduce cholesterolaemia.***