Palmoleïne

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

Palmolein

Second opinion regarding consumer safety, in accordance with European Regulation 258/97 concerning novel foods and novel 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, Natuur en Voedselkwaliteit/
the Minister of Agriculture, Nature and Food Quality

Nr 2003/05VNV, Den Haag, 5 december 2003
No. 2003/05VNV, The Hague, December 5, 2003

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Uw kenmerk : VGB/VL 2407859
Ons kenmerk : 2003/05VNV, U-1555/MR/cv/622-CN
Datum : 5 december 2003

Mijnheer de minister,

Dit schrijven dient ter beantwoording van de door u mede namens de Minister van Landbouw, Natuur en Voedselkwaliteit 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 palmoleïne met een verhoogd gehalte aan vitamine E, carotenoïden en fytosterolen. Het nieuwe product zal niet als spijsolie worden toegepast. Het kan als ingrediënt worden verwerkt in allerlei levensmiddelen en voedingsupplementen. De aanvrager die dit product op de markt wil brengen is Expanscience Laboratories. De 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 de hoeveelheid PAK's (polycyclische aromatische koolwaterstoffen) die dit product als verontreiniging bevat en bij de voedingskundige waarde van het product. De AFSSA heeft de nieuwe palmoleïne beoordeeld als onveilig. De bevoegde autoriteit, de Franse overheid, heeft dit advies integraal overgenomen en maakt bezwaar tegen het op de markt brengen van de nieuwe palmoleïne.

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Onderwerp : Tweede beoordeling veiligheid palmoleïne
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De Commissie VNV baseert haar oordeel op het rapport van de eerste beoordeling door de AFSSA en op de informatie in het dossier.[1] De Commissie VNV stemt grotendeels in met de Franse beoordeling. Door een speciaal productieproces bevat de nieuwe palmoleïne meer vetoplosbare vitamines (E en A) en fytosterolen dan traditionele palmoleïne. Volgens de aanvrager zijn de gehaltes tocoferolen, tocotriënolen, carotenoïden en fytosterolen respectievelijk 15, 17, 4 en 14 maal verhoogd. Daar staat tegenover dat het totale vetzuurgehalte is afgenomen met 4,5%. De vetzuursamenstelling is echter niet gewijzigd.

De palmoleïne bevat volgens de aanvrager geen microbiologische verontreinigingen of andere ongewenste bestanddelen. Uit de beoordeling van de AFSSA blijkt echter dat tijdens het proces waarbij de onverzeepbare fractie (de vitaminen en fytosterolen) wordt geconcentreerd, ook het gehalte aan PAK's 15 tot 20 maal toeneemt**.** De Commissie VNV is van mening dat een product dat is bedoeld als "extra" en een positief imago beoogt door het verhoogde gehalte aan vitamines, uiteraard geen hoge gehaltes PAK's mag bevatten. Een voedselingrediënt dat in deze mate is geconcentreerd kan verhoudingsgewijs een aanzienlijke bijdrage leveren aan het PAK-gehalte van het eindproduct. De commissie is van mening dat ten aanzien van het toegestane gehalte PAK's het ALARA principe (as low as reasonably achievable) moet worden gehanteerd. De Nederlandse Keuringsdienst van Waren,Voedsel en Warenautoriteit (KvW, VWA) hanteert als handhavingsnorm voor PAK's in voedingssupplementen 1 µg benzo(a)pyreen/kg product. PAK-verontreiniging is een aandachtspunt voor alle oliën en vetten. De commissie spreekt haar waardering uit voor het feit dat de AFSSA aanvullende gegevens omtrent PAK-gehalten aan de aanvrager heeft gevraagd. Door dezelfde aanvrager zijn al eerder twee dossiers ingediend voor producten waarbij hetzelfde bezwaar van hoge gehalten PAK's zou kunnen gelden. De commissie stelt voor dat de producten geconcentreerde maïskiemolie en raapzaadolie alsnog kritisch worden bekeken op het gehalte aan PAK's .

Aanvullend op de eerste beoordeling constateert de Commissie VNV dat in het dossier de samenstellinggegevens niet eenduidig zijn weergegeven. Bij de productspecificatie maakt de Commissie VNV er bezwaar tegen dat voor fytosterolen, vitamine E en carotenoïden slechts een

[1] De Commissie VNV merkt op dat in de Engelse vertaling van de beoordeling door de AFSSA wordt gesproken over "palm kernel oil" (palmpitolie). Het nieuwe ingrediënt betreft echter palmoleïne, zoals in de oorspronkelijk, Franse versie van de beoordeling wordt vermeld.

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minimaal gehalte wordt vermeld. Zij concludeert dat de samenstelling duidelijker moet worden gespecificeerd waarbij de aanvrager ook bovengrenzen voor deze bestanddelen moet aangeven. Ook de berekeningen die de aanvrager uitvoert, dienen duidelijker te worden uitgewerkt.

De commissie plaatst een kanttekening bij de wijze waarop zowel de aanvrager als de AFSSA de vitamine E activiteit van de nieuwe palmoleïne afleidt. Beiden gaan ervan uit dat tocotriënolen een aanzienlijke bijdrage aan de vitamine E activiteit leveren. Het staat echter ter discussie of tocotriënolen vitamine E activiteit vertonen (FSA03, IOM00, SCF03).

In de Nederlandse regelgeving en voedingsnormen ontbreekt een bovengrens voor inneming van vitamine E. De Commissie VNV brengt onder de aandacht dat zowel het Europese Wetenschappelijk Comité voor de menselijke voeding als de Amerikaanse Food and Nutrition Board (AFNB) een veilige bovengrens voor vitamine E hebben vastgesteld (IOM00, SCF03). De SCF houdt een grens aan van 300 mg per persoon per dag (natuurlijke tocoferolen en tocotriënolen), de AFNB een grens van 1000 mg per persoon per dag (synthetisch vitamine E). De aanvrager maakt niet duidelijk wat de verwachte inneming van vitamine E door consumptie van de nieuwe palmoleïne zal zijn.

De Commissie VNV heeft kritiek op de wijze waarop in het dossier de vitamine A activiteit wordt afgeleid. Volgens het dossier bevat 1 gram nieuwe palmoleïne 1,5 –2 mg carotenen, waarvan 66% β-caroteen en 33% α-caroteen. De commissie constateert dat één gram van de nieuwe palmoleïne ten hoogste 1,3 mg β-caroteen en 0,7 mg α-caroteen bevat. Indien de recent herziene conversiefactoren worden toegepast voor carotenoïden in groenten en fruit (IOM00), bevat 1 gram nieuwe palmoleïne 0,14 mg vitamine A activiteit (retinol equivalenten). In het dossier zijn echter de klassieke conversiefactoren toegepast. Dat suggereert 0,28 mg vitamine A equivalenten per gram palmoleïne.

De veiligheid van hoge doseringen carotenoïden stond tot voor kort niet ter discussie. De Commissie VNV wijst er echter op dat de Engelse Food Standard Agency voor β-caroteen een bovengrens van inneming aanhoudt van 7 mg per dag bij een lichaamsgewicht van 60 kg (FSA03). De aanvrager maakt niet duidelijk wat de verwachte inneming van carotenoïden door consumptie van de nieuwe palmoleïne zal zijn.

Overigens wijst de Commissie VNV er op dat voor de beoordeling van de veiligheid van producten volgens Verordening 258/97 het gebrek aan voedingskundig “nut” van een product geen criterium is. De AFSSA lijkt dat in haar beoordeling wel als zodanig te hanteren.

De aanvrager stelt dat de levensmiddelenindustrie, die de nieuwe olie zal gaan verwerken, zich moet houden aan de (nationale) regelgeving inzake aanbevolen dagelijkse hoeveelheden en

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bovengrenzen voor inneming van de betreffende (pro)vitamine. De aanvrager maakt in het dossier geen inschatting van de te verwachten dagelijkse hoeveelheid palmoleïne die geconsumeerd zal gaan worden. De Commissie VNV vindt dit een tekortkoming.

De Commissie VNV is het eens met het oordeel van de AFSSA en maakt bezwaar tegen toelating van de nieuwe palmoleïne als voedselingrediënt op de Europese markt. De bezwaren van de commissie gelden de onduidelijke samenstellingsgegevens, het hoge gehalte aan PAK's in het nieuwe ingrediënt en het ontbreken van een inschatting van de consumptie van het nieuwe ingrediënt en de daaraan gerelateerde inneming van vitamine E en carotenoïden.

Ik onderschrijf de conclusies van de commissie.

Hoogachtend,

prof. dr JGAJ Hautvast

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Letter to the Dutch Minister of Health, Welfare and Sport

On December 5, 2003, 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 and Food Quality. The subject in question is a second opinion, in accordance with European Regulation 258/97, concerning palm olein with high levels of vitamin E, carotenoids and phytosterols. The new product will not be used as cooking or salad oil. It may be incorporated in a wide range of foods and food supplements. The applicant wishing to market this novel ingredient is the company Expanscience Laboratories. This assessment has been carried out by the Committee on the Safety Assessment of Novel Foods (VNV Committee) of the Health Council of the Netherlands.

The initial assessment of the application for market introduction was carried out by the French Food Safety Agency (*Agence française de sécurité sanitaire des aliments*). The AFSSA makes critical comments regarding the level of PAH (polycyclic aromatic hydrocarbon) impurities contained in this product and regarding the product's nutritional value. The AFSSA has judged the novel palm olein to be unsafe. The French government, as the Competent Authority, has adopted this opinion in its entirety and is formally objecting to the placing of the novel palm olein on the market.

The VNV Committee bases its opinion on the report of the initial assessment by the AFSSA and on the information contained in the dossier.* The VNV Committee is largely in agreement with the French assessment. As a result of a special production

process, the novel palm olein contains more fat-soluble vitamins (E and A) and phytosterols than traditional palm olein. According to the applicant, the concentrations of tocopherols, tocotrienols, carotenoids and phytosterols are increased by factors of 15, 17, 4 and 14, respectively. Conversely, the total fatty acid content has been reduced by 4.5%. The fatty acid composition is, however, unchanged.

According to the applicant, the palm olein contains neither microbiological contaminants nor any other undesirable components. The AFSSA assessment shows, however, that during the process in which the unsaponifiable fraction (the vitamins and phytosterols) is concentrated, the level of PAHs also rises by a factor of 15 to 20. In the opinion of the VNV Committee, a product that is intended both to provide something "extra" and, by virtue of its increased vitamin content, to convey a positive image must clearly not contain high levels of PAH compounds. A food ingredient that has undergone this degree of concentration can account for a relatively substantial proportion of the PAH content of the final product. In view of the permitted concentration of PAHs, the Committee believes that the ALARA (As Low As Reasonably Achievable) principle must be applied. The enforcement standard adopted for PAHs in food supplements by the Dutch Food and Consumer Product Safety Authority (VWA) is 1 µg benzo(a)pyrene/kg product. PAH contamination is a point of particular interest for all oils and fats. The Committee welcoms the fact that the AFSSA has asked the applicant for supplementary data concerning PAH concentrations. The same applicant has already submitted two dossiers for products to which the same objection of high PAH levels could apply. The Committee proposes that the products in question, concentrated maize-germ oil and rapeseed oil, should yet be critically examined for their level of PAHs.

Further to the initial assessment, the VNV Committee notes that the compositional data have not been clearly specified in the dossier. The VNV Committee objects to the fact that in the product specification only a minimum level is mentioned for phytosterols, vitamin E and carotenoids. It concludes that the composition needs to be more clearly specified, with the applicant being required to state upper limits for these components as well. Also, the calculations performed by the applicant should be set out in more detail.

The Committee comments on the way in which both the applicant and the AFSSA deduce the vitamin-E activity of the novel palm olein. Both proceed on the assumption that tocotrienols make a substantial contribution to the vitamin-E activity, whereas it is, in fact, debatable whether tocotrienols exhibit vitamin-E activity (FSA03, IOM00, SCF03).

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* The Committee notes that in the English translation of the AFSSA assessment the product is mistakenly referred to as "palm kernel oil". The novel ingredient, however, is "palm olein" as mentioned in the original French version of the assessment.

Dutch regulations and nutritional standards do not stipulate an upper limit for intake of vitamin E. The VNV Committee points out that both the European Commission's Scientific Committee on Food (SCF) and the US Food and Nutrition Board (FNB) have established a safe upper limit for vitamin E (IOM00, SCF03). The SCF applies a limit of 300 mg per person per day (naturally occurring tocopherols and tocotrienols), while the limit applied by the FNB is 1000 mg per person per day (synthetic vitamin E). The applicant does not specify what the anticipated intake of vitamin E will be following consumption of the novel palm olein.

The VNV Committee is critical of the manner in which the vitamin-A activity is deduced in the dossier. According to the dossier, 1 gram of novel palm olein contains 1.5 - 2 mg carotenes, 66% of this being β-carotene and 33% α-carotene. The Committee notes that one gram of the novel palm olein contains a maximum of 1.3 mg β-carotene and 0.7 mg α-carotene. If the recently revised conversion factors are used for carotenoids in vegetables and fruit (IOM00), then 1 gram of novel palm olein will contain 0.14 mg vitamin-A activity (retinol equivalents). However, the dossier uses the conventional conversion factors, suggesting 0.28 mg vitamin-A equivalents per gram of palm olein.

Up until recently, the safety of high doses of carotenoids was not under discussion. The VNV Committee points out, however, that the UK Food Standards Agency applies an upper intake level of 7 mg per day for β-carotene, assuming a bodyweight of 60 kg (FSA03). The applicant does not make it clear what the anticipated intake of carotenoids will be following consumption of the novel palm olein.

The VNV Committee points out that the fact that a product possesses no nutritional "benefit" is not a valid criterion when assessing the safety of products according to Regulation 258/97. The AFSSA nevertheless appears to apply this as a criterion in its assessment.

The applicant states that the food industry, which will be processing the novel oil, must comply with the (national) regulations concerning the recommended daily allowances and tolerable upper intake levels of the (pro)vitamin in question. The applicant gives no estimate in the dossier of the daily amounts of palm olein that can be expected to be consumed. The VNV Committee regards this as a shortcoming.

The VNV Committee agrees with the opinion of the AFSSA and formally objects to introduction of the novel palm olein as a food ingredient on the European market. The Committee's objections relate to the unclear compositional data, the high level of PAHs in the novel ingredient and the applicant's failure to estimate the consumption of the novel ingredient and the associated intake of vitamin E and carotenoids.

I endorse the conclusions and recommendations of the VNV Committee,

(signed) professor JGAJ Hautvast

Literatuur/Literature

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A	De adviesaanvraag/Request for advice
B	De commissie/The committee
C	EU-procedure/EU-procedure
D	Samenvatting van het dossier/Executive summary of the dossier
E	Eerste beoordeling/First assessment

Bijlagen/Annexes

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 1997, 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 the application dossier (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
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  toxicologist; State Institute for Quality Control of Agricultural Products, Wageningen
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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 (EG97). 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 (EG97a). 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 WHO/FAO (FAO96, WHO91). Ook de Gezondheidsraad heeft zich al eerder over dit onderwerp gebogen (GR92). Sinds het verschijnen van de aanbevelingen van de EU wordt in internationaal verband gewerkt aan explicitering en aanpassing aan de stand van de wetenschap (FAO01, OECD98, OECD00, SCF99, SSC99, WHO00).

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 veiligheids-beoordelingsautoriteit in actie. In Nederland is dat de Minister van Volksgezondheid,

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 (EG97a, 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 de voedselketen en de diergezondheid. 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 ensured. In 1997, a European Regulation (EG97) 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 (EG97a). 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 WHO/FAO (FAO96, WHO91). The Health Council of the Netherlands has also considered the question earlier (GR92). 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 (EG97a, 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 the Food Chain and Animal Health. 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

SUMMARY

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

This novel ingredient is obtained via concentration of the unsaponifiable fraction of edible palm olein. 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.

Palm olein high in unsaponifiable matter consists on average of 95% fatty acids, in the form of triglycerides, and 5% **unsaponifiable matter**, which in turn consists of **1.5% tocotrienols, 0.5% tocopherols, 0.2% carotenes and 1.5% phytosterols**.

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

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

The microbiology and allergenicity of the novel ingredient are also comparable to those of ordinary edible palm olein.

From a toxicological point of view, the novel ingredient 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 ingredient, **palm olein high in unsaponifiable matter**, thus presents **no microbiological, allergenic or toxicological risks**.

From a nutritional point of view, the novel ingredient is substantially equivalent to palm olein (source) in terms of palmitic acid (C16:0) and oleic acid content (C18:1 n-9).

The novel ingredient is nutritionally beneficial in that it is a prime source of tocotrienols, the antioxidizing effects of which are now well-known. The novel ingredient is also a food source high in vitamin E and provitamin A, helping to supply the Recommended Daily Intake (RDI).

The novel ingredient is **a supplementary source of vitamin E and vitamin A**; it is not intended as a replacement for any existing foodstuff. **Consequently, the novel ingredient will not be used as a "salad oil"; it is not an ingredient intended for consumption in large quantities**.

It is recommended that this novel ingredient be used as a **food ingredient** to **top up vitamin E, vitamin A and phytosterol intake** in **everyday foodstuffs, 'functional foods' or food supplements**.

The target daily intake of the novel ingredient via a food product or food supplement will be defined by the user industry, the latter being obliged to observe in the finished product the recommended daily intake (RDI) and maximum intake limits in force for vitamin E and vitamin A.

Bijlage **E**

Eerste beoordeling/First assessment

Initial assessment report relating to a request for an opinion on the use of palm kernel oil rich in unsaponifiables as a food ingredient

Application relating to EC Regulation 258/97 on novel foods and novel food ingredients

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Chapter 1
Introduction

On 17 December 2001, a request was submitted to the French Food Authority (*Agence française de securite sanitaire des aliments*) by the French General Directorate of Consumption, Competition and the Repression of Fraud for an assessment of the use of palm kernel oil rich in unsaponifiables as a novel food ingredient under EC Regulation 258/97 on novel foods and novel food ingredients.

Following consultations with the expert committee on 'Human nutrition' on 19 February, 25 June and 24 September 2002 and consultation with the expert committee on 'Chemical and physical residues and contaminants' on 30 September 2002, the initial assessment report was drawn up, then validated on 24 April 2003.

In accordance with article 6, paragraph 2 of EC Regulation 258/97 on novel foods and novel food ingredients, this initial assessment report was drawn up to accompany the notification of the application to the European Commission.

Chapter 2
Presentation of the file

2.1 Administrative data

The application was made by the Laboratoires Pharmascience, Division Industrie 3, rue des Quatre filles, 28230 EPERNON, France. The persons responsible for the file are P. Msika (Director of the Research Centre: 73, Boulevard de la Mission, Marchand BP 302 - 92402 Courbevoie, cedex France) and A. Piccirilli (Manager of the Lipochemistry Department: 51, rue Saint-Denis BP 34 A - 28231 Epernon, France).

2.2 General description of the product

The product is a palm kernel oil which is rich in its unsaponifiable fraction. It is proposed by the applicant as a food ingredient that has a rebalancing effect at a nutritional level on the intake of vitamin E and provitamin A in various food products, in functional foods or in food supplements.

The unsaponifiable fraction is a series of compounds of which the molecular weight is less than that of triglycerides and which are obtained by a new process (molecular distillation).

2.3 The application

The application falls under EC Regulation 258/97 of the European Parliament and of the Council of 27 January 1997 on novel foods and novel food ingredients.

In view of the influence of the manufacturing process on the chemical and nutritional composition of the novel food, it falls into **category f** under the terms of article 1, paragraph 2: "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 Classification with a view to the assessment of the safety of the novel food (NF)

According to the Commission Recommendation of 29 July 1997 (97/618/EC) concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients, the NI belongs to 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 an NI 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 Assessment protocol for the NI

For a product belonging to class 6, the protocols to be followed to assess the safety and the characteristics of the NI are as follows:

Protocol I Specification of the NI

Protocol II Effect of the production process applied to the NI
Protocol III Prior use of the organism used as the source of the NI
Protocol IX Anticipated consumption and level of use of the NI
Protocol X Information supplied by prior human exposure to the NI or to its source
Protocol XI Nutritional information on the NI
Protocol XII Microbiological information on the NI
Protocol XIII Toxicological information on the NI

Chapter 3
Assessment of the file

3.1 Protocol I: Specification of the NI

Palm oil is extracted from the fleshy mesocarp of the fruit of the oil palm (*Elaeis guineensis*). The palm kernel oil constitutes the liquid fraction obtained after cracking of the palm oil.

The palm kernel oil which is used as the source of the NI has undergone several stages of refinement to eliminate the hydrophilic substances. However, it is not discoloured.

The palm kernel oil used as the neutralised source of the NI (not discoloured and double-cracked) is an salad oil which in this regard meets the standard of the *Codex Alimentarius*.

It is composed mainly of triglycerides (99%) with small amounts of various substances (carotenoids, which give it a dark orange colour, sterols, phytosterols, etc.), which are covered by the general term unsaponifiable fraction (0.5 to 1.2%).

The nature and the quantity of the nutrients contained in the NI are not significantly modified in relation to those of the original oil, with the exception of the unsaponifiable fraction, which is increased by a factor of around 10.

The NI consists essentially of triglycerides (and in particular palmitic acid (30 to 45%), oleic acid (35 to 50%), linoleic acid (10 to 16%) and stearic acid (1.5 to 6.5%)).

However, the triglycerides are partially eliminated in the process.

The unsaponifiable content is 4 to 7g/100g, consisting of tocopherols and tocotrienols (> 1.6g/100g), sterols, triterpenic and methylsterol alcohols (> 1.2g/100g) and carotenoids (> 130 mg/100g). The trans fatty acids are present in the NI only in trace concentrations.

The characteristic specifications of the quality of the NI (appearance, smell, colour, oxidative stability, percentage of free fatty acids) and the specifications of the undesirable compounds of the NI (water and volatile matter, insoluble impurities and metal traces) have been assessed and are in line with the recommendations of the *Codex Alimentarius* for edible oils.

The physicochemical characteristics have also been studied.

The viscosity of the NI is increased by a factor of around 2.5 compared with the source oil because of an increase in the unsaponifiable fraction.

The NI clouds over at 25°C.

As regards contaminants (residues of organochlorinated and organophosphorated pesticides and heavy metals), the specifications of the NI are also in line with the recommendations of the *Codex Alimentarius* for edible oils.

The levels of aflatoxin and solvents have not been investigated, in the former case because these mycotoxins are generally absent from the neutralised crude palm oil, and in the second case because no solvents are used in the process as described.

Finally, the level and the nature of polycyclic aromatic hydrocarbons (PAHs) in the NI were assessed based on the available data derived from the analysis of a single batch.

The levels of total PAHs, heavy PAHs and benzo(a)pyrene of the source oil are within the limits classically observed and recommended by the FEDIOL for the analysis of other refined vegetable oils which are marketed for human consumption.

However, the new process increases the PAH content by a factor of 15 to 20 compared with the source oil.

The assessment of the risk for human consumption correlated to the nature and the levels of PAH in the NI was carried out by the expert committee on 'Chemical and physical residues and contaminants', whose opinion is given below.

Opinion of the expert committee on 'Chemical and physical residues and contaminants' concerning the presence of PAHs in the NI

Analysis of the results and origin of the PAHs

Palm kernel oil (the source oil) has levels of PAHs of which the values are within the limits classically observed in the analysis of other refined vegetable oils which are marketed for human consumption;

Palm kernel oil rich in unsaponifiables (novel ingredient) has a much higher level of PAHs;

While the overall level of PAHs is 13 times higher in the novel ingredient (15Ø205 µg/kg), the concentrations measured for heavy PAHs (five or more kernels) are 17 to 21 times higher (0.16Ø3.4 µg/kg for benzo(a)pyrene alone) than those observed in the source oil.

The presence of PAHs in foodstuffs is linked to pyrolysis of the organic matter and/or incomplete combustion, which involves temperatures over 350-400°C.

In the case under review, because of the relatively low temperatures used in the process, the high total PAH levels observed in the novel ingredient cannot be attributed to the molecular distillation process. However, this process yields a concentration of compounds of the unsaponifiable fraction and, because of their physicochemical properties (liposolubility), as the PAHs form an integral part of the unsaponifiable fraction of vegetable oils, they are concentrated with this fraction;

Assessment of the toxicity of the PAHs

The AFSSA is currently reflecting on the possibility of assessing the exposure of the French

population to PAHs based on the analysis of 10 PAHs in food matrices and of identifying the toxicological reference values which might be recommended to assess the risk for the consumer; In this file, the sum of the 10 PAHs is 7 µg TEQ/kg for the novel ingredient, compared with 0.4 µg TEQ/kg for the source oil, and, for benzo(a)pyrene alone, this value is 3.4 µg TEQ/kg in the novel ingredient (cf. table);

[1] The expert committee on 'Chemical and physical residues and contaminants' recommends analysing the 10 most toxic PAHs in the food matrices (classified as 2A, 2B or 3 by the International Centre for Research on Cancer).

In order to determine the relative toxicity of these PAHs, weighting coefficients referred to as toxic equivalency factors (TEFs) are assigned to each PAH in reference to the benzo(a)pyrene considered to be the most toxic. By adding together these TEFs, we determine a toxic equivalency value (TEQ) for benzo(a)pyrene.

(a) Nisbet, I.C.T. and LaGoy, P.K. (1992) Toxic equivalency factors (TEFs) for polycyclic aromatic hydrocarbons (PAHs). *Regulatory Toxicology and Pharmacology*, 16, 290-300.

PAH
Source oil
Novel ingredient
TEF µg/kg µg TEQ / kg B(a)P µg/kg (µg TEQ / kg B(a)P Benzo(a)anthracene 0.1 0.29 0.03 5.48 0.55 Benzo(b+j)fluoranthene 0.1 0.66 0.07 11.77 1.18 Benzo(k)fluoranthene 0.1 0.17 0.02 2.75 0.28 Benzo(g, H, i)perylene 0.01 0.38 0.00 6.79 0.07 Benzo(a)pyrene **1** 0.16 0.16 3.38 3.38 Chrysene 0.01 0.97 0.01 16.99 0.17 Dibenzo(a, h)anthracene 1 0.03 0.03 0.64 0.64 Fluoranthene 0.01 2.47 0.02 32.39 0.32 Indeno(1,2,3,cd)pyrene 0.1 0.23 0.02 4.55 0.46 **Total 5.36 0.36 84.74 7.05**

Assessment of exposure

Based on the example given by the applicant, who proposes to add 1 g per person and per day of this novel ingredient, this would translate into a consumption level of 0.0034 µg TEQ/pers/day of benzo(a)pyrene and 0.007 µg TEQ/pers/day of PAHs (10 PAHs);

Conclusion

Under the conditions of use of the novel ingredient as described by the applicant and for a product corresponding to that of which the analysis was presented in the file, the toxicological impact of the PAHs present in the novel ingredient on the health of the consumer can be considered as negligible;

However, the heavy PAHs (5 and more kernels), which include the most toxic, are concentrated 15 to 20 times during the molecular distillation process;

The human organism is, moreover, exposed to contamination by this type of molecule through many sources and that it is necessary to limit the intake of PAHs in food as much as possible;

A systematic analysis should be carried out of the batches of source oil, and only the batches with benzo(a)pyrene levels not exceeding 0.2 µg TEQ/kg (micrograms of TEQ per kilogram) and, for the 10 PAHs, levels not exceeding 0.50 µg TEQ/kg (micrograms of TEQ per kilogram), should be approved.

In December 2002, the Scientific Committee on Food (SCF) gave an opinion on the assessment of the risks of PAHs in food for human health in which it stressed that it is difficult to set a safe limit for these substances and that, given the carcinogenic and genotoxic nature of these

molecules, it is advisable to adopt an approach that aims to limit as much as possible the presence of PAHs in food (ALARA).

[2] The average exposure of the French population, estimated in 2003 based on 948 samples of foodstuffs taken at distribution and from the data from the INCA survey (national food consumption survey 1999), shows that the average intake of benzo(a)pyrene in food is 90 ng/person/d.

Taking as an example the consumption of 1 g/day of the NI produced on the basis of palm kernel oil containing no more than 0.2 µg/kg of benzo(a)pyrene, for a concentration factor of 20 the intake of benzo(a)pyrene in the NI would represent 4.4% of the total intake.

[3] Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food - SCF/CNTM/PAH/29 Final - 4 December 2002 - http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

Conclusion

The Committee confirms that most of the usual characteristics of edible palm kernel oil are to be found in the NI. The relative fatty acid composition of the NI is equivalent to that of the source, non-discoloured palm kernel oil. The unsaponifiable content is increased by the new process by a factor of around 10. The oxidative stability of the product is good and comparable with that of the original product. The viscosity of the NI is increased by a factor of around 2.5 in relation to the source oil, and the NI clouds over at 25°C. The characteristic specifications of the quality of the product, the levels of residues of chlorinated and organophosphorated pesticides and the levels of heavy metals are in line with the recommendations of the *Codex Alimentarius*.

However, the available data on a single batch of the NI show that the new process leads to an increase in the level of polycyclic aromatic hydrocarbons (PAHs) in the NI by a factor of 15 to 20 in relation to the source oil. Taking into account the assessment of the Scientific Committee on Food (SCF) and in view of the PAH intake in food in the NI, we feel it is difficult to recognise any health benefit deriving from this NI of which the production process may increase exposure to PAHs.

3.2 Protocol II: Effect of the production process applied to the NI

The industrial process used to obtain oil enriched with the unsaponifiable fraction is molecular distillation. This is a physical process used in the food industry to produce food additives (emulsifiers of the monoglyceride and diglyceride type, tocopherol-rich antioxidants of the natural extract type, vitamins, flavourings, etc.). The principle of molecular distillation consists of very short vaporisation (approximately 0.1 seconds) under high vacuum (10-2 to 10-3 mm Hg) and at high temperature (200-300°C). This process in particular provides a means of carrying out certain operations (separation, purification, discolouration and deodorisation). When applied to vegetable oils, molecular distillation provides a means of extracting preferentially the lightest components (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 the distillation of palm kernel oil, the unsaponifiable fraction is concentrated by a factor of around 10. This increase in the unsaponifiable fraction is accompanied by partial elimination of the triglycerides.
The Committee stresses that it is claimed that the enriched palm kernel oil contains around 10 times more unsaponifiables than the original kernel oil and that, however, the comparison of the levels of unsaponifiables claimed in the specifications of red palm kernel oil (< 1.3g/100g) and in the specifications of the NI (4 to 7 g/100g) shows that this factor could be lower. The applicant also claims that the process is controlled to preserve the nutritional qualities of the NI, in particular the vitamin E, the tocotrienols, the phytosterols and the carotenes. We will see in

section 3.4 that this claim is not borne out for the carotenes. Nonetheless, with the exception of the increase in the unsaponifiable fraction, the relative percentages of the other compounds of the original oil have not been appreciably modified.

3.3 Protocol III Prior use of the organism used as the source of the NI

Palm kernel oil comes from the oil palm (*Elais Guineensis*), which belongs to the family of palmaceae. This tree originates in the Gulf of Guinea, but it is also found in Africa, Malaysia, Indonesia and Brazil. It is grown very extensively in the latter three countries. The applicant claims that the source is not genetically modified but does not provide any details regarding his system of traceability and control.
Palm oil is the second most common oil produced in the world after soya oil. It is consumed as 'salad oil', especially in the production countries. The applicant states by way of indication that 2 million tons of palm oil were imported to Europe in 1997, including 180,000 tons to France. At the time, the average food consumption (direct consumption and agrifood industries) of palm oil was 1.6g per day in Europe and in France.
Palm kernel oil, for its part, is intended primarily for the agrifood industries of the importing countries, the most common use being industrial chip production.

The Committee stresses that while palm kernel oil, including in particular the discolouration stage, is commonly consumed in Europe, refined but non-discoloured palm kernel oil, which is the source of the NI, is not. However, non-discoloured palm kernel oil is listed in the guidelines of the *Codex Alimentarius* concerning edible oils and specifications are assigned to it.

3.4 Protocol IX: Anticipated consumption and level of use of the NI

The use of palm kernel oil concentrated with unsaponifiables is recommended by the applicant as a food ingredient that has a rebalancing effect at a nutritional level on the intake of vitamin E and provitamin A. The applicant adds that the NI will not replace any already existing foodstuffs and that its use will not be geographically limited. He also states that the possible fields of application are, on the one hand, food supplements and, on the other hand, any foodstuffs for which the intake of vitamin E and/or vitamin A is claimed (functional foods, supplemented foods which might include margarines, composite edible oils, milk and dairy products, seasonings and sauces, cakes and baking products, cooked and sterilised dishes, cooked meat products, etc.). On average, 100 g of palm kernel oil concentrated with unsaponifiables contain 5 g of unsaponifiables, including 0.6 g of tocopherols, 1.5 g of tocotrienols, 1.5 g of phytosterols, 0.2 g of carotenes and 1.2 g of miscellaneous compounds (squalene, hydrocarbons). The triglyceridic fraction represents 95 g for 100 g of the NI.

4 http://apps.fao.org

For example, the applicant indicates the nutritional intake resulting from the consumption of 1g per day of the NI. He also indicates that direct daily consumption of the NI as a food supplement or indirect consumption as a foodstuff supplemented with the NI will be defined by the industrial user. Thus, substantial equivalence with the source palm kernel oil for the unsaponifiable fraction (tocopherols, tocotrienols and phytosterols) will be as follows:
• 1 g of the NI (9 kcal or 37 kJ) corresponds to approximately 12 g (108 kcal or 452 kJ) or to one tablespoon of the source palm kernel oil, i.e. a reduction by around a factor of 12 in the energy supply and the following distributions of the triglyceridic and unsaponifiable fractions of the source palm kernel oil and the NI: The table shows and corrects the data of the applicant taking account of the conversion factor between triglycerides (TG) and total fatty acid (TFAs).

One tablespoon (12 g) of the source provides 1.0 g of the new ingredient
Triglyceridic fraction (mg)
Energy supply (kcal)
Total fatty acids (TFAs)
of which:
• SFA_2 (mg)
• $MIFA_3$ (mg)
• $PIFA_4$
11940 107.5 10750 4085 5052 1612 **855** 8.55 855 368 359 128
Unsaponifiable fraction (mg)
of which:
• Sterols (mg)
• Tocopherols (mg)
• Tocotrienols (mg)
• Carotenes (mg)
• Miscellaneous compounds (mg)
60 13 5 11 6.24 **50** 15.6.0 15 2 12 1
$_1$ taking into account the coefficient 0.9 corresponding to the ratio in weight [TFA of the TG] TG;
$_2$ SFA = saturated fatty acids,
$_3$ MUFAs = monounsaturated fatty acids,
$_4$ PUFAs = polyunsaturated fatty acids

The Committee points out that it should be specified that this equivalence can be admitted for the sterols and the tocopherols but not for the tocotrienols, the carotenoids or the miscellaneous compounds (in these three cases equivalence is 16 g for 1 g, 4 g for 1 g and 6 g for 1 g respectively). It specifies that the unsaponifiable fraction presents a relative loss of carotenes.
In any case, the Committee confirms that the NI has a calorific value which is lower than that of the source oil by approximately a factor of 12.

3.5 Protocol X: Information provided by a human prior exposure to the NI or its source

The applicant states that refined palm kernel oil, the source of the NI, is widely and commonly consumed in all European countries and by people of all ages and classes.
Moreover, the industrial process involved in the production of palm kernel oil is perfectly controlled.
The applicant indicates that he has no information relating to prior exposure to this NI. However, in terms of its level of unsaponifiables, the NI is equivalent to other vegetable fatty foodstuffs: shea butter (which is very rich in unsaponifiables, mainly karitene), wheat germ oil (very rich in α-tocopherol) and avocado oil (very rich in sterols).
Five percent of the unsaponifiable fraction of the NI is equivalent to 7 to 10%, 3 to 4%, and 1 to 12% of the unsaponifiable fraction of these 3 fatty substances respectively.
In terms of intake of fatty acids, the NI is substantially equivalent to its source, refined palm kernel oil. It is also equivalent to avocado oil and shea butter.
In terms of intake of vitamin E or provitamin A, the applicant indicates that the NI is equivalent to a vegetable oil enriched with vitamin E or enriched with carotenoids.

The Committee considers that the principle of equivalence with the palm kernel oil commonly consumed in France and Europe is founded, with the exception of the levels of unsaponifiables, in particular the vitamin E and the carotenoids.

3.6 Protocol XI: Nutritional information on the NI

3.6.1 Substances

Taking into account its composition, the arguments put forward by the applicant to demonstrate the nutritional properties of the NI are based on the intake of fatty acids, vitamin E (tocopherols and tocotrienols), provitamin A and phytosterols.
The applicant stresses that the principal nutritional interest of the NI is its high level of liposoluble vitamins (vitamin E and provitamin A).

- Intake of fatty acids: The applicant claims that the NI, like the source palm kernel oil, is an excellent source of palmitic acid (C16:0) and oleic acid (18:1 n-9).

The file reports the quantities present in 100 g of the NI (palmitic acid 28.5-43 g, oleic acid 33 - 47.5 g).
Finally, the NI contains 9.5 to 15 g/100g of linoleic acid (C18:2 n-6).
Concerning **oleic acid**, the applicant cites recent nutritional studies carried out on olive oil which suggest that oleic acid leads to a reduction in LDL cholesterol and at the same time to an increase in HDL cholesterol, thus helping prevent cardiovascular diseases.
He adds that the NI can also contribute to the intake of monounsaturated fatty acids in the oleic acid. A dose of 3g of the NI provides 1.2g of oleic acid.
Concerning **palmitic acid**, the applicant cites animal studies and observations of populations that consume palm oil in large quantities. These suggest that palm oil plays a protective role with respect to cardiovascular risks. The applicant thus points out that palm oil is different from other fatty acids in that it does not increase the total plasma cholesterol level.
Concerning **linoleic acid**, an essential fatty acid, the applicant reiterates that it plays a role in the synthesis of eicosanoids (prostaglandins, leukotrienes and thromboxanes) in the arachidonic acid. Eicosanoids act as oxygenated chemical mediators in the mechanism of platelet aggregation, but they are also involved in the inflammatory and immunitary phenomena.
In addition, the applicant refers to nutritional studies which highlight the hypocholesterolemiant effect of the fatty acids of the series $\omega 6$.
However, the applicant indicates that a dose of 1g of the NI provides 0.1 to 0.15 g of linoleic acid, i.e. a level which is lower by a factor of approximately 100 than that obtained by traditional salad oils.
The applicant therefore concludes that the NI is thus not intended to supplement or to rebalance the level of dietary fatty acids.

The Committee confirms that 1 g of the NI does not significantly affect the balance of saturated, monounsaturated and polyunsaturated fatty acids and cannot therefore have any effect on the level of dietary fatty acids.
However, the Committee regrets the choice of a source oil mostly made up of saturated fatty acids, which means that this oil is atherothrombogenic.

- Intake of vitamin E: The applicant reiterates that the vitamin E activity can be provided by tocopherols and tocotrienols of which palm oil is the most naturally rich vegetable oil.

The nature and relative proportions of tocopherols and tocotrienols are the same in the source oil and in the NI.
The applicant indicates that the γ and δ forms of the tocopherols are ten times weaker than the

α form and that only the α form of the tocotrienols has a vitamin activity which is significant but nonetheless weaker than that of the tocopherols.
He briefly presents the biological roles of vitamin E as an antioxidant, in particular through its action at the level of the membranes and the lipoproteins and by capturing the free radicals.
He also cites other actions of vitamin E in the prevention of ischaemic cardiovascular diseases, the prevention of certain cancers, boosting of the immune response in the elderly, reducing the risk of cataracts, delaying the onset of degenerative diseases, etc.
The applicant points out that nutritional studies show that there is no vitamin E deficiency in French diets, but that in certain cases the intake can be lower than the RDA.
As regards the doses of vitamin E, the applicant cites the reference value of the recommended daily allowance (RDA) set in 1981 at 10 mg of α-tocopherol equivalent (α-TE) or 15 IU.
In addition, he points out that the safe limit proposed for vitamin E in France by the CSHPF is 60 IU (40 mg α-TE) per day.
The applicant indicates that the NI provides 6 mg of α-TE per gram, i.e. 50% of the RDA of vitamin E. The intake of vitamin E with the NI is therefore 10 to 100 times higher than that of 14 different widely consumed edible vegetable oils (wheat germ oil, sunflower oil, hazelnut oil, rapeseed oil and soya oil).

The Committee stresses that it is discrepant from the results of the controlled intervention studies to claim that vitamin E helps prevent cardiovascular diseases.
The recent meta-analyses show that there are no convergent results as regards the efficacy of the pharmacological doses in the intervention studies and lead to the conclusion that there is no demonstrated effect at nutritional doses in 4 studies out of 6.
The intervention studies cited by the applicant are carried out using supranutritional doses, outside the fields of nutritional doses.
Concerning the dose recommended by the applicant, the Committee stresses that according to the levels of tocotrienols and tocopherols in the NI and the table of equivalence given by the applicant, 1 g of the NI provides a quantity of vitamin E expressed as α-TE which is closer to 8.5 mg than to 6 mg, i.e. 85% of the RDA and 70% of the recommended nutritional intake for the French population (RNI).

• Intake of carotenoids

The applicant stresses that palm oil is a vegetable source which is particularly concentrated with carotenoids, giving it a characteristic orange colour.
He reiterates that carotenoids include various substances (especially carotenes, lycopenes and xanthophylls).
The NI contains only trans β-carotene and trans α-carotene.
Compared with crude palm kernel oil (680-760 mg/kg), the NI is enriched with carotenes (1500-2000 mg/kg, with a trans γ-carotene loss), lycopenes and xanthophylls.
The applicant reiterates that carotenes can play a role in oxidoreduction reactions and free radical reactions and can have a pro-vitamin A activity, trans β-carotene having the most significant activity.
The applicant mentions a relatively widespread deficiency in vitamin A in humans.
He then reiterates the risks of hypervitaminosis A connected with the ingestion of retinol, then stresses that carotenoids as such are not toxic.
With regard to the doses of vitamin A, the applicant cites the reference value of the recommended daily allowance (RDA), which is 800 μg of Retinol Equivalents (RE) of vitamin A.
The NI provides 150 to 200 mg of total carotenes for 100g, of which 66% is in the β form at

100% activity and 33% in the α form at 50% activity.

The NI therefore provides 200 to 300 µg of RE per gram, i.e. 25% to 35% of the RDA and 35% to 50% of the RNI of vitamin A.

The Committee stresses that thanks to two surveys recently carried out in France relatively reliable data are available on the dietary intake of vitamin A in the French population.
The dietary intake is satisfactory, and the levels of circulating retinol are normal.
It can therefore be concluded that the level of vitamin A in the general French population is correct and that it is wrong to claim that there are widespread deficiencies.
The Committee confirms that provitamin A carotenoids have never shown hepatic toxicity or teratogenic effects. However, it should be pointed out that β-carotene as a single supplement (at a dose of 20 mg/d) or accompanied by vitamin E was found to be procarcinogenic and proatherogenic in smokers. It is thus false to say that the carotenoids are not toxic at strong doses.

[5] Léger, Ann.Biol.Clin. 2000, 58: 527-540; Léger, O.C.L., 2000, 7: 258-265.
[6] RDA = 10 mg α-TE
[7] RNI = 12 mg α-TE
[8] ASPCC, SU.VI.MAX
[9] ATBC, Rapola et al, Lancet, 1997, 349: 1715-1520; Heinonen et al, N. Engl. J. Med, 1994, 330: 1029-1035.

Furthermore, in its opinion of 28 November 2000, the Scientific Committee on Food (SCF) indicates that it is not possible in the current state of knowledge to set a safe limit for the daily intake of carotenoids, because it is not possible to establish a dose-response relationship and because one cannot be sufficiently specific in distinguishing the various isomeric forms of β-carotene.
However, the Committee considers that the carotene intake with the NI at a dose of 1g is acceptable. It yields an intake of between 200 and 300 µg of RE/g, i.e. 25% to 35% of the RDA and 35 to 50% of the RNI for vitamin A.

• Intake of phytosterols

Phytosterols, which are natural vegetable constituents present in vegetable oils (0.1 to 0.5%), are mainly terpenic constituents of the vegetable unsaponifiables with a molecular structure similar to that of cholesterol. This similarity effectively inhibits the intestinal absorption of cholesterol.
For this reason, they are added to certain fatty substances intended for hypercholesterolemic patients.
The applicant cites the nutritional studies carried out on phytosterols which show that a supplement of between 0.8 and 3 g/d of phytosterols (depending on the population and the objectives pursued) reduces total cholesterol and LDL cholesterol.
He adds that no significant harmful effects are reported and that no maximum safe dose is given for phytosterols.
A daily dose of the NI of 1g provides 15 mg of total phytosterols. The applicant indicates that this dose does not have a significant and immediate effect on hypercholesterolemia but can contribute to an intake of phytosterols in certain diets which are low in these substances.

The Committee confirms that the hypocholesterolemiant action of phytosterols is now well documented in the scientific literature.
On average, a daily dose of 1g of the NI provides 15 mg of total sterols.
According to the literature, the effective dose to achieve a reduction of approximately 10 to 15% in LDL cholesterol is between 750 mg and 3000 mg/d.
The Committee confirms that the claim that phytosterols have a hypocholesterolemiant effect is

inadmissible for the dose of this substance contained in the NI.

• Intake of squalene: The applicant has achieved a dosage of aliphatic hydrocarbons and squalene.

The levels of aliphatic hydrocarbons and squalene in the NI are 10 mg/100g and 1.36 mg/100g respectively, which suggests that these constituents were concentrated by the new process.

The Committee points out that it has been demonstrated that elevated doses of squalene (1 g/d) increase the LDL cholesterol level. In the NI, the squalene level is similar to that found in olive oil.
The Committee notes that there are no known adverse effects for the squalene levels contained in 1 g of the NI.

3.6.2 Claims

The applicant indicates that the industrial user of the NI, based on a food product or a food supplement, could claim the following:

[10] RDA = 800 µg RE
[11] RNI for female adults = 600 µg RE
[12] Miettinen et al., Am.J.Clin.Nutr. 1994, 59: 356 - 363

• Nutritional labelling:

Within the framework of French decree no. 93-1130 of 27.9.93, the industrial user can give for 100g: the energy value, the levels of protein, glucides and lipids including the quantities in saturated, monounsaturated and polyunsaturated fatty acids and the levels of vitamin E and vitamin A.

• Functional claims: In reference to the opinion of 18.12.96 of the Interministerial Commission on Special Food Products (CEDAP) on vitamin E, the claim can be put forward for the NI that it "protects the cellular membranes and/or protects against oxidation of fatty acids".

• Health claims: No health claims are put forward for the NI.

The Committee confirms that the quantitative and functional nutritional claims put forward are acceptable under the envisaged conditions of use.
It also confirms that no health claims can be made.

3.7 Protocol XII: Microbiological information on the NI

The applicant states that because of the lipophilic nature of the NI, the absence of water and solid impurities and the microbial cleanliness of the source, no risks of bacterial proliferation can be envisaged.
Furthermore, the production temperature of the NF (230°C) eliminates any risk of the presence of microorganisms.
He points out that the conditioning and storage of the NI are carried out away from the light and under inert gas, thereby reducing the risk of bacterial proliferation and contamination.

The Committee confirms that as the process involves vaporisation by heating for a very short

period (0.1 secs) under high vacuum (10-3 mm Hg), the NI does not present a risk of microbiological contamination.

3.8 Protocol XIII: Toxicological information on the NI

The toxicological study of the NI carried out according to the Good Laboratory Practice (GLP) recognised by the interdepartmental Group on Chemical Substances and by the French Authority for the Health Safety of Health Products (*Agence française de sécurité sanitaire des produits de santé*) comprised:

• an assessment of acute oral toxicity in the mouse and in the rat: The objective of the tests was to assess in qualitative and quantitative terms the toxic phenomena and the time of their appearance after single oral administration (force-feeding) of the NI at a dose of 18 mg/kg of body weight in the mouse and 5000 mg/kg of body weight in the rat.
The results of the autopsy carried out 14 days after the administration of the NI show that under these conditions the NI caused no mortalities or clinical disorders, did not modify body weight gain and did not cause any macroscopically visible organ or tissue alteration.
Under the experimental conditions adopted, the oral DL_{50} of the NI is greater than 18 mg/kg for the mouse and greater than 5,000 mg/kg for the rat.

• an Ames test for a possible mutagenic potential: The Ames test was carried out in accordance with Directive 84/449/EEC and OECD Guideline 471 on five bacterial strains (*Salmonella typhimurium his*) and showed that the NI did not have a mutagenic capacity under the conditions of the test.

The Committee accepts the conclusions put forward by the applicant and indicates that generally speaking the quality criteria of the new ingredient are in line with the recommendations of the *Codex Alimentarius*.

Chapter 4
Conclusions

The French Food Authority considers that:

Concerning nutritional interest:

• Refined non-discoloured palm kernel oil enriched with unsaponifiables proposed as a food ingredient at a dose of 1 g/d provides the following, without leading to an inappropriate energy supplement of the intake:
(i) 8.5 mg of vitamin E expressed as α-tocopherol equivalents, i.e. 85% of the recommended daily intake (RDI) and 70% of the nutritional intake recommended for the French population (RNI),
(ii) 200 to 300 µg of carotenes expressed as retinol equivalents, i.e. 25 to 38% of the RDA and 35 to 50% of the RNI for vitamin A.

However, it must be stressed that:
- the nutritional status of the population in vitamin A and β-carotene is satisfactory (in France at least);
- most of the fatty acids in the new ingredient are saturated, but these foodstuffs are associated with atherothrombogenic properties.

• The claim that the new ingredient reduces cholesterolemia cannot be made for the phytosterols, because the product does not provide effective doses.

Concerning health risks:

• The dietary intake of polycyclic aromatic hydrocarbons (PAHs) estimated based on the available data for a dose of 1 g of the new ingredient is not negligible: the level of benzo(a)pyrene (B(a)P) accounts for 4.4% of the total intake of B(a)P in food.

• The new process leads to a concentration of the level of PAHs by a factor of 15 to 20 in relation to the source oil, which is discrepant from the recommendations of the Scientific Committee on Food (SCF), which recommends limiting the presence of PAHs in food as much as possible (ALARA).

In conclusion, the Authority considers that:
(i) the new ingredient is of no nutritional interest, and
(ii) its consumption significantly increases the exposure of populations to toxic compounds.

[13] Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food - SCF/CNTM/PAH/29 Final - 4 December 2002 - http://europa.eu.int/comm/food/fs/sc/scf/index_en.html