Bureau Nieuwe Voedingsmiddelen
Novel Foods Unit

Allanblackiazaadolie

Allanblackia seed oil

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

Assessment of safety for the consumer, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients

aan/to:

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

Nr. 2017-07 BNV, Utrecht, 13 december 2017
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Bureau Nieuwe Voedingsmiddelen
CBG
Postbus 16229
2500 BE Den Haag
novelfoods@cbg-meb.nl
www.nieuwevoedingsmiddelen.nl

Novel Foods Unit
MEB
P.O. box 16229
2500 BE The Hague
The Netherlands
novelfoods@cbg-meb.nl
www.novel-foods.nl

Inhoudsopgave

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Samenvatting en conclusies

De aanvrager, de firma de firma Unilever, heeft een veiligheidsdossier ingediend over allanblackiazaadolie die wordt verkregen uit zaden van allanblackiabomen (*A. floribunda* en *A. stuhlmannii)*. Op basis van een eerdere beoordeling is sinds 2008 het gebruik van allanblackiazaadolie in smeersels op basis van gele vetten en smeerbare producten op basis van room toegestaan in de EU. De aanvrager wil nu het maximaal gehalte van allanblackiazaadolie in de al goedgekeurde toepassing verhogen van 20 % naar maximaal 30 %. Daarnaast vraagt de firma toelating voor het gebruik van maximaal 30 % allanblackiazaadolie in mengsels van plantaardige olie en melk (roomalternatieven).

De commissie VNV concludeert dat de nieuwe informatie over de verwachte inname kan worden beoordeeld op basis van de beschikbare veiligheidsgegevens van de oorspronkelijke aanvraag omdat het product dat indertijd toxicologisch is onderzocht representatief is voor de olie die nu wordt geproduceerd. Ook zijn er, voor zover bekend, geen nieuwe resultaten van toxicologisch onderzoek. Allanblackiazaadolie bestaat voornamelijk uit de vetzuren stearinezuur (C18:0) en oliezuur (C18:1). De commissie heeft geen bezwaar tegen de vernieuwde productspecificatie die de aanvrager voorstelt. Dit is een vereenvoudigde versie van de specificatie zoals die is opgenomen in de bijlage van het toelatingsbesluit van allanblackiazaadolie. Tegelijk wordt rechtgezet dat het gehalte onverzeepbare bestanddelen maximaal 1,0 gewichtsprocent van de olie is, en niet maximaal 0,1 gewichtsprocent zoals per abuis in het verleden is vastgelegd (EU08).

Voor de innameberekeningen van de nieuwe olie heeft de aanvrager gebruik gemaakt van voedselconsumptiegegevens voor verschillende bevolkingsgroepen in Nederland en Verenigd Koninkrijk. Hierbij gaat men uit van het maximale gehalte van de nieuwe olie in alle voorgestelde producten. Ook geeft de aanvrager per productcategorie een overzicht van de levensmiddelen die in deze berekeningen zijn meegenomen. Volgens de commissie VNV heeft de aanvrager voldoende gedetailleerde informatie verstrekt. Het is voor de verschillende leeftijdsgroepen duidelijk weergegeven wat de berekende inname van de nieuwe olie zal zijn bij gemiddeld gebruik en bij hoog consumptieniveau van de voorgestelde producten. Op basis van de hoogste berekende blootstelling bij Nederlandse peuters, concludeert de commissie VNV dat deze tenminste een factor 20 lager is dan de blootstelling die in het subchronisch onderzoek met ratten geen nadelige effecten teweegbracht. Gezien het type voedingsmiddel vindt de commissie VNV dit voldoende.

1 Inleiding

Het Bureau Nieuwe Voedingsmiddelen (BNV) van het Agentschap voor het College ter Beoordeling van Geneesmiddelen (CBG) adviseert het ministerie van VWS over de veiligheid van nieuwe voedingsmiddelen. Deze advisering is onderdeel van de Europese toelatingsprocedure voor nieuwe voedingsmiddelen, die is vastgelegd in EU verordening 258/97 (EC97). Dit rapport is het verslag van een zogenoemde eerste beoordeling volgens deze procedure. De tekst van het rapport is opgesteld door het Bureau Nieuwe Voedingsmiddelen, in nauwe samenspraak met de commissie Veiligheidsbeoordeling Nieuwe Voedingsmiddelen (commissie VNV). De samenstelling van deze commissie is als bijlage opgenomen in dit rapport.

De huidige aanvraag betreft geraffineerde olie verkregen uit zaden van Afrikaanse allanblackia bomen. De veiligheid van deze olie is al eerder beoordeeld onder de nieuwe voedingsmiddelen verordening. Deze oorspronkelijk aanvraag uit 2004 (Uni04) resulteerde in een Europese toelating in 2008 (EU08) voor het gebruik in smeersels op basis van gele vetten en smeerbare producten op basis van room, op grond van een positief EFSA advies (EFSA07). De vergunninghouder wil het maximaal gehalte van allanblackiazaadolie in de al goedgekeurde toepassing verhogen en de olie tevens verwerken in andere type producten. Voor deze uitbreiding van het gebruik is een veiligheidsdossier opgesteld dat BNV ontving op 22 september 2014 (Uni14). De beoordelingsprocedure is als volgt verlopen. De commissie VNV heeft kennis genomen van het dossier in de vergadering van 29 september 2014. Op basis van de discussie in de vergadering van 26 mei 2015 heeft de commissie VNV op 10 juni 2015 om opheldering gevraagd over enkele onderdelen, in het bijzonder over de productspecificatie. Vervolgens verstrekte de aanvrager op 15 november 2016 aanvullende informatie (Uni16), die de commissie VNV besprak in haar vergadering van 29 november 2016. Tenslotte heeft de commissie VNV in de plenaire vergadering van 31 oktober 2017 de beoordeling afgerond. Dit rapport is het verslag van haar bevindingen.

2 Volledigheid en juistheid van het dossier

2.1 Administratieve gegevens

De aanvraag is is de firma Unilever met een hoofdkantoor op twee locaties: Unilever PLC (100 Victoria Embankment, London, Verenigd Koninkrijk) en Unilever N.V. (Weena 455, Rotterdam). Het dossier is opgesteld door Unilever Research and Development Vlaardingen B.V. (Olivier van Noortlaan 120, Vlaardingen).

2.2 Algemene beschrijving van het voedingsmiddel

De aanvraag betreft olie uit zaden van de allanblackia boom. Rijpe zaden worden geperst waarna de ruwe olie wordt gezuiverd net zoals dat gebeurt voor andere plantaardige spijsoliën. De nieuwe olie is bedoeld als ingrediënt van smeersels op basis van gele vetten, smeerbare producten op basis van room en van mengsels van plantaardige olie en melk (als alternatieven voor room).

2.3 Classificatie van het voedingsmiddel voor beoordeling

De oorspronkelijke aanvraag beschrijft dat allanblackiazaadolie valt onder categorie ‘e’ ’voedingsmiddelen geïsoleerd uit planten’ van artikel 1, lid 2, van de nieuwe voedingsmiddelen verordening (EC97). De aanvrager heeft het nieuwe product indertijd ingedeeld in klasse 1.2 zoals beschreven in deel I van Aanbeveling 97/618 van de Europese Commissie (EC97a). Dit betekent dat het een eenvoudig mengsel is van chemische stoffen, afkomstig van niet genetisch gemodificeerde bronnen die niet eerder voor de voeding zijn gebruikt in de Europese Unie (EFSA07, Uni04).

Volgens de commissie VNV ligt het meer voor de hand om het product te beschouwen als een “complex nieuw voedingsmiddel uit niet genetisch gemodificeerde bron, die nog niet eerder voor de voeding is gebruikt” (klasse 2.2). De commissie VNV meent dat een dergelijke indeling in klasse 2.2 overeenkomt met de classificatie van andere zaadoliën die als nieuw voedingsmiddel zijn beoordeeld, zoals geraffineerde echiumolie, korianderzaadolie, chia-olie en geraffineerde buglossoïdesolie. De indeling in klasse 1 of klasse 2 maakt echter voor de veiligheidsbeoordeling geen verschil, omdat dezelfde thema’s worden geëvalueerd (EC97a).

2.4 Informatievergaring over het voedingsmiddel

De informatie die essentieel is voor de beoordeling van de veiligheid van consumptie van het voedingsmiddel in klasse 1.2 of 2.2 is gespecificeerd aan de hand van de onderstaande thema’s die zijn voorgeschreven in Aanbeveling 97/618 van de Europese Commissie (EC97a):

I Specificatie van het nieuwe voedingsmiddel
II Effecten van het gevolgde productieprocedé op het voedingsmiddel
III Achtergrondinformatie over het als bron voor het voedingsmiddel gebruikte organisme
IX Verwachte opname en gebruiksfrequentie van het voedingsmiddel

XI Informatie over de voedingswaarde van het voedingsmiddel
XII Microbiologische informatie over het voedingsmiddel
XIII Toxicologische informatie over het voedingsmiddel

Bij thema IX bespreekt de aanvrager de nieuwe consumptiegegevens, die de basis vormen van deze aanvraag voor uitbreiding van gebruik. Voor de meeste andere thema's uit de Europese aanbeveling verwijst de aanvrager naar de eerdere aanvraag, maar bespreekt sommige onderwerpen opnieuw. Het dossier heeft ook een hoofdstuk gewijd aan thema X "Informatie op basis van eerdere blootstelling van de mens aan het nieuwe voedingsmiddel of zijn bron", waarin de aanvrager echter verklaart dat geen van de eerder goedgekeurde producten met allanblackiazaadolie (EU08) tot nu toe is verhandeld op de EU markt (Uni14).

De commissie VNV stelt dat het volstaat om de nieuwe informatie over de verwachte inname (thema IX) te beoordelen op basis van de beschikbare veiligheidsgegevens van de oorspronkelijke aanvraag, mits het product identiek is aan het al toegelaten product. Verder hoort de allanblackiazaadolie in de nieuw voorgestelde toepassingen net zo stabiel te zijn als in de al toegelaten productcategorieën. Ook zijn er volgens de commissie VNV geen relevante nieuwe gegevens en is een herevaluatie van de toxicologische veiligheid niet nodig.

2.5 Beknopt overzicht door de aanvrager

Het dossier bevat een samenvatting die aan de andere EU lidstaten is toegezonden, zoals is vereist volgens Verordening (EG) nr. 258/97 (EC97). Deze samenvatting is ook als bijlage bij dit rapport gevoegd.

2.6 Overige beoordelingen

Er zijn de commissie VNV geen andere beoordelingen van dit product bekend dan die van de oorspronkelijke aanvraag (EFSA07, EU08).

2.7 Etiketteringsvoorstel van de aanvrager

In het dossier is geen informatie opgenomen over etikettering. De commissie VNV wijst erop dat de nieuwe olie op het etiket van het levensmiddel waarin het is verwerkt, moet worden aangeduid als Allanblackiazaadolie zoals vastgelegd in het toelatingsbesluit van 2008 (EU08). Tevens moet de etikettering voldoen aan de Europese Verordening 1169/2011 (EU11). In Nederland wordt de etikettering van voedingsmiddelen overigens niet beoordeeld door het Bureau Nieuwe Voedingsmiddelen, maar door het Regulier Overleg Warenwet.

3 Interpretatie en evaluatie van de voorgelegde gegevens

3.1 I Specificatie van het nieuwe voedingsmiddel

Het dossier bevat een productspecificatie die een vereenvoudigde versie is van de specificatie die is opgenomen in de bijlage van het toelatingsbesluit van allanblackiazaadolie (EU08). De grenswaarden voor de belangrijkste vetzuren stearinezuur (C18:0) en oliezuur (C18:1) zijn onveranderd: respectievelijk 45-58 % en 40-51% van het totaal aan vetzuren. Ook de vermelde waarden voor het gehalte aan vrije vetzuren (≤0,1% van het totaal aan vetzuren) en het verzepingsgetal (185 – 198 mg KOH/g olie) zijn niet gewijzigd. In plaats van individuele grenswaarden voor de vetzuren laurinezuur (C12:0), myristinezuur (C14:0) en palmitinezuur (C16:0) waarvan geringe hoeveelheden kunnen voorkomen, vermeldt de specificatie nu een gezamenlijke waarde van ten hoogste 4%. Verder worden de vetzuren linolzuur (C18:2 n-6) en linoleenzuur (C18:3) niet meer apart vermeld, maar is er een nieuwe parameter 'meervoudig onverzadigde vetzuren' in de specificatie opgenomen waarvan het gehalte ten hoogste 2% is . Daarnaast is de grenswaarde voor transvetzuren verhoogd van ten hoogste 0,5 % naar 1 % van het totaal aan vetzuren. De oorspronkelijke peroxidewaarde van maximaal 0,8 meq/kg is vervangen door maximaal 1,0 meq/kg. In de aanvullende informatie verklaart de aanvrager dat de bovengrens van de fractie met onverzeepbare bestanddelen maximaal 1,0 gewichtsprocent van de olie is (Uni16), en dat de 10-maal lagere grenswaarde zoals vermeld in de originele specificatie (EU08), onjuist is. De aanvrager licht uitgebreid toe dat het gehalte onverzeepbare bestanddelen van de huidige olie niet anders is als dat van de olie die indertijd is gebruikt in de verschillende toxicologische onderzoeken op basis waarvan het product is toeglaten. Men onderbouwt dit met de chemische analyseresultaten van de onverzeepbare bestanddelen van meerdere productiepartijen, waarbij de gegevens van twaalf batches uit de oorspronkelijke aanvraag (geproduceerd in de periode 2001-2004; Uni04) zijn vergeleken met die afkomstig van negen meer recente partijen, geproduceerde in de periode 2014-2015.

De commissie VNV heeft geen bezwaar tegen de aanpassingen die de aanvrager voorstelt in de productspecificatie. Afgezien van het gecorrigeerde gehalte onverzeepbare bestanddelen, verschilt de vernieuwde specificatie (Uni14, Uni16) niet wezenlijk van die vastgelegd is in de bijlage van het toelatingsbesluit (EU08). Dat palmitoleïnezuur (C16:1) ontbreekt in de vernieuwde specificatie is aanvaardbaar volgens de commissie VNV omdat de olie hooguit sporen van dit vetzuur bevat. In de oorspronkelijk onderzochte productiepartijen was het gehalte palmitoleïnezuur ten hoogste 0,02 %. Arachidinezuur (C20:0) komt eveneens niet meer voor in de vernieuwde specificatie. Omdat er geen meetwaarden van dit vetzuur zijn gerapporteerd in de oorspronkelijke aanvraag, gaat de commissie VNV er vanuit dat de olie geen detecteerbare hoeveelheden arachidinezuur bevat. Ook het jood getal, dat een maat is voor het totaal aan onverzadigde bindingen, is niet meer in de specificatie opgenomen. Deze parameter heeft volgens de commissie VNV geen meerwaarde omdat het een afgeleide is van de vetzuursamenstelling. Het belangrijkste aandachtspunt van de commissie VNV betreft het gehalte onverzeepbare bestanddelen van de olie dat ontbrak in de voorgestelde specificatie. Een hoger gehalte onverzeepbare bestanddelen dan in de indertijd beoordeelde olie, zou namelijk betekenen dat aanwezigheid

van schadelijke verbindingen niet meer geheel kan worden uitgesloten. In antwoord op vragen van de commissie VNV (Uni16) heeft de aanvrager rechtgezet dat de grenswaarde van het gehalte onverzeepbare bestanddelen maximaal 1,0 gewichtsprocent van de olie is, en niet maximaal 0,1 gewichtsprocent (EU08). De commissie VNV accepteert de uitleg hierover van de aanvrager. Zo bestaat de onverzeepbare fractie van plantaardige oliën gewoonlijk voor 20-30 % uit sterolen. In het verleden heeft de aanvrager alleen de sterolfractie van de onverzeepbare componenten geanalyseerd, voornamelijk van geraffineerde allanblackiazaadolie. Het totaal aan sterolen bedroeg toen ongeveer 0,1 tot 0,2 gewichtsprocent van de olie (Uni04, Uni16). Meer recent heeft men zowel de grootte van de onverzeepbare fractie als ook het totaal sterolgehalte bepaald, maar dan alleen van de ruwe olie (Uni16). Op basis van deze meetwaarden waarvoor voldoende batches zijn onderzocht, concludeert de commissie VNV dat het totaal sterolgehalte van de ruwe en geraffineerde olie vergelijkbaar is. Zij vindt het daarom aannemelijk dat de olie die oorspronkelijk is onderzocht, aantoonbaar meer dan 0,1 gewichtsprocent onverzeepbare bestanddelen bevatte. De commissie VNV stelt vast dat er voldoende gegevens zijn verstrekt waaruit kan worden afgeleid dat de teststof, die indertijd in het 90-dagen toxicologisch onderzoek met ratten is gebruikt, representatief is voor de olie zoals die nu wordt geproduceerd.

3.2 II Effecten van het gevolgde productieprocédé op het voedingsmiddel

De aanvrager verklaart dat er sinds 2004 geen belangrijke wijzigingen zijn aangebracht in het productieproces. Dit betreft allemaal gangbare procedures zoals die worden toegepast bij de bereiding van spijsoliën (Uni14). Net als in het oorspronkelijke dossier (EFSA07, Uni04) verklaart de aanvrager dat het productieproces zal worden gecontroleerd volgens het HACCP–systeem in overeenstemming met de Europese verordening 852/2004 inzake levensmiddelen-hygiëne. Ook verklaart men dat er geproduceerd wordt volgens goede productiepraktijken (Uni14). Bij navraag van de commissie over de stabiliteit van de olie bij hoge temperaturen nodig voor bakken en braden, licht de aanvrager toe dat het effect van hoge temperaturen voor allanblackiazaadolie niet anders is dan voor andere plantaardige triglyceriden oliën zoals zonnebloemolie en raapzaadolie (Uni16). Verder verwijst men naar het rapport van EFSA (EFSA07) dat stelt dat er geen aanwijzingen zijn om anders te veronderstellen.

De commissie VNV gaat ervan uit dat de genoemde kwaliteitssystemen adequaat zijn geïmplementeerd voordat de commerciële productie begint. Verder heeft zij geen opmerkingen.

3.3 III Achtergrondinformatie over het als bron voor het voedingsmiddel gebruikte organisme

Allanblackiabomen groeien in Afrika en behoren tot de *Guttiferae* familie, subfamilie *Clusiodeae*. De oorspronkelijke aanvraag (Uni04) bevat een uitgebreide beschrijving van de gebruikte soorten, het traditioneel gebruik en ook van de milieueffecten en duurzaamheidsaspecten. De aanvrager verklaart dat men zaden gebruikt van dezelfde allanblackiasoorten die zijn beschreven in het oorspronkelijke dossier. Dit betreft voornamelijk de soorten *A. floribunda* (synoniem met *A. parviflora*) en *A. stuhlmannii*.

De commissie VNV merkt op dat de bijlage van de Europese beschikking (EU08) alleen de twee hierboven genoemde soorten vermeldt als bron van geraffineerde allanblackiazaadolie. De commissie VNV heeft verder geen opmerkingen bij dit onderdeel.

3.4 IX Verwachte opname en gebruiksfrequentie van het voedingsmiddel

Voorgesteld gebruik. De huidige toelating voor allanblackiazaadolie in smeersels op basis van gele vetten en smeerbare producten op basis van room (EU08) is gebaseerd op de aanvraag indertijd voor maximale gebruiksconcentraties van 20 % (w/w). De aanvrager stelt nu voor om dit gebruik te verhogen naar maximaal 30 % (w/w). Net als in de oorspronkelijk aanvraag betreft dit zowel producten met een verlaagd vetgehalte als volvette producten. De aanvrager noemt dat met name de laatst genoemde varianten ook gebruikt zullen worden om mee te koken en bakken. Daarnaast vraagt men nu om toelating van maximaal 30 % allanblackiazaadolie in mengsels van plantaardige olie en melk. Deze nieuwe categorie omvat alternatieven voor verschillende roomproducten die gebruikt kunnen worden als slagroom en bij het koken. Ook hier betreft het zowel producten met een lager vetgehalte als volvette varianten. De aanvrager illustreert dit aan de hand van verschillende alternatieve roomproducten die nu in bepaalde lidstaten op de markt zijn.

Consumptieonderzoek. De aanvrager heeft gebruik gemaakt van voedselconsumptie-gegevens in Nederland (NL) en Verenigd Koninkrijk (VK) om de inname van de nieuwe olie voor verschillende bevolkingsgroepen te berekenen. Voor VK betreft dit gegevens die zijn verzameld in de periode 2008-2011 voor inwoners ouder dan 1,5 jaar. De Nederlandse gegevens zijn een combinatie van de voedselconsumptiepeilingen uit 2007-2008 bij kinderen van 2 tot 6 jaar en die uit 2007-2010 bij kinderen en volwassenen van 7 tot 69 jaar. Bij deze berekeningen gaat men uit van het maximale gehalte van de nieuwe olie in alle voorgestelde producten. Voor elke productcategorie is een lijst van levensmiddelen, die in deze berekeningen zijn meegenomen, opgenomen in de dossierbijlagen met voedselconsumptiegegevens (voor NL in annex E van bijlage E, en voor VK in annex C van bijlage D) (Uni14). De aanvrager vat de resultaten voor zowel NL als VK samen in het kerndossier; dit betreft naast het gemiddelde, ook de 90^{e} en 95^{e} percentiel van de inname voor elke onderzochte bevolkingsgroep ingedeeld naar leeftijd en geslacht. Omdat de berekende inname van de allanblackiazaadolie bij Nederlanders ongeveer 1,5 à 2 maal hoger uitkwam dan bij de Engelse bevolking, beschouwt de aanvrager de Nederlandse consumptiegegevens als leidend voor de veiligheidsbeoordeling. In dit advies zijn daarom alleen die resultaten weergegeven, zie “Nederlandse consumptiegegevens” hieronder.

Daarnaast heeft de aanvrager voor elke onderzochte bevolkingsgroep in NL en VK berekend in welke mate de voorgestelde productcategorieën bijdraagt aan de totale gemiddelde inname van allanblackiazaadolie. Deze gegevens zijn opgenomen in de verschillende annexen van de dossierbijlagen met voedselconsumptiegegevens, namelijk in annex A en C van bijlage E voor NL, en in annex A van bijlage D voor VK (Uni14, Uni16). Voor de nieuw voorgestelde categorie van roomalternatieven blijkt dat bij kinderen tot en met 18 jaar dit type product 10-20 % zal bijdragen aan de totale olie inname. Voor volwassenen ligt dit iets hoger, namelijk 23-30 %, met uitzondering van volwassen Nederlandse mannen

die met roomalternatieven gemiddeld ongeveer 15 % van totale allanblackiazaadolie zullen binnenkrijgen.

Hoewel de aanvrager ook de blootstellingen heeft berekend die gebaseerd zijn op consumptiegegevens voor margarine en room uit de 'EFSA Comprehensive database', laat men deze verder buiten beschouwing gezien de enorme spreiding van de resultaten. Dit is volgens de aanvrager het gevolg van de samenvoeging van de productcategorieën in dit systeem en dat resulteert ook in een overschatting van de inname.

Nederlandse consumptiegegevens. De inname van allanblackiazaadolie blijkt het hoogst bij volwassen mannen die gemiddeld rond de 8 gram per dag consumeren. De 95^{e} percentiel (95P) van deze inname varieert van 18,0 tot 19,3 gram per persoon per dag voor respectievelijk de leeftijdsgroepen 19-50 jaar en 51-69 jaar. Bij volwassen vrouwen is de gemiddelde inname ongeveer 6 gram per persoon per dag en de 95P van de inname voor 19-50 jarigen bedraagt 14,8 gram per persoon per dag. Anders dan bij de mannen van 51-69 jaar, is bij de vrouwen in deze leeftijdscategorie de 95P van de inname juist lager dan van de jongere vrouwen, namelijk 13,8 gram per persoon per dag. Bij jongens van 11-18 jaar is de 95P van de inname (17,5 gram per persoon per dag) bijna hetzelfde als die van volwassen mannen, maar de consumptie van meisjes van die leeftijd bedraagt 11,7 gram per persoon per dag (95P) en is duidelijk lager dan die van volwassen vrouwen. Voor kinderen neemt de consumptie (per persoon per dag) af met de leeftijd: 11,6 gram bij 7-10 jarigen, ongeveer 10 gram bij 4-6 jarigen en ruim 8 gram bij 2-3 jarigen. Relatief gezien, krijgen kinderen echter meer allanblackiazaadolie binnen dan volwassenen. Bij jonge kinderen is de berekende blootstelling, uitgedrukt per kg lichaamsgewicht, het hoogst en is er nauwelijks verschil tussen jongens en meisjes. Zo is voor peuters van 2-3 jaar de 95P van de inname 0,53 g/kg/dag en is dit voor kinderen van 4-6 jaar net iets lager, namelijk 0,48 g/kg/dag. Volgens de aanvrager is de blootstelling bij peuters nog aanzienlijk lager dan die in het subchronisch onderzoek met ratten geen nadelige effecten teweegbracht (zie hoofdstuk 3.7).

Volgens de commissie VNV heeft de aanvrager voldoende gedetailleerde informatie verstrekt, niet alleen is het helder welke soort producten als uitbreiding van gebruik worden voorgesteld, ook is voor de verschillende leeftijdsgroepen duidelijk weergegeven wat de berekende inname van de nieuwe olie zal zijn bij gemiddeld gebruik en bij hoog consumptieniveau (95P) van de voorgestelde producten (Uni14, Uni16). De commissie VNV noemt dat voor de verschillende smeerbare producten het voorgestelde gebruiksgehalte ten hoogste 1,5 maal hoger is dan toegelaten in 2008 (EU08) en dat uit de verstrekte gegevens (Uni14, Uni16) blijkt dat bij de innameberekeningen het gebruik bij koken en bakken met margarines is meegenomen. Niet alleen kunnen de producten met allanblackiazaadolie thuis worden gebruikt bij de bereiding van allerlei gerechten, ook wordt uit de lijst met levensmiddelencodes in de dossierbijlagen duidelijk dat dergelijke producten door de levensmiddelenindustrie kunnen worden verwerkt in bijvoorbeeld verschillende soorten gebak en kant-en-klaar producten zoals aardappelpuree, sauzen en jus.

Op basis van de hoogste berekende blootstelling bij peuters concludeert de commissie VNV dat deze tenminste een factor 20 lager is dan de blootstelling die in het subchronisch onderzoek met ratten geen nadelige effecten teweegbracht.

3.5 XI Informatie over de voedingswaarde van het voedingsmiddel

Het dossier bevat een overzicht waarin de vetzuursamenstelling van gangbare harde vetten, zoals palmpitolie, kokosolie en botervet, wordt vergeleken met die van allanblackiazaadolie, die bedoeld is om deze vetten te vervangen. In de consumentenproducten zal hierdoor het gehalte verzadigde vetzuren afnemen en mono-onverzadigde vetzuren toenemen. De aanvrager illustreert dit aan de hand van de vetzuursamenstellingen van enkele geselecteerde consumentenproducten die bereid zijn met gewoon hard vet of met allanblackiazaadolie.

De commissie VNV stelt vast dat de voedingskundige waarde van de allanblackiazaadolie ongewijzigd is ten opzichte van het product van de oorspronkelijke aanvraag (EFSA07, Uni04) en heeft geen opmerkingen.

3.6 XII Microbiologische informatie over het voedingsmiddel

De aanvrager verwijst naar de gegevens uit de oorspronkelijke aanvraag (Uni04) en dit volstaat volgens de commissie VNV (EFSA07, EU08).

3.7 XIII Toxicologische informatie over het voedingsmiddel

Sinds de toelating in 2008 zijn er voor zover bekend geen nieuwe resultaten van toxicologisch onderzoek gerapporteerd. Bijlage 4 van het oorspronkelijke dossier (Uni04) bevat het volledige rapport van het 90-dagen toxicologisch onderzoek bij ratten. Hierin werd het effect van voer met 20 % allanblackiazaadolie onderzocht. Oorspronkelijk meende de aanvrager dat het niet juist was om voor een macronutriënt zoals de nieuwe olie, een NOAEL te benoemen (Uni04). Op basis van de herevaluatie van hetzelfde 90-dagen proefdieronderzoek in het huidige dossier, blijkt dat de aanvrager de blootstelling van 11,3 en 14,7 g olie per kg lichaamsgewicht per dag, die berekend is uit de voederinname van respectievelijk mannetjes en vrouwtjes dieren, beschouwt als de NOAEL.

De commissie VNV bevestigt dat het huidige dossier uitgaat van dezelfde toxicologische informatie als indertijd (EFSA07, Uni04), maar dat de samenvatting van de resultaten hiervan nu anders is beschreven. Op basis van dit 90-dagen toxicologisch onderzoek stelde EFSA in 2008 vast dat geen van de waargenomen afwijkingen ten opzichte van de controle waarden toxicologisch relevant was. Dit heeft de aanvrager, met name voor de waargenomen significante veranderingen in verschillende hematologische parameters, in het huidige dossier verder verduidelijkt onder andere aan de hand van historische controlegegevens.

Volgens de aanvrager is de allanblackiazaadolie die nu wordt geproduceerd hetzelfde als het product dat destijds beoordeeld is als veilig voor mensen. De commissie VNV is het hiermee eens en concludeert dat er voldoende aanvullende gegevens zijn verstrekt (Uni16) waaruit kan worden afgeleid dat de teststof, die indertijd in het subchronisch onderzoek met ratten is gebruikt, representatief is voor de huidige olie. Voor het geheel aan toepassingen dat de aanvrager zou willen realiseren is volgens de commissie VNV de hoogste berekende blootstelling bij peuters (zie hoofdstuk 3.4) tenminste een factor 20 lager dan de blootstelling die in het subchronisch onderzoek met ratten geen nadelige effecten teweegbracht. Deze veiligheidsmarge komt uit op 22 gebaseerd op de 95P inname bij jongens van 2 tot 3 jaar en

de blootstelling bij mannetjes ratten, en op 27 berekend voor het vrouwelijke geslacht. Gezien het type voedingsmiddel vindt de commissie VNV de veiligheidsmarge voldoende.

Executive summary

The applicant company, Unilever, has submitted a safety dossier on Allanblackia seed oil obtained from seeds of Allanblackia trees (*A. floribunda* and *A. stuhlmannii*). Based on a previous assessment, the use of Allanblackia seed oil in spreads based on yellow fats and in spreadable cream-based products has been authorised in the EU since 2008. The applicant now wishes to increase the maximum level of Allanblackia seed oil in the previously approved application from 20% to a maximum of 30%. In addition, the applicant company requests authorisation for the use of up to 30% Allanblackia seed oil in mixtures of vegetable oil and milk (cream alternatives).

The Committee on Safety Assessment of Novel Foods (VNV Committee) concludes that the new information on the anticipated intake can be assessed based on the available safety data from the original application. This is because the product that was toxicologically tested at that time is representative of the oil currently being produced. Also, as far as the Committee is aware, no new toxicity study results have been made available. Allanblackia seed oil consists mainly of two fatty acids, stearic acid (C18:0) and oleic acid (C18:1). The Committee has no objection to the renewed product specification proposed by the applicant. This is a simplified version of the specification set out in the annex to the decision on authorisation for Allanblackia seed oil. At the same time, an error regarding the unsaponifiable matter content has been rectified. This value is up to 1.0% by weight of the oil and not up to 0.1% by weight as had previously been stated (EU08).

When calculating intake levels for the novel oil, the applicant used food consumption data for different population groups in the Netherlands and the United Kingdom. This is based on the assumption that all of the proposed products will contain the maximum concentration of the novel oil. The applicant has also provided details of the foods included in these calculations, listed by product category. The VNV Committee takes the view that the information provided by the applicant is sufficiently detailed. The calculated novel oil intakes corresponding to average use of the proposed products and to high levels of consumption are clearly indicated for each of the different age groups. Based on the highest calculated exposure among Dutch toddlers, the VNV Committee concludes that this is at least a factor of 20 lower than the exposure that caused no adverse effects in the subchronic study in rats. Given the type of food involved, the VNV Committee considers this to be sufficient.

1 Introduction

The Novel Foods Unit (NFU) of the Medicines Evaluation Board Agency advises the Ministry of Health, Welfare and Sport regarding the safety of novel foods. This advice is given within the context of the European approval procedure for novel foods, which is set out in EU Regulation 258/97 (EC97). This document is the report of a so-called initial assessment, carried out in accordance with this procedure. The text of the report was drawn up by the NFU, in close consultation with the Committee on Safety Assessment of Novel Foods. The make-up of this Committee is appended to this report.

The present application concerns refined oil obtained from the seeds of African Allanblackia trees. The safety of this oil has already been assessed under the novel food Regulation. That previous assessment took place in 2004 (Uni04). It resulted in a European authorisation in 2008 (EU08) for the use of spreads based on yellow fats and for spreadable cream-based products. This approval was based on a positive opinion from the European Food Safety Authority (EFSA07). The applicant now wishes to increase the maximum concentration of Allanblackia seed oil in the previously approved application and to incorporate the oil into other types of products. A safety dossier was drawn up for this extension of use. This dossier was received by the NFU on 22 September 2014 (Uni14). Details of the assessment procedure are given below. The VNV Committee examined this dossier during its meeting on 29 September 2014. On 10 June 2015, based on discussions at the meeting on 26 May 2015, the VNV Committee requested clarification on various elements, in particular the product specification. On 15 November 2016, the applicant provided additional information (Uni16), which was discussed at a meeting of t he VNV Committee on 29 November 2016. Finally, the VNV Committee completed its assessment during the plenary meeting on 31 October 2017. This document is the report of its findings.

2 Completeness and accuracy of the dossier

2.1 Administrative details

The application company, Unilever, has two headquarters, at different sites: Unilever PLC (100 Victoria Embankment, London, United Kingdom) and Unilever N.V. (Weena 455, Rotterdam, The Netherlands). The dossier was drawn up by Unilever Research and Development Vlaardingen B.V. (Olivier van Noortlaan 120, Vlaardingen, The Netherlands).

2.2 General description of the food

The application concerns oil obtained from seeds of the Allanblackia tree. As with other edible vegetable oils, the ripe seeds are first pressed and then the crude oil is purified. The novel oil is intended for use as an ingredient in spreads based on yellow fats, in spreadable cream-based products, and in mixtures of vegetable oil and milk (as alternatives to cream).

2.3 Classification of the food for assessment

The original application states that all Allanblackia seed oil falls within Article 1(2), category ‘e’ (‘foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use’) of the novel food Regulation (EC97). At that time, the applicant classified the novel product as class 1.2, as described in part I of European Commission Recommendation No. 97/618 (EC97a). This means that it is a simple mixture of chemical substances, derived from non-genetically modified sources that have no history of food use within the European Union (EFSA07, Uni04).

The VNV Committee takes the view that the most obvious approach is to consider this product to be a ‘complex novel food from non-GM source, which has no history of food use’ (class 2.2). The VNV Committee feels that this classification into class 2.2 corresponds to the classification of other seed oils assessed as novel foods, such as refined echium oil, coriander seed oil, chia oil and refined Buglossoides oil. In terms of the safety assessment, however, it makes no difference whether the product is classified as class 1 or class 2, as the themes being assessed are the same (EC97a).

2.4 Information on the food

The specification of information essential to an assessment of the safety of the food for consumption, in class 1.2 or 2.2, was based on the following themes, which are prescribed in European Commission Recommendation 97/618 (EC97a):

I Specification of the novel food
II Effects of the production process applied to the food
III History of the organism used as the source of the food
IX Anticipated intake and extent of use of the food
XI Nutritional information on the food

XII Microbiological information on the food
XIII Toxicological information on the food

Under theme IX, the applicant discusses the new consumption data that is the subject of this application for an extension of use. For most other themes from the European Recommendation, the applicant refers to the previous application. However, some topics are revisited. Nevertheless, the dossier also contains a section devoted to theme X, 'Information from previous human exposure to the novel food or its source', in which the applicant states that none of the previously approved Allanblackia seed oil products (EU08) have yet been traded on the EU market (Uni14).

The VNV Committee states that it is sufficient to assess the new information on the anticipated intake (theme IX) based on the available safety data from the original application, provided that the product is identical to the previously authorised product. Furthermore, the Allanblackia seed oil in the newly proposed applications must be just as stable as in the previously authorised product categories. Also, the VNV Committee takes the view that there is no relevant new data and that a reassessment of toxicological safety is not necessary.

2.5 Brief summary provided by the applicant

The dossier contains a summary, which has been sent to the other EU Member States, as required under Regulation (EC) no. 258/97 (EC97). This summary is also attached to this report as an annex.

2.6 Other assessments

The VNV Committee is unaware of any assessments of this product other than that associated with the original application (EFSA07, EU08).

2.7 The applicant's labelling proposal

The dossier contains no information about labelling. The VNV Committee points out that, on the labels of any foods into which it is incorporated, the novel oil must be referred to as Allanblackia seed oil, as stipulated in the 2008 decision on authorisation (EU08). The labelling must also comply with European Regulation 1169/2011 (EU11). It should be noted that, in the Netherlands, the labelling of foods is not assessed by the NFU, but in the Regular Consultation on the Commodities Act.

3 Interpretation and evaluation of data submitted

3.1 I Specification of the novel food

The dossier contains a product specification that is a simplified version of the specification as set out in the annex to the decision on authorisation for Allanblackia seed oil (EU08). The limit values for the main fatty acids stearic acid (C18:0) and oleic acid (C18:1) are unchanged, at 45-58% and 40-51% of total fatty acid content, respectively. Nor have the stated values for free fatty acid content (≤0.1% of total fatty acid content) and saponification (185 – 198 mg KOH/g oil) changed. Instead of individual limit values for the fatty acids lauric acid (C12:0), myristic acid (C14:0) and palmitic acid (C16:0), which can occur in small amounts, the specification now indicates a collective value of up to 4%. Furthermore, the fatty acids linoleic acid (C18:2 n-6) and linolenic acid (C18:3) are no longer listed separately. Instead, a new parameter – 'polyunsaturated fatty acids' – has been included in the specification, which has a content of up to 2%. In addition, the limit value for trans fatty acids has been increased from up to 0.5% of the total fatty acid content to up to 1%. The original peroxide value of up to 0.8 meq/kg has been replaced by a value of up to 1.0 meq/kg. In the additional information, the applicant states that the upper limit of the unsaponifiable matter fraction is up to 1.0% by weight of the oil (Uni16), and that the limit value (stated in the original specification (EU08)) as being ten times lower, is incorrect. The applicant provides extensive details showing that, in terms of its unsaponifiable matter content, the oil (as it is currently being produced) is no different from the oil used in the various toxicity studies on the basis of which the product was authorised. This is supported by the results of chemical analyses of unsaponifiable matter from several production batches. Here, data on twelve batches from the original application (produced in 2001-2004; Uni04) is compared to data on nine more recent batches, produced from 2014 to 2015.

The VNV Committee has no objection to the modifications to the product specification proposed by the applicant. Leaving aside the corrected unsaponifiable matter content, the renewed specification (Uni14, Uni16) does not differ substantially from that stipulated in the annex to the decision on authorisation (EU08). The VNV Committee takes the view that the omission of palmitoleic acid (C16:1) from the renewed specification is acceptable, as the oil contains no more than a trace of this fatty acid. The production batches that were originally tested were found to have a palmitoleic acid content of up to 0.02%. Arachidic acid (C20:0), too, has been omitted from the renewed specification. As no measured values for this fatty acid were reported in the original application, the VNV Committee assumes that the oil contains no detectable amounts of arachidic acid. The iodine value (a measure of the total number of unsaturated bonds), too, is no longer included in the specification. The VNV Committee takes the view that this parameter has no added value, as it is derived from the product's fatty acid composition. The VNV Committee's main focus was the oil's unsaponifiable matter content, no details of which were included in the proposed specification. If the oil was found to have a higher unsaponifiable matter content than the previously assessed oil, this would mean the possibility of harmful compounds being present could no longer be excluded. In response to questions from the VNV Committee (Uni16), the applicant rectified an error regarding the limit value for the unsaponifiable matter content.

This value is up to 1.0% by weight of the oil and not up to 0.1% by weight (EU08). The VNV Committee accepts the applicant's explanation regarding this matter. For instance, 20-30% of the unsaponifiable vegetable oil fraction usually consists of sterols. In the past, the applicant only analysed the sterol fraction of the unsaponifiable matter, which was mainly from refined Allanblackia seed oil. In total, the sterols measured at that time amounted to about 0.1 to 0.2% by weight of the oil (Uni04, Uni16). More recently, both the size of the unsaponifiable fraction and the total sterol content have been determined, but only for the crude oil (Uni16). The number of batches used for the purpose of these measurements is considered to be adequate. Based on the results, the VNV Committee concludes that the crude and refined oil are comparable in terms of their total sterol content. Accordingly, the applicant feels that the oil used for the initial tests arguably contained more than 0.1% by weight of unsaponifiable matter. The VNV Committee has determined that sufficient data has been provided to establish that the test substance used for the 90-day toxicity study in rats is representative of the oil, as it is currently being produced.

3.2 II Effects of the production process applied to the food

The applicant states that no significant changes have been made to the production process since 2004. The procedures involved are all in common use, such as those used in the preparation of edible vegetable oils (Uni14). As stated in the original dossier (EFSA07, Uni04), the applicant indicates that the production process will be closely monitored. This monitoring will be conducted in accordance with Regulation 852/2004 on the hygiene of foodstuffs. The applicant also states that the production system used is compliant with GMP (good manufacturing practice) (Uni14). Following an enquiry by the Committee, concerning the oil's stability at the high temperatures required for baking and frying, the applicant explained that, in terms of the effects of high temperature, Allanblackia seed oil is no different from other triglyceride vegetable oils such as sunflower oil and rapeseed oil (Uni16). Furthermore, reference is made to the EFSA report (EFSA07) which states that there is no evidence to the contrary.

The VNV Committee assumes that the above-mentioned quality systems will have been adequately implemented before the start of commercial production. Aside from that, it has no comments.

3.3 III History of the organism used as the source of the food

Allanblackia trees – which are endemic to Africa – belong to the *Guttiferae* family, subfamily *Clusiodeae*. The original application (Uni04) contains a detailed description of the species used and the product's traditional use, and of the environmental impacts and sustainability aspects involved. The applicant states that the seeds used are obtained from the same Allanblackia species described in the original dossier. The species in question are *A. floribunda* (synonymous with *A. parviflora*) and *A. stuhlmannii* and will be the main sources of the oil.

The VNV Committee notes that the annex to the European Decision (EU08) lists only the two above-mentioned species as a source of refined Allanblackia seed oil. Aside from that, the VNV Committee has no comments on this section.

3.4 IX Anticipated intake and extent of use of the food

Proposed use. The current authorisation for Allanblackia seed oil, based on yellow fat spreads and cream-based spreads (EU08), is based on the previous application for maximum use concentrations of 20% (w/w). The applicant now proposes to increase this use to concentrations of up to 30% (w/w). As in the original application, this concerns both products with a reduced fat content and full-fat products. The applicant states that the latter variants, in particular, will also be used for cooking and baking. In addition, the applicant company requests authorisation for up to 30% Allanblackia seed oil in mixtures of vegetable oil and milk. This new category includes alternatives for various cream products such as a liquid cream to be used as whipped cream and for cooking, and also a solid cream similar to sour cream or crème fraîche. Here too, this concerns both products with a reduced fat content and full-fat variants. The applicant illustrates this by means of various alternative cream products which are now on the market in certain member states.

Consumption study. When calculating intake levels for the novel oil, the applicant used food consumption data for different population groups in the Netherlands (NL) and the United Kingdom (UK). The UK data, which was collected from 2008 to 2011, relates to residents above 18 months of age. The NL data is a combination of the results of food consumption surveys carried out from 2007 to 2008, in children aged from two to six, and from 2007 to 2010, in children and adults aged from seven to sixty-nine. The calculations are based on the assumption that all of the proposed products will contain the maximum concentration of the novel oil. The dossier's food consumption data annexes contain a list of foods from each product category that feature in these calculations. The NL data is in annex E of appendix E, while the UK data is in annex C of appendix D (Uni14). The applicant summarises the results for both NL and UK in the core dossier. Aside from the averages, these involve the 90^{th} and 95^{th} percentiles of the intake for each of the population groups investigated, categorised by age and gender. The calculated Allanblackia seed oil intake for Dutch individuals was found to be about one and a half to two times higher than the figure for their British counterparts. As a result, the applicant has decided to adopt the Dutch consumption data as the guideline for the safety assessment. Accordingly, this report confines itself to these results (see 'Dutch consumption data' below).

In addition, for each population group tested in NL and UK, the applicant has calculated the contribution made by each of the proposed product categories to the total average intake of Allanblackia seed oil. This data is included in the various annexes to the dossier's food consumption data appendices. These are annexes A and C of appendix E for NL, and annex A of appendix D for UK (Uni14, Uni16). With regard to the newly proposed category of cream alternatives, it has been found that products of this type are responsible for 10-20% of the total oil intake in children and young people below the age of 18. The corresponding value in adults is slightly higher, at 23-30%, with the exception of adult Dutch males for whom cream alternatives account for about 15% of the total amount of Allanblackia seed oil ingested.

The applicant company has also calculated the exposures based on consumption data for margarine and cream drawn from the EFSA Comprehensive European Food Consumption Database. However, given the enormous distribution involved, it has chosen to

disregard these results. According to the applicant, this is the result of the aggregated food grouping used in this system, which also results in an overestimate of the intake.

Dutch consumption data. Adult males have the highest Allanblackia seed oil intake, amounting to an average of about eight grams per day. The 95th percentile (95P) of this intake varies from 18.0 to 19.3 grams per person per day for the 19-50 age group and the 51-69 age group respectively. In adult women, the average intake is about 6 grams per person per day, and the 95P of intake for 19-50 year olds is 14.8 grams per person per day. Unlike men in the 51-69 age group, the 95P of intake for women in this age group (13.8 grams per person per day) is lower than it is for younger women. Boys aged 11-18 have nearly the same 95P of intake (17.5 grams per person per day) as adult man, whereas the level of consumption of girls of this age is 11.7 grams per person per day (95P), which is clearly lower than that of adult women. For children, consumption (per person per day) decreases with age: 11.6 grams for seven- to ten-year-olds, about 10 grams for four- to six-year-olds and over 8 grams for two- to three-year-olds. In relative terms, however, children ingest more Allanblackia seed oil than adults. The calculated exposure (expressed per kg body weight) is highest in young children, and differs very little between boys and girls. For toddlers aged two to three, the 95P of intake is 0.53 g/kg/day. For children aged four to six it is slightly lower, at 0.48 g/kg/day. According to the applicant, exposure in toddlers is still significantly lower than the exposure that caused no adverse effects in the subchronic study in rats (see section 3.7).

The VNV Committee takes the view that the applicant has provided sufficiently detailed information, making it quite clear which types of products are proposed as an extension of use. In addition, for each of the different age groups, the calculated novel oil intakes corresponding to average use of the proposed products and to high levels of consumption (95P) are clearly indicated (Uni14, Uni16). The VNV Committee states that, for the various spreadable products, the proposed usage concentration is at most 1.5 times higher than the value authorised in 2008 (EU08). Also, the data provided (Uni14, Uni16) shows that the intake level calculations have taken account of cooking and baking with margarines. Allanblackia seed oil products can be used at home, in the preparation of all manner of dishes. Also, food codes listed in the annexes to the dossier clearly indicate that the food industry can incorporate these products into various types of pastry, for example, as well as ready-to-use products such as mashed potatoes, sauces and gravy.

Based on the highest calculated exposure among toddlers, the VNV Committee concludes that this is at least a factor of 20 lower than the exposure that caused no adverse effects in the subchronic study in rats.

3.5 XI Nutritional information on the food

The dossier contains summary comparing the fatty acid composition of common hard fats, such as palm kernel oil, coconut oil and butterfat, with that of Allanblackia seed oil, which is intended to replace these fats. This will reduce levels of saturated fatty acids in consumer products, and increase levels of mono-unsaturated fatty acids. The applicant illustrates this

on the basis of the fatty acid compositions of a few selected consumer products prepared using ordinary hard fat or Allanblackia seed oil.

The VNV Committee has determined that, compared to the product in the original application (EFSA07, Uni04), the nutritional value of the Allanblackia seed oil is unchanged. Aside from that, it has no comments.

3.6 XII Microbiological information on the food

The applicant makes reference to the data from the original application (Uni04) which, in the view of the VNV Committee, is quite sufficient (EFSA07, EU08).

3.7 XIII Toxicological information on the food

Since the authorisation in 2008, as far as the Committee is aware, no new toxicity study results have been reported. Annex 4 of the original dossier (Uni04) contains the full report on the 90-day toxicity study in rats. This study investigated the effect of using feed with an Allanblackia seed oil content of 20%. The applicant originally believed that it was not appropriate to determine an NOAEL for a macronutrient like this novel oil (Uni04). A re-evaluation of the same 90-day experimental animal study in the current dossier shows that the applicant considers the exposures of 11.3 g and 14.7 g of oil per kg of body weight per day (as calculated from the feed intake of male and female animals respectively) to be the NOAEL.

The VNV Committee confirms that the current dossier is based on the same toxicological information as before (EFSA07, Uni04), but that the summary of the results obtained is now described differently. In 2008, based on this 90-day toxicity study, EFSA stated that, relative to the control values, none of the observed abnormalities were toxicologically relevant. This has been further clarified by the applicant in the present dossier, on the basis of historical control data, particularly with regard to observed significant changes in various haematological parameters.

According to the applicant, the Allanblackia seed oil currently being produced is the same as the previous product which, at that time, was assessed as being safe for human consumption. The VNV Committee concurs with this view. It concludes that sufficient data has been provided (Uni16) to establish that the test substance used for the subchronic study in rats is representative of the oil (as it is currently being produced). The VNV Committee takes the view that, for the entire range of applications that the applicant might wish to realise, the highest calculated exposure in toddlers (see section 3.4) is at least a factor of 20 lower than the exposure that caused no adverse effects in the subchronic study in rats. The value of this safety margin is 22, based on the 95P intake in boys from two to three years of age, and on the exposure in male rats. The corresponding value for female individuals is 27. Given the type of food involved, the VNV Committee considers the safety margin to be sufficient.

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The Committee/ De commissie

- Prof. dr. G.J. Mulder, *voorzitter / chairman*
  emeritus hoogleraar toxicologie, Universiteit Leiden
  professor emeritus toxicology, Leiden University
- Prof. dr. C.A.F.M. Bruijnzeel-Koomen, *adviseur / advisor* (tot 1-1-2017)
  hoogleraar dermatologie/allergologie; UMC Utrecht
  professor of dermatology/allergology; University Medical Centre Utrecht
- Dr. ir. M. Dekker
  levensmiddelentechnoloog; Wageningen Universiteit en Researchcentrum
  food technologist; Wageningen University and Research Centre
- Dr. ir. E.J. Kok
  toxicoloog; RIKILT Instituut voor Voedselveiligheid, Wageningen
  toxicologist; RIKILT, Institute of Food Safety, Wageningen
- Dr. C.F. van Kreijl
  moleculair-bioloog (gepensioneerd); RIVM Bilthoven
  molecular biologist (retired); National Institute of Public Health and the Environment, Bilthoven
- Dr. F.M. Nagengast
  MDL-arts (gepensioneerd); UMC St Radboud, Nijmegen
  gastroenterologist (retired); University Medical Centre St Radboud, Nijmegen
- Dr. ir. J.M.A. van Raaij
  voedingsfysioloog (gepensioneerd); Wageningen Universiteit en Researchcentrum; RIVM Bilthoven
  food physiologist (retired); Wageningen University and Research Centre; National Institute of Public Health and the Environment, Bilthoven
- Dr. G.J.A. Speijers
  toxicoloog (gepensioneerd); RIVM Bilthoven
  toxicologist (retired); National Institute of Public Health and the Environment, Bilthoven
- Dr. ir. E.H.M. Temme
  voedingskundige; RIVM Bilthoven
  nutritional expert; National Institute of Public Health and the Environment, Bilthoven
- Drs. A.I. Viloria Alebesque, *adviseur / advisor*
  Ministerie van VWS, Den Haag
  Ministry of Health, Welfare and Sport, The Hague
- Prof. dr. R.A. Woutersen
  hoogleraar translationele toxicologie / toxicologisch patholoog; TNO Kwaliteit van Leven, Zeist
  professor translational toxicology / toxicologic pathologist; TNO Quality of Life, Zeist
- Prof. dr. ir. M.H. Zwietering
  hoogleraar levensmiddelenmicrobiologie; Wageningen Universiteit en Researchcentrum
  professor food microbiology; Wageningen University and Research Centre

Bureau Nieuwe Voedingsmiddelen, CBG/ Novel Foods Unit, MEB

- H.W. Buitenhuis, M.Sc., *regulatory project officer*
- Dr. C.M.A. van Rossum, *beoordelaar voedselveiligheid / scientific assessor food safety*
- Dr. ir. M. Rutgers, *beoordelaar voedselveiligheid / scientific assessor food safety*
- Drs. E. van Galen, *hoofd BNV / head NFU*

Summary of the dossier / Samenvatting van het dossier

Extension of use of Allanblackia Seed Oil in Mixes of Vegetable Oils and Milk and in Yellow Fat and Cream Based Spreads up to 30% (w/w)

Non-Confidential Summary

Unilever Research and Development Vlaardingen B.V.
Olivier van Noortlaan 120
3133 AT Vlaardingen
The Netherlands

14 July 2014

Extension of use of Allanblackia Seed Oil in Mixes of Vegetable Oils and Milk and in Yellow Fat and Cream Based Spreads up to 30% (w/w)

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Extension of use of Allanblackia Seed Oil in Mixes of Vegetable Oils and Milk and in Yellow Fat and Cream Based Spreads up to 30% (w/w)

INTRODUCTION

Unilever is seeking approval for the extended use of Allanblackia seed oil into mixes of vegetable oils and milk and to increase the currently approved use level for fat based spreads under Regulation (EC) No 258/97 of the European Parliament and of the Council of 27th January 1997 concerning novel foods and novel food ingredients.

On 30 August 2004, Unilever Deutschland GmbH submitted a request under Article 4 of the Novel Food Regulation (EC) No 258/97 to the competent authorities of Germany for placing on the market *Allanblackia* seed oil for use in yellow fat and cream based spreads as a novel food ingredient. Following the opinion from the Scientific Panel on Dietetic Products, Nutrition and Allergies, adopted by the European Food Safety Agency (EFSA) on 25 October 2007, Commission Decision 2008/559/EC authorised the placing on the market of Allanblackia seed oil as a novel food ingredient for use in yellow fat spreads and cream based spreads. In June 2008, Unilever obtained the authorisation for the use of Allanblackia seed oil as a novel food ingredient in yellow fat spreads and cream based spreads. Whilst Commission Decision 2008/559/EC did not specify an upper level of use in yellow fat and cream based spreads, the original application dossier and the subsequent EFSA Opinion did assess the safety of Allanblackia seed oil at levels up to 20% (w/w). In this application we wish to extend the use beyond the specified conditions of use requested in the original submission and to an additional proposed use in mixes of vegetable oils and milk.

In the original application, Allanblackia seed oil was classified under class 1, sub category 1.2 (novel foods which are pure chemicals or simple mixtures derived from sources which have not been genetically modified and which have no history of food use within the Community), as defined in the recommendations of the Scientific Committee for Food (SCF) concerning the assessment of novel foods.

Allanblackia seed oil is derived from the seed of the Allanblackia tree which grows in tropical rain forests of Africa. The oil contained within the seeds is predominantly composed of stearic acid and oleic acid. Both the unique fatty acid profile and the arrangement of these fatty acids on the triglyceride backbone make Allanblackia seed oil highly suitable for use as a hardstock or hardstock component. Allanblackia seed oil is proposed to be used in the production of yellow fat spreads and cream based spreads (collectively referred to as fat based spreads) and in mixes of vegetable oils and milk. The oil will be used at a maximum level of 30% (w/w) (in the final product) in fat based spreads and in mixes of vegetable oils and milk. In summary, Unilever is seeking to extend the current authorisation for:

1) An increase in the authorised maximum use level in yellow fat spreads and cream based spreads from 20 to 30% (w/w); and

2) For use in mixes of vegetable oils and milk up to a maximum level of 30% (w/w).

The requested extension to the current approval will have an effect on the anticipated intake of Allanblackia seed oil. Replacing hard fats, such as palm oil or butterfat with Allanblackia seed oil is beneficial to the consumer because, while the total fat content will not change, the product (*i.e.*, fat based spreads or mixes of vegetable oils and milk) manufactured with Allanblackia seed oil, will have a more favourable fatty acid profile with regard to cardiovascular health, with lower saturated fatty acids and higher monounsaturated fatty acids.

I SPECIFICATION OF THE NOVEL FOOD

Identity and Specifications

Allanblackia oil is derived from the seeds of the Allanblackia tree and is an edible vegetable oil. The common name of the product is Allanblackia seed oil. The chemical structures of Allanblackia seed oil were described in the original EU Novel Foods submission made by Unilever. Allanblackia seed oil predominantly exists of triglycerides of which the fatty acids composition is approximately 45 to 58% stearic acid and 40 to 51% oleic acid plus minor amounts of other fatty acids commonly consumed in the diet *e.g.,* lauric, myristic and palmitic acid.

Allanblackia seed oil is a pale yellow, fully refined oil, derived from the seed of the Allanblackia tree. At temperatures below 25°C, it is white and semi-solid. The triglyceride composition of the oil is unique in that it contains a high level of stearic-oleic-stearic (SOS) and stearic-oleic-oleic (SOO) triglycerides. The individual fatty acids are commonly found in other vegetable oils. The product characteristics for Allanblackia seed oil are presented in Table I-1.

Table I-1 Characteristics of Allanblackia Seed Oil

Specification Parameter	Specification
Lauric - Palmitic acid (C12:0 - C16:0)	< 4%
Stearic acid (C18:0)	45 – 58%
Oleic acid (C18:1)	40 – 51%
Poly unsaturated fatty acids	< 2%
Saponification value	185 – 198 mg KOH/g

The crude oil will be refined using common refining practices of neutralisation, bleaching and deodorisation to remove unwanted free fatty acids, rancidity and colour. According to Good Manufacturing Practice, this will result in a refined oil with typically the following quality specifications as per Table I-2.

Table I-2 Specifications for Refined Allanblackia Seed Oil	
Specification Parameter	**Specification**
Free fatty acids	max. 0.1 %
Trans fatty acids	max. < 1 %
Peroxide value	max. 1 meq/kg

The full data analysis of Allanblackia seed oil (including a quality specification, batch analysis, heavy metal levels, aflatoxin levels, polyaromatic hydrocarbon levels, pesticide residues) were provided in the original EU Novel Foods application made by Unilever.

II EFFECT OF THE PRODUCTION PROCESS APPLIED TO THE NOVEL FOOD

The production process to collect, extract and refine the Allanblackia seed oil was provided in the original EU novel food application made by Unilever. The processes are widely used within the food industry in the production of vegetable oils. The proposed extended use of Allanblackia seed oil does not require changes in the collection, crushing/milling, transport and chemical/enzymatic refining of the oil. Further, the application of Allanblackia seed oil for the proposed uses will not introduce significant changes to the production processes of these foods and their use. Allanblackia seed oil meets the specifications as provided in the original EU Novel Foods application in the original EU novel application made by Unilever.

In brief, Allanblackia fruits are manually collected; the seeds within the fruit are then removed, washed and dried in the sun for several days and transported to regional warehouses and to the local crushing facility for processing to collect the oil. The crude Allanblackia seed oil is filtered to remove any plant material and is then stored in tanks for transport to the oil refinery. Subsequently the oil will be chemically or physically refined using the standard processes. Given the fatty acid composition of the Allanblackia seed oil, it is unlikely to behave any differently during the refining process compared to other food-grade oils or during the manufacturing process of the foods where it is used in.

The production process for Allanblackia seed oil will be conducted in accordance with Good Manufacturing Practice (cGMP) and controlled by Hazard Analysis Critical Control Points (HACCP) in accordance with Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.

III HISTORY OF SOURCE ORGANISM

Allanblackia belongs to the *Guttiferae* family, subfamily *Clusiodeae*. There are 10 species in the genus Allanblackia and their distribution differs. *Allanblackia floribunda* and *Allanblackia parviflora* are 2 names for the dominant species in West and Central Africa. In Tanzania *Allanblackia stuhlmani* is the dominant species. *Allanblackia floribunda* and *Allanblackia stuhlmani* will be the main sources of the oil for use in spreads and in the mixes of vegetable oils and milk. The source and classification of the Allanblackia seed oil subject of this application is identical to the Allanblackia seed oil provided in the original application.

IX ANTICIPATED INTAKE/EXTENT OF USE

Anticipated intakes from proposed uses of the novel ingredient are assessed using data from the following EU datasets:

1. The United Kingdom – survey data from the United Kingdom (UK) National Diet and Nutrition Survey (NDNS) programme

2. The Netherlands – survey data from the Netherlands are also collected at a detailed and accurate level.

3. The European Food Safety Authority (EFSA) Comprehensive database.

IX.1 Consumption Estimates Based on UK National Diet and Nutrition Survey Data (2008-2010 Rolling Survey dataset)

Estimates for the intake of Allanblackia seed oil in the EU from fat based spreads, mixes of vegetable oils and milk (and regular cream), were based on the proposed use-levels and food consumption data collected as part of the UK NDNS programme (Department of Health, 2011; UKDA, 2012). The level of Allanblackia seed oil for the proposed uses employed in the intake analysis is provided in Table IX.1-1

Table IX.1-1 Use Level Table: Maximum Use Levels for Allanblackia Seed Oil in All Proposed Food Categories (g/100 g)

Food Category	Proposed Use	Allanblackia seed oil per 100 (g)
Yellow fat and cream based spreads	Fat based spreads	30
Mixes of vegetable oils and milk	Dairy cream alternatives	30
Cream*	Whipping cream, cooking cream, sour cream and crème fraîche	30

*Allanblackia seed oil is only proposed for actual use in mixes of vegetable oils and milk, however as cream can easily be a substitute, the intake assessment was run using both cream and mixes of vegetable oils and milk

Proposed applications for fat based spreads containing Allanblackia seed oil include use in spreading and also in home-baking and preparation of home cooked foods (roasting and shallow-frying foods, in different dishes and in soups and sauces). Proposed applications for mixes of vegetable oils and milk containing Allanblackia seed oil include their use as a liquid cream in whipping and cooking and also as a solid cream similar to sour cream or crème fraîche. Although Allanblackia seed oil is only proposed for use in mixes of vegetable oils and milk, as cream can easily be substituted with mixes of vegetable oils and milk, the intake assessment was run using both proposed food uses.

As would be expected for a 4-day survey, the percentage of users was relatively high among all age groups evaluated in the current intake assessment; greater than 74.9% of the population groups consisted of users of those food products in which Allanblackia seed oil is proposed for use. Older male adults (aged ≥51 years) had the greatest percentage of users

at 83.5%. In relation to all-user intakes, older male adults (aged ≥51 years) were estimated to have the greatest mean and 95th percentile intakes of Allanblackia seed oil on an absolute basis, at 5.6 and 13.9 g/person/day. Toddlers were estimated to have the lowest all-user mean and 95th percentile all-user intakes of 2.2 and 5.2 g/person/day, respectively. On a body weight basis, toddlers were identified as potentially having the highest mean and 95th percentile intakes of any population group, of 140.3 and 395.2 mg/kg body weight/day, respectively. Female adults had the lowest mean and 95th percentile all-user intake of 55.8 and 145.2 mg/kg body weight/day, respectively.

IX.2 Consumption Estimates Based on Dutch National Food Consumption Data

To present an assessment of Allanblackia seed oil for the proposed uses, data from the 2 Dutch National Food consumption surveys were used (DNFCS young children 2005-2006 and DNFCS older children and adults 2007-2010). These data for Allanblackia seed oil intakes can be also considered as the potential highest intake estimate as total fat spread intake in the Netherlands is one of the highest in Europe.

IX.2.1 DNFCS-Young Children 2005-2006

To examine the potential intake of Allanblackia seed oil in younger children, food consumption data from The Netherlands National Food Consumption Survey - Young Children (DNFCS-YC) 2005/2006 were considered. The percentage of users was relatively high among all age groups evaluated in the current intake assessment; greater than 88.8% of the population groups consisted of users of those food products in which Allanblackia seed oil is proposed for use. Male toddlers (aged 2 to 3 years) had the greatest percentage of users at 91.9%. In relation to all-user intakes, male children (aged 4 to 6 years) were estimated to have the greatest mean and 95th percentile intakes of Allanblackia seed oil on an absolute basis, at 4.5 and 10.6 g/person/day. Female toddlers were estimated to have the lowest all-user mean and 95th percentile all-user intakes of 3.3 and 8.01 g/person/day, respectively. On a body weight basis, in relation to all-user intakes, male toddlers were identified as having the highest potential mean intake of any population group, of 235.7 mg/kg body weight/day, while female toddlers had the highest potential 95th percentile intake of 542.5 mg/kg body weight/day. Female children had the lowest mean and 95th percentile all-user intake of 199.6 and 471.0 mg/kg body weight/day, respectively.

IX.2.2 DNFCS Children-Adults 2007-2010

Estimated intakes of Allanblackia seed oil related to fat spreads and mixes of vegetable oils and milk reported in the DNFCS 2007-2010 were examined. The percentage of users was relatively high among all age groups evaluated in the current intake assessment; greater than 82.7% of the population groups consisted of users of those food products in which Allanblackia seed oil is proposed for use. Male older adults (aged ≥51 years) had the greatest percentage of users at 93.4%. In relation to all-user intakes, older male adults were estimated to have the greatest mean and 95th percentile total population intakes of

Allanblackia seed oil on an absolute basis, at 8.5 and 19.3 g/person/day. Female teenagers were estimated to have the lowest all-user mean all-user intake of 4.9 g/person/day, while children had the lowest 95th percentile all-user intakes of 11.6 g/person/day. On a body weight basis, children were identified as having the highest potential mean and 95th percentile all-user intakes of any population group, of 177.7 and 386.5 mg/kg body weight/day, respectively. Female adults had the lowest mean and 95th percentile all-user intake of 83.8 and 211.1 mg/kg body weight/day, respectively.

IX.3 Consumption Estimates Based on the EFSA Comprehensive Database

Margarine and cream consumption data from the EFSA Comprehensive dataset were used to estimate the total population and all-user Allanblackia seed oil intakes of specific demographic groups in different member states in the EU. Intakes were calculated on both an absolute and a body weight basis. This type of intake methodology can be considered as a very conservative assumption as here it is assumed that all margarine and all creams that were consumed by individuals represented in the EFSA Comprehensive database were manufactured using Allanblackia seed oil. A summary of the intakes across the different population groups for all-users are provided in Table IX.3-1.

Table IX.3-1 Estimated Daily Intake of Allanblackia Seed Oil from Proposed Use in Margarine and Cream for All-Users Based on the EFSA Comprehensive Database in Different Population Groups

		Absolute intakes (g/d)		Intakes expressed on body weight basis (mg/kg bw/d)	
Population Group	**No. Surveys**	**Mean Range**	**P95 Range**	**Mean Range**	**P95 Range**
Infants (≤ 11 months)	2	0.0 – 4.6	0.0 – 9.7	0.0 – 498.2	0.0 – 951.1
Toddlers (12-35 months)	9	1.3 – 6.1	1.3 – 12.2	83.5 – 491.2	83.5 – 1196.8
Other Children (3-9 yrs)	17	3.0 – 8.6	6.3 – 17.7	137.2 – 413.3	279.1 – 911.7
Adolescents (10-17 yrs)	12	3.2 – 10.8	6.1 – 22.5	78.9 – 219.4	117.3 – 462.9
Adults (18-64 yrs)	15	4.1 – 12.9	8.2 – 30.2	61.1 – 171.6	130.6 – 434.2
Elderly (65-74 yrs)	7	3.9 – 15.1	10.2 – 33.6	58.8 – 211.7	147.2 – 485.8
Very Elderly (≥ 75 yrs)	6	2.6 – 14.0	5.0 – 32.3	37.6 – 207.4	66.7 – 468.7

bw = body weight; P95 = 95th percentile intake

IX.4 Summary of the Estimated Intake Assessments of Allanblackia Seed Oil

In general, estimated Allanblackia seed oil intakes were found to be higher in the EFSA Comprehensive database (at the upper end of the range), while intakes estimated using the UK NDNS survey were lower than were observed for the Dutch surveys and for the EFSA Comprehensive database. However, it is important to note that different methodologies were employed in the calculations for the 3 datasets due to the way the data were presented. With the EFSA Comprehensive database, the intake assessment is conducted using more aggregated food groupings than for the other two datasets as it was not possible to separate out the food groups at FoodEx Level 2. This gives rise to an over-estimate of intakes of Allanblackia seed oil using these data. Additionally, variation from country to

country in the Comprehensive database is expected due to differences in diet across Europe. However, for all 3 datasets used, all intake estimates calculated from the databases are conservative as they assume that all fat spreads, mixes of vegetable oils and milk and creams consumed were manufactured using Allanblackia seed oil.

As the intake assessment to Allanblackia seed oil was examined using 3 separate food consumption databases, a summary of the uncertainties and the likely direction of their impact was undertaken to provide an understanding of the applicability of the data. This summary affirms that the estimates provided in the present dossier are realistic and form an adequate basis for understanding the potential exposure to Allanblackia seed oil in the EU. From this summary, it is clear that the estimates provided by the UK and the Dutch databases contain a similar level of uncertainties, while the estimates of exposure calculated using the EFSA Comprehensive database are more likely to over-estimate the intake to Allanblackia seed oil. Based on this summary of uncertainties, the intakes of Allanblackia seed oil based on the Dutch food consumption databases will be used to represent potential highest intake estimates from proposed uses in the safety section.

X INFORMATION FROM PREVIOUS HUMAN EXPOSURE

Natural Occurrence of Allanblackia Seed Oil in the Diet

Allanblackia trees grow in the evergreen forests along the Gulf of Guinea in Liberia, Cote d'Ivoire, Ghana, Nigeria and Cameroon. Some patches of rain forest also exist on mountains in Uganda and Tanzania. The oil produced from the Allanblackia seed is used locally for food preparation and soap making but has never been used on a commercial scale. It is known as mkanyi fat or kagne butter, and because it is semi-solid at room temperature, it is often mixed with other oils such as palm kernel oil, palm oil or groundnut oil to produce a liquid oil that is used in cooking. In some areas the seeds are eaten by children as a high-energy snack.

Previous Exposure to Allanblackia Seed Oil from its Authorised Use

In the original novel foods application for yellow fat and cream-based spreads provided in the original EU Novel Foods application made by Unilever, Allanblackia seed oil intake was estimated for Germany, Sweden, the UK and the Netherlands. These calculations were based on consumer purchase data (in Germany and Sweden) or based on the results of a dietary survey [in the UK (NDNS surveys 1990-2000) and the Netherlands (DNFCS 1997/98)]. In this original submission, the high intake estimates of Allanblackia seed oil intake (at the 95th percentile) from the consumption of yellow fat spreads and cream based spreads in these regions were estimated to range from 2.8 g (for British toddlers aged 1.5 to 3 years) up to 16 g of Allanblackia seed oil per day (in Swedish women aged 18 to 74 years). The intakes expressed on a body weight basis were not calculated. In these exposure estimates, the maximum use level of Allanblackia seed oil in the yellow fat and cream-based spreads was 20%.

These calculations were based on estimated intakes of Allanblackia seed oil from fat spread intake alone. Therefore, it would be anticipated, that the introduction of additional food vectors containing Allanblackia seed oil would contribute to increasing the potential exposure. Although Commission Decision 2008/559/EC authorised the placing on the market of Allanblackia seed oil as a novel food ingredient for use in yellow fat spreads and cream based spreads, these products have not been introduced to the EU market at this time.

Allergenicity

The allergenicity of foods is primarily due to the protein component of the food. Allanblackia seed oil is already refined either through chemical or physical processes, which reduces the levels of any proteins that may be present. The total nitrogen content (a measure of protein levels) in Allanblackia seed oil is below the limit of detection based on the analytical methodology of the Dumas technique, and are consistent with values obtained from typical fully refined edible oils.

There are no known allergens among the members of the Family *Clusiaceae* (Guttiferae) which includes *Allanblackia stuhlmanii*, or among the members of closely-related genera. Even though, the relationship between allergenicity/cross-allergenicity and the closeness of taxonomy has not been systematically studied, the lack of reported closely-related allergenic species provides additional reassurance that any trace residual protein in Allanblackia seed oil will neither provoke reactions in individuals sensitised to other oilseeds or foods, nor sensitise susceptible individuals.

XI NUTRITIONAL INFORMATION ON THE NOVEL FOOD

Nutritional Equivalency of Allanblackia Seed Oil

The proposed extension of use for Allanblackia seed oil into mixes of vegetable oils and milk, along with its currently approved use in fat based spreads will provide consumers with an alternative to existing products on the market. Due to its textural properties, Allanblackia seed oil is proposed to replace hard fats such as (fractionated) palm (kernel) oil, coconut oil and butter fat.

Allanblackia seed oil is generally lower in saturated fatty acids (SFA) (apart from palm oil) and higher in monounsaturated fatty acids (MUFA) than those in the solid/hard fats it is proposed to replace. Table XI.1 provide examples of the application of Allanblackia seed oil in the proposed uses – in 3 different types of fat based spreads and in a mix of vegetable oils and milk. When Allanblackia seed oil is used in these foods, there is a resultant impact on the fatty acid composition due to the different fatty acid profile of Allanblackia seed oil than the fats currently used in these products. In all products the total fat (g/100 g) remains the same, however SFA decrease and MUFA increase when Allanblackia seed oil replaces hard fats in each product.

Table XI.1 The Typical Fatty Acid Composition (g/100 g) of Three Fat Spreads and a Mix of Vegetable Oils and Milk with the Proposed Use of Allanblackia Seed Oil*

Fatty acid profile (g/100g)	Fat Spread (wrapper-type)		Fat Spread, high fat (tub)		Fat Spread, low fat (tub)		Mix of vegetable oils & milk	
	30% AB	No AB	30% AB	No AB	10% AB	No AB	30% AB	No AB
Total fat	78.0	78.0	60.0	60.0	38.0	38.0	27.0	27.0
SFA	17.4	38.6	14.8	17.8	9.3	11.3	15.9	18.5
MUFA	45.3	29.1	17.9	14.1	10.9	8.9	9.2	6.5
PUFA	14.8	9.8	27.0	27.8	17.6	17.6	1.8	1.9

AB = Allanblackia Seed Oil; MUFA = Monounsaturated Fatty Acids; PUFA = Polyunsaturated Fatty Acids; SFA = Saturated Fatty Acids
*Fatty acid profiles of the 3 fat spreads and of the mix of vegetable oils and milk product were provided by Unilever Research.

Dietary fatty acids play an important role in blood lipid metabolism and research indicates that it is not fat quantity, but fat quality (or the type of fat) that plays a role in cardiovascular health. Scientific literature shows that saturated fatty acids raise blood cholesterol concentration while replacing saturated fatty acids with unsaturated fatty acids lowers blood total and especially low-density lipoprotein cholesterol concentrations. Food products where part of the palm (kernel) oil, coconut oil or butter fat is replaced by Allanblackia seed oil will thus have a more beneficial fatty acid composition in relation to cardiovascular disease in comparison to the original products.

XII MICROBIOLOGICAL INFORMATION

Microbiological information has been previously provided in the original application. Formulation, process rules and the application of the accepted principles of Good Manufacturing Practice (GMP) for foods containing vegetable oils are equally applicable to the products made with Allanblackia seed oil.

The process and distribution conditions used to produce foods containing Allanblackia seed oil will be identical to those currently used in the approved authorisation and no additional controls are considered necessary.

XIII TOXICOLOGICAL INFORMATION ON THE NOVEL FOOD

Preclinical Studies

All studies pertinent to the safety of Allanblackia seed oil have been previously reviewed by both the UK's Advisory Committee on Novel Foods and Processes (ACNFP) and EFSA. An updated comprehensive search of the literature was conducted to identify any new studies on Allanblackia seed oil that were published after EFSA's assessment in 2007. The results of this literature search and further details regarding the safety studies available on Allanblackia seed oil are provided in the following sections.

Pharmacological Activity

Upon the comprehensive literature search as described, no studies have been identified on the pharmacological activity of Allanblackia seed oil.

Absorption, Metabolism, Distribution and Excretion

Upon the comprehensive literature search as described, no studies have been identified on the absorption, metabolism, distribution, or excretion of Allanblackia seed oil.

Acute Toxicity

Upon the comprehensive literature search as described, no studies have been identified on the acute toxicity of Allanblackia seed oil.

Subchronic Toxicity

Allanblackia seed oil is mainly composed of fatty acids that are already widely consumed in the diet. In order to determine whether any minor components of Allanblackia seed oil have the potential to cause adverse effects, a 13-week dietary toxicity study was conducted using a single dose level of 20%. Based on the results of this toxicity study, no toxicologically-relevant findings were reported in any of the parameters measured at 20% Allanblackia seed oil, equivalent to intakes of 11.3 and 14.7 g/kg body weight/day for male and female rats, respectively. This is in agreement with the assessment of the EFSA NDA Panel, who concluded that "*the Panel did not identify any toxicologically relevant effects which were attributable to administration of Allanblackia oil and which are not also seen in animal studies with other high fat diets*".

Reproduction and Developmental Toxicity

Upon the comprehensive literature search as described, no studies have been identified on the reproductive or developmental toxicity of Allanblackia seed oil.

Genotoxicity/Mutagenicity

The genotoxicity and/or mutagenicity potential for Allanblackia seed oil was evaluated in an *in vitro* bacterial mutation assay (Ames test) and an *in vitro* gene mutation assay in mouse lymphoma L5178Y cells. Both studies were conducted in compliance with Good Laboratory Practice (GLP) Standards. Overall, the results of these mutagenicity and genotoxicity studies, which were also reviewed by the EFSA NDA Panel, indicate that Allanblackia seed oil does not have any mutagenic or genotoxic properties.

Following an updated comprehensive literature search, no other pre-clinical studies or human studies on Allanblackia seed oil were identified.

RISK ASSESSMENT OF THE PROPOSED EXTENDED USE OF ALLANBLACKIA SEED OIL

Allanblackia seed oil is collected, extracted and refined using the same processes that are currently used for other edible vegetable oils and which have been evaluated in the original application. The use of Allanblackia seed oil in the manufacturing of other foods will not introduce novel elements to the processes and in addition the use of Allanblackia seed oil in the present application will not introduce novel processes and procedures in the manufacturing of the foods.

Allanblackia seed oil, as compared to commonly used hardstocks, is lower in saturated fatty acids and higher in monounsaturated fatty acids. These particular differences in the fatty acid profile provide nutritional benefits that can be associated with beneficial effects on cardiovascular health.

There are no concerns around the safety of consumption of Allanblackia seed oil for the extended use as it is so similar to other vegetable oils and the battery of toxicity tests were negative demonstrating that there are no contaminants or minor components present in the oil that pose a safety risk.

OVERALL CONCLUSIONS

Allanblackia seed oil is safe for human consumption under the specified conditions of use. The use of Allanblackia seed oil provides nutritional benefits to the consumer based on the replacement of traditional counterparts. More specifically, Allanblackia seed oil, as compared to commonly used hardstocks, is lower in saturated fatty acids and higher in monounsaturated fatty acids, which is associated with beneficial effects on cardiovascular health.