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March 10, 2014

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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Dear Dr. Gaynor:

Pursuant to the proposed rule 21 C.F.R. § 170.36 outlined at 62 Fed. Reg. 18939 (April 17, 1997), Agroindustrias Amazonicas S.A., Agroindustrias OSHO S.A.C. and Amazon Health Products S.A.C. submit this notification of their determination that the use of sacha inchi oil in select foods is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because such use is generally recognized as safe (GRAS) through scientific procedures.

To facilitate your review, this notification is submitted in the format suggested under proposed 21 C.F.R. § 170.36(c) (*see* 62 Fed. Reg. 18961). In addition, three paper copies and a CD containing an electronic copy of this notification are enclosed.

If you have any questions concerning this notification, please do not hesitate to contact me.

Sincerely,

(b) (6)

Diane B. McColl

DBM/km

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Diane B. McColl

DBM/km

RECEIVED
MAR 11 2014
OFFICE OF
FOOD ADDITIVE SAFETY

GRAS Determination for the Use of Sacha Inchi Oil in Select Foods

SUBMITTED BY:

Hyman Phelps McNamara
700 Thirteenth Street, N.W.
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Washington, DC 20005

SUBMITTED TO:

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February 7, 2014

Table of Contents

	Page
Table of Contents	**2**
List of Tables	**5**
List of Figures	**6**
List of Appendices	**7**
List of Exhibits	**8**
List of Acronyms	**9**
GRAS EXEMPTION CLAIM	**11**
Name and Address of Notifier	11
Name of GRAS Substance	12
Intended Use and Consumer Exposure	12
Basis for GRAS Determination	13
Availability of Information	14
Description of Substance	**15**
Identity	15
Chemical and Common Names	15
Chemical Abstracts Service (CAS) Registry Number	15
Molecular Weight and Empirical and Structural Formulas	15
Identity of Typical Sacha Inchi Oil	15
Production Process	18
Product Specifications	20
Stability of Sacha Inchi Oil	24
Oxidation	24
Oxidative Conditions During Storage	24
Accelerated Oxidative Conditions	24
Formation of *trans* fatty acids	26
Historical Consumption and Current Regulated Uses	**27**

Historical Consumption 27

Regulated Uses 27
In the United States 27
Outside the United States 28

Intended Use and Estimated Intakes 29

Intended Use 29

Estimated Daily Intakes 30
Data Source and Methods 30
Results 30

Safety Evaluation 32

Introduction 32

Metabolic Fate 32

Institute of Medicine 2002 Review of n-3 Fatty Acids 33

FDA Review of n-3 Fatty Acids 34

2008 GRAS Determination for Use of High Linolenic Acid Flaxseed Oil 35

α-Linolenic Acid Safety Data Published After the 2002 Institute of Medicine Review of n-3 Fatty Acids 35
Studies with Sacha Inchi Oil 36
Pre-Clinical Studies with Sacha Inchi Oil 37
Genotoxicity Studies 38
Acute Oral Toxicity Studies in Mice 38
60-Day Repeat Dose Oral Toxicity Study in Rats 38
Other Studies 39
Summary of Preclinical Studies 39
Clinical Studies with Sacha Inchi Oil 39
Single Dose Studies with Sacha Inchi Oil 41
Repeat Dose Study with Sacha Inchi Oil 41
Repeat Dose Study with *Plukenetia huayllabamba* Oil 42
Summary of Clinical Studies of Sacha Inchi Oil 42
Sensitization 43
Safety Data Summary 43

Basis for the GRAS Determination 45

Introduction 45

Safety Determination 45

General Recognition of the Safety of Sacha Inchi Oil 46

References **48**

Appendices **56**

Exhibits **121**

List of Tables

	Page
Table 1. Fatty Acid Profile of Sacha Inchi and Flaxseed Oils	16
Table 2. Specifications for Sacha Inchi Oil Intended for Use in Food	20
Table 3. Product Specifications and Representative Analytical Data for Sacha Inchi Oil	21
Table 4. Microbiological Data for Representative Sacha Inchi Oil Samples	22
Table 5. Contaminant Data for Representative Sacha Inchi Oil Samples	23
Table 6. Peroxide and Free Fatty Acid Levels in Sacha Inchi Oil During Storage	25
Table 7. Proposed Uses of Sacha Inchi Oil in Food	29
Table 8. *Per User* Estimated Daily Intake of Sacha Inchi Oil From Proposed Uses	30
Table 9. Summary of Preclinical studies with Sacha Inchi Oil	37
Table 10. Clinical Studies with Sacha Inchi Oil	40

List of Figures

Page

Figure 1. Fatty Acid Composition of Sacha Inchi Oil and Commonly Consumed Vegetable Oils 16

Figure 2. Representative Process Flow Diagram for Production of Sacha Inchi Oil 19

List of Appendices

Appendix A. Detailed Production Process Flow Chart 57

Appendix B. Product Stability Data 61

Appendix C. Food Safety Authority of Ireland Opinion of Substantial Equivalence 92

Appendix D. NHANES 2005-2010 Foods Codes Representative of Use of Sacha Inchi Oil in Food 96

Appendix E. Safety Outcomes in Clinical Studies of α-Linolenic Acid Intake from 2002 to the Present 116

List of Exhibits

Exhibit 1. Report of the Expert Panel 122

List of Acronyms

µg	Microgram
AI	Adequate Intake
AMDR	Acceptable Macronutrient Distribution Range
BMI	Body Mass Index
bw	Body weight
CAS	Chemical Abstracts Service
cGMP	Current Good Manufacturing Procedure
CHD	Coronary Heart Disease
CRP	C-Reactive Protein
DHA	Docosahexaenoic Acid
dL	Deciliter
DRI	Dietary Reference Intake
EAR	Estimated Average Requirement
EDI	Estimated Daily Intake
EFSA	European Food Safety Authority
EPA	Eicosapentaenoic Acid
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
FSAI	Food Safety Authority of Ireland
g	Gram
GRAS	Generally Recognized As Safe
HDL	High Density Lipoprotein
HOMA	Homeostatic Model Assessment
IOM	Institute of Medicine
IL	Interleukins
ITC	International Trade Centre
kg	Kilogram
LDL	Low Density Lipoprotein
meq	Milliequivalents
mg	Milligram
mL	Milliliter
MUFA	Monounsaturated Fatty Acids
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Surveys
PBMC	Peripheral Blood Mononuclear Cell
pg	Picogram
ppm	Parts Per Million
PUFA	Polyunsaturated Fatty Acids
RDA	Recommended Dietary Allowance
TNF	Tumor Necrosis Factor
TEP	Trade and Environment Program

UL	Tolerable Upper Intake Level
WHO	World Health Organization
WWEIA	What We Eat in America
y	Year

GRAS EXEMPTION CLAIM

Name and Address of Notifier

Agroindustrias Amazonicas S.A., Agroindustrias OSHO S.A.C., and Amazon Health Products S.A.C hereby notifies the Food and Drug Administration (FDA) that the use of sacha inchi oil as described below is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Agroindustrias Amazonicas S.A., Agroindustries OSHO S.A.C., and Amazon Health Products S.A.C has determined that such use is generally recognized as safe (GRAS) through scientific procedures.

(b) (6)

Agroindustrias Amazónicas S.A.
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_____ February 18th 2014

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Date

Name of GRAS Substance

The name of the substance that is the subject of this GRAS determination is sacha inchi oil, a vegetable oil derived from seeds of *Plukenetia volubilis Linneo*.

Intended Use and Consumer Exposure

Sacha inchi oil that is the subject of this GRAS determination is intended for use as an ingredient in a range of products including bars (such as granola, energy, protein and nutrition bars), breakfast cereals, condiments and relishes such as tapenades and hummus, chocolates, fats and oils (salad dressings, margarine-like spreads, salad oil), gravies, seed and nut butters, and snack foods. The proposed uses of sacha inchi oil are as follows:

- Baked Goods and Baking Mixes: Bars, all types such as granola, energy, protein and nutrition bars (e.g., Clif, breakfast, Kellogg's Nutri- Grain, Fiber One, and granola bars): up to 7% sacha inchi oil by weight
- Breakfast Cereals: All types of ready-to-eat (RTE) breakfast cereals, and all types of hot breakfast cereals: up to 6% sacha inchi oil by weight
- Condiments and relishes: Condiments and relishes used as a spread or dip, such as tapenades, Baba Ghanoush, or hummus: up to 7% sacha inchi oil by weight
- Soft Candy: Chocolates, including plain chocolate candies and candies with a chocolate ingredient: up to 6% sacha inchi oil by weight
- Fats and oils: Salad oil: up to 100% sacha inchi oil by weight
- Fats and oils: Dressings including mayonnaise and mayonnaise-type dressings, salad dressings: up to 17% sacha inchi oil by weight
- Fats and oils: Margarine-type butter spreads: up to 17% sacha inchi oil by weight
- Gravies and sauces: All types of gravies such as meat, fish, vegetable types: up to 7% sacha inchi oil by weight
- Nut and nut products: Nut and seed butters, such as peanut butter or pumpkin seed butter: up to 7% sacha inchi oil by weight
- Snack foods: "Healthy" snack foods such as trail mix or other mixtures with grain products and/or nuts and seeds: up to 7% sacha inchi oil by weight

The estimated daily intake (EDI) of sacha inchi from the proposed use in food was derived using the What We Eat in America (WWEIA) dietary component of the National Health and Nutrition Examination Surveys (NHANES) 2005-2010. For the population ages 2 years and older, the *per user* mean and 90th percentile EDIs of sacha inchi oil are 5.8 and 12.7 g/day, respectively. Adults were estimated to have the highest intakes of sacha inchi oil from the proposed use, with *per user* mean and 90th percentile EDIs of 6.4 and 13.6 g/day, respectively. At the 90th percentile, the intake of α-linolenic acid would be approximately 6.4 g.

Basis for GRAS Determination

The notifiers' GRAS determination for the intended use of sacha inchi oil is based on scientific procedures as described under 21 CFR§ 170.30(b).

The intended use of sacha inchi oil has been determined to be safe, and has also been determined to be GRAS by demonstrating that safety of intake under the proposed conditions of use is based on knowledge and information that is both publicly available and widely accepted by experts qualified by scientific training and experience to evaluate the safety of substances added to food.

Sacha inchi oil is a vegetable oil derived from the seeds of *Plukenetia volubilis Linneo*, a plant in the Euphorbiaceae family native to the rain forest of the Andean region of South America. The oil is removed from the seed under good manufacturing procedures using a press machine or similar device in a standard process known as cold pressing. The crude oil is then clarified and press-filtered, and no solvents (including hexanes), or chemicals are used to produce the oil. The resulting oil contains on average 46.4% α-linolenic acid, 35.6% linoleic acid, and 10% oleic acid, and meets specifications appropriate for a food ingredient, including limits on heavy metals and pesticide residues.

Consistent with other vegetable oils, sacha inchi oil is a vegetable oil composed of fatty acids primarily in the form of triglycerides. Sacha inchi oil and many commonly consumed vegetable oils consist predominantly of unsaturated fatty acids including oleic (C18:1, n-9), linoleic (C18:2) and α-linolenic acids (C18:3) and to a lesser extent saturated fatty acids including palmitic (C16:0) and stearic (C18:0) acids. The fatty acid profile of sacha inchi oil is similar to that of flaxseed oil, with both oils characterized by high proportions of α-linolenic acid relative to other oils.

The safety of sacha inchi oil was evaluated by a critical analysis of the safety of components in the oil, namely the predominant and characterizing α-linolenic acid. The safety evaluation for sacha inchi oil included an evaluation of the metabolic fate disposition of dietary triglycerides; a review of the IOM's 2002 evaluation of n-3 fatty acids; a review of a 2008 GRAS determination for the use of high linolenic acid flaxseed oil in food; a review of recent clinical trials assessing the safety of ingestion of α-linolenic acid; and a review of pre-clinical and clinical studies in which the test article was sacha inchi oil.

Based upon this review, intake of up to 15 g of α-linolenic acid was determined to be an appropriate benchmark for assessment of the safety of α-linolenic acid intake from the proposed use of sacha inchi oil in food.

The maximum estimated *per user* intake of α-linolenic acid from the proposed use of sacha inchi oil (6.4 g/day at the 90th percentile) is therefore below the acceptable daily intake level of 15 g/day of α-linolenic acid. It is therefore reasonable to conclude that the proposed uses of sacha inchi oil are safe and suitable, and generally recognized as safe.

Determination of the safety and GRAS status of sacha inchi oil for the direct addition to food under its intended conditions of use was made through the deliberation of an Expert Panel consisting of Joseph F. Borzelleca, Ph.D., Robert J. Nicolosi, Ph.D., and Michael W. Pariza, Ph.D., who reviewed a dossier of information pertinent to the safety of sacha inchi oil as well as other information available to them. These individuals are qualified by scientific training and experience to evaluate the safety of food and food ingredients. They individually and collectively critically evaluated published and unpublished data and information pertinent to the safety of sacha inchi oil, and unanimously concluded that the use in select foods of sacha inchi oil, produced consistent with cGMP and meeting appropriate food-grade specifications described above, is safe. It is the Expert Panel's opinion that other qualified scientists reviewing the same publicly available data and information would reach the same conclusion. Therefore, sacha inchi oil is GRAS by scientific procedures under the conditions of use described.

Availability of Information

The data and information that serve as the basis for this GRAS determination, as well as the information that has become available since the GRAS determination, will be sent to the FDA upon request, or are available for the FDA's review and copying at reasonable times at the office of Diane McColl at Hyman, Phelps & McNamara, P.C., 700 Thirteenth St. NW, Suite 1200, Washington, DC 20005.

Description of Substance

Identity

The subject of this GRAS determination is a vegetable oil derived from seeds of *Plukenetia volubis Linneo*.

Chemical and Common Names

The common name of the oil is sacha inchi oil. Sacha inchi oil is also known as Inca Inchi virgin oil. Other names for sacha inchi, the plant from which the oil is derived, include sacha mani, Mani del monte, sacha yuchi, sacha yuchiqui, sacha inchik, Amui-o, sacha inchic, sacha peanut, Mani del inca, inca peanut, wild peanut, bush peanut, and mountain peanut.

Chemical Abstracts Service (CAS) Registry Number

A CAS Registry Number has not been assigned for sacha inchi oil.

Molecular Weight and Empirical and Structural Formulas

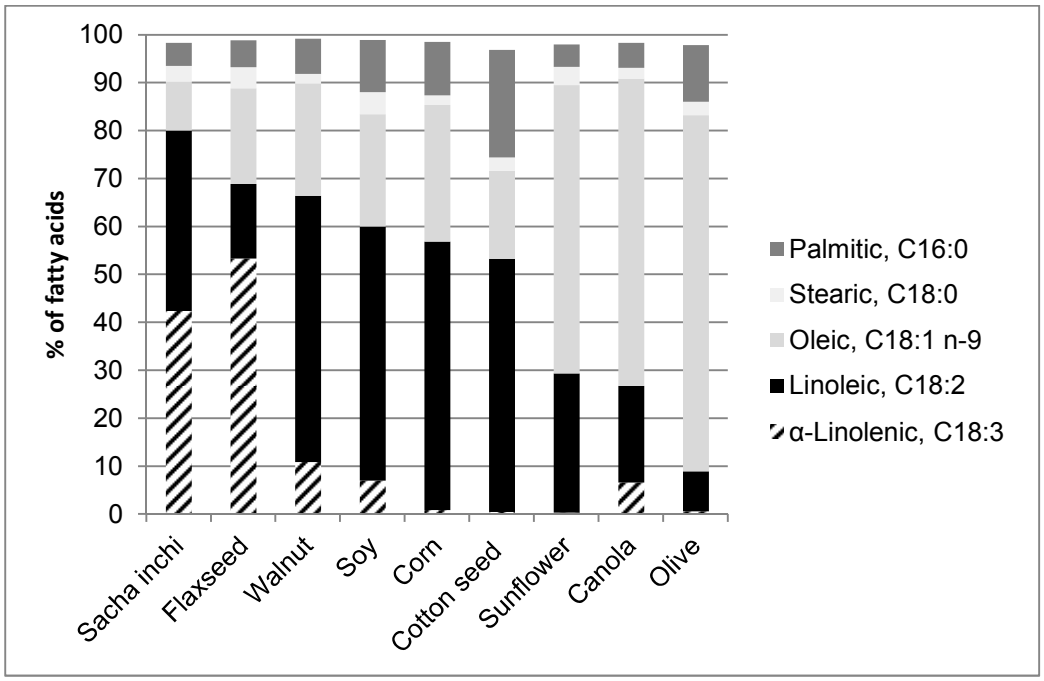
The molecular weight of sacha inchi oil w and its empirical formula was not provided.

Identity of Typical Sacha Inchi Oil

Sacha inchi oil is a vegetable oil derived from the seeds of *Plukenetia volubilis Linneo*, a plant in the Euphorbiaceae family native to the rain forest of the Andean region of South America (Fanali et al. 2011; Gutierrez et al. 2011). The sacha inchi plant is a climbing, monoecious, deciduous plant with capsular fruits. Seeds of the sacha inchi plant are brown in color with irregular darker splotches and lenticular in shape (Flores and Lock 2013).

Sacha inchi oil is a vegetable oil composed of fatty acids primarily in the form of triglycerides. The fatty acid composition of sacha inchi oil along with the composition of commonly consumed vegetables oils in the United States is shown in Figure 1. Sacha inchi oil and many commonly consumed vegetable oils consist predominantly of unsaturated fatty acids including oleic (C18:1, n-9), linoleic (C18:2, n-6) and α-linolenic acids (C18:3, n-3) and to a lesser extent saturated fatty acids including palmitic (C16:0) and stearic (C18:0) acids. The fatty acid profile of sachi inchi oil is similar to that of flaxseed oil, with both oils characterized by high proportions of α-linolenic acid relative to other oils.

Figure 1. Fatty Acid Composition of Sacha Inchi Oil and Commonly Consumed Vegetable Oils



Source: Data for walnut and soy oils derived from USDA National Nutrient Database, Standard Reference 26 (USDA 2013); data for all other oils as reported by Maurer et al. 2012, data for sachi inchi oil represent commercial oil.

Additional studies of the fatty acid composition of sacha inchi (*Plukentia volubilis L.*) oil and flaxseed (*Linum usitatissimum L.*) oil also show that α-linolenic acid is the predominant fatty acid in both oils, accounting for approximately 42-51% of fatty acids in sacha inchi oil and 47-55% of fatty acids in flaxseed oil. Approximately 33-39% of the fatty acids in sacha inchi oil are present as linoleic acid and 6-9% are present as oleic acid. In flaxseed oil, linoleic acid and oleic acid account for approximately 16-24% and 19-21% of fatty acids, respectively. A summary of the fatty acid profile in sacha inchi and flaxseed oils is shown in Table 1.

Table 1. Fatty Acid Profile of Sacha Inchi and Flaxseed Oils

		Saturated Fatty Acids		**Unsaturated Fatty Acids**			
		Palmitic C16:0	**Stearic C18:0**	**Oleic C18:1**	**LinoleicC 18:2**	**α-Linolenic C18:3**	
Description		**fatty acid %**					**Reference**
Sacha inchi	not specified	3.8	2.7	8.8	33.7	50.7	Bondioli et al. 2006
	petroleum-ether extraction[a]	5.2	3.4	11.6	37.6	41.5	Chirinos et al. 2013
	nonadulterated oil	4.0	3.0	9.0	36.0	47.0	Fanali et al. 2011
	supercritical CO_2	4.2	2.5	8.4	34.1	50.4	Follegati-Romero et al.

	Description	Saturated Fatty Acids		Unsaturated Fatty Acids			Reference
		Palmitic C16:0	Stearic C18:0	Oleic C18:1	LinoleicC 18:2	α-Linolenic C18:3	
		fatty acid %					
	extraction						2009
	crude oil[b]	-[c]	-	6.3	38.5	47.6	Guillen et al. 2003
	semi-refined oil[b]	-	-	7.1	38.5	46.8	Guillen et al. 2003
	crude oil[d]	-	-	8.9	34.5	51.5	Guillen et al. 2003
	semi-refined oil[d]	-	-	7.9	33.7	53.3	Guillen et al. 2003
	hexane extraction	4.4	2.4	9.1	33.4	50.8	Gutierrez et al. 2011
	seed roasted prior to processing	4.5	3.2	9.6	36.8	45.2	Hamaker et al. 1992
	commercial oil	4.8	3.4	10.1	37.7	42.4	Maurer et al. 2012
	authentic oil	4.7	3.5	10.7	33.5	44.0	Maurer et al. 2012
Flax-seed	commercial	5.6	4.4	20.0	15.5	53.4	Maurer et al. 2012
Flax-seed	not specified	6.0	2.0	19.0	24.0	47.0	Fanali et al. 2011
Flax-seed	commercial	-	-	21.1	18.5	55.1	Guillen et al. 2003

[a] average of 16 cultivars
[b] H NMR analysis
[c] data not provided
[d] FAME GC analysis

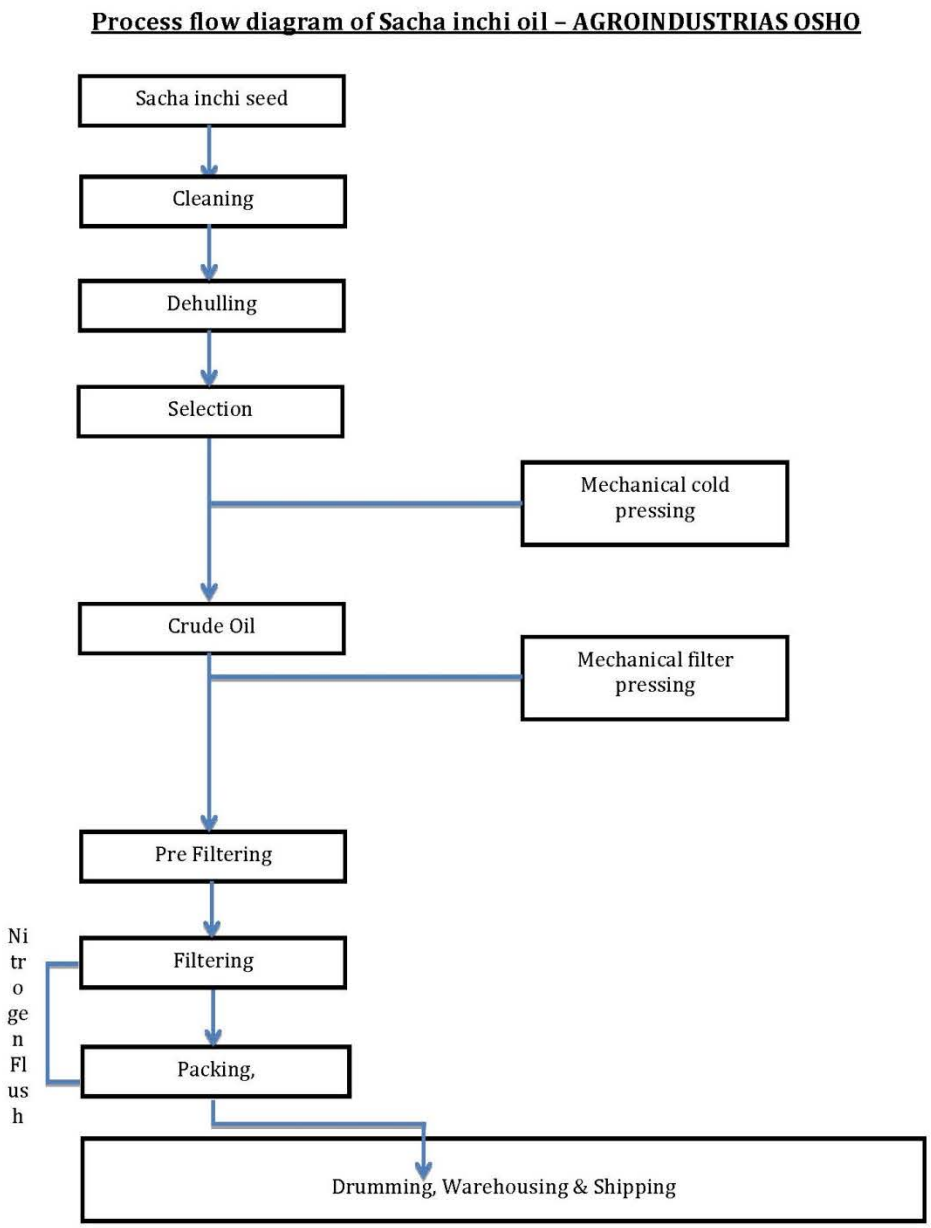
Sacha inchi oil also is reported to be a source of tocopherols, polyphenols, phytosterols, and carotene. Tocopherols are potent lipophilic antioxidant compounds and their presence in sacha inchi oil could serve to protect its inherent polyunsaturated fatty acids from oxidation. Sacha inchi oil removed from the seed using supercritical CO_2 was reported to contain 114 milligram (mg) γ-tocopherol per 100 g oil, 125 mg δ-tocopherol per 100 g oil, and no α-tocopherol (Follegatti-Romero et al. 2009). Fanali and colleagues (2011) reported similar levels of tocopherols in samples of Peruvian sacha inchi oil, namely 126 mg γ-tocopherol, 87 mg δ-tocopherol, and 0.4 mg α-tocopherol per 100 g oil. Other investigators detected 3.8-6.3 mg α-tocopherol per 100 g sacha inchi oil (Hamaker et al. 1992). The total phenolic content of sacha inchi oil was reported to be 6.20 mg per 100 g oil, with identified phenolic compounds in the oil belonging to the phenyl alcohol, flavonoid, secoiridoid, and lignin classes of polyphenols (Fanali et al. 2011). Sacha inchi oil contains 247 mg sterols per 100 g oil, with β-sitosterol accounting for the majority of sterols (56.5%), followed by stigmasterol (27.9%), campesterol (7.1%), and Δ5 Avenasterol (5.3%), and less than 1% of other sterols (Bondili et al. 2006). The level of total sterols in sacha inchi oil is comparable to or lower than levels found in commonly consumed vegetable oils (CODEX STAN 210-1999; Przybylski 2011). Sacha inchi oil is reported to contain carotenoids at a level of 0.08 mg per 100 g oil (Hamaker et al. 1992).

Production Process

Sacha Inchi oil is produced consistent with standard procedures used in the production of virgin vegetable oils. The production process is completed under current Good Manufacturing Practices (cGMP) as outlined in Peruvian Technical Regulation NTP151.401, 2012.

The oil is removed from clean, dehulled sacha inchi seeds using a press machine or similar device in a standard process known as cold pressing. The press machine is clean, disinfected, and does not transmit heat to the raw material or the finished product. The temperature is monitored during the extraction process. The crude oil is clarified by static sedimentation and press-filtering to yield a clear and transparent oil which is stored in bulk tanks under liquid nitrogen to minimize oxidative degradation. No solvents (including hexanes), or chemicals are used to extract the oil. A flow diagram representative of the process is presented in Figure 2. Flow diagrams prepared by other representative manufacturers of sacha inchi oil are presented in Appendix A.

Figure 2. Representative Process Flow Diagram for Production of Sacha Inchi Oil



Source: Agroindustrias OSHO

Product Specifications

Sacha inchi oil that is the subject of this GRAS safety assessment complies with food grade specifications for physical and chemical properties, including lead and arsenic (limits of 0.1 mg/kg). Specifications for sacha inchi oil and methods of analysis for each parameter are shown in Table 2. Analytical data from representative non-consecutive batches of sacha inchi oil as shown in Table 3 demonstrate that the oil meets the product specifications.

Table 2. Specifications for Sacha Inchi Oil Intended for Use in Food

Parameter	**Specification**	**Methods of Analysis**
Organoleptic Properties		
Color	Yellow	AOCS Cc 13e-92 (Lovibond color scale)
Smell and taste	Characteristic	ISO 4121:2003
Identity		
Density 20°C	0.926-0.931 g/cm^3	ISO 6883:2007
Iodine value (HANUS)	183-199 g/100g	AOAC 920.158.2005
Refractive index at 20°	1.478-1.481	AOCS Cc 7-25; 2009
Fatty Acids		
Oleic acid	≥8.9%	ISO 5508:2009 (prepared ISO 5509:2000)
Linoleic acid	≥32.1%	ISO 5508:2009 (prepared ISO 5509:2000)
Linolenic acid	≥44.7%	ISO 5508:2009 (prepared ISO 5509:2000)
trans fatty acid	<0.1%	AOCS Ce 1h-05:2009
Quality requirements		
Saponification value	192-196 mg	AOAC 920.160:2005
Unsaponifiable matter	≤0.45	ISO 3596:2000
Peroxide Value	<10 meq/kg	AOCS Cd 8b-90:2009
Tocopherol (δ+ γ)	>1900 mg/kg	ISO 9936:2006
Contaminants		
Lead (Pb)	≤0.1mg/kg	(ISO 13806 & 17294-2)ICP-MS
Arsenic (As)	≤0.1mg/kg	(ISO 13806 &17294-2)ICP-MS

Table 3. Product Specifications and Representative Analytical Data for Sacha Inchi Oil

Parameter	**Specification**	**Agro-industrias Amazonicas**	**Amazon Health**			**OSHO**			
		Sample 1 219125	**Sample 1 218945**	**Sample 2 219124**	**Sample 3 219229**	**Sample 1 218808**	**Sample 2 219113**	**Sample 3 219210**	**Average**
Organoleptic Properties									
Color	Yellow (Lovibond)	25	-	24	27	Char.	33	28	**27**
Smell and taste	Characteristic	Char.	Char.	Char.	Char.	Char.	Char.	Char.	**Char.**
Identity									
Density 20°C	0.926-0.931 g/cm^3	0.927	0.928	0.927	-	0.927	0.927	-	**0.927**
Iodine value (HANUS)	183-199 g/100g	185	188	182	188	190	191	189	**188**
Refractive index at 20°	1.478-1.481	1.481	1.481	1.481	-	1.481	1.481	-	**1.481**
Fatty Acids									
Oleic acid	≥8.9%	9.9	10.5	10.5	10.5	9.4	9.4	9.8	**10.0**
Linoleic acid	≥32.1%	35.1	36.1	34.1	34.3	36.3	36.3	37.2	**35.6**
Linolenic acid	≥44.7%	47.0	44.8	47.5	47.5	46.6	46.6	45.0	**46.4**
trans fatty acid	<0.1%	<0.1	-	<0.1	<0.1	-	<0.1	<0.1	**<0.1**
Quality requirements									
Saponification value	192-196 mg	194	192	193	192	195	191	193	**193**
Unsaponifiable matter	≤0.45	0.4	0.2	0.38	-	0.45	0.34	-	**0.35**
Peroxide Value	<10 meq/kg	8	2	5	4	1	3	3	**4**
Tocopherol (δ+ γ)	>1900 mg/kg	2030	2316	2031	2240	1934	2021	2050	**2089**
Contaminants									
Lead (Pb)	≤0.1mg/kg	<0.05	-	<0.05	<0.05	-	<0.05	<0.05	**<0.05**
Arsenic (As)	≤0.1mg/kg	<0.05	-	<0.05	<0.05	-	<0.05	<0.05	**<0.05**

-Value not provided. .

Results from testing of representative samples of sacha inchi oil for the presence of microbiological contaminants (Table 4) as well as dioxins, PAHs, pesticides, and aflatoxins (Table 5) also demonstrate that the oil is appropriate for food use.

Table 4. Microbiological Data for Representative Sacha Inchi Oil Samples

Parameter	**Methods of Analysis**	**Agroindustrias Amazonias**	**Amazon Health**	**OSHO**
		219125	**Sample 2**	**Sample 3**
Yeast, CFU/g	ICMSF Microorganisms in food 1 2da Edition. p:157-9.	<10	<10	<10
E. coli, CFU/g	FDA/BAM Online 8th Ed Rev A/1998 Sep2002 Chapter 4 Item G	<10	<10	<10
Mold, CFU/g	ICMSF Microorganisms in food 1 2da Edition. p:157-9.	<10	<10	<10
Standard Plate Count (SPC), CFU/g	FDA/BAM Online 8th Ed Rev A/1998 Jan2001 Chapter 3	<10 EAPC	<10 EAPC	<10

CFU = colony forming units.

Table 5. Contaminant Data for Representative Sacha Inchi Oil Samples

Parameter	Range of Acceptance	Source	Methods of Analysis	Agroindustrias Amazonias	Amazon Health		OSHO	
				Sample 1	Sample 2	Sample 3	Sample 2	Sample 3
Sum of dioxins (WHO-PCDD/F-TEQ) [Upperbound]	0.75 pg/g	(EC) 1881/2006	HRGC/HRMS; ECO/AV/IAC/005	0.42	0.42	0.42	0.42	0.4
Sum of dioxins and dioxin-like PCBs (WHO-PCDD/F-PCB-TEQ) [Upperbound]	1.5 pg/g	(EC) 1881/2006	HRGC/HRMS; ECO/AV/IAC/005 HRGC/HRMS; ECO/AV/IAC/016	0.59	0.59	0.59	0.59	0.56
Benzo(a)pyrene (µg/kg)	≤2 µg/kg	(EC) 1881/2006	NF EN ISO 15753	<0.2	0.2	<0.2	1.7	<0.3
Camphechlor (mg/kg)	0.1 mg/kg	EU MRL	NFEN 1528	<0.075	<0.075	-	<0.075	-
Pesticide residues mg/kg Sum of [4,4'-DDT, 2,4'-DDT, 4,4'-DDD] expressed us DDT	0.05 mg/kg	EU Sum of DDTs	NFEN 1528	<0.045	<0.045	<0.045	<0.045	<0.045
Aflatoxin B1	≤2.0 µg/kg	(EC) 1881/2006	ME100-ISO14718+NFEN12955+AOAC 991.31 Adaptees	1.4	0.24	<0.2	-	<0.20
Aflatoxins -Sum of B1, B2, G1, G2	≤4.0 µg/kg	(EC) 1881/2006	ME100-ISO14718+NFEN12955+AOAC 991.31 Adaptees	1.4	<0.35	<0.2	-	<0.20

Stability of Sacha Inchi Oil

Oxidation

Unsaturated fatty acids are prone to oxidation; therefore oil such as sacha inchi oil, which is comprised predominantly of unsaturated fatty acids, may be particularly susceptible to oxidation. The primary products of lipid oxidation are hydroperoxides, generally referred to as peroxides, which later decompose to alcohols, aldehydes and ketones. In oils, the concentration of peroxides and levels of free fatty acids are used to measure the extent of lipid oxidation (Gray 1978; Frega et al. 1999). The oxidation of sacha inchi oil has been examined in samples held at typical storage conditions and under accelerated oxidative conditions. The data indicate the oil is stable during storage up to two years, though it is prone to oxidation under accelerated oxidative conditions. Results from the studies are summarized below.

Oxidative Conditions During Storage

Analyses of sacha inchi oil samples in sealed bottles after one or two years of storage at ambient temperature indicate that peroxide values remain within product specifications (< 10 meq peroxides/kg) and free fatty acid levels remain below 1% (see Table 6and Appendix B). The results from these analyses indicate that the oil is stable during storage over two years.

Accelerated Oxidative Conditions

Peroxide levels in sacha inchi oil under accelerated oxidative conditions, namely temperatures of 40, 50, and 60ºC were used to predict shelf life of the oil (Castillo and Salas 2005; see Appendix B). The shelf life was estimated to be two years and eight months when maintained at a temperature of 40ºC. This evaluation is consistent with results of the testing during storage.

Maurer et al. (2012) monitored the oxidative stability of sacha inchi oils obtained from Peru under accelerated oxidative conditions. Flaxseed oil, corn oil, and high oleic sunflower oil also were examined in the study. Uncovered jars of the oils were heated to 65°C in an incubator and exposed to circulating air to facilitate oxidative conditions. Every five days for 20 days, an oil sample was removed from the incubator and peroxide values, free fatty acid levels, and methyl ester fatty acids were analyzed using standardized methods. The rate of peroxide formation in sacha inchi and flaxseed oils increased rapidly in the first days and reached a plateau after approximately 15 days in the accelerated oxidative environment. Peroxide values in sacha inchi oil were higher than values in flaxseed oil on sampling days 5, 10, 15 and 20. The rate of peroxide formation in high oleic sunflower oil and corn oil increased linearly within the 20-day storage period. At the final day of sampling (day 20), the peroxide value in corn oil was comparable to the level in sacha inchi oil. Free fatty acid levels in the oils remained below 1%. The authors concluded that sacha inchi and flax oils were the most oxidatively unstable oils among the test articles. Vitamin E levels in the oils were not reported, though the sacha inchi oil used for the testing presumably contained levels of tocopherols consistent with sacha inchi oil specifications in Peru (>1900 ppm $\delta + \gamma$ tocopherol).

Table 6. Peroxide and Free Fatty Acid Levels in Sacha Inchi Oil During Storage

Manufacturer	**Agroindustrias Amazonicas**		**Amazon Health Products**			**OSHO**	
Sample	**Agroindustrias Amazonicas 1**	**Agroindustrias Amazonicas 2**	**Amazon Health 1**	**Amazon Health 2**	**Amazon Health 3**	**OSHO 1**	**OSHO 2**
Lot	A032	A034	SIAEV 11299	SIAEV 12075	SIAEV 12335	LP14	LP15
Production Date	10/1/2007	12/10/2007	10/27/2011	3/15/2012	11/30/2012	11/18/2011	1/27/2012
Analysis Date							
Baseline	-	12/13/2007	11/2/2011	3/14/2012	11/29/2012	-	-
End of Study	12/23/2009	12/23/2009	1/22/2013	8/12/2013	12/27/2013	12/29/2013	12/29/2013
Peroxide Value (meq/kg)							
Baseline	-	2.2	1.9	0.7	0	-	-
End of Study	3.8	1.3	5.8	7.24	3.15	4.9	3.65
Free Fatty Acids (%)							
Baseline	-	0.52	0.3	0.33	0.21	-	-
End of Study	0.56	0.93	0.77	1.14	0.17	0.38	0.65

- Not assessed
Note: Certificates of Analysis are provided in Appendix B.

Formation of *trans* fatty acids

Linolenic acid is a source of *trans* fatty acids in the diet resulting from partial hydrogenation of oils or deodorization of oils (Wolff 1993). Sacha inchi oil is removed from the seed via a cold pressing procedure with no added heat, and high heat will not be added during preparation due to the oxidative instability of the oil. Consequently, *trans* bond formation and polymerization from heat applications is not a concern for sacha inchi oil.

Historical Consumption and Current Regulated Uses

Historical Consumption

Sacha inchi seed and oil have been consumed in Peru as part of the Inca diet for 3,000 years (Krivankova et al. 2007). Sacha inchi flour and oil are consumed by the Peruvian Indians, and are used in the elaboration of different meals and beverages (Follegatti-Romero et al. 2009; Fanali et al. 2011). Roasted or toasted seeds are an important component of the diets of the Chancas Indians (Krivankova et al. 2007; Huamani and Flores 2009; Fanali et al. 2011).

Regulated Uses

In the United States

Sacha inchi oil does not have a history of consumption as a food in the United States, though the key fatty acids in sacha inchi oil (α-linolenic, linoleic, oleic, palmitic, stearic acids) are consumed in vegetable oils and other lipid-containing foods present in the diet. Food sources of α-linolenic acid include flaxseed and flaxseed oil, walnuts and walnut oil, canola oil, soybeans, and soybean oil (Gebauer 2006). Flaxseed oil is recognized as a rich food source of α-linolenic acid in the Dietary Reference Intakes (DRI) for fatty acids (IOM 2002/2005), and the Dietary Guidelines for Americans list flaxseed among the plant sources of the fatty acid (USDA/DHHS 2010).

Modified flaxseed oils have been determined to be GRAS. High linolenic acid flaxseed oil, marketed under the name HiOmega™ flaxseed oil, received a letter of no objection from the U.S. Food and Drug Administration (FDA) in response to GRAS Notification 000256 (FDA 2009). The composition of high linolenic acid flaxseed oil, a cold pressed oil, is described as containing approximately 70% α-linolenic acid by weight. In comparison, typical flaxseed oil contains approximately 50% α-linolenic acid by weight. High α-linolenic acid flaxseed oil is intended for use as a replacement for edible oils in various food categories, though it was noted that the oil is not appropriate for use as a frying oil (Polar Foods, Inc. 2008). The categories of use include: beverages (alcoholic); beverage and beverage bases (nonalcoholic); gelatins, puddings, and fillings; processed fruits and fruit juices; processed vegetables and vegetable juices; grain products and pastas; chewing gum; soups and soup mixes; sugar, white, granulated; cereals; soft candy; baked goods and baking mixes; coffee and tea; cheeses; condiments and relishes; confections and frostings; dairy product analogs; fish products; fruit and water ices; gravies and sauces; jams and jellies, commercial; milk (whole and skim); milk products; nut and nut products; plant protein products; snack foods; sweet sauces, toppings and syrups; hard candy; sugar substitutes; and fats and oils. The intended level of use ranges from 0.86% (in beverages (alcoholic); beverage and beverage bases (nonalcoholic); gelatins, puddings, and fillings) to 17% (in fats and oils). The estimated intake of high linolenic acid flaxseed oil from the intended uses is less than 22 grams per day, which is equivalent to 15 grams of α-linolenic acid per day.

Low linolenic acid flaxseed oil or low linolenic acid linseed oil marketed under the name Solin oil received a no objection letter from FDA in response to GRAS Notification 000002 (FDA 1998). Available information on Solin oil indicates that the α-linolenic acid accounts for approximately 2% of fatty acids in the oil compared to approximately 50% in traditional flaxseed oil.

Outside the United States

Recently, sacha inchi oil was allowed into European markets. In December 2012, the Food Safety Authority of Ireland (FSAI) released a Substantial Equivalence Opinion recognizing sacha inchi oil from *Plukenetia volubilis L*. as a Novel Food under Article 5 of Regulation EC No. 258/97 based on substantial equivalence of the oil with flaxseed oil in terms of its composition, nutritional value, metabolism, intended use and level of undesirable substances (Appendix C). Sacha inchi oil is therefore subject to the same conditions of general and specific legislation governing the marketing and use of vegetable oils in the European Union (EU). The intended uses of the novel ingredient on the EU market are the same food categories and the same use levels at which flaxseed oil is currently marketed, for example use as a dressing on salads and its incorporation into a range of foods and food supplements.

Intended Use and Estimated Intakes

Intended Use

Sacha inchi oil is intended for use as a source of n-3 polyunsaturated fatty acids. The proposed uses of sacha inchi oil are summarized in Table 7 and include use as an ingredient in a range of products including bars (such as granola, energy, protein and nutrition bars), breakfast cereals, condiments and relishes such as tapenades and hummus, chocolates, fats and oils (salad dressings, margarine-like spreads, salad oil), gravies, seed and nut butters, and snack foods. The proposed uses of sacha inchi oil represent a subset of the uses of high α-linolenic flaxseed oil as described in GRN 256, the GRAS notification for use of HiOmega™ oil. Sacha inchi oil therefore is intended to be used as an alternative to flaxseed oil. Due to the high levels of polyunsaturated fatty acids in sacha inchi oil and compositionally similar flaxseed oil, both oils are highly unstable and prone to oxidation and therefore are not suitable for frying (Polar Foods 2008; Singh et al. 2011).

Table 7. Proposed Uses of Sacha Inchi Oil in Food

21CFR Food Category	Food Types	Maximum Proposed Use of Sacha Inchi Oil (% oil in food)
Baked Goods and Baking Mixes	Bars, all types such as granola, energy, protein and nutrition bars (e.g., Clif, breakfast, Kellogg's Nutri- Grain, Fiber One, and granola bars)	7
Breakfast Cereals	All types of ready-to-eat (RTE) breakfast cereals, and all types of hot breakfast cereals	6
Condiments and relishes	Condiments and relishes used as a spread or dip, such as tapenades, Baba Ghanoush, or hummus	7
Soft Candy	Chocolates, including plain chocolate candies and candies with a chocolate ingredient	6
Fats and oils	Salad oil	100
	Dressings including mayonnaise and mayonnaise-type dressings, salad dressings	17
	Margarine-type butter spreads	17
Gravies and sauces	All types of gravies such as meat, fish, vegetable types	7
Nut and nut products	Nut and seed butters, such as peanut butter or pumpkin seed butter	7
Snack foods	“Healthy” snack foods such as trail mix or other mixtures with grain products and/or nuts and seeds	7

Estimated Daily Intakes

Data Source and Methods

The estimated intake of sacha inchi from the proposed use in food was derived using the What We Eat in America (WWEIA) dietary component of the National Health and Nutrition Examination Surveys (NHANES) 2005-2010. This continuous survey uses a complex multistage probability sample designed to be representative of the civilian U.S. population (NCHS 2008, 2010, 2012). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the United States. As part of the examination, trained dietary interviewers collected detailed information on all foods and beverages consumed by respondents in the previous 24 hour time period (midnight to midnight). A second dietary recall was administered by telephone three to ten days after the first dietary interview, but not on the same day of the week as the first interview. A total of 24,673 individuals in the survey period 2005-2010 provided 2 complete days of dietary recalls.

Using the WWEIA consumption data, 2-day average intakes of oil for the U.S. population 2+ years and four sub-populations were estimated. Estimates of daily intake were generated on a *per user* basis, where a user was defined as anyone who reported consuming oil on either of the survey days. The list of foods reported consumed in WWEIA representative of the proposed uses and used to complete the analysis is presented in Appendix D.

In the analysis, the 2-day average intake of sacha inchi oil was estimated by multiplying the reported intake of foods from the WWEIA data with the maximum proposed levels of sacha inchi oil (see Table 7) and the cumulative sum over the two 24-hr recalls was divided by two. For example, if someone reported consuming 5 grams of oil on day 1 and 10 grams of oil on day 2, his 2-day average oil consumption would be 7.5 grams ([5+10]/2). The analysis was limited to individuals who provided two complete and reliable dietary recalls as determined by the National Center for Health Statistics (NCHS). The intakes were calculated using statistical weights that compensate for variable probabilities of selection and adjust for non-response. The resulting estimates therefore provide estimates of intake that are representative of the U.S. population.

Results

The estimates of sacha inchi oil intake are shown in Table 8. The estimated daily intakes (EDIs) are provided on a *per user* basis at the mean and the 90th percentile of intake for the population ages 2 years and older and subpopulations of children, adolescents, teenagers, and adults. For the population ages 2 years and older, the *per user* mean and 90th percentile EDIs are 5.8 and 12.7 g/day, respectively. Adults were estimated to have the highest intakes of sacha inchi oil from the proposed uses, with *per user* mean and 90th percentile EDIs of 6.4 and 13.6 g/day, respectively. With α-linolenic acid accounting for an average of 46.4% of fatty acids in sacha inchi oil, intake of the oil at the 90th percentile of intake corresponds to approximately 6.4 g α-linolenic acid.

Table 8. *Per User* Estimated Daily Intake of Sacha Inchi Oil From Proposed Uses

Population	No of Users	% Users	Sachi Inchi Oil (g/day)		α-Linolenic Acid (assume 46.4%*) (g/day)	
			Mean	90th	Mean	90th
US 2+ y	19,776	89	5.8	12.7	2.7	5.9
Children 2-5 y	1,988	92	3.1	6.6	1.4	3.1
Children 6-11 y	2,533	91	4.0	8.8	1.9	4.1
Adolescents 12-18 y	2,941	83	4.7	10.0	2.2	4.6
Adults 19+ y	12,314	89	6.4	13.6	3.0	6.3

Total sample = 22,755 individuals
*Percent fatty acids in typical sacha inchi oil; see Table 1

These estimates of intake provide a conservatively high estimate of sacha inchi oil intake as all foods are assumed to contain sacha inchi oil at the maximum intended uses. In reality, not all foods may contain sacha inchi oil at the maximum intended use level, and consumers may not choose to exclusively consume products containing sacha inchi oil. Additionally, the flavor of sacha inchi oil has been described as "intense", and more intense with increasing dose (Garmendia et al. 2011), which may limit consumption of the oil by some individuals, in particular children and adolescents. This suggests a self-limiting level based on unpleasant organoleptic properties. As previously noted, the intended uses of sacha inchi oil represent a subset of the uses of high α-linolenic flaxseed oil as described in GRN 256, the GRAS notification for use of HiOmega™ oil. Intake of sacha inchi oil as an ingredient in these foods would replace intake of high α-linolenic flaxseed oil as an ingredient; consequently there would be no increase in α-linolenic acid consumption among consumers of these foods.

Safety Evaluation

Introduction

Sacha inchi oil, the subject of this safety evaluation, is a vegetable oil composed of fatty acids primarily in the form of triglycerides. Sacha inchi oil is compositionally similar to flaxseed oil, as both oils contain a high concentration of polyunsaturated fatty acids and in particular a high concentration of α-linolenic acid relative to commonly consumed vegetable oils. An individual consuming sacha inchi oil or flaxseed oil in the diet in place of other commonly consumed vegetable oils or fat sources will therefore likely increase their intake of α-linolenic acid. Sacha inchi and flaxseed oils also contain large proportion of total fatty acids as linoleic acid (approximately 30-40%). However, given that sacha inchi and flaxseed oils are not a unique concentrated source of linoleic acid, consumption of sacha inchi oil (or flaxseed oil) in place of many commonly consumed vegetable oils (e.g., soy, corn, or sunflower oil) will not likely affect total intakes of linoleic acid.

The safety of sacha inchi oil was evaluated by a review of the safety of components in the oil, namely the predominant and characterizing α-linolenic acid. Studies addressing the safety of flaxseed oil or other dietary sources of α-linolenic acid therefore provide information to assess the safety of the proposed use of sacha inchi oil in food.

This safety evaluation includes an overview of the metabolic handling of dietary triglycerides; a summary of the Institute of Medicine(IOM)'s 2002 review of n-3 fatty acids and the 2008 GRAS determination for the use of high linolenic acid flaxseed oil; a review of recent clinical trials assessing the safety of ingestion of α-linolenic acid; and a review of preclinical and clinical studies in which the test article was sacha inchi oil.

A database of literature pertaining to the characterization, history of use, and safety of sacha inchi oil was provided by the International Trade Centre (ITC) – Trade and Environment Program (TEP) for use in completing this safety assessment. The database was reviewed and independent searches of the published literature were completed for information bearing on the safety of sacha inchi oil, flaxseed oil, and α-linolenic acid. The searches were first conducted in July, 2013, and updated in November, 2013. The PubMed, TOXNET, and AGRICOLA database were searched electronically, as well as websites for the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA), FAO/ WHO Codex Alimentarius Committee for International Food Standards, the Flax Council of Canada, the National Center for Complementary and Alternative Medicine, the European Food Safety Authority (EFSA), and the FDA.

Metabolic Fate

The metabolic fate of α-linolenic acid is an important consideration in evaluating the safety of sacha inchi oil because α-linolenic comprises nearly half of the total fatty acids in the oil and dietary intake of this fatty acid would likely increase if sacha inchi oil were consumed.

Dietary fat undergoes lipolysis by lipases in the gastrointestinal tract prior to absorption. Most lipolysis occurs in the small intestine, although there are lipases in the saliva and gastric secretion. In the intestine, fat is emulsified with bile salts and phospholipids secreted into the intestine in bile, and hydrolyzed by pancreatic enzymes. The absorption of dietary fats from the digestive tract is highly efficient, as the ingested fat is almost completely absorbed (IOM 2002/2005). The digestion and absorption of α-linolenic acid is similar to other long chain fatty acids. Saunders and Sillery (1988) reported absorption levels of 98% of α-linolenic acid from flaxseed oil in individuals with ileostomies. A comparable level of absorption in human adults also was reported by Burdge and Calder (2005a). The authors reported that greater than 96% of the administered dose of ^{13}C α-linolenic acid was absorbed (Burdge and Calder 2005a).

Once absorbed, there are several possible fates of α-linolenic acid that enters the blood stream, though the majority of the ingested α-linolenic acid is utilized for energy. The body can also store the fatty acids in adipose tissue, synthesize other non-essential saturated or monounsaturated fatty acids (MUFA), or convert them to longer-chain n-3 polyunsaturated fatty acids (PUFA) through the sequential action of desaturases and elongases as shown in Figure 1 (Calder 2012). Small amounts of n-3 fatty acids are lost during sloughing of skin and other epithelial cells (IOM 2002/2005).

Conversion of α-linolenic acid to EPA and DHA is very inefficient. Factors that influence estimates of conversion include gender, background diet, tissue type, and timing (Burdge and Calder 2005, a,b). Plourde and Cunnane (2007) concluded upon review of several studies in humans that approximately 5% of α-linolenic acid is converted to EPA and <0.5% of α-linolenic acid is converted to DHA. Several clinical studies with nut or seed oils reported no effect of dietary α-linolenic acid on blood levels of DHA (Francois et al. 2003, Harper et al. 2006a; Kaul et al. 2008; Lane et al. 2014). In a small study of young women the estimated net fractional α-linolenic acid interconversion was determined to be 21% for EPA and 9% for DHA in plasma (Burdge and Wootton, 2002). Overall, rates of conversion of α-linolenic acid to EPA are in the range of 0.2-21% and rates of conversion of α-linolenic acid to DHA are in the range of 0-9 % (DeFilippis and Sperling 2006; DeFilippis et al. 2009). The typical conversion of α-linolenic acid to EPA + DHA is likely in the range of 8-12% (Burdge and Calder 2005b, Polar Foods 2008).

Institute of Medicine 2002 Review of n-3 Fatty Acids

Dietary Reference Intakes (DRIs) for macronutrients, including α-linolenic acid, were established by the IOM in 2002 and published in 2005 (IOM 2002/2005). As previously noted, there was insufficient information to identify an EAR or RDA for α-linolenic acid. An AI was set which was based on the observed median intake in the United States. In addition to identifying recommended intakes of nutrients to maintain health, establishment of the DRIs also included review of the available data to determine, when possible, "the highest average daily intake of a nutrient that is likely to pose no risk of adverse health effects for nearly all persons in the general population;" this level of intake is referred to as the Tolerable Upper Intake Level, or UL. The IOM also notes that "as intake increases above the UL, the potential risk for adverse effects increases," therefore the UL provides a reference value to guide policymakers and scientists involved in ensuring a safe food supply and protecting public health.

In the hazard identification for n-3 fatty acids which collectively includes α-linolenic acid, DHA, and EPA, evidence was found to suggest that high intakes of n-3 polyunsaturated fatty acids may have adverse effects on immune function, increase the risk of excessive bleeding and hemorrhagic stroke, and cause oxidative damage to tissues (IOM 2002/2005). The available evidence primarily though not exclusively examined DHA and EPA.

Numerous studies in vitro and ex vivo have shown suppression of various aspects of human immune system. The level of EPA that caused some type of immunosuppression ranged from 0.9 to 9.4 g/d when fed for 3 to 24 weeks; the level of DHA that caused immunosuppression ranged from 0.6 to 6.0 g/d (IOM 2002/2005). Reduced platelet aggregation, and therefore prolonged bleeding time has been suggested to link n-3 polyunsaturated fatty acid intake with reduced risk of coronary heart disease (CHD). Although prolonged bleeding times have been shown to be beneficial in preventing heart disease, bleeding times can become prolonged enough to result in excessive bleeding and bruising. Long-chain polyunsaturated fatty acids, particularly DHA and EPA, are vulnerable to lipid peroxidation, resulting in oxidative damage of various tissues. In addition, caution has been suggested for the use of n-3 fatty acids in those individuals who already exhibit glucose intolerance or diabetic condition and individuals taking anticoagulants, such as aspirin, warfarin, and coumadin because simultaneous ingestion of n-3 fatty acids may excessively prolong bleeding times.

Based on their review of the available information, the IOM concluded that while there was some evidence to suggest adverse effects associated with consumption of n-3 polyunsaturated fatty acids, there was inadequate evidence to establish a tolerable upper intake level. It is important to note that most of the studies reviewed by IOM that addressed hazards associated with high consumption of n-3 polyunsaturated fatty acids were conducted using the longer-chain n-3 fatty acids, EPA and DHA, and not α-linolenic acid. DHA and EPA are more potent than α-linolenic acid, and the rate of conversion of α-linolenic acid to EPA and DHA is reported to be very low, making it less likely for α-linolenic acid to exert these adverse effects observed with EPA and DHA. Studies specifically addressing the safety of α-linolenic acid cited in the 2002 review include a study of daily intake of 20 g flaxseed oil by 10 men (Kelley et al. 1991) that found depressed peripheral blood mononuclear cell (PBMC) proliferation in response to T-cell mitogen but not to B-cell mitogen with the flaxseed oil-supplemented diet; and a study of 30 men showing depressed PBMC TNF-α, IL1β, and PGE2 in subjects consuming on average 13.7 ± 5.5 g α-linolenic acid/day from flaxseed compared to a control diet (Caughey et al. 1996).

FDA Review of n-3 Fatty Acids

In June 1997, FDA released a final rule in which the use of menhaden oil as a direct food ingredient was determined to be GRAS, provided that the combined daily intake of the n-3 fatty acids EPA and DHA from consumption of menhaden oil did not exceed 3 grams per person per day (62 FR30751– 30757). Maximum levels of use of menhaden oil were established for specific food categories to ensure that the combined exposure of 3 g EPA and DHA would not be exceeded. In the process of making this GRAS determination, the FDA reviewed scientific data on potential adverse effects associated with high intakes of the n-3 fatty acids, namely increased bleeding time, increased levels of low-density lipoprotein cholesterol, and adverse effects on glycemic control in non-insulin dependent diabetics. Intake of up to 3 g/person/day of EPA and DHA from fish oils was determined to be safe

with regard to these parameters. The hazards identified by FDA in the review of menhaden oil are consistent with the hazards identified by the IOM in the more recent review of n-3 fatty acids.

2008 GRAS Determination for Use of High Linolenic Acid Flaxseed Oil

In 2008, Polar Food, Inc. notified FDA of their determination that use of high linolenic acid flaxseed oil, marketed under the name HiOmega™ flaxseed oil, was GRAS for proposed uses in foods. The notification was filed as GRAS Notification 000256. In their response letter to Polar Foods following review of the notification, FDA noted that the review completed by Polar Foods addressed safety issues pertaining to EPA and DHA, namely the potential for increased bleeding time, reduced glycemic control for diabetics, increased levels of low-density lipoprotein cholesterol among diabetics and hyperglycemics, and immunosuppressive effects. FDA concluded the response letter by saying "the agency has no questions at this time regarding Polar Foods' conclusion that high linolenic acid flaxseed oil is GRAS under the intended conditions of use." The intended uses of the oil in foods were estimated to result in intakes of less than 22 grams of the oil per day, which is equivalent to 15 grams of α-linolenic acid per day.

α-Linolenic Acid Safety Data Published After the 2002 Institute of Medicine Review of n-3 Fatty Acids

The published literature was searched for human clinical data addressing safety aspects of α-linolenic acid. Studies available since release of the IOM report (2002 to the present) and studies in non-diseased populations were considered for the current review. The search was updated on November 5, 2013, in PubMed with the terms: (("flaxseed oil" OR "flax oil" OR "linseed oil" OR flax oil) OR (alpha-linolenic)) AND (intervention OR trial OR supplement OR supplemental OR pilot or randomized); the search was limited to terms in the title/abstract, English language studies, studies in humans, and clinical trials. Abstracts of the identified studies were screened for information related to the potential hazards previously identified for n-3 fatty acids by the IOM and/or the FDA, namely immune function, risk of excessive bleeding and hemorrhagic stroke, oxidative damage to tissues, glycemic control, and effects on low density lipoprotein (LDL)-cholesterol.

Overall the identified interventions with flaxseed oil or some other dietary manipulation to increase α-linolenic acid intakes were primarily designed to assess the efficacy of increased α-linolenic acid intakes on fatty acid profiles as compared to intake of DHA and EPA, effects of dietary α-linolenic acid intakes on blood lipids, and effects on immune function.

The studies identified with an outcome of interest (i.e., immune function, excessive bleeding, oxidative damage, glycemic control, LDL cholesterol) are briefly tabulated in Appendix E. Intakes of α-linolenic acid in the identified studies ranged from approximately 2.2 to 20.6 g per day in these studies, with the interventions spanning 3 to 26 weeks.

Intake of α-linolenic acid did not adversely affect immune function in humans. Inflammatory or immune markers such as C-reactive protein (CRP), interleukins (IL-1β, IL-6, IL-2, IFN-γ, IL-4, IL-10, IL-6), tumor necrosis factor (TNFα) and lymphocyte number were either decreased or unchanged (Barcelo-Coblijn et al. 2008; Cornish et al. 2009; Finnegan et al. 2003a,b; Gillingham et al.2011; 2013; Kew et al. 2003; Kontogianni et al. 2013; Nelson et al. 2011; Rallidis et al. 2003; Schwab et al. 2006; Wallace et al. 2003; West et al. 2010; Zhao et al. 2004, 2007).

In addition, α-linolenic acid did not increase risk for bleeding as indicated by the fact that platelet aggregation, plasma fibrinogen, blood clotting factors and plasminogen activator activity, which are markers for bleeding, were unchanged in these studies (Austria et al. 2008; Finnegan et al. 2003a,b; Kew et al. 2003; Knudsen et al. 2006; Metcalf et al. 2007; Schwab et al. 2006; Wilkinson et al. 2005). Modest decreases, however, in collagen-induced platelet aggregation were observed in older subjects in one study (Patenaude et al. 2009); as noted by the study investigators, the significant decrease in collagen-induced aggregation observed in older adults may be a beneficial effect in a population in which cardiovascular and thrombotic diseases are highly prevalent.

No consistent untoward effects on α-linolenic acid on glycemic control were observed. Of the seven clinical studies that investigated the effects of α-linolenic acid, six studies reported no statistically significant changes in fasting blood sugar or insulin levels (Barre et al. 2008; Finnegan et al. 2003a,b; Kew et al. 2003; Kontogianni et al. 2013; Nelson et al. 2007; Schwab et al. 2006; Taylor et al. 2010). In a study in individuals with metabolic syndrome, 3.5 g α-linolenic acid per day from rapeseed oil administered for 26 weeks decreased plasma insulin levels (Baxheinrich et al. 2012).

Alpha-linolenic acid did not cause oxidative damage as indicated by the finding that α-linolenic acid did not enhance oxidative susceptibility of LDL in healthy volunteers given 2.2 g α-linolenic acid daily for 3 weeks (Egert et al. 2007). Other investigators also have observed no untoward effects of α-linolenic acid on oxidative damage (Barden et al. 2009; Finnegan et al. 2003a,b; Kew et al. 2003).

Additionally, α-linolenic was not observed to increase levels of LDL-cholesterol (Baxheinrich et al. 2012; Egert et al. 2007; Finnegan et al. 2003a,b; Gillingham et al.2011, 2013; Harper et al. 2006b; Kew et al. 2003; Kontogianni et al. 2013; Nelson et al. 2011; Patenaude el. 2009; Wilkinson et al. 2005).

In summary, findings from the reviewed studies do not provide evidence of safety concerns regarding immune function, excessive bleeding, oxidative damage, glycemic control, or LDL-cholesterol from intake of α-linolenic acid. These findings do not challenge the GRAS status of up to 15 g of α-linolenic acid per day as acknowledged by FDA in 2009 (FDA 2009).

Studies with Sacha Inchi Oil

Pre-clinical and clinical studies of sacha inchi oil intake also were identified and reviewed. Studies (in Spanish with translations to English) were provided by the ITC – TEP. An independent search of PubMed and ToxLine was conducted using the terms “Sacha inchi OR

Plukenetia volubilis" with no limits. Two pre-clinical studies and three clinical studies were reviewed.

Pre-Clinical Studies with Sacha Inchi Oil

Pre-clinical studies including assessments of genotoxicity, acute toxicity, and repeated-dose toxicity were conducted to assess the safety of sacha inchi oil. These studies are described below and briefly summarized in Table 9.

Table 9. Summary of Preclinical studies with Sacha Inchi Oil

Reference	Study Design	Study Doses (sacha inchi oil)	Results
Huang et al. 2012[a]	**Genotoxicity:** *in vitro* Ames assay with *Salmonella typhimurium* strains TA97a, TA98, TA100, TA102	8, 40, 200, 1000, 5000 µg per plate were assessed with respect to negative control [~50% ALA in oil]	No significant increase in number of revertant colonies compared to control
	Genotoxicity*: In vivo* micronucleus test; 5 mice/group. Test substances include control and 3 doses of sacha inchi oil	2.5, 5, 10 g/kg bw [~50% ALA in oil]	No statistically significant increase in micronucleus rates compared to control
	Genotoxicity: Sperm Shape Abnormality test; 5 mice/group. Test substances include control and 3 doses of sacha inchi oil	2.5, 5 and 10 g/kg bw [~50% ALA in oil]	No increase in sperm deformity rate above negative control
	Acute Study: mice	3 administrations within 24 hours, total dose 54 g/kg bw [assume 50% ALA in oil]	LD_{50} >54 g/kg bw
Gorriti et al. 2010[b]	**Acute Study:** Balb C57 male and female mice (n=10)	Increasing oral doses, reaching 1 mL/mouse (37 g/kg bw) [47.06% ALA in oil]	LD_{50} >37 g/kg bw
	Repeat-dose 60-day study: 24 male Holtzman rats (n=8/group); body weight measured weekly, signs of toxicity, total cholesterol, HDL cholesterol, triglycerides, glucose, urea, alanine aminotransferase, and alkaline phosphatase measured at days 30 and 60. Test substances include saline (control), sacha inchi oil, linseed oil	0.5 mL/kg bw (0.45 g/kg bw)[c] [47.06% ALA in oil]	No significant differences among groups in serum parameters (total cholesterol, HDL cholesterol, triglycerides, glucose, urea, alanine aminotransferase, and alkaline phosphatase) at 60 days

ALA = α-linolenic acid
[a] The paper was published in Chinese with an English abstract; the body of the paper was reviewed by a native Chinese speaker.
[b] The paper was published in Spanish; an English translation was available for review.
[c] 1 Tablespoon (Tbsp) = 15 mL = 13.6 g; therefore 1 teaspoon (tsp) = 5 mL = 4.5 g.

Genotoxicity Studies

Genotoxicity studies were conducted to determine the potential for sacha inchi oil to cause molecular change in the DNA or structural or numerical changes in chromosomes of cells. Huang et al. (2012) evaluated the mutagenicity of sacha inchi oil (obtained from South America) in a three-genotoxicity test battery including an in vitro reverse mutation assay (Ames Assay), an in vivo micronucleus test of bone marrow of mice, and a sperm shape abnormality test in mice. The test oil was described as containing 50% α-linolenic acid. There was no increase in the number of revertant colonies in the bacterial reverse mutation (Ames) assay, and at all doses of sacha inchi oil (2.5, 5 and 10 g/kg bw) both the micronucleus rates and the sperm abnormality rates in mice were not significantly different from rates in the negative control. Results from this battery of tests provide evidence that sacha inchi oil was not mutagenic under the conditions of these studies.

Acute Oral Toxicity Studies in Mice

Two acute oral toxicity tests of sacha inchi oil in mice were conducted (Huang et al 2012; Gorriti et al. 2010). Following three administrations of sacha inchi oil to male and female mice within 24 hours, the acute oral median lethal dose LD50 of sacha inchi oil was determined to be more than 54 g/kg bw, the total administered dose (Huang et al 2012). In another study in male mice of the Balb C57 strain, the LD50 for raw sacha inchi oil was determined to be above 37 g/kg bw, the highest dose administered (Gorriti et al. 2010).

60-Day Repeat Dose Oral Toxicity Study in Rats

Gorriti et al. (2010) evaluated the oral toxicity of sacha inchi (*Plukenetia volubilis L.*) and linseed (*Linum ussitatisimum*) oils in young Holtzman rats (mean body weight of 100 ± 20 g) over a period of 60 days. The raw sacha inchi oil used in this study was obtained from seeds collected in Peru; the oil contained 47.06 ± 0.02% α-linolenic acid and 36.19 ± 0.02% linoleic acid. Twenty-four male rats were divided into three study groups (8 per group) and administered one of three substances daily: 4 mL/kg bw physiologic saline solution; 0.5 mL per/kg bw sacha inchi oil; or 0.5 mL/kg bw linseed oil. Body weights were measured weekly as a sign of toxicity. Total cholesterol, high density lipoprotein (HDL) cholesterol, glucose, triglycerides, and alkaline phosphatase were assessed at days 30 and 60 after initiating the diets.

There were no differences in mean body weights across the three study groups at any week during the study. After 30 days of feeding, there were significant differences among the three groups in measures of total cholesterol, HDL-cholesterol, and triglycerides. Total cholesterol levels at 30 days in the sacha inchi group (180.3 ± 18.2 mg/dL) were higher than levels in the linseed oil group (142.3 ± 27.8 mg/dL), but not different than levels in the control group (155.3 ± 26.2 mg/dL). At 30 days, triglyceride levels in the sacha inchi group were significantly higher than levels in the control group (151.3 ± 22.8 mg/dL vs. 124.3 ± 23.3 mg/dL), but not different than levels in the linseed oil group (130.5 ± 17.4 mg/dL). HDL cholesterol levels at 30 days in the sacha inchi group did not differ from levels in either the control or linseed oil groups. After 60 days of feeding, there were no significant differences in measures of total cholesterol, HDL-cholesterol, and triglycerides across the three groups. At 30 and 60 days of feeding, there were no significant differences among the groups in serum parameters of glucose, urea, alanine aminotransferase, or alkaline phosphatase. There was no gross or histopathological examination of any tissue or organ. Based on the findings

in the study, the investigators concluded that the test oils, including sacha inchi oil, were non-toxic to rats over 60 days of repeated oral exposure.

Other Studies

Sensitization, chronic toxicity, developmental and reproductive toxicity of sacha inchi oil have not been evaluated in animal studies.

Summary of Preclinical Studies

Preclinical studies of sacha inchi oil include a mutagenicity studies, two acute toxicity studies, and a 60-day oral toxicity study of 0.45 g oil/kg bw. Results from the studies indicate that sacha inchi oil is neither mutagenic nor toxic to rats and mice under the conditions of these experiments.

Clinical Studies with Sacha Inchi Oil

Three clinical studies of sacha inchi oil intake by humans were identified, including two single dose studies (Huaman et al. 2008; Gonzales et al. 2013) and a repeat dose study (Gonzales and Gonzales 2014). These clinical studies are described below and summarized in Table 10. Also described below is a small open trial in which participants consumed oil from seeds of *Plukenetia huayllabamba* (Garmendia et al. 2011), a wild species related *to Plukentia volubilis L* (sacha inchi) (Bussmann et al. 2009).

Table 10. Clinical Studies with Sacha Inchi Oil

Reference	Study Design, Population, Duration	Sacha inchi dose	Outcome Measures	Results
Huaman et al. 2008[a]	Single dose study; healthy adults, mean age 21.9 y n = 12 (8 M/4 F); sacha inchi seed with or without olive oil (not randomized order)	50 g seeds (~23 g oil based on n-3 FA content)	Postprandial triglycerides (0, 1.5 h, 3 h, 4.5 h, 6 h) following intake of olive oil with or without sacha inchi seeds	Significantly decreased postprandial triglycerides area-under-the-curve with sacha inchi compared to without; decreased response at 1 ½ and 4 ½ h.
Gonzales et al. 2013	Single dose study; healthy adults 20-55 y n = 18 enrolled (9 M/9 F) n = 12 receiving sacha inchi oil (6 per dose); n = 6 receiving sunflower oil (3 per dose)	9.0 g oil (10 mL)[b] 13.5 g oil (15 mL)[b]	Postprandial fatty acid concentrations (0, 0.5, 1, 2, 4, 8, 24 h) following intake of 9 or 13.5 g oil	Plasma α-linolenic acid, DHA, lauric acid, palmitic acid, heptadecanoic acid, linolelaidic acid, cis-8,11,14-eicosatrienoic acid, and cis-13,16-docosadienoic acid increased after sacha inchi oil but not after sunflower oil. Greater increase in α-linolenic acid Cmax in women than men (2.84±0.36 vs 0.94±0.57 mg/mL, $p<0.05$). Higher plasma α-linolenic acid levels after 15 mL dose vs 10 mL dose though not statistically significant.
Gonzales and Gonzales 2014	Randomized, double-blind placebo controlled study; healthy adults, mean age 25-55 y n=34 randomized, 30 completed (13 M/17 F) n=16 in sacha inchi groups; n=14 in sunflower groups	9.0 g oil (10 mL)[b] 13.5 g oil (15 mL)[b]	Acceptability; adverse effects; biochemical markers (hemoglobin, hematocrit, CRP, AST, ALT, alkaline phosphatase, bilirubin, gamma glutamyl transferase, serum albumin, serum total proteins, serum creatinine, serum uric acids); blood glucose; serum lipids; serum insulin; HOMA; testosterone; estradiol; blood pressure; measured at baseline, 1, 2, 3, and 4 months	4 subjects withdrew (3 in sacha inch oil group, 1 in sunflower oil group). Low acceptability of sacha inchi oil at baseline; increased at week 6. Adverse side-effects primarily nausea and eructation; decreased over time. No change in biochemical markers other than total protein and albumin; total protein increased in sacha inchi oil group, albumin increased in both oil groups. No change in glucose; increase in insulin and HOMA in both oil groups. Decrease in total- and LDL-cholesterol in both oil groups, increase in HDL-cholesterol in sacha inchi oil group. Decrease in blood pressure in both oil groups. No change in testosterone or estradiol.

[a] The paper was published in Spanish; an English translation was available for review.
[b] 1 Tablespoon (Tbsp) = 15 mL = 13.6 g; therefore 1 teaspoon (tsp) = 5 mL = 4.5 g.

Single Dose Studies with Sacha Inchi Oil

Huaman et al. (2008) determined the effect of sacha inchi seed ingestion in combination with olive oil on postprandial triglycerides in healthy young adults (n = 12) in a single dose non-randomized crossover study. The seeds provided 11 g α-linolenic acid, which is the amount of this fatty acid in approximately 23 g of oil assuming 50% α-linolenic acid. The area-under-the-curve postprandial triglyceride response following intake of 82 g of olive oil with 50 g of sacha inchi seeds was significantly lower than the response after intake of olive oil alone ($p<0.001$). Results from this study indicate that consumption of sacha inchi seed, which contains sacha inchi oil, may decrease the postprandial triglyceride response. The study did not, however, assess the effects of sacha inchi oil alone in the postprandial triglyceride response.

Gonzales and colleagues recently examined plasma fatty acid responses after ingestion of sacha inchi oil or sunflower oil in 18 healthy men and women 20 to 55 years of age. The sacha inchi oil contained 47.7% α-linolenic acid, 34.9% linoleic acid and 9.6% oleic acid, while the sunflower oil contained 0.6% α-linolenic acid, 57.2% linoleic acid, and 28.9% oleic acid. There were differences in postprandial fatty acid levels between the oils, including increases in plasma α-linolenic acid and DHA levels following intake of the sacha inchi oil that were not observed after intake of sunflower oil. Following intake of sacha inchi oil, the maximal plasma concentration of α-linolenic acid was higher in women than in men (2.84 ± 0.36 vs 0.94 ± 0.57 mg/mL, $p<0.05$); the maximal response of DHA was higher in women than men though the difference was not statistically significant (2.60 ± 0.84 vs 1.00 ± 0.38 mg/mL, $p>0.05$). Higher plasma α-linolenic acid and DHA levels were observed after the higher dose of sacha inchi oil, though the differences were not statistically significant. A single dose of sacha inchi oil was administered in this study; further research is needed to determine the impact of repeated doses of sacha inchi oil on blood levels of fatty acids.

Repeat Dose Study with Sacha Inchi Oil

Acceptability, safety, and efficacy of sacha inchi oil were recently assessed by Gonzales and Gonzales (2014) in a small 4-month randomized, controlled study. Thirty-four (34) adults were randomized to consume 10 or 15 mL (equivalent to 9.0 or 13.5 g) of sacha inchi oil or sunflower oil daily throughout the study. The sacha inchi oil contained 47.4% α-linolenic acid and 34.9% linoleic acid whereas the sunflower oil contained 57.2% linoleic acid. Each 10 mL dose of sacha inchi oil provided 4.4 g α-linolenic acid and each 15 mL dose provided 6.6 g of the fatty acid. At baseline and monthly throughout the study, anthropometrics, hematology parameters, biochemical markers of hepatic and kidney function, lipid parameters, glucose parameters, and blood pressure were assessed in the study participants. Acceptance of the oils was assessed weekly, and adverse side-effects were assessed daily. At baseline there were no differences among the study groups in age, sex, anthropometrics, blood pressure, hemoglobin/hematocrit, and blood glucose. Three women withdrew from the sacha inchi oil groups within the first 18 days of the study due to personal reasons or intolerance of the oil taste; one woman withdrew from the sunflower oil group due to a surgical intervention unrelated to the study. The remaining 30 subjects completed the study: 16 consumed sacha inchi oil and 14 consumed sunflower oil. The majority of subjects in the sacha inchi oil group (62.5%) found the oil to have an unacceptable taste the first week of the study, however, acceptability increased over time.

During the first three weeks of the study, the majority of participants in the sacha inchi oil groups reported adverse side effects though reports of adverse effects decreased over time. Nausea was the most commonly reported side effect (14 subjects) followed by eructation (5 subjects); additional side effects reported included hot flashes, headaches, cramping, and constipation. Biochemical markers of hepatic, renal, and biliary function and serum CRP were unchanged in both the sacha inchi oil and sunflower oil groups over the 4-month intervention. Serum albumin increased significantly in both oil groups. At baseline, serum total protein levels were significantly lower in the sacha inchi oil group compared to the sunflower oil group; total protein increased significantly in the sacha inchi oil group during the study. Serum total and LDL-cholesterol levels decreased significantly from baseline values in both the sacha inchi oil and sunflower groups. Serum HDL-cholesterol levels were higher in the sacha inchi oil group compared to the sunflower group. Systolic and diastolic blood pressure decreased in both the sacha inchi oil and sunflower oil groups. Blood glucose levels were unchanged in both oil groups during the study, though serum insulin and the Homeostatic Model Assessment (HOMA) index increased in both the sacha inchi oil and sunflower oil groups. Overall, the study investigators concluded that findings from this study provide evidence that daily intake of 10 or 15 mL of sacha inchi oil daily over a period of 4 months is safe. The observed adverse side-effects, which decreased over time, were regarded as minor and likely attributable to the taste and flavor of the oil rather than an adverse effect of the oil.

Repeat Dose Study with *Plukenetia huayllabamba* Oil

Garmendia et al. (2011) conducted an open pilot study to assess the effects of *Plukenetia huayllabamba* oil on the lipid profiles of 24 patients (mean age 53.4 ± 9.9 years) with hypercholesterolemia. *Plukenetia huayllabamba* is a wild species related to *Plukentia volubilis* L (sacha inchi) (Bussmann et al. 2009). Study participants were randomized to consume 5 or 10 mL of the oil (equivalent to 4.5 or 9.0 g of oil) daily for 4 months. The doses delivered approximately 2 g of α-linolenic acid per 5 mL. At the end of 4 months, HDL cholesterol levels were significantly higher and total cholesterol, LDL cholesterol, non-HDL cholesterol, and nonesterified fatty acid levels were significantly lower than baseline levels in participants consuming either 4.5 or 9.0 g of *Plukenetia huayllabamba* oil daily. In the group of adults consuming 9.0 g of *Plukenetia huayllabamba* oil daily, measures of glucose, insulin, and the HOMA index of insulin sensitivity were significantly higher after 4 months of the study compared to baseline values; levels also increased in the low dose group (5 mL oil, or 4.5 g oil), though the differences were not statistically different. There were no differences in any measures between groups (4.5 vs. 9.0 g oil) at the end of the study. Results from this study are somewhat difficult to interpret because the study was not placebo controlled, rather it was conducted within a small sample size, and information on other dietary factors was not provided. Overall, the study is of limited value in the safety assessment of sacha inchi oil.

Summary of Clinical Studies of Sacha Inchi Oil

Three clinical studies of sacha inchi intake in humans were identified in the scientific literature. One paper described a single dose study designed to address the efficacy of sacha inchi seed on lipid profile (Gonzales et al. 2013) and one study described the postprandial triglyceride response (Huaman et al. 2008); these studies therefore provide limited information pertaining to a safety

assessment of long term ingestion. Results from a small, 4-month randomized, controlled study provide evidence that daily intake of 9.0 or 13.5 g sacha inchi oil (4.4 or 6.6 g α-linolenic acid) is safe based on assessment of biochemical markers, blood lipids, and glucose measures (Gonzales and Gonzales 2014). Adverse effects, primarily nausea and eructation, were observed at the beginning of the beginning of the study in the sacha inchi oil group but the effects decreased over time. The effects were regarded as minor and likely attributable to the taste and flavor of the oil rather than an adverse effect of the oil.

Sensitization

As reported by Bueso et al. (2010), a 40-year-old woman developed rhinoconjunctivitis and bronchial asthma related to occupational exposure to the crushing of sacha inchi seeds. No reports of allergic reactions associated with consumption of the seed or oil were identified in the literature.

Safety Data Summary

Sacha inchi oil is a vegetable oil composed of fatty acids primarily in the form of triglycerides. It is compositionally similar to flaxseed oil, as both oils contain a high concentration of polyunsaturated fatty acids and in particular a high concentration of α-linolenic acid relative to commonly consumed vegetable oils. Flaxseed oil is recognized as a rich food source of α-linolenic acid in the DRIs for fatty acids (IOM 2002/2005), and the Dietary Guidelines for Americans list flaxseed among the plant sources of the fatty acid (USDA/DHHS 2010).

The safety of the intended use of sacha inchi oil in food was evaluated by a critical evaluation of the safety of components in the oil, namely the predominant and characterizing fatty acid, α-linolenic acid. Alpha-linolenic acid is an essential fatty acid, which means it must be consumed in the diet. Adequate Intakes of α-linolenic acid are in the range of 1.3 to 1.6 g/day for adults. A maximum average daily intake of α-linolenic acid that is likely to pose no risk of adverse health effects for nearly all persons in the general population, i.e., a UL, was not established by the IOM in the course of developing DRIs for macronutrients. Potential hazards of n-3 fatty acid intake were identified by the IOM, namely potentially adverse effects of n-3 fatty acids on immune function, excessive bleeding, oxidative damage, and glycemic control in diabetics; however, no UL was established due to a lack of adequate evidence. These hazards are consistent with the hazards the FDA identified for high intakes of DHA + EPA, namely increased bleeding time, increased levels of low-density lipoprotein cholesterol, and adverse effects on glycemic control in non-insulin dependent diabetics as part of the GRAS determination of menhanden oil in 1997 when intake of up to 3 g/person/day of EPA and DHA from fish oils was determined to be safe.

Intake of 15 grams of α-linolenic acid per day from the use of a high α-linolenic acid oil in foods was determined to be GRAS (Polar Foods 2008; FDA 2009). As part of the GRAS determination, Polar Foods conducted a thorough review of safety data regarding intake of α-linolenic acid, including a review of information on the potential hazards of n-3 fatty acids identified by the IOM (i.e., immune function, excessive bleeding, oxidative damage, glycemic

control). FDA had no concerns about the determination that intake of up to 15 g of α-linolenic acid from an oil source was GRAS (FDA 2009). An intake of 15 g of α-linolenic acid would deliver up to 1.8 g EPA + DHA assuming the upper end of the typical range for the conversion of dietary α-linolenic acid to EPA + DHA of 8-12% (Burdge and Calder 2005b; Polar Foods 2008). The estimated intake of EPA + DHA by the U.S. population from current dietary sources is approximately 0.1 g (USDA 2012). Consumption of α-linolenic acid from use of α-linolenic acid rich oils in foods in combination with background sources of EPA and DHA would result in an estimated dietary equivalent of up to 1.9 g combined EPA + DHA which is well within the 3 g/person/day limit from fish oils established by the FDA in 1997. This GRAS determination for the use of sacha inchi oil therefore established 15 g of α-linolenic acid as an acceptable daily intake of the fatty acid from a supplemental source in the typical diet. Sacha inchi oil is intended to be used as an alternative to flaxseed or other oils and the level of use is self-limiting due to unpleasant organoleptic effects.

A review of the literature published since IOM completed their 2002 review identified no new evidence that would call into question the safety of daily intake of up to 15 grams of α-linolenic acid from a supplemental source in the diet.

A limited number of pre-clinical and clinical studies were conducted with sacha inchi oil and information from these studies was critically evaluated in this safety assessment. Results from a series of *in vitro* and *in vivo* genotoxicity studies two acute oral toxicity studies in mice and a 60-day single dose, (0.45 g sachi inchi oil/kg bw) oral toxicity study in Holtzman rats demonstrate that sacha inchi oil is neither mutagenic nor toxic to rats and mice under the conditions of these experiments. Results from a single-dose clinical study provide evidence that plasma α-linolenic acid levels increase following intake of sacha inchi oil. Results from a small repeat dose study in adults suggest no untoward effects following intake of 9.0 or 13.5 g of sacha inchi oil (4.4 or 6.6 g α-linolenic acid) daily for a period of 4 months.

Based on this critical safety review, it may be concluded that the intake of up to 15 grams of α-linolenic acid is an appropriate benchmark for assessment of the safety of α-linolenic acid intake from the proposed use of sacha inchi oil in foods.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered generally recognized as safe (GRAS) for its intended use in accordance with section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data information.

These criteria are applied in the analysis below to determine whether the intended use of sacha inchi oil as a food is safe by scientific procedures.

Safety Determination

Sacha inchi oil is a vegetable oil derived from the seeds of *Plukenetia volubilis Linneo*, a plant in the Euphorbiaceae family native to the rain forest of the Andean region of South America. The oil is removed from the seed under good manufacturing procedures using a press machine or similar device in a standard process known as cold pressing. The crude oil is then clarified and press-filtered, and no solvents (including hexanes), or chemicals are used to produce the oil. The resulting oil contains on average 46.4% α-linolenic acid, 35.6% linoleic acid, and 10% oleic acid, and meets specifications appropriate for a food ingredient, including limits on heavy metals and pesticide residues.

Consistent with other vegetable oils, sacha inchi oil is a vegetable oil composed of fatty acids primarily in the form of triglycerides. Sacha inchi oil and many commonly consumed vegetable oils consist predominantly of unsaturated fatty acids including oleic (C18:1, n-9), linoleic (C18:2) and α-linolenic acids (C18:3) and to a lesser extent saturated fatty acids including palmitic (C16:0) and stearic (C18:0) acids. The fatty acid profile of sacha inchi oil is similar to

that of flaxseed oil, with both oils characterized by high proportions of α-linolenic acid relative to other oils.

The safety of sacha inchi oil was evaluated by a critical analysis of the safety of components in the oil, namely the predominant and characterizing α-linolenic acid. The safety evaluation for sacha inchi oil included an evaluation of the metabolic fate of dietary triglycerides; a review of the IOM's 2002 evaluation of n-3 fatty acids; a review of a 2008 GRAS determination for the use of high linolenic acid flaxseed oil in food; a review of recent clinical trials assessing the safety of ingestion of α-linolenic acid; and a review of pre-clinical and clinical studies in which the test article was sacha inchi oil.

Based upon this critical review, it may be concluded that intake of up to 15 g of α-linolenic acid is an appropriate benchmark for assessment of the safety of α-linolenic acid intake from the proposed use of sacha inchi oil in food.

Sacha inchi oil is intended for use as a source of n-3 polyunsaturated fatty acids. The proposed uses of sacha inchi oil include use as an ingredient in a range of products including bars (such as granola, energy, protein and nutrition bars), breakfast cereals, condiments and relishes such as tapenades and hummus, chocolates, fats and oils (salad dressings, margarine-like spreads, salad oil), gravies, seed and nut butters, and snack foods. The proposed uses of sacha inchi oil are consistent with uses of flaxseed oil which include use in foods as described in GRN 256, the GRAS notification for use of HiOmega™ oil. Due to the high levels of polyunsaturated fatty acids in sacha inchi oil and compositionally similar flaxseed oil, both oils are highly unstable and prone to oxidation and therefore are not suitable for frying (Polar Foods 2008; Singh et al. 2011).

For the population ages 2 years and older, the *per user* mean and 90th percentile EDIs of sacha inchi oil are 5.8 and 12.7 g/day, respectively. Adults were estimated to have the highest intakes of sacha inchi oil from the proposed use, with *per user* mean and 90th percentile EDIs of 6.4 and 13.6 g/day, respectively. At the 90th percentile, the intake of α-linolenic acid would be approximately 6.4 g.

The maximum estimated *per user* intake of α-linolenic acid from the proposed use of sacha inchi oil (6.4 g/day at the 90th percentile) is therefore below the acceptable daily intake level of 15 g/day of α-linolenic acid. It is therefore reasonable to conclude that the proposed uses of sacha inchi oil are safe and suitable, and generally recognized as safe.

General Recognition of the Safety of Sacha Inchi Oil

The intended use of sacha inchi oil has been determined to be safe through scientific procedures as set forth in 21 CFR§170.30(b), thus satisfying the so-called "technical" element of the GRAS determination. Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination. Determination of the safety and GRAS status of sacha inchi oil for addition to foods under its intended conditions of use has been made through the deliberations of

an Expert Panel comprised of Joseph F. Borzelleca, Ph.D., Robert J. Nicolosi, Ph.D., and Michael W. Pariza, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to food. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that sacha inchi oil, produced consistent with Good Manufacturing Practice and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that these uses of sacha inchi oil are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food ingredients would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit I to this document.

Information that would be inconsistent with a finding that the proposed use of sacha inchi oil meeting appropriate specifications and used according to cGMP, is GRAS, was not identified. A recent search of the scientific literature revealed no potential adverse health concerns.

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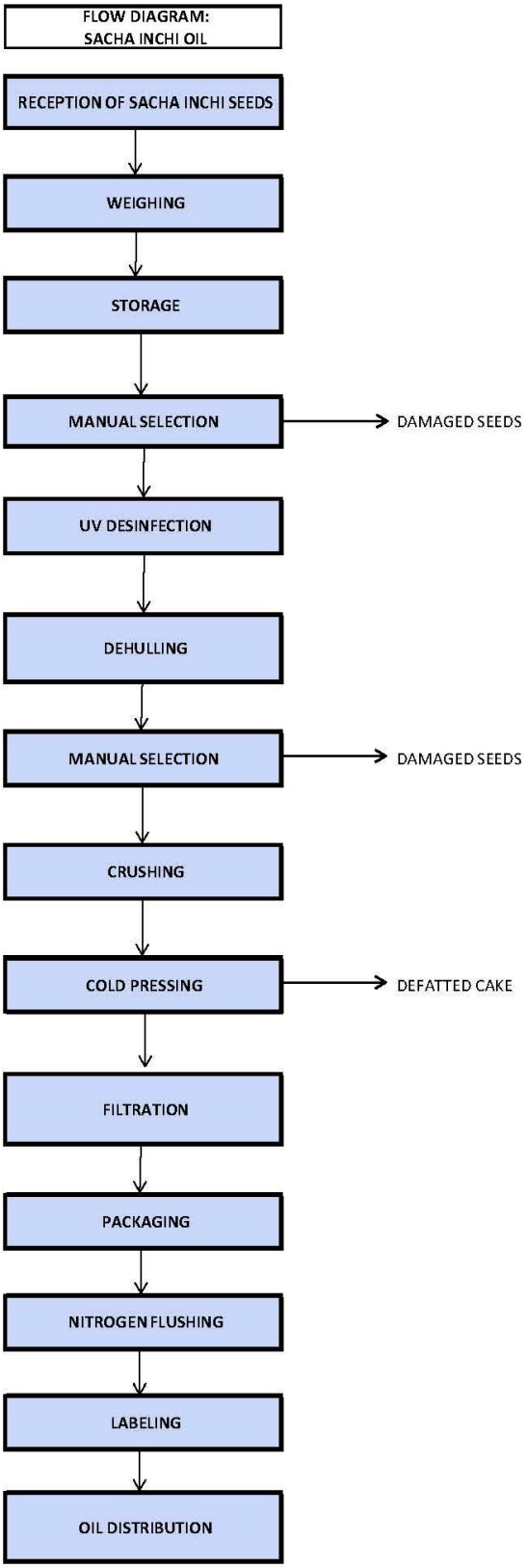
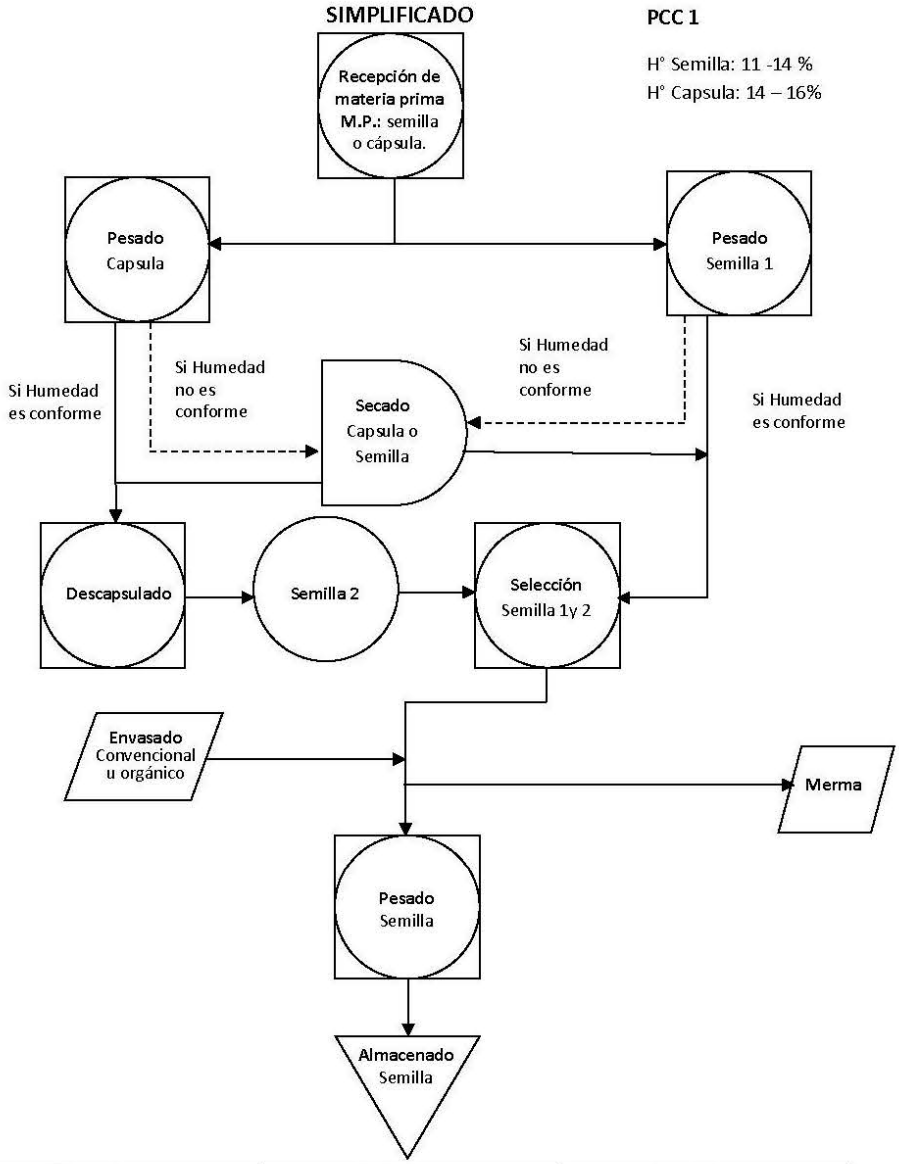
Appendices

Appendix A. Detailed Production Process Flow Chart


FLOW DIAGRAM:
SACHA INCHI OIL
RECEPTION OF SACHA INCHI SEEDS
WEIGHING
STORAGE
MANUAL SELECTION
DAMAGED SEEDS
UV DESINFECTION
DEHULLING
MANUAL SELECTION
DAMAGED SEEDS
CRUSHING
COLD PRESSING
DEFATTED CAKE
FILTRATION
PACKAGING
NITROGEN FLUSHING
LABELING
OIL DISTRIBUTION

VI. FLUJOGRAMA Y DESCRIPCIÓN DE PROCESO DE ACEITE Y TORTA INCA INCHI



Elaborado por:	Revisado por:	Aprobado por:
Ing. Johana Montilla Pérez Jefe de aseguramiento de calidad	Sr. David Aguilar Rodríguez Gerente General	Sr. José Anaya Yabar Directorio

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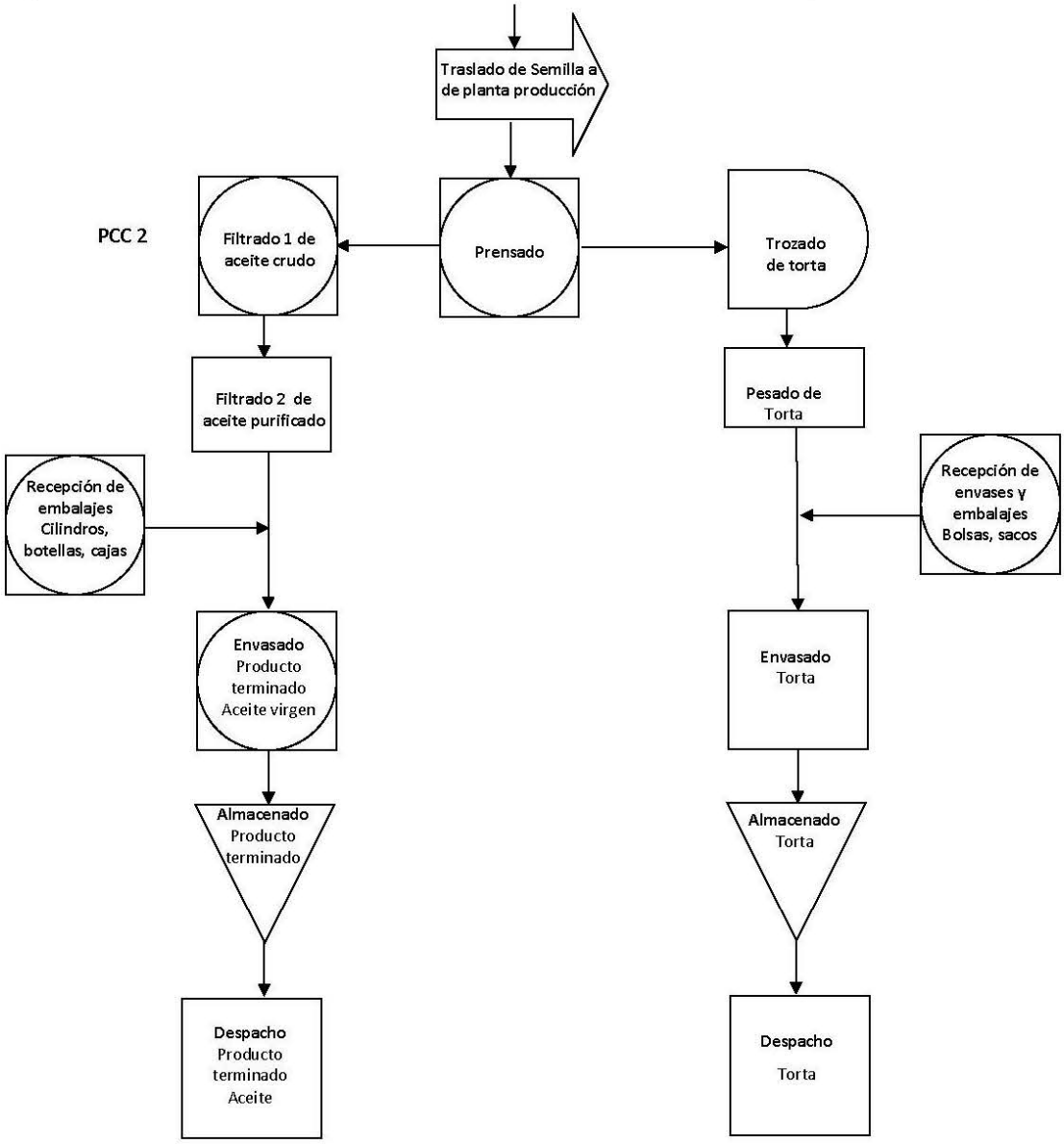

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Appendix B. Product Stability Data

Agroindustrias Amazonicas

(2 samples)

Agroindustrias Amazonicas

Sample 1: A032

LABS - ITP

LABORATORIO DE ENSAYO ACREDITADO POR EL SISTEMA NACIONAL DE ACREDITACION REGISTRO N° LE-013

LABORATORIO DEL INSTITUTO TECNOLÓGICO PESQUERO DEL PERU

Registro N° LE-13

INFORME DE ENSAYO N° 402-09

Solicitante: AGROINDUSTRIAS AMAZONICAS S.A.

Dirección: Jr. Calcuchimac Nº 306, Lima 03 **Telf.:** 437-2395

Solicitud de Servicio Nº: 159 **Fecha de Recepción de la Muestra:** 18.12.09

Producto: Aceite Inca Inchi Extra Virgen Lote AO32. Fecha de Producción Octubre 2007. Muestra de 10 sachets de 10mL Aprox. c/u.

Condiciones de Recepción: A temperatura ambiente, en sachets herméticamente sellados.

Fecha de Ejecución del Ensayo: 21.12.09

CARACTERISTICAS	METODO DE ENSAYO	RESULTADOS
Determinación de Ácidos grasos libres en aceites crudos y refinados (Expresado como ácido oleico)	AOAC 940.28, 18th Edition, 2005	0,56 %
Determinación del Valor Peróxido	AOAC 965.33 18th Edition, 2005	3,8 meq Peróxido/kg

OBSERVACIONES: xxx

Fecha de Emisión: 23 de Diciembre del 2009

Los resultados emitidos en el presente Informe sólo se refieren a la muestra analizada.

El nombre del producto declarado es de responsabilidad del cliente.

Los resultados ☒**si** ☐**no** se emitieron vía ☒**fax** ☐**telefónica** a solicitud del cliente

Salvo disposiciones especiales y solo para ensayos Físicos – Químicos, la presente muestra será conservada por los Laboratorios durante un periodo de 30 días desde la fecha de emisión del Informe de Ensayo. El cliente o destinatario podrá solicitar la dirimencia 10 días útiles antes de su vencimiento ante el Sistema Nacional de Acreditación de INDECOPI

INSTITUTO TECNOLOGICO PESQUERO GERENCIA TECNICA LABS-ITP

(b) (6) [redacted]

Gerente Técnico
Ing. Alberto Salas Maldonado

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TELEFAX: 5773130 E-mail: postmast@itp.org.pe

Agroindustrias Amazonicas

Sample 2: A034

INFORME DE ENSAYO N° 456-07

Solicitante: AGROINDUSTRIAS AMAZONICAS S.A.

Dirección: Jr. La Niña Nº 272, Chacarilla del Estanque - Surco **Telf:** 372-2364

Solicitud de Servicio Nº: 265 **Fecha de Recepción de la Muestra:** 11.12.07

Producto: Aceite de Inca Inchi, Lote A-O34, Fecha Fabricación: 10-12-07. Muestra de 100mL. aprox.

Condiciones de Recepción: A temperatura ambiente, en frasco de vidrio con tapa.

Fecha de Ejecución de Ensayo: 12.12.07

CARACTERISTICAS	METODO DE ENSAYO	RESULTADOS
Determinación del Valor Peróxido	AOAC 965.33, 18th Edition 2005	2,2 meq Peróxido/Kg. muestra
Determinación de Ácidos grasos libres en aceites crudos y refinados (Ácido oleico)	AOAC 940.28, 18th Edition 2005	0,52 %

OBSERVACIONES: XXX
Fecha de Emisión: 13 de Diciembre del 2007.
Los resultados emitidos en el presente Informe sólo se refieren a la muestra analizada.
El nombre del producto declarado es de responsabilidad del cliente.
Los resultados ☒**si** ☐**no** se emitieron vía ☒**fax** ☐**telefónica** a solicitud del cliente

(b) (6)

INSTITUTO TECNOLOGICO PESQUERO DEL PERU · GERENCIA TECNICA · LABS-ITP

Gerente Técnico
Ing. María Estela Ayala G.

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INFORME DE ENSAYO N° 403-09

Solicitante: AGROINDUSTRIAS AMAZONICAS S.A.

Dirección: Jr. Calcuchimac N° 306, Lima 03 **Telf.:** 437-2395

Solicitud de Servicio N°: 159 **Fecha de Recepción de la Muestra:** 18.12.09

Producto: Aceite Inca Inchi Extra Virgen Lote AO34. Fecha de Producción 10-12-2007. Muestra de un frasco de 250mL Aprox..

Condiciones de Recepción: A temperatura ambiente, en frasco de vidrio con tapa.

Fecha de Ejecución del Ensayo: 21.12.09

CARACTERISTICAS	METODO DE ENSAYO	RESULTADOS
Determinación de Ácidos grasos libres en aceites crudos y refinados (Expresado como ácido oleico)	AOAC 940.28, 18th Edition, 2005	0,93 %
Determinación del Valor Peróxido	AOAC 965.33 18th Edition, 2005	1,3 meq Peróxido/kg

OBSERVACIONES: xxx

Fecha de Emisión: 23 de Diciembre del 2009

Los resultados emitidos en el presente Informe sólo se refieren a la muestra analizada.

El nombre del producto declarado es de responsabilidad del cliente.

Los resultados ☒**si** ☐**no** se emitieron vía ☒**fax** ☐**telefónica** a solicitud del cliente

Salvo disposiciones especiales y solo para ensayos Físicos – Químicos, la presente muestra será conservada por los Laboratorios durante un periodo de 30 días desde la fecha de emisión del Informe de Ensayo. El cliente o destinatario podrá solicitar la dirimencia 10 días útiles antes de su vencimiento ante el Sistema Nacional de Acreditación de INDECOPI

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GERENCIA TECNICA LABS-ITP

Gerente Técnico
Ing. Alberto Salas Maldonado

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Amazon Health Products

(3 samples)

Amazon Health Products

Sample 1: SIAEV 11299

LA MOLINA CALIDAD TOTAL LABORATORIOS

Instituto de Certificación, Inspección y Ensayos

INFORME DE ENSAYOS
Nº 007420 - 2011

SOLICITANTE	: **AMAZON HEALTH PRODUCTS S.A.C.**
DIRECCIÓN LEGAL	: Jr. Heidinger 450 Oxapampa - Oxapampa - Pasco RUC: **20492997294** Teléfono: 435-3983 Fax :995199900
PRODUCTO	: **ACEITE DE SACHA INCHI**
NÚMERO DE MUESTRAS	: Uno
IDENTIFICACIÓN/MTRA.	: Código: SIAEV 11299
CANTIDAD RECIBIDA	: 520 g de muestra proporcionada por el solicitante.
MARCA(S)	: S.M.
FORMA DE PRESENTACIÓN	: Envasado en botella de vidrio sellada
SOLICITUD DE SERVICIO	: S/S NºEN-004706 -2011
REFERENCIA	: ACEPTACION TELEFONICA
FECHA DE RECEPCIÓN	: 28/10/2011
ENSAYOS SOLICITADOS	: **MICROBIOLÓGICO Y FÍSICO/QUÍMICO**
PERÍODO DE CUSTODIA	: No aplica

RESULTADOS :

ENSAYOS MICROBIOLÓGICOS :

ENSAYOS	RESULTADO
1.- N. Aerobios Mesófilos Viables (UFC/g)	<10 Estimado

MÉTODOS UTILIZADOS EN EL LABORATORIO :

1.- ICMSF Vol. I Parte II Ed. II Pág. 120-124 (Traducción Versión Original 1978) Reimpresión 2000 (Ed. Acribia) 1983

ENSAYOS FÍSICOS/QUÍMICOS :

ENSAYO	RESULTADOS
1.- Índice de Peróxido (Miliequivalentes / kg de muestra original)	1,9
2.- Acidez Libre (g / 100 g de muestra original) (Expresado como ácido oleico)	0,3

MÉTODOS UTILIZADOS EN EL LABORATORIO :

1.- NTP 209.006 1968
2.- NTP 209.005 1968

FECHA DE EJECUCIÓN DE ENSAYOS: Del 28/10/2011 Al 02/11/2011.

ADVERTENCIA :

1.- El muestreo, las condiciones de muestreo, tratamiento y transporte de la muestra hasta su ingreso a La Molina Calidad Total - Laboratorios son de responsabilidad del Solicitante.

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La Molina, 2 de Noviembre de 2011

LA MOLINA CALIDAD TOTAL - LABORATORIOS
(b) (6)
M. Sc. DAVID ROLDÁN ACERO
DIRECTOR TECNICO
CIP Nº 27184

Pág 1/1

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E-mail: calitot@infonegocio.net.pe / mktg@lamolina.edu.pe
Página Web: www.lamolina.edu.pe/calidadtotal

LA MOLINA CALIDAD TOTAL LABORATORIOS

Instituto de Certificación, Inspección y Ensayos

INFORME DE ENSAYOS
Nº 000436 - 2013

SOLICITANTE	: **AMAZON HEALTH PRODUCTS S.A.C.**
DIRECCIÓN LEGAL	: Calle Camino Real 1801- Interior B5 - Surco RUC: **20492997294** Teléfono: 435-3983 Fax :991887116
PRODUCTO	: **ACEITE DE SACHA INCHI**
NÚMERO DE MUESTRAS	: Uno
IDENTIFICACIÓN/MTRA.	: SIAEV 11299-2
CANTIDAD RECIBIDA	: 130 g (+ envase) de muestra proporcionada por el solicitante.
MARCA(S)	: S.M.
FORMA DE PRESENTACIÓN	: Envasado, la muestra ingresa en frasco cerrado con 250 ml aprox.
SOLICITUD DE SERVICIO	: S/S N°EN-000249 -2013
REFERENCIA	: ACEPTACION TELEFONICA
FECHA DE RECEPCIÓN	: 18/01/2013
ENSAYOS SOLICITADOS	: **FÍSICO/QUÍMICO**
PERÍODO DE CUSTODIA	: No aplica

RESULTADOS :

ENSAYOS FÍSICOS/QUÍMICOS :

ENSAYO	RESULTADOS
1.- Índice de Peróxido (Miliequivalentes / kg de muestra original)	5,8
2.- Acidez (g / 100 g de muestra original) (Expresado como ácido oleico)	0.77

MÉTODOS UTILIZADOS EN EL LABORATORIO :

1.- NTP 209.006 1968
2.- NTP 209.005 1968

FECHA DE EJECUCIÓN DE ENSAYOS: Del 18/01/2013 Al 22/01/2013.

ADVERTENCIA :

1.- El muestreo, las condiciones de muestreo, tratamiento y transporte de la muestra hasta su ingreso a La Molina Calidad Total - Laboratorios son de responsabilidad del Solicitante.
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La Molina, 22 de Enero de 2013

LA MOLINA CALIDAD TOTAL LABORATORIOS Dirección Técnica

LA MOLINA CALIDAD TOTAL - LABORATORIOS
(b) (6)
M. Sc. DAVID ROLDÁN ACERO
DIRECTOR TÉCNICO
CIP. Nº 27184

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Página Web: www.lamolina.edu.pe/calidadtotal

Amazon Health Products

Sample 2: SIAEV 12075

LA MOLINA CALIDAD TOTAL LABORATORIOS

Instituto de Certificación, Inspección y Ensayos

INFORME DE ENSAYOS
N° 001479 - 2012

SOLICITANTE : **AMAZON HEALTH PRODUCTS S.A.C.**
DIRECCIÓN LEGAL : Calle Camino Real 1801- Interior B5 - Surco
RUC: **20492997294** Teléfono: 435-3983 Fax :991887116
PRODUCTO : **ACEITE DE SACHA INCHI**
NÚMERO DE MUESTRAS : Uno
IDENTIFICACIÓN/MTRA. : SIAEV12075
CANTIDAD RECIBIDA : 520 g (+ envase) de muestra proporcionada por el solicitante.
MARCA(S) : S.M.
FORMA DE PRESENTACIÓN : Envasado, la muestra ingresa en frasco cerrado con 250 ml aprox.
SOLICITUD DE SERVICIO : S/S N°EN-000922 - 2012
REFERENCIA : **ACEPTACIÓN TELEFÓNICA**
FECHA DE RECEPCIÓN : 13/03/2012
ENSAYOS SOLICITADOS : **FÍSICO/QUÍMICO**
PERÍODO DE CUSTODIA : No aplica

RESULTADOS :

ENSAYOS FÍSICOS/QUÍMICOS :

ENSAYO	RESULTADOS
1.- Índice de Peróxido (Milliequivalentes / kg de muestra original)	0,7
2.- Acidez (g / 100 g de muestra original) (Expresado como ácido oleico)	0,33

MÉTODOS UTILIZADOS EN EL LABORATORIO :
1.- NTP 209.006 1968
2.- NTP 209.005 1968

FECHA DE EJECUCIÓN DE ENSAYOS: Del 13/03/2012 Al 14/03/2012.

ADVERTENCIA :
1.- El muestreo, las condiciones de muestreo, tratamiento y transporte de la muestra hasta su ingreso a La Molina Calidad Total - Laboratorios son de responsabilidad del Solicitante.
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La Molina, 14 de Marzo de 2012

LA MOLINA CALIDAD TOTAL - LABORATORIOS
(b) (6)
M. Sc. DAVID ROLDÁN ACERO
DIRECTOR TECNICO
CIP. N° 27184

LA MOLINA CALIDAD TOTAL LABORATORIOS - Dirección Técnica

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Página Web: www.lamolina.edu.pe/calidadtotal

Informe de Ensayo Nº 77781-23

DATOS DEL CLIENTE

Solicitante	AMAZON HEALTH PRODUCTS SOCIEDAD ANONIMA CERRADA
Domicilio legal	Camino Real 1801, Mz. B, Lt. 5 (Parque Industrial San Pedrito I)
Contacto	Ing. Ricardo Diaz
Dirección de entrega	Camino Real 1801, Mz. B, Lt. 5 (Parque Industrial San Pedrito I)

DATOS DEL PRODUCTO

Producto	ACEITE DE SACHA INCHI		
Ensayos realizados en	Av. La Marina 3035 San Miguel - Lima		
Fecha de recepción	2013.08.03	Fecha de inicio de análisis	2013.08.03
Referencia	Correo 02.08.2013,77560-01	Fecha de término de análisis	2013.08.12
Procedencia	Muestra proporcionada por el Cliente		
Validez del documento	30 días	Custodia dirimencia	Muestra no sujeta a dirimencia por su perecibilidad y/o muestra única

DATOS DE LA MUESTRA: M - 118905

Identificación	Cantidad	Descripción / Presentación	Precinto	FV	FP
SIAEV 12075	250ml aprox.	Frasco de vidrio cerrado e identificado	--	--	--

DATOS DEL SERVICIO

Análisis	Unidad	Resultado
Acidez (Exp. Como acido oleico)	%	1.14

Métodos

Acidez: AOCS Official Method Ca 5a-40, Sixth edition (2009). Free Fatty Acids

INTERNATIONAL ANALYTICAL SERVICES SAC
(b) (6)
Erlma Aguinaga Mejica
Jefe de División de Laboratorios
C.I.P. Nº 29217

Lima, 13 de agosto de 2013

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PAITA-PIURA : Jr. Junin 490 Telf.: (073) 214036 - Nextel: 99 8118413 - E-mail: inassapaita@inassagroup.com.pe CHIMBOTE: Enrique Palacios 247 Of. 205/207 - Telefax: (043)-344258 - Email: inassachimbote@inassagroup.com.pe

Informe de Ensayo Nº 77781-24

DATOS DEL CLIENTE

Solicitante	AMAZON HEALTH PRODUCTS SOCIEDAD ANONIMA CERRADA
Domicilio legal	Camino Real 1801, Mz. B, Lt. 5 (Parque Industrial San Pedrito I)
Contacto	Ing. Ricardo Diaz
Dirección de entrega	Camino Real 1801, Mz. B, Lt. 5 (Parque Industrial San Pedrito I)

DATOS DEL PRODUCTO

Producto	ACEITE DE SACHA INCHI		
Ensayos realizados en	Av. La Marina 3035 San Miguel - Lima		
Fecha de recepción	2013.08.03	Fecha de inicio de análisis	2013.08.03
Referencia	Correo 02.08.2013,77560-01	Fecha de término de análisis	2013.08.12
Procedencia	Muestra proporcionada por el Cliente		
Validez del documento	30 días	Custodia dirimencia	Muestra no sujeta a dirimencia por su perecibilidad y/o muestra única

DATOS DE LA MUESTRA: M-118905

Identificación	Cantidad	Descripción / Presentación	Precinto	FV	FP
SIAEV 12075	250ml aprox.	Frasco de vidrio cerrado e identificado	--	--	--

DATOS DEL SERVICIO

Análisis	Unidad	Resultado
Valor de Peróxidos	meq de peróxido/1000 g de muestra	7.24

Métodos

Valor de Peróxidos: AOCS Official Method Cd 8b-90, Sixth Edition. (2009) Revised (2011). Peroxide Value Acetic Acid-Isooctane Method.

INTERNATIONAL ANALYTICAL SERVICES SAC

(b) (6)

Emma Aguinaga Malca
Jefe de División de Laboratorios
C.I.P. N° 29217

Lima, 13 de agosto de 2013

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Amazon Health Products

Sample 3: SIAEV 12335

LA MOLINA CALIDAD TOTAL
LABORATORIOS

Instituto de Certificación, Inspección y Ensayos

INFORME DE ENSAYOS
Nº 008239 - 2012

SOLICITANTE	: **AMAZON HEALTH PRODUCTS S.A.C.**
DIRECCIÓN LEGAL	: Calle Camino Real 1801- Interior B5 - Surco RUC: **20492997294** Teléfono: 435-3983 Fax :991887116
PRODUCTO	: **ACEITE DE SACHA INCHI**
NÚMERO DE MUESTRAS	: Uno
IDENTIFICACIÓN/MTRA.	: SIAEV 12335
CANTIDAD RECIBIDA	: 500 g (+ envase) de muestra proporcionada por el solicitante.
MARCA(S)	: S.M.
FORMA DE PRESENTACIÓN	: Envasado, la muestra ingresa en frasco cerrado con 250 ml aprox.
SOLICITUD DE SERVICIO	: S/S NºEN-004732 -2012
REFERENCIA	: Aceptación telefónica
FECHA DE RECEPCIÓN	: 27/11/2012
ENSAYOS SOLICITADOS	: **FÍSICO/QUÍMICO**
PERÍODO DE CUSTODIA	: No aplica.

RESULTADOS :

ENSAYOS FÍSICOS/QUÍMICOS :

ENSAYO	RESULTADOS
1.- Índice de Peróxido (Miliequivalentes / kg de muestra original)	0,0
2.- Acidez (g / 100 g de muestra original) (Expresado como ácido oleico)	0,21

MÉTODOS UTILIZADOS EN EL LABORATORIO :

1.- NTP 209.006 1968
2.- NTP 209.005 1968

FECHA DE EJECUCION DE ENSAYOS: Del 27/11/2012 Al 29/11/2012.

ADVERTENCIA :

1.- El muestreo, las condiciones de muestreo, tratamiento y transporte de la muestra hasta su ingreso a La Molina Calidad Total - Laboratorios son de responsabilidad del Solicitante.

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La Molina, 29 de Noviembre de 2012

LA MOLINA CALIDAD TOTAL LABORATORIOS Dirección Técnica

LA MOLINA CALIDAD TOTAL LABORATORIOS
(b) (6)
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Página Web: www.lamolina.edu.pe/calidadtotal

Informe de Ensayo Nº 81679-07

DATOS DEL CLIENTE

Solicitante	AMAZON HEALTH PRODUCTS SOCIEDAD ANONIMA CERRADA
Domicilio legal	Camino Real 1801 Mz. B, Lt. 5 (parque industrial San Pedrito I)
Contacto	Ing. Ricardo Diaz
Dirección de entrega	Camino Real 1801 Mz. B, Lt. 5 (parque industrial San Pedrito I)

DATOS DEL PRODUCTO

Producto	ACEITE DE SACHA INCHI		
Ensayos realizados en	Av. La Marina 3035 San Miguel - Lima		
Fecha de recepción	2013.12.19	Fecha de inicio de análisis	2013.12.19
Referencia	Env. de Muestra 19.12.2013	Fecha de término de análisis	2013.12.27
Procedencia	Muestra proporcionada por el Cliente		
Validez del documento	30 días	Custodia dirimencia	Muestra no sujeta a dirimencia por su perecibilidad y/o muestra única.

DATOS DE LA MUESTRA:M - 124439

Identificación	Cantidad	Descripción / Presentación	Precinto	FV	FP
SIAEV 12335	250mL aprox.	01 Frasco de vidrio ambar cerrado e identificado	--	--	--

DATOS DEL SERVICIO

Identificación	Análisis	Unidad	Resultado
SIAEV 12335	Acidez (Exp. Como acido oleico)	%	0.17

Métodos

Acidez: AOCS Official Method Ca 5a-40, 6th. Edition 2009. Free Fatty Acids

INTERNATIONAL ANALYTICAL SERVICES SAC

Emma Aguinaga Malca
Jefe de División de Laboratorios
C.I.P. Nº 29217

Lima, 27 de diciembre de 2013

Forma: L-012/13 ava Ed.

pág. 1 de 1

Informe de Ensayo Nº 81679-08

DATOS DEL CLIENTE

Solicitante	AMAZON HEALTH PRODUCTS SOCIEDAD ANONIMA CERRADA
Domicilio legal	Camino Real 1801 Mz. B, Lt. 5 (parque industrial San Pedrito I)
Contacto	Ing. Ricardo Diaz
Dirección de entrega	Camino Real 1801 Mz. B, Lt. 5 (parque industrial San Pedrito I)

DATOS DEL PRODUCTO

Producto	ACEITE DE SACHA INCHI		
Ensayos realizados en	Av. La Marina 3035 San Miguel - Lima		
Fecha de recepción	2013.12.19	Fecha de inicio de análisis	2013.12.19
Referencia	Env. de Muestra 19.12.2013	Fecha de término de análisis	2013.12.27
Procedencia	Muestra proporcionada por el Cliente		
Validez del documento	30 días	Custodia dirimencia	Muestra no sujeta a dirimencia por su perecibilidad y/o muestra única.

DATOS DE LA MUESTRA:M - 124439

Identificación	Cantidad	Descripción / Presentación	Precinto	FV	FP
SIAEV 12335	250mL aprox.	01 Frasco de vidrio ambar cerrado e identificado	--	--	--

DATOS DEL SERVICIO

Identificación	Análisis	Unidad	Resultado
SIAEV 12335	Valor de Peróxidos	meq/1000g de muestra	3.15

Método

Valor de Peróxidos: AOCS Official Method Cd 8b-90, 6th. Edition. 2009. Revised 2011. Peroxide Value Acetic Acid-Isooctane Method.

INTERNATIONAL ANALYTICAL SERVICES SAC

Emma Aguinaga Malca
Jefe de División de Laboratorios
C.I.P. Nº 29217
Lima, 27 de diciembre de 2013

Forma: L-012/13 ava Ed.

pág. 1 de 1

OSHO

(2 samples)

OSHO

Sample 1: LP14

CERPER
CERTIFICACIONES DEL PERU S.A.

INFORME DE ENSAYO N° 3-11973/13

Solicitante	: **AGROINDUSTRIAS OSHO S.A.C.**
Domicilio Legal	: Calle Manuel Arispe Nº 210 Z.I. Urb. Industrial La Chalaca - Callao - Callao - Callao
Producto Declarado	: **ACEITE DE SACHA INCHI**
Cantidad recibida	: 01 muestra x 100 mL. **Muestra proporcionada por el solicitante**
Forma de Presentación	: En frasco de vidrio, sellada y conservada a temperatura ambiente.
Identificación de las muestras	: **LOTE: LP14** **FECHA PROD: 18/11/2011**
Fecha de Recepción	: 2013 – 12 – 26
Fecha de Inicio del ensayo	: 2013 – 12 – 29
Fecha de Término del ensayo	: 2013 – 12 – 29
Ensayo realizado en	: Laboratorio de Fisico Química
Identificado con	: **H/S 13017622 (20321)**
Validez del documento	: Este documento es válido solo para la muestra descrita.

Ensayo	Resultado
Acidez (Exp. en g de acido oleico/100g)	0,38
Índice de Peróxido (meq/kg)	4,90

Método:
Acidez: ISO – 660. 2009. Animal and vegetable fats and oils. Determination of acid value and acidity.
Índice de Peróxido: ISO 3960.2007. Animal and vegetable fats and Oil.-Determination of peroxide value.

OBSERVACIONES

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Callao, 06 de Enero del 2014.
LO

CERTIFICACIONES DEL PERU S.A.
(b) (6)
QCO. YERRY MORALES BERROCAL
C.Q.P. N° 845
SUPERVISOR DE LAB. AMBIENTAL

"EL USO INDEBIDO DE ESTE INORME DE ENSAYO CONSTITUYE DELITO SANCIONADO CONFORME A LA LEY, POR LA AUTORIDAD COMPETENTE"

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OSHO

Sample 2: LP15

CERPER
CERTIFICACIONES DEL PERU S.A.

INFORME DE ENSAYO N° 3-11974/13

Solicitante	: **AGROINDUSTRIAS OSHO S.A.C.**
Domicilio Legal	: Calle Manuel Arispe Nº 210 Z.I. Urb. Industrial La Chalaca - Callao - Callao - Callao
Producto Declarado	: **ACEITE DE SACHA INCHI**
Cantidad recibida	: 01 muestra x 100 mL. **Muestra proporcionada por el solicitante**
Forma de Presentación	: En frasco de vidrio, sellada y conservada a temperatura ambiente.
Identificación de las muestras	: **LOTE: LP15** **FECHA PROD: 27/01/2012**
Fecha de Recepción	: 2013 – 12 – 26
Fecha de Inicio del ensayo	: 2013 – 12 – 29
Fecha de Término del ensayo	: 2013 – 12 – 29
Ensayo realizado en	: Laboratorio de Fisico Química
Identificado con	: **H/S 13017622 (20321)**
Validez del documento	: Este documento es válido solo para la muestra descrita.

Ensayo	Resultado
Acidez (Exp. en g de acido oleico/100g)	0,65
Índice de Peróxido (meq/kg)	3,65

Método:
Acidez: ISO – 660. 2009. Animal and vegetable fats and oils. Determination of acid value and acidity.
Índice de Peróxido: ISO 3960.2007. Animal and vegetable fats and Oil.-Determination of peroxide value.

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Callao, 06 de Enero del 2014.
LO

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"EL USO INDEBIDO DE ESTE INFORME DE ENSAYO CONSTITUYE DELITO SANCIONADO CONFORME A LA LEY POR LA AUTORIDAD COMPETENTE"

Estimation of Shelf Life of Sacha Inchi Oil

(Technical Report)

Agriculture National University La Molina

Faculty of Food Industry

Study: estimation of shelf life of Sacha Inchi Oil

Done by: Eng. Liliana Castillo

Eng. Walter Salas

Product: Sacha Inchi Oil Extra Virgin

La Molina

Technical Report

1. Introduction

   The stability of oil as well as any other food product is influenced by its quality which depends directly from the raw matter, production process and the condition of storage of the final product.

   The useful life of a food product is a very important factor for the determination of the appropriate storage conditions. Using the accelerated tests the time that a food is kept stable can be estimated using a short test time.

2. Description of experimental scheme.

   To make the present technical report the data from physicochemical analysis (provided by the client) of sacha inchi oil sample stored at different temperatures 40, 50, 60 C for a period of 570 hours was used.

   After a technical evaluation of these results, the indexes of peroxide during the first 96 hours for each of the temperature evaluated were used.

   Table 01 shows the results of the oil evaluation.

   Table 01. Results of the indexes of peroxide (meq O_2/kg) of sacha inchi oil.

Time (hrs)	Temperatures		
	40°C	50°C	60°C
0	0.67	0.67	0.67
7	0.6	0.66	1.34
24	1.07	2.95	3.59
31	1.5	3.54	3.56
48	3.76	3.68	3.59
55	3.86	3.86	3.88
72	4.06	4.07	4.07
79	4.22	4.18	4.05
96	4.8	4.21	3.99
103	4.36	4.28	3.99

Fig 1. Indexes of peroxide vs. time (hours)

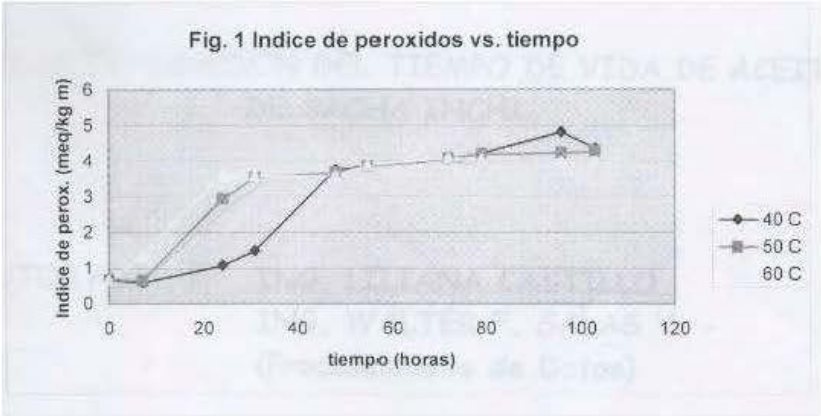


Fig.2 Relationship between time and LN(IP) at 40 C

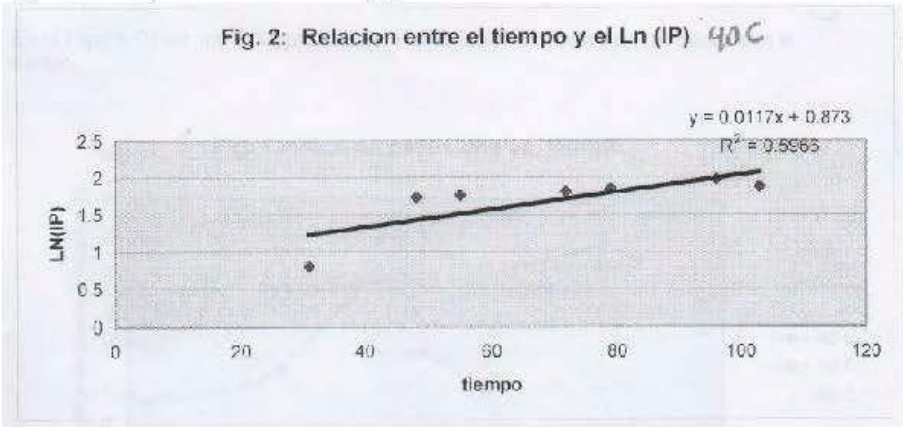


Fig.3 Relationship between time and LN(IP) at 50 C

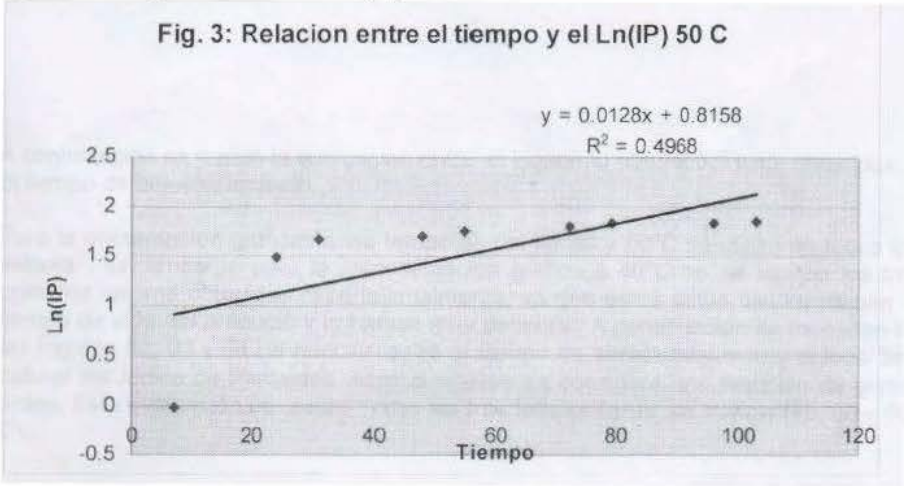


Fig. 4 Relationship between time and Ln(IP) at 60 C

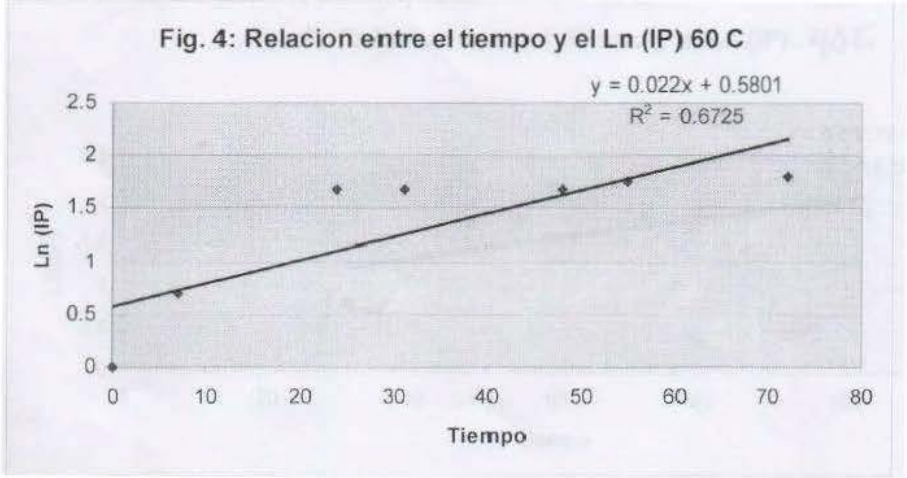


Table 2. Value of constant of reaction K with temperature

Cuadro 2: Valores de la constante de reacción K con la temperatura

K (1/hora)	Temperatura
0.0117	40
0.0128	50
0.0220	60

Fig. 5 Relationship between 1/T vs value of K

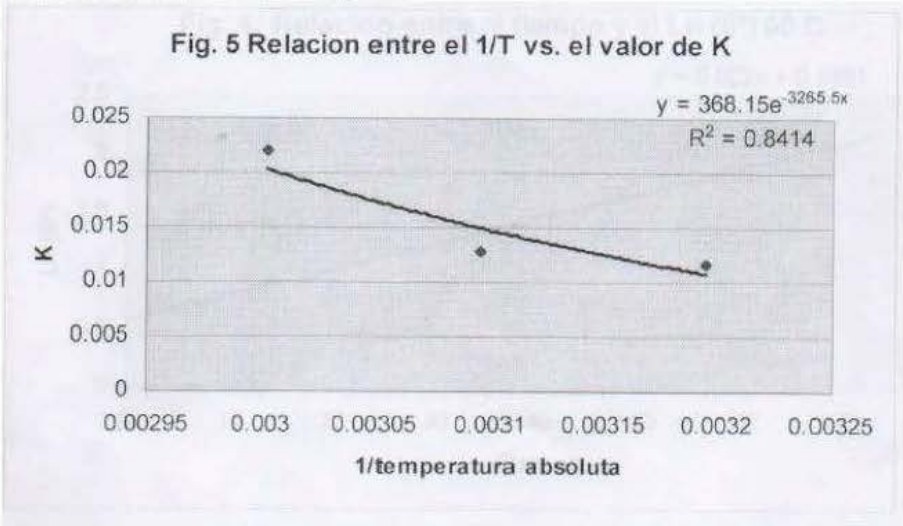
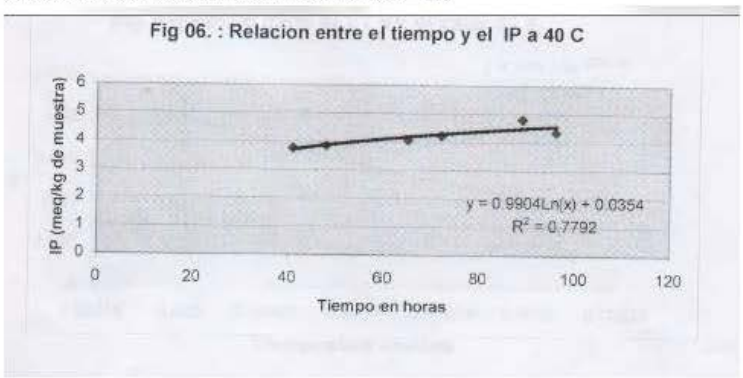


Fig. 06. Relationship between time and IP at 40 C



(Vertical axis: IP (meq/kg of sample)); (horizontal axis: time in hours)

The results from Fig. 06 showed an equation which fixes the points relatively good.
IP = 0.9904*Ln(time)+0.034
Therefore the time for a value of IP of 10 meq/kg of sample will be two years and 8 months is stored at 40 C.
For the case when temperature is 20 C, it can be said that the useful time will be longer but can not be calculated with precision.

Appendix C. Food Safety Authority of Ireland Opinion of Substantial Equivalence

Food Safety
AUTHORITY OF IRELAND

SUBSTANTIAL EQUIVALENCE OPINION

Inca Inchi Virgin Oil

SUMMARY

The Food Safety Authority of Ireland (FSAI) received an application in May of 2012 from Perles de Gascogne Sarl (France) and Agroindustrias Amazonicas (Peru) for an opinion on the substantial equivalence of vegetable oil derived from the seeds of *Plukenetia volubilis linneo* (Inca Inchi virgin oil) to a vegetable oil similarly extracted from the seeds of *Linum usitatissimum linneo* (flaxseed or linseed oil). Having reviewed the information provided, along with subsequent clarifications from the applicant, the FSAI is satisfied that the novel ingredient is substantially equivalent to linseed oil in terms of composition, nutritional value, metabolism, intended use and the level of undesirable substances as set out in *Article 3.4* of the novel food Regulation EC No 258/97.

Introduction

Inca Inchi virgin oil is a vegetable oil mechanically derived from the seeds of *Plukenetia volubilis linneo* in a process similar to that for virgin linseed oil (*Linum usitatissimum linneo*), and does not involve any refinement. The applicant considers the ingredient to be novel and fall within the category of "foods and food ingredients consisting of or isolated from plants and food 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", as set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97.

Composition

The applicant provided data on the composition of Inca Inchi virgin oil which is 100% vegetable oil with no protein or carbohydrate present, and with general characteristics conforming to Codex standards for edible oils. The composition of the novel ingredient compares favourably with that of linseed oil based on data which was obtained by the applicant from French sources. The characteristics for both virgin oils are very similar in terms of visual perception, taste, flavour and odour. Both ingredients are also compositionally equivalent in terms of water and volatiles, impurities insoluble in hexane and trans-fatty acid content. Both oils are predominantly made up of polyunsaturated fatty acids (>90%) and to a lesser extent saturated fatty acids (<10%) and very low levels of trans-fatty acids (<0.5%). The total phytosterol and triglyceride content in both ingredients are also very similar. Inca Inchi virgin oil has higher levels of total tocopherols than linseed oil which the applicant notes can help to maintain oxidative stability.

Production of the novel ingredient

The novel ingredient is produced by standard procedures used in the production of virgin vegetable oils, including linseed oil, and the quality is controlled by Codex and GPP standards. Dehulled seeds of non-GM *Plukenetia volubilis linneo* are cold-pressed to release approximately 80% of the available seed oil. The crude oil is clarified by static sedimentation and press-filtering to yield clear and transparent oil which is stored in bulk tanks under liquid nitrogen to minimise oxidative degradation.

Nutritional Value and Metabolism

Inca Inchi virgin oil possesses the same energy value as linseed oil. Both vegetable oils are a rich source of mono- and poly-unsaturated fatty acids, particularly alpha linoleic acid, with relatively low levels of saturated fatty acids. The novel ingredient is equivalent to linseed oil in terms of its content of total cholesterol and trans-fatty acids, but contains slightly higher levels of vitamin E. The applicant demonstrates that Inca Inchi oil is as stable as linseed oil, aided by the natural presence of tocopherols that serve to maintain oxidative stability. The compositional and nutritional similarity of the novel ingredient to linseed oil suggests that its metabolism will be equivalent. However, the applicant provides some evidence that digestibility and bioavailability of the novel ingredient are equivalent to those for linseed oil.

Intended Uses

The applicant intends placing the novel ingredient on the EU market in the same food categories and at the same use levels at which linseed oil is currently marketed. This will include its use as a dressing, for example on salads, and its incorporation into a range of foods and food supplements.

Level of Undesirable Substances

The applicant provides data which demonstrates that levels of heavy metals, pesticides, dioxins, PAHs or microbiological contaminants are within regulatory or guideline limits. Erucic acid is not present while allergenicity is not a concern since protein is not detectable in the novel ingredient.

Conclusions

The FSAI is satisfied that the information provided by the applicant, along with subsequent clarifications, demonstrates that Inca Inchi virgin oil is substantially equivalent to linseed oil in terms of its composition, nutritional value, metabolism, intended use and level of undesirable substances. Linseed oil has a history of safe consumption within the EU and the novel ingredient (Inca Inchi virgin oil) would be subject to the same conditions of general and specific legislation governing the marketing and use of vegetable oils in the EU.

Appendix D. NHANES 2005-2010 Foods Codes Representative of Use of Sacha Inchi Oil in Food

Baked goods and baking mixes

41435110	High protein bar, candy-like, soy and milk base
41435120	Zone Perfect Classic Crunch nutrition bar
41435300	Balance Original Bar
41435500	Clif Bar
41435700	South Beach Living High Protein Cereal Bar
41435710	South Beach Living Meal Replacement Bar
53540000	Breakfast bar, NFS
53540200	Breakfast bar, cereal crust with fruit filling, lowfat
53540250	Breakfast bar, cereal crust with fruit filling, fat free
53540300	Fiber One Chewy Bar
53540400	Kellogg's Nutri-Grain Cereal Bar
53540402	Kellogg's Nutri-Grain Yogurt Bar
53540404	Kellogg's Nutri-Grain Fruit and Nut Bar
53540500	Breakfast bar, date, with yogurt coating
53540600	Milk 'n Cereal bar
53540700	Kellogg's Special K bar
53540800	Kashi GOLEAN Chewy Bars
53540802	Kashi TLC Chewy Granola Bar
53540804	Kashi GOLEAN Crunchy Bars
53540806	Kashi TLC Crunchy Granola Bar
53540900	Nature Valley Chewy Trail Mix Granola Bar
53540902	Nature Valley Chewy Granola Bar with Yogurt Coating
53540904	Nature Valley Sweet and Salty Nut Granola Bar
53540906	Nature Valley Crunchy Granola Bar
53541000	Quaker Chewy Granola Bar
53541002	Quaker Chewy 90 Calorie Granola Bar
53541004	Quaker Chewy 25% Less Sugar Granola Bar
53541006	Quaker Chewy Dipps Granola Bar
53541200	Meal replacement bar
53541300	Slim Fast Original Meal Bar
53542000	Snack bar, oatmeal
53542100	Granola bar, oats, sugar, raisins, coconut
53542200	Granola bar, oats, fruit and nuts, lowfat
53542210	Granola bar, nonfat
53543000	Granola bar, oats, reduced sugar
53543100	Granola bar, peanuts, oats, sugar, wheat germ
53544200	Granola bar, chocolate-coated

53544210	Granola bar, with coconut, chocolate-coated
53544220	Granola bar with nuts, chocolate-coated
53544230	Granola bar, oats, nuts, coated with non-chocolate coating
53544250	Granola bar, coated with non-chocolate coating
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating
53544400	Granola bar, with rice cereal
53544410	Quaker Granola Bites
53544450	PowerBar (fortified high energy bar)
91780010	Snickers Marathon Energy bar
91781010	Snickers Marathon Protein bar

Cereals

56200300	Cereal, cooked, NFS
56200350	Cereal, cooked, instant, NS as to grain
56200390	Barley, cooked, NS as to fat added in cooking
56200400	Barley, cooked, fat not added in cooking
56200500	Buckwheat groats, cooked, fat not added in cooking
56200510	Buckwheat groats, cooked, fat added in cooking
56200990	Grits, cooked, corn or hominy, NS as to regular, quick or instant, NS as to fat added in cooking
56201000	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat not added in cooking
56201010	Grits, cooked, corn or hominy, regular, fat not added in cooking
56201020	Grits, cooked, corn or hominy, regular, fat added in cooking
56201030	Grits, cooked, corn or hominy, regular, NS as to fat added in cooking
56201040	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat added in cooking
56201060	Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, NS as to fat added in cooking
56201061	Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, fat not added in cooking
56201062	Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, fat added in cooking
56201070	Grits, cooked, corn or hominy, with cheese, regular, NS as to fat added in cooking
56201071	Grits, cooked, corn or hominy, with cheese, regular, fat not added in cooking
56201072	Grits, cooked, corn or hominy, with cheese, regular, fat added in cooking
56201081	Grits, cooked, corn or hominy, with cheese, quick, fat not added in cooking
56201082	Grits, cooked, corn or hominy, with cheese, quick, fat added in cooking
56201091	Grits, cooked, corn or hominy, with cheese, instant, fat not added in cooking
56201092	Grits, cooked, corn or hominy, with cheese, instant, fat added in cooking
56201110	Grits, cooked, corn or hominy, quick, fat not added in cooking
56201120	Grits, cooked, corn or hominy, quick, fat added in cooking
56201130	Grits, cooked, corn or hominy, quick, NS as to fat added in cooking
56201210	Grits, cooked, corn or hominy, instant, fat not added in cooking
56201220	Grits, cooked, corn or hominy, instant, fat added in cooking

56201230	Grits, cooked, corn or hominy, instant, NS as to fat added in cooking
56201240	Grits, cooked, flavored, corn or hominy, instant, fat not added in cooking
56201300	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, NS as to fat added in cooking, made with milk
56201510	Cornmeal mush, made with water
56201520	Cornmeal mush, fried
56201530	Cornmeal mush, made with milk
56201540	Cornmeal, made with milk and sugar, Puerto Rican Style (Harina de maiz)
56201550	Cornmeal dumpling
56201600	Cornmeal, lime-treated, cooked (Masa harina)
56201700	Cornstarch with milk, eaten as a cereal (2 tbsp cornstarch in 2-1/2 cups milk)
56202000	Millet, cooked, fat not added in cooking
56202960	Oatmeal, cooked, NS as to regular, quick or instant; NS as to fat added in cooking
56202970	Oatmeal, cooked, quick (1 or 3 minutes), NS as to fat added in cooking
56202980	Oatmeal, cooked, regular, NS as to fat added in cooking
56203000	Oatmeal, cooked, NS as to regular, quick or instant, fat not added in cooking
56203010	Oatmeal, cooked, regular, fat not added in cooking
56203020	Oatmeal, cooked, quick (1 or 3 minutes), fat not added in cooking
56203030	Oatmeal, cooked, instant, fat not added in cooking
56203050	Oatmeal, cooked, regular, fat added in cooking
56203060	Oatmeal, cooked, quick (1 or 3 minutes), fat added in cooking
56203070	Oatmeal, cooked, instant, fat added in cooking
56203080	Oatmeal, cooked, instant, NS as to fat added in cooking
56203200	Oatmeal with fruit, cooked
56203210	Oatmeal, NS as to regular, quick, or instant, made with milk, fat not added in cooking
56203220	Oatmeal, NS as to regular, quick, or instant, made with milk, fat added in cooking
56203230	Oatmeal, NS as to regular, quick, or instant, made with milk, NS as to fat added in cooking
56203610	Oatmeal, multigrain, cooked, fat not added in cooking
56205050	Rice, cream of, cooked, fat not added in cooking
56205080	Rice, creamed, made with milk and sugar, Puerto Rican style
56205090	Rice, cream of, cooked, fat added in cooking
56206970	Wheat, cream of, cooked, quick, NS as to fat added in cooking
56206990	Wheat, cream of, cooked, NS as to regular, quick, or instant, NS as to fat added in cooking
56207000	Wheat, cream of, cooked, NS as to regular, quick, or instant, fat not added in cooking
56207010	Wheat, cream of, cooked, regular, fat not added in cooking
56207020	Wheat, cream of, cooked, quick, fat not added in cooking
56207030	Wheat, cream of, cooked, instant, fat not added in cooking
56207040	Wheat, cream of, cooked, made with milk
56207060	Wheat, cream of, cooked, instant, fat added in cooking
56207080	Wheat, cream of, cooked, NS as to regular, quick, or instant, fat added in cooking
56207110	Bulgur, cooked or canned, fat not added in cooking

56207120 Bulgur, cooked or canned, fat added in cooking
56207130 Bulgur, cooked or canned, NS as to fat added in cooking
56207150 Couscous, plain, cooked, fat not added in cooking
56207160 Couscous, plain, cooked, NS as to fat added in cooking
56207180 Couscous, plain, cooked, fat added in cooking
56207190 Whole wheat cereal, cooked, NS as to fat added in cooking
56207200 Whole wheat cereal, cooked, fat not added in cooking
56207220 Wheat, cream of, cooked, regular, fat added in cooking
56207230 Wheat, cream of, cooked, quick, fat added in cooking
56207300 Whole wheat cereal, wheat and barley, cooked, fat not added in cooking
56207330 Whole wheat cereal, wheat and barley, cooked, fat added in cooking
56207360 Wheat cereal, chocolate flavored, cooked, fat not added in cooking
56207370 Wheat cereal, chocolate flavored, cooked, NS as to fat added in cooking
56208500 Oat bran cereal, cooked, fat not added in cooking
56208510 Oat bran cereal, cooked, fat added in cooking
56208520 Oat bran cereal, cooked, NS as to fat added in cooking
56208530 Oat bran cereal, cooked, made with milk, fat not added in cooking
56210000 Nestum cereal
57000000 Cereal, NFS
57000050 Kashi cereal, NS as to ready to eat or cooked
57000100 Oat cereal, NFS
57100100 Cereal, ready-to-eat, NFS
57100400 Character cereals, TV or movie, General Mills
57100500 Character cereals, TV or movie, Kelloggs
57101000 All-Bran
57101020 All-Bran with Extra Fiber
57102000 Alpen
57103000 Alpha-Bits
57103050 Amaranth Flakes
57103100 Apple Cinnamon Cheerios
57103500 Apple Cinnamon Squares Mini-Wheats, Kellogg's (formerly Apple Cinnamon Squares)
57104000 Apple Jacks
57106050 Banana Nut Crunch Cereal (Post)
57106100 Basic 4
57106250 Berry Berry Kix
57106260 Berry Burst Cheerios
57106530 Blueberry Morning, Post
57107000 Booberry
57110000 All-Bran Bran Buds, Kellogg's (formerly Bran Buds)
57111000 Bran Chex
57117000 Cap'n Crunch

57117500 Cap'n Crunch's Christmas Crunch
57119000 Cap'n Crunch's Crunch Berries
57120000 Cap'n Crunch's Peanut Butter Crunch
57123000 Cheerios
57124000 Chex cereal, NFS
57124200 Chocolate flavored frosted puffed corn cereal
57124300 Chocolate Lucky Charms
57124500 Cinnamon Grahams, General Mills
57125000 Cinnamon Toast Crunch
57125010 Cinnamon Toast Crunch Reduced Sugar
57125900 Honey Nut Clusters (formerly called Clusters)
57126000 Cocoa Krispies
57126500 Cocoa Blasts, Quaker
57127000 Cocoa Pebbles
57128000 Cocoa Puffs
57128880 Complete Oat Bran Flakes, Kellogg's (formerly Common Sense Oat Bran, plain)
57130000 Cookie-Crisp
57131000 Crunchy Corn Bran, Quaker
57132000 Corn Chex
57134000 Corn flakes, NFS
57135000 Corn flakes, Kellogg
57137000 Corn Puffs
57138000 Total Corn Flakes
57139000 Count Chocula
57143000 Cracklin' Oat Bran
57143500 Cranberry Almond Crunch, Post
57144000 Crisp Crunch
57148000 Crispix
57148500 Crispy Brown Rice Cereal
57151000 Crispy Rice
57152000 Crispy Wheats'n Raisins
57160000 Curves Fruit and Nut Crunch Cereal
57201800 Disney cereals, Kellogg's
57201900 Dora the Explorer Cereal
57206000 Familia
57206700 Fiber One
57206800 Fiber 7 Flakes, Health Valley
57207000 Bran Flakes, NFS (formerly 40% Bran Flakes, NFS)
57208000 Complete Wheat Bran Flakes, Kellogg's (formerly 40% Bran Flakes)
57209000 Natural Bran Flakes, Post (formerly called 40% Bran Flakes, Post)
57211000 Frankenberry

57212100 French Toast Crunch, General Mills
57213000 Froot Loops
57213005 Froot Loops Cereal Straws
57213850 Frosted Cheerios
57214000 Frosted Mini-Wheats
57214100 Frosted Wheat Bites
57215000 Frosty O's
57218000 Frosted Rice Krispies
57219000 Fruit & Fibre (fiber), NFS
57221000 Fruit & Fibre (fiber) with dates, raisins, and walnuts
57221650 Fruit Harvest cereal, Kellogg's
57221700 Fruit Rings, NFS
57221810 Fruity Cheerios
57223000 Fruity Pebbles
57224000 Golden Grahams
57227000 Granola, NFS
57228000 Granola, homemade
57229000 Granola, lowfat, Kellogg's
57229500 Granola with Raisins, lowfat, Kellogg's
57230000 Grape-Nuts
57231000 Grape-Nut Flakes
57231200 Great Grains, Raisin, Date, and Pecan Whole Grain Cereal, Post
57231250 Great Grains Double Pecan Whole Grain Cereal, Post
57232100 Healthy Choice Almond Crunch with raisins, Kellogg's
57237100 Honey Bunches of Oats
57237200 Honey Bunches of Oats with Vanilla Clusters, Post
57237300 Honey Bunches of Oats with Almonds, Post
57238000 Honeycomb, plain
57239000 Honeycomb, strawberry
57239100 Honey Crunch Corn Flakes, Kellogg's
57240100 Honey Nut Chex
57241000 Honey Nut Cheerios
57241200 Honey Nut Shredded Wheat, Post
57243000 Smacks, Kellogg's (formerly Honey Smacks)
57245000 Just Right Fruit and Nut (formerly Just Right with raisins, dates, and nuts)
57301100 Kaboom
57301500 Kashi, Puffed
57301505 Kashi Autumn Wheat
57301510 Kashi GoLean
57301511 Kashi GoLean Crunch
57301512 Kashi GOLEAN Crunch Honey Almond Flax

57301520 Kashi Good Friends
57301530 Kashi Heart to Heart
57302100 King Vitaman
57303100 Kix
57304100 Life (plain and cinnamon)
57305100 Lucky Charms
57305150 Frosted oat cereal with marshmallows
57305170 Malt-O-Meal Coco-Roos
57305180 Malt-O-Meal Corn Bursts
57305210 Malt-O-Meal Frosted Flakes
57305300 Malt-O-Meal Fruity Dyno-Bites
57305500 Malt-O-Meal Honey and Nut Toasty O's
57305600 Malt-O-Meal Marshmallow Mateys
57306100 Malt-O-Meal Puffed Rice
57306120 Malt-O-Meal Puffed Wheat
57306500 Malt-O-Meal Golden Puffs (formerly Sugar Puffs)
57306700 Malt-O-Meal Toasted Oat Cereal
57306800 Malt-O-meal Tootie Fruities
57307010 Maple Pecan Crunch Cereal, Post
57307150 Marshmallow Safari, Quaker
57307500 Millet, puffed
57307600 Mini-Swirlz Cinnamon Bun Cereal, Kellogg's
57308150 Mueslix cereal, NFS
57308190 Muesli with raisins, dates, and almonds
57308300 Multi Bran Chex
57308400 Multi Grain Cheerios
57309100 Nature Valley Granola, with fruit and nuts
57316200 Nutty Nuggets, Ralston Purina
57316300 Oat Bran Flakes, Health Valley
57316410 Apple Cinnamon Oatmeal Crisp (formerly Oatmeal Crisp with Apples)
57316450 Oatmeal Crisp with Almonds
57316500 Oatmeal Raisin Crisp
57316710 Oh's, Honey Graham
57316750 Oh's, Fruitangy, Quaker
57318000 100% Bran
57319000 100% Natural Cereal, plain, Quaker
57319500 Sun Country 100% Natural Granola, with Almonds
57320500 100 % Natural Cereal, with oats, honey and raisins, Quaker
57321500 100 % Natural Wholegrain Cereal with raisins, lowfat, Quaker
57321700 Optimum, Nature's Path
57321800 Optimum Slim, Nature's Path

57322500 Oreo O's cereal, Post
57323000 Sweet Crunch, Quaker (formerly called Popeye)
57323050 Sweet Puffs, Quaker
57324000 Peanut Butter Toast Crunch, General Mills
57325000 Product 19
57327450 Quaker Oat Bran Cereal
57327500 Quaker Oatmeal Squares (formerly Quaker Oat Squares)
57329000 Raisin bran, NFS
57330000 Raisin Bran, Kellogg
57330010 Raisin Bran Crunch, Kellogg's
57331000 Raisin Bran, Post
57332050 Raisin Bran, Total
57332100 Raisin Nut Bran
57335550 Reese's Peanut Butter Puffs cereal
57336000 Rice Chex
57337000 Rice Flakes, NFS
57339000 Rice Krispies
57339100 Rice Krispies with Real Strawberries, Kellogg's
57339500 Rice Krispies Treats Cereal (Kellogg's)
57340000 Rice, puffed
57340700 Scooby Doo Cinnamon Marshmallow Cereal, Kellogg's
57341000 Shredded Wheat'N Bran
57341200 Smart Start, Kellogg's
57342010 Smorz, Kellogg's
57344000 Special K
57344005 Special K Chocolatey Delight
57344010 Special K Red Berries
57344015 Special K Fruit & Yogurt
57344020 Special K Vanilla Almond
57344025 Special K Cinnamon Pecan, Kellogg's
57346500 Oatmeal Honey Nut Heaven, Quaker (formerly Toasted Oatmeal, Honey Nut)
57347000 Corn Pops
57347500 Strawberry Squares Mini-Wheats, Kellogg's (formerly Strawberry Squares)
57348000 Frosted corn flakes, NFS
57349000 Frosted Flakes, Kellogg
57349020 Reduced Sugar Frosted Flakes Cereal, Kellogg's
57355000 Golden Crisp (Formerly called Super Golden Crisp)
57401100 Toasted oat cereal
57403100 Toasties, Post
57404100 Malt-O-Meal Toasty O's
57404200 Malt-O-Meal Apple and Cinnamon Toasty O's

57406100 Total
57406105 Total Cranberry Crunch
57407100 Trix
57407110 Trix, reduced sugar
57408100 Uncle Sam's Hi Fiber Cereal
57409100 Waffle Crisp, Post
57410000 Weetabix Whole Wheat Cereal
57411000 Wheat Chex
57412000 Wheat germ, plain
57416000 Wheat, puffed, plain
57416010 Wheat, puffed, presweetened with sugar
57417000 Shredded Wheat, 100%
57418000 Wheaties
57419000 Yogurt Burst Cheerios
75217490 Hominy, cooked, NS as to fat added in cooking
75217500 Hominy, cooked, fat not added in cooking
75217520 Hominy, cooked, fat added in cooking

Condiments and relishes

41205070 Hummus
63307010 Cranberry-orange relish, uncooked
74405010 Tomato relish
75412030 Eggplant dip
75501010 Corn relish
75503020 Cucumber pickles, relish
75515010 Vegetable relish

Fats and oils - Butter spreads (margarine-type)

81103040 Margarine-like spread, stick, salted
81103041 Margarine-like spread, made with yogurt, stick, salted
81103080 Margarine-like spread, tub, salted
81103090 Margarine-like spread, liquid, salted
81103100 Margarine-like spread, stick, unsalted
81103120 Margarine-like spread, tub, unsalted
81103130 Margarine-like spread, whipped, tub, salted
81103140 Margarine-like spread, tub, sweetened
81104010 Margarine-like spread, reduced calorie, about 40% fat, tub, salted
81104011 Margarine-like spread, reduced calorie, about 40% fat, made with yogurt, tub, salted
81104020 Margarine-like spread, reduced calorie, about 40% fat, stick, salted
81104050 Margarine-like spread, reduced calorie, about 20% fat, tub, salted
81104070 Margarine-like spread, reduced calorie, about 20% fat, tub, unsalted
81104100 Margarine-like spread, fat free, tub, salted
81104110 Margarine-like spread, fat free, liquid, salted

81104510	Vegetable oil-butter spread, tub, salted
81104550	Vegetable oil-butter spread, reduced calorie, stick, salted
81104560	Vegetable oil-butter spread, reduced calorie, tub, salted

Fats and oils - Salad dressing

12350100	Spinach dip, sour cream base*
14620100	Dip, cream cheese base*
14620120	Shrimp dip, cream cheese base*
14640000	Cheese sandwich*
27250040	Crab cake*
27416250	Beef salad*
27420020	Ham or pork salad*
27446200	Chicken or turkey salad*
27446205	Chicken or turkey salad with nuts and/or fruits*
27446220	Chicken or turkey salad with egg*
27450010	Crab salad*
27450020	Lobster salad*
27450030	Salmon salad*
27450060	Tuna salad*
27450070	Shrimp salad*
27450080	Seafood salad*
27450090	Tuna salad with cheese*
27450100	Tuna salad with egg*
27450130	Crab salad made with imitation crab*
27500050	Sandwich, NFS*
27510220	Cheeseburger, with mayonnaise or salad dressing, on bun*
27510230	Cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510250	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun*
27510280	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on bun*
27510340	Double cheeseburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
27510350	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510355	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, tomato and/or catsup on bun*
27510370	Double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510380	Triple cheeseburger (3 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes, on bun*
27510425	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510430	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes, on bun*
27510435	Double bacon cheeseburger (2 patties,1/3 lb meat each), with mayonnaise or salad dressing, on bun*
27510440	Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510520	Hamburger, with mayonnaise or salad dressing and tomatoes, on bun*

27510550	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on double-decker bun*
27510560	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510590	Hamburger, with mayonnaise or salad dressing, on bun*
27510670	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
27510690	Double hamburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on double-decker bun*
27510950	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread*
27513040	Roast beef submarine sandwich, with lettuce, tomato and spread*
27513041	Roast beef submarine sandwich, with cheese, lettuce, tomato and spread*
27520130	Bacon, chicken, and tomato club sandwich, with lettuce and spread*
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread*
27520150	Bacon, lettuce, and tomato sandwich with spread*
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread*
27520165	Bacon, chicken fillet (breaded, fried), and tomato club with lettuce and spread*
27520166	Bacon, chicken fillet (breaded, fried), and tomato club sandwich with cheese, lettuce and spread*
27520300	Ham sandwich, with spread*
27520310	Ham sandwich with lettuce and spread*
27520320	Ham and cheese sandwich, with lettuce and spread*
27520350	Ham and cheese sandwich, with spread, grilled*
27520360	Ham and cheese sandwich, on bun, with lettuce and spread*
27520370	Hot ham and cheese sandwich, on bun*
27520390	Ham and cheese submarine sandwich, on multigrain roll, with lettuce, tomato and spread*
27540110	Chicken sandwich, with spread*
27540120	Chicken salad or chicken spread sandwich*
27540150	Chicken fillet (breaded, fried) sandwich with lettuce, tomato and spread*
27540170	Chicken patty sandwich, miniature, with spread*
27540190	Chicken patty sandwich, with lettuce and spread*
27540210	Wrap sandwich filled with chicken strips (breaded, fried), cheese, lettuce, and spread*
27540230	Chicken patty sandwich with cheese, on wheat bun, with lettuce, tomato and spread*
27540240	Chicken fillet, (broiled), sandwich, on whole wheat roll, with lettuce, tomato and spread*
27540260	Chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread*
27540290	Chicken submarine sandwich, with lettuce, tomato, and spread*
27540291	Chicken submarine sandwich, with cheese, lettuce, tomato, and spread*
27540300	Wrap sandwich filled with chicken strips (broiled), cheese, lettuce, and spread*
27540310	Turkey sandwich, with spread*
27540350	Turkey submarine sandwich, with cheese, lettuce, tomato and spread*
27541000	Turkey, ham, and roast beef club sandwich*
27541001	Turkey, ham, and roast beef club sandwich with cheese, lettuce, tomato, and spread*
27550720	Tuna salad sandwich*
27550750	Tuna salad submarine sandwich, with lettuce and tomato*

27550751	Tuna salad submarine sandwich, with cheese, lettuce and tomato*
27560110	Bologna sandwich, with spread*
27560510	Salami sandwich, with spread*
27560910	Submarine, cold cut sandwich, with lettuce and tomato*
32102000	Egg, deviled*
32103000	Egg salad*
58127500	Vegetable submarine sandwich*
58134640	Tortellini, cheese-filled, meatless, with vinaigrette dressing*
58148110	Macaroni or pasta salad*
58148120	Macaroni or pasta salad with egg*
58148130	Macaroni or pasta salad with tuna*
58148140	Macaroni or pasta salad with crab meat*
58148150	Macaroni or pasta salad with shrimp*
58148160	Macaroni or pasta salad with tuna and egg*
58148170	Macaroni or pasta salad with chicken*
58148180	Macaroni or pasta salad with cheese*
58148500	Pasta or macaroni salad with oil and vinegar-type dressing*
58148550	Pasta or macaroni salad with meat*
63401010	Apple salad with dressing*
63401020	Apple and cabbage salad with dressing*
63402950	Fruit salad (excluding citrus fruits) with salad dressing or mayonnaise*
63403010	Fruit salad (including citrus fruits) with salad dressing or mayonnaise*
63412010	Pear salad with dressing*
63413010	Pineapple salad with dressing*
71601010	Potato salad with egg*
71603010	Potato salad*
73101110	Carrots, raw, salad*
73101210	Carrots, raw, salad with apples*
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing*
75141000	Cabbage salad or coleslaw, with dressing*
75141100	Cabbage salad or coleslaw with apples and/or raisins, with dressing*
75141200	Cabbage salad or coleslaw with pineapple, with dressing*
75145000	Seven-layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise, cheese, eggs, and/or bacon)*
75302080	Bean salad, yellow and/or green string beans*
75416500	Pea salad*
75416600	Pea salad with cheese*
83100100	Salad dressing, NFS
83100200	Salad dressing, NFS, for sandwiches
83101000	Blue or roquefort cheese dressing
83101500	Bacon dressing (hot)

83101600	Bacon and tomato dressing
83102000	Caesar dressing
83103000	Coleslaw dressing
83103500	Feta Cheese Dressing
83104000	French dressing
83105000	Fruit dressing, made with fruit juice and cream
83105100	Fruit dressing, made with honey, oil, and water
83105500	Honey mustard dressing
83106000	Italian dressing, made with vinegar and oil
83107000	Mayonnaise, regular
83107200	Mayonnaise, made with tofu
83108000	Mayonnaise, imitation
83108100	Mayonnaise, imitation, cholesterol free
83109000	Russian dressing
83110000	Mayonnaise-type salad dressing
83110010	Mayonnaise-type salad dressing, cholesterol-free
83112000	Green Goddess dressing
83112500	Creamy dressing, made with sour cream and/or buttermilk and oil
83112600	Cream cheese dressing
83112900	Milk, vinegar, and sugar dressing
83112950	Poppy seed dressing
83112960	Peppercorn Dressing
83112980	Celery seed dressing
83112990	Sesame dressing
83113000	Sweet and sour dressing
83114000	Thousand Island dressing
83115000	Yogurt dressing
83200100	Salad dressing, low-calorie, NFS
83201000	Blue or roquefort cheese dressing, low-calorie
83201050	Blue or roquefort cheese dressing, reduced calorie
83201200	Blue or roquefort cheese dressing, reduced calorie, fat-free, cholesterol-free
83202000	French dressing, low-calorie
83202010	French dressing, reduced calorie, fat-free, cholesterol-free
83202020	French dressing, reduced calorie
83203000	Caesar dressing, low-calorie
83203250	Mayonnaise-type salad dressing, fat-free
83204000	Mayonnaise, low-calorie or diet
83204020	Mayonnaise, reduced calorie or diet, cholesterol-free
83204050	Mayonnaise-type salad dressing, low-calorie or diet
83204060	Mayonnaise-type salad dressing, low-calorie or diet, cholesterol-free
83204500	Honey mustard dressing, reduced calorie

83205000	Italian dressing, low calorie
83205450	Italian dressing, reduced calorie
83205500	Italian dressing, reduced calorie, fat-free
83206000	Russian dressing, low-calorie
83207000	Thousand Island dressing, low-calorie
83207100	Thousand Island dressing, reduced calorie, fat-free, cholesterol-free
83208000	Vinegar, sugar, and water dressing
83208500	Korean dressing or marinade
83210000	Creamy dressing, made with sour cream and/or buttermilk and oil, diet, NS as to low or reduced calorie
83210050	Creamy dressing made with sour cream and/or buttermilk and oil, low calorie
83210100	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie
83210200	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, fat-free, cholesterol-free
83210250	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, cholesterol-free
83220000	Salad dressing, low calorie, oil-free
91511070	Gelatin dessert, dietetic, with fruit and sour cream, sweetened with low calorie sweetener*

Fats and oils - Salad oil

72116140	Caesar salad (with romaine)*
74506000	Tomato and cucumber salad made with tomato, cucumber, oil, and vinegar*
75142550	Cucumber salad made with cucumber, oil, and vinegar*
75201030	Artichoke salad in oil*
82101000	Vegetable oil, NFS
82101500	Coconut oil
82102000	Corn oil
82103500	Flaxseed oil
82104000	Olive oil
82105000	Peanut oil
82105500	Rapeseed oil
82106000	Safflower oil
82107000	Sesame oil
82108000	Soybean oil

Gravies and sauces

27112000	Beef with gravy (mixture)*
27112010	Salisbury steak with gravy (mixture)*
27118180	Puerto Rican style beef stew, meat with gravy (potatoes reported separately)*
27120020	Ham or pork with gravy (mixture)*
27120120	Sausage gravy
27135010	Veal with gravy (mixture)*
27142000	Chicken with gravy (mixture)*
27142200	Turkey with gravy (mixture)*

27211200	Beef stew with potatoes, gravy*
27211300	Beef (roast) hash*
27212200	Beef and noodles with gravy (mixture)*
27213200	Beef and rice with gravy (mixture)*
27220510	Ham or pork and potatoes with gravy (mixture)*
27231000	Lamb or mutton and potatoes with gravy (mixture)*
27241010	Chicken or turkey and potatoes with gravy (mixture)*
27242200	Chicken or turkey and noodles with gravy (mixture)*
27250122	Shrimp and noodles with gravy (mixture)*
27260050	Meatballs, with breading, NS as to type of meat, with gravy*
27311410	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27311420	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27311510	Shepherd's pie with beef*
27311600	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27311605	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27313410	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27313420	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27315410	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27315420	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320120	Sausage, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27320130	Sausage, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320140	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27320150	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27330010	Shepherd's pie with lamb*
27330030	Lamb or mutton stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27330050	Lamb or mutton, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27330110	Lamb or mutton stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27336200	Venison/deer, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27336250	Venison/deer, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27341000	Chicken or turkey, potatoes, corn, and cheese, with gravy*

27341025	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27341030	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27341310	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27341320	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27343410	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27343420	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27345210	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27345220	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27347220	Chicken or turkey, stuffing, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27347230	Chicken or turkey, stuffing, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27347240	Chicken or turkey, dumplings, and vegetables (including carrots, broccoli, and/or dark green leafy), gravy (mixture)*
27347250	Chicken or turkey, dumplings, and vegetables (excluding carrots, broccoli, and dark green leafy), gravy (mixture)*
27360100	Brunswick stew*
27416450	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27416500	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27430400	Lamb or mutton stew with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy*
27430410	Lamb or mutton stew with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy*
27442110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27442120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
28110220	Sirloin, chopped, with gravy, mashed potatoes, vegetable (frozen meal)*
28110270	Sirloin beef with gravy, potatoes, vegetable (frozen meal)*
28110310	Salisbury steak with gravy, potatoes, vegetable (frozen meal)*
28110330	Salisbury steak with gravy, whipped potatoes, vegetable, dessert (frozen meal)*
28110350	Salisbury steak with gravy, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28110370	Salisbury steak with gravy, macaroni and cheese, vegetable (frozen meal)*
28110380	Salisbury steak with gravy, macaroni and cheese (frozen meal)*
28110510	Beef, sliced, with gravy, potatoes, vegetable (frozen meal)*
28110660	Meatballs, Swedish, in gravy, with noodles (diet frozen meal)*
28145000	Turkey dinner, NFS (frozen meal)*
28145100	Turkey with dressing, gravy, vegetable and fruit (diet frozen meal)*

28145210 Turkey with gravy, dressing, potatoes, vegetable (frozen meal)*
28145610 Turkey with gravy, dressing, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28500000 Gravy, poultry
28500010 Gravy, meat or poultry, with wine*
28500040 Gravy, beef or meat
28500050 Gravy, giblet
28500070 Gravy, beef or meat, home recipe
28500080 Gravy, poultry, home recipe
28500100 Gravy, mushroom
28501010 Gravy, beef or meat, fat free
28501110 Gravy, poultry, fat free
28510010 Gravy or sauce, poultry-based from Puerto Rican-style chicken fricasse
28510030 Gravy, meat-based, from Puerto-Rican style beef stew
28520000 Gravy or sauce, Chinese (soy sauce, stock or bouillon, cornstarch)
41811950 Swiss steak, with gravy, meatless*
42204100 Brown nut gravy, meatless
55502000 Flour and water gravy
58121510 Dumpling, meat-filled*
58126110 Turnover, meat-filled, no gravy*
58126170 Turnover, meat-and vegetable- filled (no potatoes, no gravy)*
58126180 Turnover, meat-, potato-, and vegetable-filled, no gravy*
58126310 Turnover, chicken, with gravy*
58128000 Biscuit with gravy*
58146200 Pasta, meat-filled, with gravy, canned*
58163110 Rice with gravy*
75439010 Vegetable stew without meat*

Nut and nut products

42200500 Almond butter
42200600 Almond paste (Marzipan paste)
42201000 Cashew butter
42202000 Peanut butter
42202010 Peanut butter, low sodium
42202100 Peanut butter, reduced sodium
42202130 Peanut butter, reduced sugar
42202150 Peanut butter, reduced fat
42202200 Peanut butter, vitamin and mineral fortified
42203000 Peanut butter and jelly*
42204050 Peanut sauce*
42301010 Peanut butter sandwich*
42302010 Peanut butter and jelly sandwich*
43103200 Sesame paste (sesame butter made from whole seeds)

43103300	Sesame butter (tahini) (made from kernels)
53115450	Cake, peanut butter, with icing*
53226600	Cookie, marshmallow and peanut butter, with oat cereal (no-bake)*
53231400	Cookie, multigrain, high fiber*
53233100	Cookie, oatmeal, with chocolate and peanut butter (no-bake)*
53234250	Cookie, peanut butter with rice cereal (no-bake)*
53235500	Cookie, with peanut butter filling, chocolate-coated*
53346000	Pie, peanut butter cream*
54328110	Cracker, sandwich-type, peanut butter filled, reduced fat*
91304070	Topping, peanut butter, thick, fudge type*
91713050	Fudge, peanut butter*
91718000	Honey-combed hard candy with peanut butter*
Snack foods	
42501000	Nut mixture with dried fruit and seeds
42502000	Nut mixture with seeds
54402200	Salty snack mixture, mostly corn or cornmeal based, with pretzels, without nuts
54420010	Multigrain mixture, pretzels, cereal and/or crackers, nuts
54420200	Multigrain mixture, bread sticks, sesame nuggets, pretzels, rye chips
62101050	Fruit mixture, dried (mixture includes three or more of the following: apples, apricots, dates, papaya, peaches, pears, pineapples, prunes, raisins)
0	*
91700500	M&M's Almond Chocolate Candies
91700	Almonds, chocolate covered
91703040	Caramel candy, chocolate covered
91703050	Caramel with nuts and cereal, chocolate covered
91703060	Caramel with nuts, chocolate covered
91703070	Rolo
91703150	Toblerone, milk chocolate with honey and almond nougat
91703200	TWIX Cookie Bars
91703250	TWIX Chocolate Fudge Cookie Bars
91703300	TWIX Peanut Butter Cookie Bars
91703400	Whatchamacallit
91703600	Espresso coffee beans, chocolate-covered
91705010	Milk chocolate candy, plain
91705020	Milk chocolate candy, with cereal
91705030	Kit Kat
91705040	Chocolate, milk, with nuts, not almond or peanuts
91705050	Milk chocolate candy, with fruit and nuts
91705060	Milk chocolate candy, with almonds
91705070	Chocolate, milk, with peanuts

91705090	Chocolate candy with fondant and caramel
91705200	Chocolate, semi-sweet morsel
91705300	Chocolate, sweet or dark
91705400	Chocolate, white
91705410	Chocolate, white, with almonds
91705420	Chocolate, white, with cereal
91705500	Mexican chocolate (tablet)
91706000	Coconut candy, chocolate covered
91707010	Fondant, chocolate covered
91709000	Gumdrops, chocolate covered
91713010	Fudge, chocolate, chocolate-coated
91713030	Fudge, chocolate
91713040	Fudge, chocolate, with nuts
91715000	Fudge, caramel and nut, chocolate-coated candy
91715100	SNICKERS Bar
91715200	Baby Ruth
91715300	100 GRAND Bar
91718050	Honey-combed hard candy with peanut butter, chocolate covered
91718100	Butterfinger
91718200	Chocolate-flavored sprinkles
91723010	Marshmallow, chocolate covered
91726110	Nougat, with caramel, chocolate covered
91726130	MILKY WAY Bar
91726140	MILKY WAY DARK Bar
91726150	MARS Bar
91726410	Nougat, chocolate covered
91726420	3 MUSKETEER Bar
91727010	Nuts, chocolate covered, not almonds or peanuts
91728000	Nut roll, fudge or nougat, caramel and nuts
91731000	Peanuts, chocolate covered
91731010	M&M's Peanut Chocolate Candies
91731060	M&M's Peanut Butter Chocolate Candies
91733200	Peanut Bar, chocolate covered candy
91734000	Peanut butter, chocolate covered
91734100	Reese's Peanut Butter Cup
91734300	Reese Sticks
91734400	Reese's Fast Break
91734450	Reese's Crispy Crunchy Bar
91739010	Raisins, chocolate covered
91746010	Sugar-coated chocolate discs
91746100	M&M's Plain Chocolate Candies

91746120	Sixlets
91746150	Easter egg, candy coated chocolate
91760100	Toffee, chocolate covered
91760200	Toffee, chocolate-coated, with nuts
91760500	Truffles
91770030	Dietetic or low calorie candy, chocolate covered

* Only intended use component of food included in analysis

Appendix E. Safety Outcomes in Clinical Studies of α-Linolenic Acid Intake from 2002 to the Present

Appendix E. Clinical Studies α-Linolenic Acid Intake with Safety Outcomes, 2002 to the Present

Reference	Study Population	Duration (wk)	α-Linolenic/ day[a]	Outcomes for α-Linolenic
Gillingham et al.2011; 2013	Crossover 36 (13 M) hyperlipidemic adults; Consumed high oleic/canola diet, high ALA/oleic/canola diet (flaxseed oil) or typical Western diet in random order [n=36] Mean age 47.5±11.9 y	4	20.6 g	**Immune function:** No change in CRP, IL-6, sVCAM-1, sICAM-1;↓ E-selectin **Lipid profile:** ↓in LDL-C
Wilkinson et al. 2005	RCT 57 (57 M) adults expressing an atherogenic lipoprotein phenotype (ALP); Randomized to consume one of three diets with supplemental oil: high ALA diet (flaxseed oil) [n=21], high LA+DHA/EPA diet (sunflower oil + fish oil) [n=19], or high LA control diet (sunflower oil) [n=17] Mean age 47-51 y per group	12	19.4g	**Adverse events**: Oil was well tolerated **Bleeding risk:** No change in concentration of plasma fibrinogen, Factor VIIc, or PAI-1 plasma activity **Lipid profile:** ↓ in LDL-C
Zhao et al. 2004, 2007; West et al. 2010	Crossover 23 (20 M) hypercholesterolemic adults Randomly assigned to sequence of 3 diets: average American diet (control), high PUFA/ALA diet (6.5% of energy as ALA), or high PUFA/LA (12.6% of energy as LA) [23 each diet]; Mean age 49.8 ± 1.6 y	6	19.1 17.3 g (6.5%in 2400 kcal)	**Immune function:** ↓ in CRP, serum ICAM-1, E-selectin, VCAM-1, TNF-α compared to control diet; no difference in IL-6, IL-1β. ↓ in IL-6, IL-1 β, TNF-α in PBMC cultures from ALA diet compared to control diet
Schwab et al. 2006	Crossover 14 (8 M) healthy volunteers; Consumed hempseed oil or flaxseed oil in food in random order [n=14] Mean age 45±7 y	4	14.4 g	**Bleeding risk:** No change in D-dimer, fibrinogen, FVII, PAI-1 activity **Glycemic control**: No change in fasting blood glucose, insulin **Immune function:** No change in CRP
Cornish et al. 2009	RCT 51 (28 M) adults; Randomized to consume a diet with supplemental ALA (flaxseed oil) [n=25] or control (corn oil) [n=26] while participating in resistance training 3 times/week Mean age 65.4 ± 0.8 y	12	14 g	**Adverse effects:** none attributed to flaxseed oil **Immune function:** ↓ in IL-6 in males and no change in women; no change in TNF- α
Nelson et al. 2007	RCT 57 (11 M) obese adults: Randomized to consume flaxseed capsules (n=30; 24 F) or isocaloric control diet (n =27; 22 F), Mean age 38.80±11.97	8	11 g (5% in 2000 Kcal)	**Glycemic control:** ↓adiponectin; no changes in fasting insulin and glucose
Finnegan et	RCT	26	9.5 g; 4.5 g	**Bleeding risk:** No change in coagulation and

Appendix E. Clinical Studies α-Linolenic Acid Intake with Safety Outcomes, 2002 to the Present

Reference	Study Population	Duration (wk)	α-Linolenic/ day[a]	Outcomes for α-Linolenic
al. 2003a,b; Kew et al. 2003	150 (87 M) moderately hyperlipidemic adults; Randomized to consume spread and capsules in 1 of 5 groups: control (no n-3s) [n=30], ALA (2 doses) [n=30, 31], EPA+DHA (2 doses) [n=30, 29] Mean age 53.3±11.1 y			fibrinolytic factors expressed as % change (FVIIa, FVIIc, FVIIag, fibrinogen, PAI-1, tissue plasminogen activator activity) **Glycemic control:** No effect on fasting glucose or insulin, or postprandial glucose AUC **Immune function:** No change in production of TNF-α, IL-1β, IL-6, IL-10, IL-2, IL-4, IFN-γ lymphocyte proliferation, or delayed-type hypersensitivity response **Lipid profile:** No change in plasma LDL-C **Oxidative damage**: ↑ in % change in LDL lag phase time in high ALA group vs. high EPA+DHA group; no change in plasma α-tocopherol or FRAP
Rallidis et al. 2003	RCT 76 M dyslipidaemic patients; Linseed oil grp, mean age 50.4±7.3; Safflower oil group Mean age 52±7.7	12	8 g	**Immune function:** ↓CRP, IL-6, serum amyloid A (SAA)
Kontogianni et al. 2013	Crossover 37 (8 M) [53 randomized] normal weight adults; Consumed supplemental olive oil and flaxseed oil in random order [n=37] Mean age 25.6 y	6	8 g	**Adverse event**: Exacerbation of IBS (n =1) **Glycemic control:** no change in glucose, adiponectin **Immune function:** no change in TNF-α; CRP, **Lipid profile:** ↓ in LDL-C
Taylor et al. 2010	RCT 34 (17 M) adults with type 2 diabetes Randomized to diet with bakery products containing milled flaxseed [n=13], flaxseed oil [n=12], or control (no flax) [n=9] Mean age 52.4±1.5 y	12	7.4 g	**Glycemic control:** No change in glucose, insulin, HbA1c
Nelson et al. 2011	RCT 59 (15 M) healthy adults Randomized to consume capsules containing olive oil (control) [n=19], flaxseed oil [n=20], fish oil [n=20] Mean age 58.6±6.3 y (control), 63.4±8.2 y (flaxseed oil), 62.1±7.7 y (fish oil)	8	7 g	**Immune function:** No effect on Lp-PLA_2 mass or activity **Lipid profile:** No effect on LDL-C
Austria et al. 2008	Randomized controlled trial 30 (15 M) health adults; Randomized to consume daily a muffin containing whole flaxseed, ground flaxseed, flaxseed oil [n=8] Ages 18–49 y	12	5.7 g	**Adverse event**: Gastrointestinal discomfort (flatulence, bloating, and stomach aches/cramps) during the first 4 wk leading to 2 withdrawals; moderate severity **Bleeding risk:** No change in platelet aggregation

Appendix E. Clinical Studies α-Linolenic Acid Intake with Safety Outcomes, 2002 to the Present

Reference	Study Population	Duration (wk)	α-Linolenic/ day[a]	Outcomes for α-Linolenic
Patenaude el. 2009	Randomized controlled trial 37 (17-20 M, not specified) younger and older adults; Randomized to consume daily a muffin containing ground flaxseed [n=17] or flaxseed oil [n=20] Mean age 25.1±3.7 y and 49.6±5.1 y for younger and older adults	4	6 g	**Adverse events:** No significant side effects **Bleeding risk:** ↓ in collagen-induced platelet aggregation in older adults only **Lipid profile:** No change in plasma LDL-C
Barre et al. 2008	Randomized controlled trial 32 (18 M) patients with Type 2 diabetes; Randomized to consume capsules with sunflower oil (control) [n=14] or flaxseed oil [n=18] Mean age 59.5 y in flaxseed oil group, 60.7 y in control group	12	5.5 g	**Glycemic control:** No change in fasting blood serum glucose, insulin and HbA1c levels. Trend for increased insulin in flaxseed oil group over time: 17.7±5.2 vs. 12.8±3.1 mU/mL
Barden et al. 2009	Randomized controlled trial 36 (36 M) healthy nonsmokers; Randomized to consume capsules with flaxseed oil [n=18] or olive oil [n=18] Age 20-65 y	4	5.4 g	**Oxidative Damage**: Significant ↑ in plasma F(1)-phytoprostanes, trend for increase in urine F(1)-phytoprostanes (p=0.06); no change in F(2)-isoprostanes
Metcalf et al. 2007	Randomized controlled trial 84 (54 M) patients with low self-reported fish intake, accepted for elective cardiac surgery; Randomized to consume supplemental fish oil (3 durations) [n=13-15/group], flaxseed oil [n=16], olive oil [n=16], or no oil (control) [n=10] Mean age 60.7-68.3 y/group	3 (18-118 d)	5.3 g	**Bleeding risk:** No difference in blood loss
Barcelo-Coblijn et al. 2008	Randomized controlled trial 62 (59 M) firefighters; Randomized to consume capsules with sunflower oil (control) [n=9], flax oil (3 doses) [n=10-12/dose], or fish oil (2 doses) [n=10-11/dose] Mean age 36.3±8.0 - 43.7±10.0 y/group	12	1.2 g 2.4 g 3.6 g	**Immune function:** No effect on inflammatory markers- plasma TNF-α, CRP, sVCAM-1
Wallace et al. 2003	Randomized controlled trial 40 healthy adults; Randomized to consume capsules containing palm/soybean oil (control) [n=8], flaxseed oil [n=8], fish oil (3 doses) [n=8/dose] Mean age 22.0±1.2 – 25.8±2.5 y	12	3.5 g	**Immune function:** No change in TNF-α, IL-1β, IL-6, IL-2, IFN-γ, IL-4, IL-10, peripheral blood mononuclear cell subsets
Baxheinrich et al. 2012	Randomized controlled trial 81 (26 M) with metabolic syndrome; Rapeseed oil [n =40]; Control group- olive oil [n = 41];	26	3.5	**Glycemic control:** ↓Insulin **Lipid Profile:** ↓ LDL-C;

Appendix E. Clinical Studies α-Linolenic Acid Intake with Safety Outcomes, 2002 to the Present

Reference	Study Population	Duration (wk)	α-Linolenic/ day[a]	Outcomes for α-Linolenic
	Mean age 52.3±10.6 y			
Harper et al. 2006b	Randomized controlled trial 49 (6 M) predominantly African American patients with multiple chronic diseases; Randomized to consume capsules containing olive oil (control) [n=22] or flaxseed oil [n=27], fish oil (3 doses) [n=8/dose] Mean age 51 y	26	3 g	**Adverse effects:** Overall well tolerated, with minimal symptoms in both groups including dry mouth (3%), change in bowel habits (3%), dyspepsia (3%0 **Lipid profile**: No change in LDL-C; no change in LDL particle size, though trend for increase in LDL_1 (p=0.058) and LDL_2 (p=0.083) subfractions – less atherogenic fractions
Knudsen et al. 2006	Randomized controlled trial 3098 (0 M) pregnant women reporting low fish intake Randomized to consume capsules containing fish oil (5 doses) [n=383-393 group], flaxseed oil [n=389], or control [n=774] from gestation wk 17-27 until delivery Mean age 28.4-28.9 y/group	11-21	2.2 g	**Adverse events:** Only 23% of women took the capsules until delivery **Bleeding risk:** No effect on spontaneous delivery
Egert et al. 2007	Randomized controlled trial 48 (13 M); Healthy adults; Rapeseed oil fortified with ALA [n=15]; Rapeseed oil diet fortified with EPA [n=17]; Rapeseed oil fortified with DHA [n=16]; Mean age 25.9±6.82 y	3	2.2 (1% 2000 Kcal)	**Lipid profile:** No change in serum LDL-C **Oxidative damage:** No enhancement in LDL oxidizability

Exhibits

Exhibit 1. Report of the Expert Panel

EXPERT PANEL OPINION
THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF THE PROPOSED USES OF SACHA INCHI OIL

Introduction

The undersigned, an independent panel of experts, qualified by their scientific training and national and international experience to evaluate the safety of food and food ingredients (the "Expert Panel"), was specially convened by the International Trade Centre (ITC), and asked to evaluate the safety and "generally recognized as safe" ("GRAS") status of the proposed use of sacha inchi oil in food.

Exponent Inc. ("Exponent") performed a comprehensive search of the scientific literature through 05 November relating to the safety of sacha inchi oil for human consumption. Exponent summarized the results of the literature search and prepared a safety dossier, "GRAS Self-Determination for the Use of Sacha Inchi Oil in Food," for consideration by the Expert Panel.

The Expert Panel critically evaluated Exponent's safety documentation (the dossier), and other available data and information that the members of the Expert Panel believed to be pertinent to the safety of sacha inchi oil under the conditions of intended use. In addition, the Expert Panel critically evaluated the method of manufacture and specifications for sacha inchi oil, analytical data confirming compliance with appropriate food-grade specifications and consistency of production, the conditions of intended use in food, and the estimated dietary exposure to sacha inchi oil. The Expert Panel convened via telephone conference call and email communications on December 18 and 19, 2013. Available to answer the Panel's questions during the meeting were Diana Flores, ITC National Consultant; Ms. Mary Murphy and Dr. Nga Tran of Exponent; and Diane McColl, Counsel to ITC. The Expert Panel independently, jointly, and unanimously concluded that the intended use in food of sacha inchi oil, produced consistent with current good manufacturing practice (cGMP) and meeting appropriate food-grade specifications, is safe and suitable. The Expert Panel further concluded that such intended use is GRAS based on scientific procedures. It is also the opinion of this Expert Panel that other qualified experts would concur with these conclusions.

Summarized below is the Expert Panel's scientific analysis supporting our conclusions.

Description

Sacha inchi oil is a vegetable oil derived from the seeds of *Plukenetia volubilis Linneo*, a plant in the Euphorbiaceae family native to the rain forest of the Andean region of South America.

Consistent with other vegetable oils, sacha inchi oil is a vegetable oil composed of fatty acids primarily in the form of triglycerides. Sacha inchi oil and many commonly consumed vegetable oils consist predominantly of unsaturated fatty acids including oleic (C18:1, n-9), linoleic (C18:2), and α-linolenic acids (C18:3) (an n-3 fatty acid), and to a lesser extent saturated fatty acids including palmitic (C16:0) and stearic (C18:0) acids. The fatty acid profile of sachi inchi oil is similar to that of flaxseed oil, with both oils characterized by high proportions of α-linolenic acid relative to other oils.

Manufacturing Process

The oil is removed from sacha inchi seed under good manufacturing procedures using a press machine or similar device in a standard process known as cold pressing. The crude oil is then clarified and press-filtered, and no solvents (including hexanes) or chemicals are used to extract or further process the oil. The resulting oil meets specifications appropriate for a food ingredient, with a minimum fatty acid composition of 44.7% α -linolenic acid, 32.1% linoleic acid, and 8.9% oleic acid. The typical fatty acid composition of sacha inchi oil is 46.4% α-linolenic acid, 35.6% linoleic acid, and 10% oleic acid.

Intended Use and Estimated Intake

α-Linolenic acid is an essential fatty acid for humans because it cannot be synthesized by the body. Therefore, essential fatty acids must be consumed from the diet. Similar to flaxseed oil, which is recognized as a concentrated source of α-linolenic acid, sacha inchi oil is intended to provide a dietary source of α-linolenic acid.

The intended uses of sacha inchi oil include use in a range of products including breakfast cereals and chocolates (up to 6% by weight); bars (such as granola, energy, protein and nutrition bars), condiments and relishes such as tapenades and hummus, gravies, seed and nut butters, and snack foods (up to 7% by weight); and fats and oils such as salad dressings and margarine-like spreads (up to 17% by weight) and salad oil (up to 100% by weight).

For the population ages 2 years and older, the *per user* mean and 90th percentile estimated daily intakes (EDI) of sacha inchi oil are 5.8 and 12.7 g/day, respectively. Adults were estimated to have the highest intakes of sacha inchi oil from the proposed use, with *per user* mean and 90th percentile EDIs of 6.4 and 13.6 g/day, respectively. At the 90th percentile, the intake of α-linolenic acid would be approximately 6.4 g.

Safety

The safety of sacha inchi oil was evaluated by a critical analysis of the safety of components in the oil, namely the predominant and characterizing α-linolenic acid. The safety evaluation for sacha inchi oil included an evaluation of the metabolic fate disposition of dietary triglycerides; a review of the Institute of Medicine's (IOM) 2002 evaluation of n-3 fatty acids; a review of a

2008 GRAS determination for the use of high α-linolenic acid flaxseed oil in food; a review of recent clinical trials assessing the safety of ingestion of α-linolenic acid; and a review of pre-clinical and clinical studies in which the test article was sacha inchi oil. All the information critically evaluated that formed the basis for this GRAS determination is available in the publicly available literature.

The absorption of dietary fats from the digestive tract is highly efficient; the ingested fat is almost completely absorbed, and the digestion and absorption of α-linolenic acid is similar to other long chain fatty acids. The absorbed (into the blood stream) α-linolenic acid is utilized for energy. The body can also store fatty acids in adipose tissue, synthesize other non-essential saturated or monounsaturated fatty acids, or convert them to longer-chain n-3 polyunsaturated fatty acids through the sequential action of desaturases and elongases. Conversion of α-linolenic acid to eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), however, is very inefficient.

In 2002, the IOM established that Adequate Intakes (AI) of α-linolenic acid are in the range of 1.1 to 1.6 g/day for teenagers and adults, while AIs of α-linolenic acid for children and adolescents range from 0.7 to 1.2 g/day. A maximum average daily intake of α-linolenic acid that is likely to pose no risk of adverse health effects for nearly all persons in the general population, i.e., a tolerable upper intake level (UL), was not established by the IOM in the course of developing Dietary Reference Intakes for macronutrients. Potential hazards of n-3 fatty acid intake were identified by the IOM, namely potentially adverse effects of n-3 fatty acids on immune function, excessive bleeding, oxidative damage, and glycemic control in diabetics; however, no UL was established due to a lack of adequate evidence.

The intake of 15 grams of α-linolenic acid per day from the use of a high α-linolenic acid oil in foods was determined to be GRAS (Polar Foods 2008; FDA 2009). As part of its GRAS determination, Polar Foods conducted a thorough review of safety data regarding intake of α-linolenic acid, including a review of information on the potential hazards of n-3 fatty acids identified by the IOM (i.e., immune function, excessive bleeding, oxidative damage, glycemic control). The FDA responded to the GRAS notification with a letter stating there were no questions about the determination that intake of up to 15 g of α-linolenic acid from an oil source was GRAS. Consumption of α-linolenic acid from use of α-linolenic acid rich oils in foods in combination with background sources of EPA and DHA would result in an estimated dietary equivalent of up to 1.9 g combined EPA + DHA which is well within the 3 g/person/day limit from fish oils established by the FDA in 1997. Therefore, this GRAS determination for the proposed use of sacha inchi oil also established 15 g of α-linolenic acid as an acceptable daily intake of the fatty acid from a supplemental source in the typical diet. A review of the literature published since IOM completed its review (2002) identified no new evidence that would call into question the safety of a daily intake of 15 grams of α-linolenic acid from a supplemental source in the diet.

A limited number of pre-clinical and clinical studies were conducted with sacha inchi oil and information from these studies was critically evaluated in this safety assessment. Results from a

series of in vitro and in vivo genotoxicity studies two acute oral toxicity studies in mice and a 60-day single dose, (0.45 g sacha inchi oil/kg bw) oral toxicity study in Holtzman rats demonstrate that sacha inchi oil is neither mutagenic nor toxic to rats and mice under the conditions of these experiments. Results from a single-dose clinical study provide evidence that plasma α-linolenic acid levels increase following intake of sacha inchi oil. Results from a small, randomized, controlled study in adults provide evidence of safe intake of 9.0 or 13. 5 g of sacha inchi oil (4.4 or 6.6 g α-linolenic acid) daily over a period of four months.

This history of use of sacha inchi oil provides corroborative evidence of safety. Sacha inchi oil has a history of use in Peru spanning 3,000 years. Recently sacha inchi oil was allowed into European markets. In December 2012, the Food Safety Authority of Ireland (FSAI) released a Substantial Equivalence Opinion recognizing sacha inchi oil from *Plukenetia volubilis* L. as a Novel Food under Article 5 of Regulation EC No. 258/97 based on substantial equivalence of the oil with flaxseed oil in terms of its composition, nutritional value, metabolism, intended use and level of undesirable substances.

Summary and Conclusion

The EDI of sacha inchi oil and α-linolenic acid from the proposed uses of the oil were determined for the US population and subpopulations on a *per user* basis at the mean and 90th percentile. Adults were estimated to have the highest potential intake of sacha inchi oil, with *per user* mean and 90th percentile EDIs of 6.4 and 13.6 g/day, respectively. With α-linolenic acid accounting for an average of 46.4% of fatty acids in sacha inchi oil, intake of the oil at the 90th percentile of intake corresponds to approximately 6.4 g of α-linolenic acid, which is well below the level of 15 α-linolenic acid per day previously determined to be a safe level of intake. Therefore, the proposed use of sacha inchi oil in food is safe and suitable within the terms of the Federal Food, Drug, and Cosmetic Act (i.e., meets the statute's safety standard of reasonable certainty of no harm). The data and information upon which this conclusion is based are publicly available, generally known and generally accepted by the broader scientific community of experts qualified by experience and training to evaluate the safety of food ingredients, including the current Expert Panel. The proposed use of sacha inchi oil is also generally recognized as safe (GRAS).

Expert Panel Conclusion

We, the undersigned expert panel members, have individually and collectively critically evaluated published and unpublished data and information pertinent to the safety of the proposed use as an ingredient in select foods of sacha inchi oil, produced consistent with cGMP and meeting appropriate food-grade specifications, and unanimously conclude that it is safe and suitable.

We, the undersigned expert panel members, have individually and collectively critically evaluated published and unpublished data and information pertinent to the safety of the proposed use as an ingredient in select foods of sacha inchi oil, produced consistent with cGMP and meeting appropriate food-grade specifications, and unanimously conclude that it is "generally recognized as safe" (GRAS) based on scientific procedures.

It is our opinion that other qualified experts would concur with our conclusions.

By:

_____ _____

Joseph F. Borzelleca, Ph.D. Date
Professor Emeritus
Department of Pharmacology and Toxicology
Virginia Commonwealth University School of Medicine

_____ _____

Robert J. Nicolosi, Ph.D. Date
Professor Emeritus
Department of Clinical Laboratory and Nutritional Sciences
University of Massachusetts Lowell

_____ _____

Michael W. Pariza, Ph.D. Date
Professor Emeritus, Department of Food Science
Director Emeritus, Food Research Institute
University of Wisconsin-Madison

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By:

(b) (6)

17 January 2014

Joseph F. Borzelleca, Ph.D.
Professor Emeritus
Department of Pharmacology and Toxicology
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Date

Robert J. Nicolosi, Ph.D.
Professor Emeritus
Department of Clinical Laboratory and Nutritional Sciences
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Robert J. Nicolosi, Ph.D.
Professor Emeritus
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University of Massachusetts Lowell

16 January 2014
Date

Michael W. Pariza, Ph.D.
Professor Emeritus, Department of Food Science
Director Emeritus, Food Research Institute
University of Wisconsin-Madison

Date

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Joseph F. Borzelleca, Ph.D. Date
Professor Emeritus
Department of Pharmacology and Toxicology
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_____ _____

Robert J. Nicolosi, Ph.D. Date
Professor Emeritus
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_____ 17 Jan 2014

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MAR 14 2014
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FOOD ADDITIVE SAFETY

March 13, 2014

Richard E. Bonnette M.S.
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Dear Mr. Bonnette:

As requested, enclosed are three copies of a replacement page 11 for insertion into the GRAS Notice for use of sacha inchi oil in select foods. Also enclosed is a new electronic version of the GRAS Notice that includes the replacement page 11. We confirm that the enclosed electronic version is virus free.

If you need any additional information, please do not hesitate to contact me.

Yours truly,

(b) (6)

Diane B. McColl

DBM/fjr

GRAS EXEMPTION CLAIM

Name and Address of Notifier

Agroindustrias Amazonicas S.A., Agroindustrias OSHO S.A.C., and Amazon Health Products S.A.C hereby notifies the Food and Drug Administration (FDA) that the use of sacha inchi oil as described below is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Agroindustrias Amazonicas S.A., Agroindustries OSHO S.A.C., and Amazon Health Products S.A.C has determined that such use is generally recognized as safe (GRAS) through scientific procedures.

(b) (6)

Agroindustrias Amazónicas S.A.
GONZALO DAVID F. AGUILAR RODRIGUEZ
GERENTE GENERAL

February 18th 2014
Date

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WALLIS WINDER BARRENECHEA
AMAZON HEALTH PRODUCTS SAC
GERENTE GENERAL

February 18th 2014
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SUBMISSION END