IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent of:	SAMPALIS, Fotini	Confirmation No.:	1897
Control No.:	95/001,774	Group Art Unit:	3991
Filed:	October 19, 2011	Examiner:	CAMPELL, Bruce R.

FOR: **INTER PARTES REEXAM OF U.S. PATENT 8,030,348: NATURAL MARINE SOURCE PHOSPHOLIPIDS COMPRISING POLYUNSATURATED FATTY ACIDS AND THEIR APPLICATIONS**

Mail Stop Declaration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF FEREIDOON SHAHIDI, PH.D. UNDER 37 C.F.R. § 1.132

I, Fereidoon Shahidi, declare as follows:

1. I am a tenured University Research Professor at Memorial University of Newfoundland in St. John's, Canada. My appointment is in the Department of Biochemistry, with a cross-appointment with the Aquaculture Program, Biology Department and Ocean Sciences Centre. I have been a professor at Memorial University since 1987. I am also an Honorary Professor at Chung Shan Medical University in Taichung, Taiwan; a Chair Professor in the Department of Food Science at National Chung Hsing University in Taichung, Taiwan; and an Adjunct Professor at Dalhousie University in Halifax, Nova Scotia, Canada and the Nova Scotia Agricultural College in Truro, Nova Scotia, Canada. Prior to being at Memorial, I was in the Department of Chemistry and the Department of Chemical Engineering at the University of Toronto.

2. I earned a Ph.D. in 1977 in Physical Organic Chemistry from the Department of Chemistry at McGill University in Montréal, Canada. Prior to that, I earned a Bachelors of Science, with

Honours, from the Department of Chemistry at Shiraz (Pahlavi) University in Shiraz, Iran. After my doctoral work, I was a Postdoctoral Fellow in the Department of Chemistry at McGill University.

3. I have been a scientist for almost 40 years, as outlined in my Curriculum Vitae (**Appendix A**).

4. I have been recognized with a variety of awards, including, for example: European Lipid Technology Award, Eurofed Lipid (2010); Fellow, American Chemical Society (2010); Distinguished Service Award, Agricultural and Food Chemistry Division, American Chemical Society (2008); Fellow, American Oil Chemists' Society (2008); Outstanding Division Member, Nutraceutical and Functional Food Division, Institute of Food Technologists (2008); Advancement of Application of Agricultural and Food Chemistry, American Chemical Society (2007), Fellow, International Academy of Food Science and Technology (2006); Stephen S. Chang Award, Institute of Food Technologists (2005); Fellow, Institute of Food Technologists (2005); Fellow, Royal Society of Chemistry (UK) (1998); Earl P. McFee Award, Atlantic Fisheries Technological Society (1998); Fellow, Chemical Institute of Canada (1996); William J. Eva Award, Canadian Institute of Food Science and Technology (1996); Fellow, Agricultural and Food Chemistry Division, American Chemical Society (1994); Platinum Award, American Chemical Society (1994); Fellow, Canadian Institute of Food Science and Technology (1993).

5. I have published about 450 peer reviewed articles, about 260 book chapters and conference proceedings, and about 60 books. I have been recognized as the ISI most published author (1st) in the area of Food, Nutrition and Agricultural Science for the period of 1996-2006; the ISI most cited (4th) author in Food, Nutrition and Agricultural Science for the period of 1997-2007; the ISI most cited (7th) author in the area of Food, Nutrition and Agricultural Science for the period of 1996-2006; the ISI most cited (3rd) author in the area of Agricultural Science for the period of 2001-2011; and author of the American Oil Chemists Society, Best Paper Award for 1995, 1997, 1998, 1999, 2002, and 2003.

6. I am the Editor-in-Chief of the *Journal of Functional Foods*. I am also an Editor of *Food Chemistry*, and I am or have been on the Editorial Board of: *Journal of Food Science,*

International Journal of Food Properties, *Nutraceuticals and Food*, *Current Nutrition and Food Science*, *Inform*, and the *Journal of Aquatic Food Product Technology*, and on the Editorial Advisory Board of the *Journal of Agricultural and Food Chemistry*. I was the Editor-in-Chief of the *Journal of Food Lipids* from 1993 to 2009.

7. I am or have been a member of the following exemplary professional organizations: International Society for Nutraceuticals and Functional Foods, International Union of Food Science and Technology, International Commission on Natural Health Products, American Oil Chemists' Society, American Meat Science Association, Chemical Institute of Canada, Groupe Polyphenol International, Canadian Meat Science Association, Institute of Food Technologists, Canadian Institute of Food Science and Technology, American Chemical Society, and the Royal Chemical Society.

8. I have been a preceptor for 25 post-doctoral fellows/research assistants/associates and 50 graduate-level thesis students.

9. I have been a member of various food standards committees, including being an Expert Advisory Committee member for the U.S. Pharmacopeia (USP), Food Ingredients (2010-present); Member, Expert Advisory Panel, Health Canada, Standards of Evidence for Health Claims for Foods (1999-2010); and Member, Standards Council of Canada (2000-2010).

10. I was a technical expert witness in a patent infringement lawsuit concerning the pharmaceutical Lovaza, a drug that contains ethyl esters of omega 3 fatty acids, namely DHA and EPA (*Pronova BioPharma Norge AS v. Apotex Corp.*, 1:09-cv-00304-SLR -MPT).

11. I am an inventor of 4 U.S. Patents (5,443,852, 5,425,956, 5,230,915, and 4,559,234), a European Patent (0,554,283), as well as other patent applications.

12. In December of 2011, I was engaged by counsel for Neptune Technologies and Bioressources ("Neptune") to review U.S. Patent 8,030,348 ("the '348 patent") and its substantive prosecution history, including the Declaration of Dr. Earl L. White; the Corrected Request for Reexamination filed by Aker Biomarine ("Aker"), listed as U.S.S.N. 95/001,714, including the Declaration of Mr. Bjorn Ole Haugsgjerd and the Declaration of Dr. Thomas Gundersen and WO 00/23546 ("Beaudoin I"); and supporting materials, and to provide my

expert scientific opinion. I have had no prior direct involvement with either Neptune or Aker. I am being compensated at my customary hourly rate for my time spent on developing, forming, and expressing the facts and opinions in this declaration. I have no personal interest in the ultimate outcome of the reexamination proceedings involving the '348 patent.

13. I have carefully read the information provided. Below I provide my expert scientific opinion.

The '348 Patent Discloses and Claims a Biologically Effective Amount of an Extract With a Phospholipid Containing Two of EPA and DHA.

14. I have read the disclosure and claims of the '348 patent and understand them to be directed to a biologically effective amount of an extract containing a phospholipid composition bearing two of EPA and DHA. That is, amounts of phospholipid compositions containing two of EPA and DHA that would allow these compositions to be active ingredients. Therefore, it is my understanding that the '348 patent is not directed to nor encompasses *de minimis* amounts of the phospholipid composition.

15. Specifically, claim 1 includes the phrase "wherein the composition is suitable for human consumption." This strongly suggests that the claim is directed to a biologically effective amount of the composition. My reading of the '348 patent's specification supports this point. Under "Field of the Invention," Patentee states that "[t]he present invention is directed to nutraceutical, pharmaceutical or cosmetic compositions." '348 Patent, Column 1, lines 22-25. Claim 1 would not cover "nutraceutical, pharmaceutical or cosmetic compositions" if it encompassed preparations containing *de minimis* amounts of the recited composition. Further, Column 4, lines 3-5, states: "[t]he composition . . . [is] useful in the prevention or treatment of a variety of disease states." Again, biologically effective amounts of the composition, and not *de minimis* levels, would be needed to have a medical effect with the claimed phospholipids as the active ingredient. Further, Examples 2 and 3 show the medical uses of this composition, underscoring the need for biologically effective quantities. This is also seen in Column 19, line 63 to Column 21, line 31, which recites, among others, various

pharmaceutical and medical uses of the composition, based on the assumption that the composition is in biologically active amounts. Therefore, it is my opinion that this patent is directed to a biologically effective amount of the composition.

The White Declaration of May 31, 2011 Concludes that Beaudoin I Does Not Contain a Biologically Effective Amount of a Phospholipid Containing Two of EPA and DHA.

16. I have read the Declaration of Earl L. White submitted on May 31, 2011 in support of the '348 patent. My scientific opinion of this declaration is that Dr. White properly concluded that Beaudoin I does not contain a biologically effective amount of a phospholipid containing two of EPA and DHA.

17. This reading is necessitated by not only Dr. White's statements but also a reasonable interpretation by a scientist in the field.

18. As to the latter, I do not, nor would any other scientist, interpret Dr. White's conclusion to mean that trace amounts of the phospholipid containing two of EPA and DHA are not present in Beaudoin oil. As a veteran scientist, Dr. White would not make such a definitive statement, nor would a typical scientist draw such a conclusion. On the contrary, a scientist would look at the White data and understand that his conclusion was that, on the whole, and limited by the instrumental caveats that come with every experiment, biologically effective amounts of the composition were not detected.

19. Dr. White explicitly states this as he reports his "opinion that the Beaudoin Oil Fractions received and tested by [Dr. White] do not contain PLs [phospholipids] which have attached to them DHA and DHA, EPA and EPA, DHA and EPA, or EPA and DHA, at the detection limits described above in paragraph 7 [outlining LC/MS and MS/MS techniques]." White Declaration of May 31, 2011, ¶ 13 (emphasis added).

20. Therefore, the only reasonable reading of the Earl L. White Declaration of May 31, 2011 is that Dr. White concluded that Beaudoin I does not contain a biologically effective amount of a phospholipid containing two of EPA and DHA.

21. The Gundersen Declaration challenges the conclusions of Dr. White by asserting that some amount of the phospholipid containing two of EPA and DHA is present in the Beaudoin oil. However, this declaration does not quantify the amount detected and uses a very sensitive technique (MRM mass spectrometry) for the detection. This technique alone suggests that a very small amount of the composition, if any, is present in the Beaudoin oil, according to Gundersen. However, as described above, the reasonable reading of White is not that the Beaudoin oil lacks any, even *de minimis*, amount of the composition of the '348 Patent, but that there is not a biologically effective amount of the composition.

22. By way of analogy, in the United States, when a vitamin or mineral is present in a product at less than 2% of Recommended Daily Intake (RDI), such a value may be reported on a food label as "zero" or with "an asterisk that refers to the statement "Contains less than 2% of the Daily Value of this (these) nutrient (nutrients)."[1] Also, as a second analogy, Aker, the requestor in U.S.S.N. 95/001,774, has received a Generally Recognized as Safe (GRAS) affirmation from the FDA that states that a maximum of 3% residual ethanol is acceptable in its krill oil products.[2] Therefore, such *de minimis* amounts are viewed in the food industry as miniscule enough to be irrelevant. As Beaudoin reports an oil potentially with a small amount of the phospholipid containing two of EPA and DHA (*i.e.* about 0.1 to 1%), it is my opinion that this is not a biologically effective amount. As the claims of the '348 patent are directed to biologically effective amounts of this composition, they are distinct from Beaudoin.

23. In summary, it is my opinion that the '348 patent describes and claims a biologically effective amount of a phospholipid composition containing EPA and/or DHA. This interpretation is consistent with standard practices in the food industry. Further, I read the Declaration of Earl L. White, submitted May 31, 3011, to conclude that the Beaudoin oil does not contain a biologically effective amount of a phospholipid containing two of EPA and DHA. Also, in my expert opinion, the Gundersen declaration corroborates the

[1] *See, e.g.,* Nutritional Labeling and Education Act (NLEA) Requirements (8/94 - 2/95), U.S. Food and Drug Administration (*available at* http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114098.htm, last accessed March 4, 2011, **Appendix B**).

[2] *See* Aker GRAS Notice of 12/14/2010, Table 1 at page 4 of 38, **Appendix C**.

conclusion of Dr. White as it employs a sensitive technique to allegedly detect a *de minimis* amount of the phospholipid containing two of EPA and DHA. As the '348 patent is directed to biologically effective amounts of this composition, and Beaudoin does not contain these amounts, my opinion is that the claims of the '348 patent are distinct from Beaudoin.

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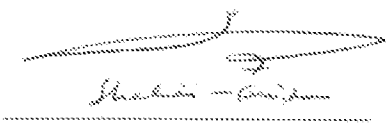
24. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of U.S. Patent 8,030,348.

By: 

Fereidoon Shahidi, Ph.D.

Dated: March 16, 2012

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Appendix A

Curriculum Vitae of Dr. Fereidoon Shahidi

CURRICULUM VITAE OF

Fereidoon Shahidi

POSITION: University Research Professor, Department of Biochemistry
(Cross-appointed with Aquaculture Program, Biology Department and Ocean Sciences Centre)

ADDRESS: Department of Biochemistry
Memorial University of Newfoundland
St. John's, NL, Canada
A1B 3X9

TELEPHONE: (709) 864-8552

FAX: (709) 864-4000

E-MAIL: fshahidi@mun.ca

Research Interests:

Chemistry, biochemistry and nutrition of food components; Natural antioxidants; Phytochemicals and phytopharmaceuticals; Nutraceuticals and functional foods; Mechanisms of action of antioxidants at cellular and subcellular levels; Antinutritional factors in plant foods; Food and flavour chemistry; Functional properties of protein preparations; Seafood processing and utilization of processing by-products; Nutraceutical and Food lipids; Lipid biotechnology; Seal research; Omega-3 fatty acids and seafoods; Lipid oxidation and its prevention; Process-induced chemical and biochemical changes in foods; Aquaculture.

Education:

1977 Ph.D. (Physical Organic Chemistry), Department of Chemistry, McGill University, Montréal, Canada.
Thesis Title: *Solvent and Conformational Effects on Molecular Volumes.*

1973 B.Sc. (Honours), Department of Chemistry, Shiraz (Pahlavi) University, Shiraz, Iran.
Project Title: *Synthesis of Tetracycline Analogs.*

Awards:

2010	European Lipid Technology Award, Eurofed Lipid
2010	Fellow, American Chemical Society
2008	Distinguished Service Award, Agricultural and Food Chemistry Division, American Chemical Society
2008	Fellow, American Oil Chemists' Society
2008	Outstanding Division Member, Nutraceutical and Functional Food Division, Institute of Food Technologists
2007	Advancement of Application of Agricultural and Food Chemistry, American Chemical Society
2007	Outstanding Division Member Awards, Nutraceutical and Functional Food Division, Institute of Food Technologists
2007	ISI Most cited (4^{th}) author in Food, Nutrition and Agricultural Science for the period of 1997-2007
2006	ISI Most cited (7^{th}) author in the area of Food, Nutrition and Agricultural Science for the period of 1996-2006
2006	ISI Most published author (1^{st}) in the area of Food, Nutrition and Agricultural Science for the period of 1996-2006
2006	Fellow, International Academy of Food Science and Technology
2006	Outstanding Division Member Award, Nutraceutical and Functional Food Division, Institute of Food Technologists
2005	Stephen S. Chang Award, Institute of Food Technologists
2005	Fellow, Institute of Food Technologists
2003	AOCS, best paper award, Kansas City, MO
2002	ISI Most highly cited Recognition Award (top 15) in the discipline of Agriculture, Plant and Animal Sciences for 1991-2001 decade
2002	ADM Award. Protein and Co-product Division of American Oil Chemists' Society.

1998-	University Research Professor, Memorial University of Newfoundland, St. John's, NL
1998	Fellow, Royal Society of Chemistry (UK)
1998	Earl P. McFee Award, Atlantic Fisheries Technological Society
1996	Fellow, Chemical Institute of Canada
1996	William J. Eva Award, Canadian Institute of Food Science and Technology
1995-2002	Best Paper Award, AOCS for 1995, 1997, 1998, 1999 and 2002.
1994	Fellow, Agricultural and Food Chemistry Division, American Chemical Society
1994	Platinum Award, American Chemical Society
1993	Fellow, Canadian Institute of Food Science and Technology
1975-1976	T. Sterry Hunt Prize for Teaching Excellence, McGill University, Montréal, Canada
1973-1976	Max Binz Scholarship, McGill University, Montréal, Canada
1973-1978	Scholarship, Ministry of Science and Higher Education of Iran
1973	Gold Medal, Shiraz (Pahlavi) University, Shiraz, Iran
1970-1973	Scholarship, Shiraz (Pahlavi) University, Shiraz, Iran

Experience:

Jun. 2011-	Honorary Professor, Chung Shan Medical University, Taichung, Taiwan
Jul. 2010-	Visiting Professor, King Saud University, Riyadh, Saudi Arabia
Aug. 2009-	Chair Professor, Department of Food Science, National Chung Hsing University, Taichung, Taiwan

Aug. 2009-	Adjunct Professor, Graduate Studies, Dalhousie University, Halifax, NS, Canada
Aug. 2009-	Adjunct Professor, Nova Scotia Agricultural College, Truro, NS, Canada
Jul.-Nov. 2000	Visiting Professor, Department of Chemistry, National University of Singapore, Singapore
May 1998-	University Research Professor, Department of Biochemistry, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Sep. 1992-	Professor, Department of Biochemistry, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Mar.-Aug. 1996	Visiting Professor, Department of Systemic Botany, Aarhus University and International Food Science Centre, Aarhus, Denmark.
Jan.-Feb. 1996	Visiting Professor, Department of Food Science, Ochanomizu University by Invitation of Japan Society for Promotion of Science, Tokyo, Japan.
Sep. 1994-	Cross-Appointment, Department of Biology, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
May 1994-	Aquaculture Committee, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Jan. 1993-1996	Cross-Appointment, Department of Chemistry, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Jan. 1991-	Cross-Appointment, Ocean Sciences Centre, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Sept. 1988-1997	Cross-Appointment, School of Pharmacy, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Jan. 1987-Aug. 1992	Associate Professor, Department of Biochemistry, Memorial University of Newfoundland, St. John's, Newfoundland, Canada.
Jul. 1984-Dec. 1986	Adjunct Professor of Food Engineering, Department of Chemical Engineering and Applied Chemistry, University of Toronto, Toronto, Canada.

Sep. 1978-Jun. 1984	Research Associate/Lecturer of Chemistry and Food Engineering, Departments of Chemistry as well as Chemical Engineering and Applied Chemistry, University of Toronto, Toronto, Canada.
Nov. 1976-Aug. 1978	Postdoctoral Fellow, Department of Chemistry, McGill University, Montréal, Canada.

Teaching Experience:

2008-	Lecturer, Bioenergetics, BC 4200.
1987-	Lecturer, Food Chemistry, BC 3402; Food Biochemistry, BC 6530; Instrumental Methods of Food Analysis, BC4400 (ended 1996); Food Science Topics, BC 4501 (ended 1996). Science and Technology of Marine Foods, BC 4650/6650 (BC4650 ended 1996). Marine Biochemistry, BC 6630. Biochemical Techniques, BC 4211.
1984-1986	Lecturer, Industrial Biological Processes CHE 448F and CHE 1132H; Fundamentals of Biotechnology CHE 335S; Fundamentals of Food Engineering CHE 462S and CHE 1133H; Organic Chemistry CHE 203F.
1978-1983	Lecturer/Tutor, General Chemistry CHM 135; Organic Chemistry CHM 240.
1976-1978	Lecturer/Tutor, Organic Chemistry CHEM 212 and 222.
1975-Dec. 1976	Instructor/Tutor, Advanced Organic Chemistry CHEM 362 and 392.
1974-1975	Teaching Assistant/Tutor, Analytical Chemistry CHEM 257
1972-1975	Teaching Assistant, Organic Chemistry CHEM 212 and 222.

Professional Organizations Membership:

2008-	International Society for Nutraceuticals and Functional Foods
1995-	Associate Member, International Union of Food Science and Technology
1995-	Associate Member, International Commission on Natural Health Products
1992-	American Oil Chemists' Society
1989-	American Meat Science Association
1988-	Chemical Institute of Canada
1988-	Group Polyphenol International

1985-	Canadian Meat Science Association
1985-	Institute of Food Technologists
1981-	Canadian Institute of Food Science and Technology
1976-	American Chemical Society
1974-	Royal Chemical Society

Offices and Committees:

Extensive administrative experience as executive/chair/CEO in several scientific organizations and major national and international committees/events or large companies.

2008-	Appointed Editor-in-Chief of the Journal of Functional Foods
2008-	Associate Editor, Journal of Food Science
2005-	Editorial Board Member, Inform
2005-	Past Chair and Newsletter Editor, Lipid Oxidation and Quality Division of the American Oil Chemists' Society
2004-	Past Chair, Agricultural and Food Chemistry Division of the American Chemical Society
2004-	North American Editor of Food Chemistry journal
2004-	Editorial Board Member of Current Nutrition & Food Science journal
2003	Chair, USDA-ARS review panel on Functional Foods and Phytochemicals
2003-	Advisory Board Member, Journal of Agricultural Food Chemistry
2003-	Editorial Board Member, Journal of Food Science
2003-	Editorial Board Member, International Journal of Food Properties
2003-2007	Councillor (Alternate), Functional Food and Nutraceutical Division of Institute of Food Technologists (IFT)
2001-2003	Chair, Functional Food and Nutraceutical Division of Institute of Food Technologists.
2001-2003	Chair, Lipid Oxidation and Quality Division of the American Oil Chemists' Society.

2001-2002	Chair, Agricultural and Food Chemistry Division of the American Chemical Society
2000-	Member, Canadian Functional Foods Network
2000-	Member, Standards Council of Canada
2000-	Member, Expert Committee on Plant Products, Agriculture and Agri-Food Canada
1999-	Member, Expert Advisory Panel, Health Canada, Standards of Evidence for Health Claims for Foods
2002-	Editorial Board Member of the journal of Nutraceuticals and Food
2000-2001	Vice Chair, Institute of Food Technologists, Functional Foods and Nutraceuticals Division - The Division was co-founded by F. Shahidi and colleagues.
1999-2001	Vice Chair, American Oil Chemists' Society, Lipid Oxidation and Quality Division
1999-2000	Vice Chair, American Chemical Society, Food and Agricultural Chemistry Division
1999-2000	Chair, American Chemical Society, Flavor Subdivision of Agricultural and Food Chemistry
1999-2000	Chair, American Oil Chemists' Society, Young Scientist Award Committee
1997-2000	Member, NSERC Strategic Committee on Biotechnology
1997-1998	Vice Chair, American Chemical Society, Flavor Subdivision of Agricultural and Food Chemistry
1997-2000	Executive Committee Member, American Oil Chemists Society, Lipid Oxidation and Quality Division as well as Protein and Co-Product Division
1996-98	President, Canadian Institute of Food Science and Technology, Newfoundland Section

1994-	President and/or Executive Committee Member, Atlantic Fisheries Technology Society
1993-2009	Editor-in-Chief, Journal of Food Lipids
1994-2004	Editorial Board of Food Chemistry
1998-	Editorial Board of International Journal of Food Properties
1992-2006	Network Member, Meat Focus International
1995-2001	Past-President and Board Member-at-Large, Protein and Co-Product Division, American Oil Chemists' Society
1995-1996	Secretary, Flavor Chemistry Subdivision, American Oil Chemists' Society
1995-1996	President-Elect, Newfoundland and Labrador, Canadian Institute of Food Science and Technology
1994-1995	President, Protein and Co-product Division, American Oil Chemists' Society
1993-1994	Vice-President and President-Elect, Protein and Co-Product Division, American Oil Chemists' Society
Jun. 1992-1995	National Secretary, Canadian Institute of Food Science and Technology
Jan. 1990-Dec. 1992	Editorial Board of Journal of Muscle Foods, January 1990-December 1992
1989-1993	Membership Chairman and Past President, Newfoundland and Labrador, Canadian Institute of Food Science and Technology
May 1989-1992	National Education Committee Chairman, Canadian Institute of Food Science and Technology
1989-1992	National Scaling Advisory Committee of the Department of Fisheries and Oceans
1988-89	President, Newfoundland and Labrador, Canadian Institute of Food Science and Technology
1988	Chair, Conference in Newfoundland, Atlantic Fisheries Technology Society

1987-1988	Director, Newfoundland and Labrador, Canadian Institute of Food Science and Technology

Grant Review/Review Committees **(Most recent)**

2011	Expert advisor, Chile Functional Food evaluation for CREAS (Creation and Continuity Projects), Santiego, Chile
2010	Expert Advisory Committee member, US Pharmacopea, Food Ingredients
2009, 2011	Review Panel for EC grant applications
2008	Executive Committee Member and Founder of International Society for Nutraceuticals and Functional Foods
2006 and 2008	Chair, CFI Review Panel for Nutrition as well as Infrastructure funds
2008	Reviewer, Life Sciences, Scientific Foundation of Ireland
2008-	Reviewer, Danish Agency for Science
2008	Program Review, NCE, Hokaido University, Japan
2007	Reviewer, FAO

Conference Organizations:

2011	Co-organizer of 2011 ISNFF Sapporo conference
2010	Co-organizer of 2010 ISNFF Bali Conference
2010	Co-organizer of two symposia in Pacifichem Conference in Honolulu
2010	Organizer of several symposia in American Chemical Society, Institute of Food Technologists and American Oil Chemists' Society
2009	Organizer of several symposia for American Chemical Society, Institute of Food Technologists and American Oil Chemist" Society
2009	Co-organizer of the 12th International Flavor Conference, Skiathos, Greece

2009	Organizer of an International Forum on Nutraceuticals and Functional Foods in Skiathos, Greece
2008-	Co-organizer of the Meeting of the International Society for Nutraceuticals and Functional Foods.
2008-	Organizer of a symposium at the American Oil Chemists' Society.
2008-	Organizer of a symposium at the Institute of Food Technologists.
2007	Organizer of 5 symposia at Institute of Food Technologist
2007	Organizer of one symposium at the American Oil Chemists Society
2007-	Organizer of one symposium at the American Chemical Society.
2006	Organizer of 6 symposia and co-organizer, 7th International Conference and Exhibition for Nutraceuticals and Functional Foods, Reno, NV
2005	Organizer of 3 symposia and co-organizer, 6th International Conference and Exhibition for Nutraceuticals and Functional Foods, Anaheim, CA
2005	Organizer of a symposium at Pacifichem Conference in Honolulu
2004	Organizer of 6 symposia and/or conferences in the ACS, AOCS and IFT, and co-organizer, 5th International Conference and Exhibition on Nutraceuticals and Functional Foods 18 symposia.
2003	Organizer of 7 symposia and/or conferences in the ACS, AOCS and IFT, and co-organizer of the 4th International Conference and Exhibition on Nutraceuticals and Functional Foods.
2002	Organizer of 6 symposia in the ACS, AOCS, IFT, and AOCS international. Also organizer of the Third International Conference and Exhibition on Nutraceuticals and Functional Foods.
2001	Organizer of 7 symposia in the ACS, IFT, AOCS, and IUFoST, among others. Also co-organizer of the Second International Conference and Exhibition on Nutraceutical and Functional Food.
2000	Co-organizer of 2 symposia on "Functional Foods: Ingredients and Prospects" and "Quality of Fresh and Processed Foods", Pacifichem 2000, Honolulu,

	December 14-19. Also co-organizer of the First International Conference and Exhibition on Nutraceutical and Functional Foods.
2000/2001/2002	Organizer, International Conference and Exhibition on Functional Foods and 2003 Nutraceuticals, Houston, TX, September 13-17, 2000; November 2001 Portland, OR, November 2002, San Diego, CA, and September/October 2003, Las Vegas, NV.
2000	Co-organizer, 10th International Flavor Conference, Paros, Greece, July 4-7.
2000	Co-organizer, Symposia on "Phytosterols: Chemistry, Sources and Nutraceutical Applications", American Oil Chemists' Society, April 25-29, 2000, San Diego, CA
2000	Co-organizer, Symposium on "Free Radicals in Foods", American Chemical Society, March 26-31, San Francisco, CA
1999	Chair, symposia on Recent Trends in structural Antioxidants, 2nd International Conference on Food Factors: Chemistry and Health Effects, December 12-17, Kyoto, Japan.
1999	Member, Organizing Committee, Atlantic Fisheries Technological Conference, November 10-14, Newbern, NC.
1999	Co-organizer, 2 symposia on "Functional Foods and Health Claims" and "Seafoods Quality and Nutrition", 10th IUFoST, Sydney, Australia, October 3-8.
1999	Co-organizer, Symposium on "antioxidants", American Oil Chemists' Society, May 3-8, Orlando, FL.
1999	Co-organizer of a symposium on Highly Unsaturated Fatty Acids: Chemistry and Nutrition. American Chemical Society, Spring Meeting, March 28-April 2. Anaheim, CA.
1998	Co-organizer of a symposium on Meat Quality. American Chemical Society, Spring Meeting, March 26-April 2, Dallas, TX.
1998	Conference Chairperson, Atlantic Fisheries Technology Conference, to be held in St. John's, Newfoundland, July 25-29.
1998, 1999 and 2000	Co-organizer, A Workshop on Nutraceuticals/Functional Foods, Texas A & M University, February, Houston, TX.

1997	Canadian Contact Person for Agrochemistry and Co-organizer of one symposium, American Chemical Society, Spring Meeting, March 28-April 3, Atlanta, GA.
1997	Co-organizer of four symposia, Fifth Chemical Congress of North America, Canadian Contact for Agrochemistry, November 11-15, Cancun, Mexico.
1997	Co-organizer, Ninth International Flavor Conference, July 1-4, Greece.
1996	Co-organizer of a symposium on "Flavor and Lipid Chemistry of Seafoods", American Chemical Society, Orlando, FL.
1996	Organizer of a symposium on "Natural Antioxidants", World Congress on Fats and Oils, October 6-11, Istanbul, Turkey.
1996	Organizer of a symposium on "Antioxidants and Prevention of Oxidation", American Oil Chemists' Society, April 28-May 2, Indianapolis, IN.
1995	Canadian Co-ordinator for Agrochemistry Division of Pacifichem, American Chemical Society/Chemical Institute of Canada, December 17-22, in Honolulu and Organizer/Co-organizer of two symposia entitled "Process-Induced Chemical Changes in Foods" and "Analytical and Nutritional Aspects in Seafood Research."
1995	Served on the International Advisory Board for the Congress on Antioxidants, Anticarcinogenity and Aging, held in Japan.
Jul.-Aug. 1995	Symposium Organizer for the Ninth World Congress of Food Science and Technology (IUFoST) held in Hungary in July-August.
1995	Organizer of a symposium on "Antinutrients and Phytochemicals in Foods", American Chemical Society, Chicago.
1995	Co-organizer of two symposia on "Natural Antioxidants" and "Oilseed Proteins", American Oil Chemists' Society, San Antonio.
1994	Co-organizer of a symposium on "Antioxidants/Protein Co-products", American Oil Chemists' Society, Atlanta.
1994	Co-organizer of a symposium on New Developments in Seafood Science and Technology, Canadian Institute of Food Science and Technology, Vancouver.
1992	Session Chair, Fourth American Chemical Congress, June, New York.

1992	Organizer of a symposium on "Canola Proteins and Co-products", American Oil Chemists' Society Meeting, May 10-14, Toronto.
1991	Member, Technical Organizing Committee, Eighth World Congress of Food Science and Technology (IUFoST), September 29 - October 4, Toronto and Organizer/ Chairperson for two symposia entitled "Flavour of Meat and Meat Products" and "Seafoods: Chemistry, Processing Technology and Quality".
1989	The 1989 International Chemical Congress of Pacific Basin Societies, December, Honolulu.
1989	Chairman, subsymposium on Use of Fish Minces and Surimi Products by the Food Industry - Quality and Regulatory Aspects.
1988	Canadian Program Chairman, Agricultural and Food Chemistry Third Chemical Congress of North America, June, Toronto and Organizer/Chairperson for two symposia entitled New Trends and Developments in Rapeseed Research and New trends and Developments in Flavour Chemistry

Editorials:

Editor-in-Chief:	Journal of Functional Foods
Editor-in-Chief:	Journal of Food Lipids; Ended 2009
Editor:	Food Chemistry
Associate Editor	Journal of Food Science
Editorial Board:	Journal of Food Science International Journal of Food Properties Nutraceuticals and Food Current Nutrition and Food Science Inform Journal of Aquatic Food Product Technology

Editorial Advisory Board: Journal of Agricultural and Food Chemistry

Publications:

a) Journal Articles (for book chapters see the following section)

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441. Tan, Z., and Shahidi, F. 2011. A novel method to chemoenzymatic synthesis of phytosteryl caffeates and evaluation of their antioxidant activity. *Food Chem*. In revision.
440. Chavan, U.D., McKenzie, D.B. and Shahidi, F. 2011. Extraction of phenolic compounds and tannins from seeds of beach pea (*Lathyrus maritinus* L.). *Food Chem*. Submitted.
439. Chavan, U.D., McKenzie, D.B. and Shahidi, F. 2011. Effect of processing on nutritional quality of beach pea (*Lathyrus maritinus* L.) seeds. *Food Chem*. Submitted.
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436. Zhong, Y. and Shahidi, F. 2011. Antioxidant behavior in bulk oil: limitations of polar paradox theory. *J. Agric. Food Chem*. http://dn.doi.org/10.1021/jf204165g
435. Maqsood, S., Benjakul, S., and Shahidi, F. 2011. Emerging role of phenolic compounds as the alternative natural food additives in fish and fish products. *Crit. Rev. Food Sci. Nutr*. In press.
434. Zhong, Y., Ma, C-M., and Shahidi, F. 2011. Antioxidant and antiviral activities of lipophilic epigallocatechin gallate (EGCG) derivatives. *J. Functional Foods*. DOI: 10.1016/j.jff 2011.08.003
433. Tan, Z., and Shahidi, F. 2011. Chemoenzymatic synthesis of phytosteryl ferulates and evaluation of their antioxidant activity. *J. Agric. Food Chem*. DOI 10.1021/jf203 4237 In press.
432. Tan, Z., and Shahidi, F. 2011. Optimization of enzymatic synthesis of phytosteryl caprylates using response surface methodology. *J. Amer. Oil Chem. Soc*. DOI 10.1007/511746-011-1949-Y
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270. Shahidi, F. and Senanayake, S.P.J.N. 2001. Seal blubber oil and its long-chain polyunsaturated fatty acids: Processing technologies and application. Presented at the Japanese Society of Fisheries Science. Tokohama, Japan.
269. Hamam, F., and Shahidi, F. 2001. Structured lipids from highly unsaturated single cell oils and capric acid. International Conference and Exhibition on Nutraceutical and Functional Foods/ Las Vegas, USA.
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259. Shahidi, F. 2000. Metabolism and uptake of dietary carotenoids by Arctic char (*Salvelinus alpinus*). 91st American Oil Chemists' Society Meeting. San Diego, CA, April 25-28.
258. Shahidi, F. 2000. Antioxidants from Oleaginous seeds. 219th American Chemical Society Meeting, San Francisco, CA, March 26-30.

257. Shahidi, F. 2000. Marine oils as affected by processing of their Quality preservation by natural antioxidants: An overview. 219th American Chemical Society Meeting. San Francisco, CA, March 26-30.
256. Shahidi, F. 2000. Nutraceuticals 2000 Conference: Understanding, Production, Process and Business Aspects of Nutraceuticals. St. John's, NF, March 6 and 7.
255. Shahidi, F. 2000. Plant Phytochemicals. Short course on Functional Foods and Nutraceuticals. College Station, TX, February 20-24.
254. Shahidi, F. 1999. Oilseeds as a source of natural antioxidants. 2nd International Conference on Food Factors: Chemistry and Health Effects. Kyoto, Japan, December 12-17.
253. Shahidi, F. 1999. Food Application of Marine Lipids, Atlantic Fisheries Technological Conference, Newbern, NC, November 10-14.
252. Shahidi, F. 1999. Effect of dietary carotenoids and lipid levels on the pigmentation of Arctic charr. 10th World Congress of Food Science and Technology, Sydney, Australia, October 3-8.
251. Shahidi, F. 1999. Plant antioxidants as functional food ingredients. 10th World Congress of Food Science and Technology, Sydney, Australia, October 3-8.
250. Shahidi, F. 1999. Plant phytoceuticals and natural antioxidants. Short course at the University of Hong Kong, Hong Kong, September 28-30.
249. Shahidi, F. 1999. Nutraceuticals Marine Sources. Short course at the University of Hong Kong, Hong Kong, September 28-30.
248. Shahidi, F. 1999. Quality preservation of seafoods and marine lipids. 8th Asian Congress of Nitrite. Seoul, South Korea, August 29-September 2, 1999. Abstract 57-5.
247. Naczk, M. and Shahidi, F. 1999. Recovery of canola condensed tannins by acetone-water solvent system. Institute of Food Technologists Annual Meeting, Chicago, IL, July 24-25. Abstract 79D-19.
246. Chavan, U.D. and Shahidi, F. 1999. Protein classification of whole and dehulled beach pea seeds in comparison with green and grass peas. Institute of Food Technologists Annual Meeting, Chicago, IL, July 24-25, Abstract 65A-34.
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239. Shahidi, F. Plant-derived antioxidants. Pre-conference workshop on Herbs and Botanicals. Canadian Institute of Food Science and Technology Conference, Kelowna, BC. June 5.
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236. Senanayake, S.P.J.N. & Shahidi, F. 1999. Oxidative stability of enzymatically modified borage and evening primrose oils. 217th American Chemical Society National Meeting, Anaheim, CA, March 21-25.
235. Cadwallader, K.R. and Shahidi, F. 1999. Identification of odourants in seal blubber oil by direct thermal desorption-gas chromatography-olfactormetry. 217th American Oil Chemical Society National Meeting, Anaheim, CA, March 21-25.
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218. Shahidi, F. 1997. Seal meat, oil and carcass components B Potential and problems for product development (keynote presentation). International Conference and Exhibition on Sealing. St. John's, NF, November 25-27,.
217. Shahidi, F. and Wanasundara, P.K.J.P.D. 1997. Effect of acylation on flax protein functionality. Fifth Chemical Congress of North America. November 11-15, Cancun, Mexico.
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213. Spurvey, S. and Shahidi, F. 1997. Optimization of process conditions for the preparation of gamma linolenic acid (GLA) concentrates from borage oil. *Canadian Institute of Food Science and Technology*. September 19-24, Montreal, PQ.
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139. Amarowicz, R. and Shahidi, F. 1994. Chromatographic separation and purification of green tea catechins. Abstract P. 227. Food, Nutrition and Health Congress. May 30-June 1, Warsaw, Poland.

138. Shahidi, F. and Amarowicz, R. 1994. Chromatographic separation of individual tea catechins and evaluation of their antioxidant activity. Abstract P 71, page 53, Polyphenols Actualities No. 11 (May). Presented at the Seventeenth International Conference of Groupe Polyphenols. May 22-27, Palma de Mallorca, Spain.
137. Shahidi, F. and Wanasundara, W.M.U.N. 1994. Antioxidant activity of canola phenolics. Abstract L7 Page 28, Polyphenols Actualities No. 11 (May), Presented at the Seventeenth International Conference of Groupe Polyphenols. May 22-27, Palma de Mallorca, Spain.
136. Wanasundara, P.K.J.P.D. and Shahidi, F. 1994. Flaxseed protein isolates and their acylated derivatives. Abstract P 205, p. 51. Presented at the Thirty-Seventh Annual Conference of the Canadian Institute of Food Science and Technology. May 15-18, Vancouver, BC.
135. Han, X.-Q. and Shahidi, F. 1994. Extraction and immobilization of seal gastric proteases. Abstract P 206, p. 51. Presented at the Thirty-Seventh Annual Conference of the Canadian Institute of Food Science and Technology. May 15-18, Vancouver, BC.
134. Pegg, R.B., Gogan, N.J., DeSilva, S.I. and Shahidi, F. 1994. Meat Pigments: Electron paramagnetic resonance studies. Abstract P 207, p. 54. Presented at the Thirty-Seventh Annual Conference of the Canadian Institute of Food Science and Technology. May 15-18, Vancouver, BC.
133. Wanasundara, W.M.U.N. and Shahidi, F. 1994. Flavonoids as natural antioxidants for stabilization of canola oil. Abstract P 208, p. 54. Presented at the Thirty-Seventh Annual Conference of the Canadian Institute of Food Science and Technology. May 15-18, Vancouver, BC.
132. Shahidi, F. and Venugopal, V. 1994. Protein concentrates from mackerel (*Scomber scumbrus*). Abstract P 110, p. 48. Presented at the Thirty-Seventh Annual Conference of the Canadian Institute of Food Science and Technology. May 15-18, Vancouver, BC.
131. Shahidi, F. 1994. Utilization of underutilized species and marine processing by-products. Presented at the symposium on New Developments in Seafood Science and Technology. May 11-14, Vancouver, BC.
130. Shahidi, F. 1994. Natural antioxidants: Protein co-products and otherwise. Presented at the Eighty-Fifth American Oil Chemists' Society Annual Meeting. May 8-12, Atlanta, GA.
129. Shahidi, F., Wanasundara, U.N. and Amarowicz, R. 1994. Antioxidants: Protein Co-products and Otherwise. Presented in Eighty-Fifth Annual Meeting of American Oil Chemists' Society, May 8-12, Atlanta, GA.
128. Shahidi, F., Synowiecki, J. and Han, X.Q. 1993. Marine protein hydrolyzates. Third joint meeting of Atlantic Fisheries Technology and Tropical and Subtropical Fisheries. Aug. 29-Sept. 1, Williamsburg, VA.
127. Shahidi, F. and Dunajski, E. 1993. Some quality characteristics of farmed cod. Third joint meeting of Atlantic Fisheries Technology and Tropical and Subtropical Fisheries *Conference*. Aug. 29-Sept. 1, Williamsburg, VA.
126. Shahidi, F. 1993. Process-induced chemical changes in canola glucosinolates. The Two-Hundredth and Sixth ACS National Meeting. August 22-27, Chicago, IL.
125. Shahidi, F., Onodenalore, A.C. and Synowiecki, J. 1993. Heat-induced changes of sulfhydryl groups of muscle foods. The Two-Hundredth and Sixth ACS National Meeting. August 22-27, Chicago, IL.

124. Shahidi, F. and Saleemi, Z.O. 1993. Antioxidant activity of oilseed flours and their extracts in meat model systems. The Thirty-Ninth International Congress of Meat Science and Technology. August 1-6, Calgary, Canada.
123. Shahidi, F., Pegg, R.B. and Sen, N.P. 1993. Volatile N-nitrosamines in nitrite-cured and nitrite-free treated muscle foods. The Thirty-Ninth International Congress of Meat Science and Technology. August 1-6, Calgary, Canada.
122. Shahidi, F., Synowiecki, J. and Han, X.Q. 1993. Production of protein hydrolyzates from Newfoundland capelin (*Mallotus villosus*). Annual Conference of the Institute of Food Technologists. July 10-14, Chicago, IL. Abstract No. 399.
121. Shahidi, F., Pegg, R.B. and Saleemi, Z.O. 1993. Hexanal as an indicator of meat flavour deterioration. The Thirty-Sixth Annual Conference of the Canadian Institute of Food Science and Technology. Toronto, ON, June 15-18. Abstract No. 57. p. 43.
120. Shahidi, F. and Synowiecki, J. 1993. Amino acid composition of cultured Arctic char (*Salvelinus alpinus*) as affected by feed formulations. The Thirty-Sixth Annual Conference of the Canadian Institute of Food Science and Technology. June 15-18, Toronto, ON. Abstract No. 56. p. 43.
119. Onodenalore, A. and Shahidi, F. 1993. Aqueous washing of mechanically deboned chicken meat. The Thirty-Sixth Annual Conference of the Canadian Institute of Food Science and Technology. June 15-18, Toronto, ON. Abstract No. 55. p. 43.
118. Wanasundara, J. and Shahidi, F. 1993. Removal of antinutrients from flaxseed meal. The Thirty-Sixth Annual Conference of the Canadian Institute of Food Science and Technology. June 15-18, Toronto, ON. Abstract No. 33. p. 38.
117. Wanasundara, U., Amarowicz, R. and Shahidi, F. 1993. Stabilization of canola oil by novel extracts from canola meal. The Thirty-Sixth Annual Conference of the Canadian Institute of Food Science and Technology. June 15-18, Toronto, ON. Abstract No. 32. p. 37.
116. Shahidi, F., Amarowicz, R. and Naczk, M. 1993. Extraction and concentration of omega-3 fatty acids of seal blubber. The Sixth International Congress on Engineering and Food. May 23-27, Makuhari Messe, Chiba, Japan. Paper No. 3.07.
115. Shahidi, F., Wanasundara, P.K.J.P.D. and Amarowicz, R. 1993. Solvent extraction of flaxseed. The Sixth International Congress on Engineering and Food. May 23-27, Makuhari Messe, Chiba, Japan. Paper No. P4.26.
114. Shahidi, F. 1993. Further utilization of seafood processing discards. The Eighty-Fourth American Oil Chemists' Society Annual Meeting. April 25-29, Anaheim, CA. Inform 4 (4): 517.
113. Shahidi, F. 1993. Canola Proteins. The Eighty-Fourth American Oil Chemists' Society Annual Meeting. April 25-29, Anaheim, CA. Inform 4(4): 492.
112. Shahidi, F. and Wanasundara, U. 1993. Application of nuclear magnetic resonance spectroscopy for measurement of oxidative stability of edible oils. The Eighty-Fourth American Oil Chemists' Society Annual Meeting. April 25-29, Anaheim, CA. Inform 4(4): 478.
111. Shahidi, F., Synowiecki, J. and Amarowicz, R. 1993. Lipid fatty acids of seal meat and blubber. The Two-Hundred and Fifth American Chemical Society National Meeting. March 28-April 2, Denver, CO. Abstract AGFDS9.

110. Shahidi, F. and Wanasundara, U. 1993. Stability of canola oil. The Two-Hundred and Fifth American Chemical Society National Meeting. March 28-April 2, Denver, CO. Abstract AGFD47.
109. Shahidi, F. 1993. Current status of research on whole carcass of harp seal (*Phoca groenlandica*). Annual meeting of the Canadian Sealers Association. St. John's, NF, March 25-26.
108. Shahidi, F. 1993. Usage of marine underutilized species and processing by-products. The First International Conference on the Impact of Food Research on New Product Development. January 24-26, Karachi, Pakistan.
107. Shahidi, F., Pegg, R.B. and Sen, N. 1993. Novel nitrite-free processed meats. The First International Conference on the Impact of Food Research on New Product Development. January 24-26, Karachi, Pakistan.
106. Shahidi, F. and Hong, C. 1992. Nitrite-binding properties of dietary fibers. Food and Cancer Prevention '92. September 13-16, Norwich, UK.
105. Shahidi, F. and Pegg, R.B. 1992. Nitrite-free meat curing systems and the N-nitrosamine problem. Food and Cancer Prevention '92. September 13-16, Norwich, UK.
104. Shahidi, F., Synowiecki, J. and Balejko, J. 1992. Utilization of seal meat by-products. The Thirty-Eighth International Congress of Meat Science and Technology. August 23-28, Clermont Ferrand, France.
103. Shahidi, F. and Pegg, R.B. 1992. Application of Colormet in muscle food quality evaluation. The Thirty-Eighth International Congress of Meat Science and Technology. August 23-28, Clermont Ferrand, France.
102. Shahidi, F., Ke, P., Zhao, X., Yang, Z. and Wanasundara, J. 1992. Antioxidant activity of green and black tea in meat model system. The Thirty-Eighth International Congress of Meat Science and Technology. August 23-28, Clermont Ferrand, France.
101. Shahidi, F., Han, X.Q., Synowiecki, J. and Balejko, J. 1992. Enzymatic modification of marine proteins: 1. Male and spent capelin. The Thirty-Seventh Atlantic Fisheries Technological Conference. August 23-26, Percé, QC.
100. Shahidi, F., Naczk, M., Dunajski, E. and Walsh, K. 1992. Omega-3 fatty acids of seal blubber. The Thirty-Seventh Atlantic Fisheries Technological Conference. August 23-26, Percé, QC.
99. Pink, D., Naczk, M. and Shahidi, F. 1992. Second derivative ultraviolet spectrophotometry of phenolic of Brassica oilseeds. The Sixteenth International Conference of Groupe Polyphenols. July 13-16, Lisbon, Portugal.
98. McDonald, K., Naczk, M. and Shahidi, F. 1992. Iron-binding phenolics of canola seeds. The Sixteenth International Conference of Groupe Polyphenols. July 13-16, Lisbon, Portugal.
97. Shahidi, F., Synowiecki, J. and Penney, R.W. 1992. Dietary carotenoids and their uptake by Arctic char. Institute of Food Technologists Annual Meeting. June 20-24, New Orleans, LA.
96. Shahidi, F. 1992. Processed meats, poultry and seafoods. Canadian Institute of Food Science and Technology Meeting. May 31-June 3, Ottawa, ON. Presentation to Meat, Poultry and Seafood Interest Group. By invitation.

95. Srivastava, R.K., Brown, J.A. and Shahidi, F. 1992. Influence of egg carotenoids of Atlantic salmon (*Salmo salar*) on embryonic growth and survival. Canadian Institute of Food Science and Technology Meeting. May 31-June 3, Ottawa, ON.
94. Shahidi, F., Synowiecki, J. and Penney, R.W. 1992. Effect of feed carotenoids on growth and pigmentation of Arctic char (*Salvelinus alpinus, L.*). Canadian Institute of Food Science and Technology Annual Meeting. May 31-June 3, Ottawa, ON.
93. Saleemi, Z.O., Pegg, R.B., Wanasundara, P.K.J.P.D. and Shahidi, F. 1992. Application of deheated mustard flour (DMF) in nitrite-free cured meat products. Canadian Institute of Food Science and Technology Annual Meeting. May 31-June 3, Ottawa, ON.
92. Dunajski, E., Chong, X., Pegg, R.B. and Shahidi, F. 1992. Changes in the colour characteristics of harp seal (*Phoca groenlandica*) during post-mortem and heat processing. Canadian Institute of Food Science and Technology Annual Meeting. May 31-June 3, Ottawa, ON.
91. Pink, D., Naczk, M. and Shahidi, F. 1992. Theoretical analysis of ultraviolet spectroscopic studies on the rapeseed phenolic acids. Canadian Institute of Food Science and Technology Annual Meeting. May 31-June 3, Ottawa, ON.
90. Sen, N.P., Synowiecki, J. and Shahidi, F. 1992. Nitrite curing of seal meat. Canadian Institute of Food Science and Technology Annual Meeting. May 31-June 3, Ottawa, ON.
89. Naczk, M. and Shahidi, F. 1992. Quantification of rapeseed tannins by different methods. Canadian Institute of Food Science and Technology Annual Meeting. May 31-June 3, Ottawa, ON.
88. Shahidi, F. 1992. Current and novel methods for stability testing of canola oil. The Twentieth ISF World Congress and Eighty-Third AOAC Annual Meeting. May 10-14, Toronto, ON. By invitation.
87. Shahidi, F. and Naczk, M. 1992. Upgrading of canola meal. The Twentieth ISF World Congress and Eighty-Third AOAC Annual Meeting. May 10-14, Toronto, ON.
86. Naczk, M., Shahidi, F. and Sullivan, A. 1992. Condensed tannins of canola: Recovery and quantification. The Twentieth ISF World Congress and Eighty-Third AOAC Annual Meeting. May 10-14, Toronto, ON.
85. Shahidi, F. and Pegg, R.B. 1992. Stabilization of the cooked cured-meat pigment by cyclodextrins. The Sixth International Cyclodextrin Symposium. April 21-24, Chicago, IL.
84. Shahidi, F., Naczk, M. and Myhara, R.M. 1992. Extraction of galactosides from legume and oilseed meals. International Food Legume Research Conference II. April 12-16, Cairo, Egypt.
83. Shahidi, F. 1992. Full utilization of the seal carcass. Lecture to government, industry and academic representatives. Newfoundland Department of Fisheries. March 12, St. John's, NL. By invitation.
82. Shahidi, F. 1992. Status and potential for better utilization of fisheries discards in Canada. Aquatech. '92. March 1-3, Halifax, NS. By invitation.
81. Shahidi, F. and Wanasundara, U.N. 1992. Processed meat, poultry and sea foods. Can. Inst. Food Sci. Technol. Annual Meeting. May 31-June 3, Ottawa, ON.

80. Shahidi, F. and Synowiecki, J. 1991. Quality and compositional characteristics of Newfoundland shellfish processing discards. The Fifth International Conference on Chitin and Chitosan. October 17-20, Princeton, N.J.
79. Shahidi, F. 1991. Nutrients of fishery by-products and their potential use in feed and compost formations. Fishery By-product Composting Conference. October 21-23, Madison, WI.
78. Shahidi, F. 1991. Seafood processing by-products. The Eighth World Congress of Food Science and Technology. September 29-October 4, Toronto, ON.
77. Shahidi, F. 1991. Assessment of lipid oxidation and off-flavour development in meats. The Eighth World Congress of Food Science and Technology. September 29-October 4. Toronto, ON.
76. Shahidi, F. 1991. Nutritional Value of Seal Products and Preparation of Value-added Products Thereof as well as Underutilized and Unutilized Fish Species in Newfoundland Waters. A series of presentations to Industry, Government and Academia Representatives in several locations in Singapore, Taiwan and Hong Kong, June 1991 (by invitation from the Government of Newfoundland and Labrador as a delegation member to East Asia).
75. Shahidi, F. 1991. Prospects for sealing industries in Canada and recent research developments. A series of presentations to Industry, Government and Academia representatives in several locations in Tokyo, Japan, March 1991 (by Invitation from the Canadian Government as a delegation member to Japan).
74. Srivastava, R.K., Brown, J.A. and Shahidi, F. 1991. The carotenoids pigments in eggs of Atlantic salmon (*Salmo salar*) and their significance in early development, growth and survival. The Thirtieth Conference of the Canadian Society of Zoologists. May 8-11, Thunder Bay, ON.
73. Shahidi, F., Synowiecki, J. and Heeley, D. 1991. Quantification of hemoproteins in seal meat and other muscle foods. The Thirty-Seventh International Congress of Meat Science and Technology. September 1-6, Kulmbach, Germany.
72. Shahidi, F., Pegg, R.B. and Shamsuzzaman, K. 1991. Encapsulation of the cooked cured-meat pigment and irradiation of nitrite-free cured products. The Thirty-Seventh International Congress of Meat Science and Technology. September 1-6, Kulmbach, Germany.
71. Shahidi, F. 1991. Phenolic compounds of Brassica oilseeds. The Fourth Chemical Congress of North America. August 25-30, New York, NY (by invitation).
70. Shahidi, F., Wanasundara, P.K.J.P.D., and Hong, C. 1991. Antioxidant activity of phenolic compounds in meat model systems. The Fourth Chemical Congress of North America. August 25-30, New York, NY (by invitation).
69. Shahidi, F. 1991. Prevention of lipid oxidation in muscle foods by nitrite and nitrite-free compositions. The Fourth Chemical Congress of North America. August 25-30, New York, NY (by invitation).
68. Shahidi, F. 1991. Effect of ammoniation on the quality of solvent-extracted rapeseed products. The Eighth International Rapeseed Congress. July 9-11, Saskatoon, SK.
67. Naczk, M. and Shahidi, F. 1991. Critical evaluation of quantification methods of rapeseed tannins. The Eighth International Rapeseed Congress. July 9-11, Saskatoon, Canada.

66. Naczk, M. and Shahidi, F. 1991. Phenolic constituents of rapeseed. The Second International Tannin Conference. June 17-21, Michigan, IL.
65. Shahidi, F. and Synowiecki, J. 1991. Carotenoids and chitin of crustacean offals. Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal, PQ,.
64. Dunajski, E., Hong, C. and Shahidi, F. 1991. Quality of farmed cod (*Gadus morhua*). Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal, PQ.
63. Shahidi, F. and Synowiecki, J. 1991. Fatty acids profile and content of cholesterol and nucleic acids in seal meat. Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal, PQ.
62. Synowiecki, J., Hall, D. and Shahidi, F. 1991. Amino acids and mineral constituents of snow crab processing discards. Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal, PQ.
61. Onodenalore, A.C., Synowiecki, J. and Shahidi, F. 1991. Characteristics of washed mechanically deboned chicken meat (MDCM). Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal, PQ.
60. Shahidi, F. and Pegg, R.B. 1991. Application of the cooked cured-meat pigment (CCMP) to comminuted and solid cuts of meat. Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal PQ.
59. Naczk, M., Myhara, R.M. and Shahidi, F. 1991. Removal of flatulence-causing sugars from legumes and oilseeds. Canadian Institute of Food Science and Technology Annual Meeting. June 16-19, Montréal, PQ.
58. Shahidi, F. 1991. Quality of Seal Meat and Seal-Based Products. Annual Convention of Canadian Sealers. February 3, Twillingate, NF, (by invitation).
57. Shahidi, F. 1991. Pigmentation and depigmentation of Arctic char. Arctic char research workshop. March 12, St. John's, NF, (by invitation).
56. Shahidi, F. and Synowiecki, J. 1990. Seal meat: the ultimate test of surimi technology. Second joint conference of Tropical and Subtropical Fisheries Technology and Atlantic Fisheries Technology Societies. Dec. 2-5, Orlando, FL.
55. Shahidi, F. and Synowiecki, J. 1990. Nutrient and chemical composition of Atlantic snow crab offals. The Second Joint Conference of Tropical and Subtropical Fisheries Technology and Atlantic Fisheries Technology Societies. Dec. 2-5, Orlando, FL.
54. Shahidi, F. 1990. The 2-thiobarbituric acid (TBA) methodology for the evaluation of warmed-over flavour and oxidative rancidity of meat products. The Thirty-Sixth International Congress of Meat Science and Technology. August 27-September 1, Havana, Cuba.
53. Shahidi, F. and Synowiecki, J. 1990. Seal meat: A potential source of muscle food or waste? The Thirty-Sixth International Congress of Meat Science and Technology. August 27-September 1, Havana, Cuba.
52. Shahidi, F. and Naczk, M. 1990. Contribution of sinapic acid to the phenolic constituents of solvent-extracted cruciferae oilseeds. Groupe Polyphenols 1990 International Conference. July 9-11, Stratsburg, France.

51. Naczk, M. and Shahidi, F. 1990. Effect of processing on the free and esterified phenolic constituents of cruciferae oilseeds. Institute of Food Technologists Annual Meeting. June 17-20, Anaheim, CA.
50. Shahidi, F., Naczk, M. and Myhara, M. 1990. Effect of processing on the content of low molecular-weight carbohydrates of glandless cottonseed. Institute of Food Technologists Annual Meeting. June 17-20, Anaheim, CA.
49. Srivastava, R.K., Brown, J.A. and Shahidi, F. 1990. Egg quality of Arctic char. International Congress of Aquaculture. June 10-17, Halifax, NS.
48. Shahidi, F., Pegg, R.B. and Hong, C. 1990. Composite non-nitrite meat curing systems. Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
47. Pegg, R.B. and Shahidi, F. 1990. Effects of myoglobin and nitrite or pre-formed cooked cured-meat pigment concentrations on the colour of cooked meats. Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
46. Synowiecki, J. and Shahidi, F. 1990. Nutrient and pigment composition of seal meat. Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
45. Shahidi, F. and Pegg, R.B. 1990. Reactions of malonaldehyde with 2-thiobarbituric acid and sulfanilamide: Spectroscopic studies. Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
44. Naczk, M. and Shahidi, F. 1990. Some chemical and functional characteristics of solvent-extracted soybean meals. Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
43. Naczk, M., Shahidi, F. and Myhara, M. 1990. Extraction of soluble sugars of oilseeds by methanol-ammonia-water. Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
42. Shahidi, F., Murphy, G. and Brooker, J. 1990. Effect of live storage on the depletion of lipids in male capelin (*Mallotus villosus*). Canadian Institute of Food Science and Technology Annual Meeting. June 3-6, Saskatoon, SK.
41. Shahidi, F., Murphy, G. and Naczk, M. 1990. Accumulation of lipid in farmed cod (*Gadus morhua*). Seafood 2000 International Conference. May 13-16, Halifax, NS.
40. Shahidi, F., Synowiecki, J. and Naczk, M. 1990. Utilization of shellfish processing discards. Seafood 2000 International Conference. May 13-16, Halifax, NS.
39. Shahidi, F. and Naczk, M. 1990. Effect of processing on quality enhancement of rapeseed with particular reference to Hu You 9 Chinese variety. China International Rapeseed Conference. April 24-May 2, Shanghai, P.R. China.
38. Synowiecki, J. and Shahidi, F. 1989. Some technological properties of seal meat. Atlantic Fisheries and Technology Conference. August 27-30, St. John's, NF.
37. Naczk, M. and Shahidi, F. 1989. Chemical composition and chitin content of crustacean offal. Seafood Biotechnology workshop. August 31-Sept. 1, St. John's, NF.
36. Shahidi, F. 1989. Processing of cruciferae oilseeds: Benefits and drawbacks of alkanol-ammonia extraction. Fifth International Conference of Engineering and Food. May 29-June 3, Cologne, Germany.

35. Shahidi, F. and Naczk, M. 1989. Solvent extraction of tannins from canola. Institute of Food Technologists Annual Meeting. June 25-29, Chicago, IL.
34. Shahidi, F. 1989. Validity of the 2-thiobarbituric acid (TBA) test for the evaluation of oxidative rancidity in cured meat product. The Thirty-Fifth International Congress of Meat Science and Technology. August 20-25, Copenhagen, Denmark.
33. Shahidi, F. 1989. Current status of nitrite-free meat curing system. The Thirty-Fifth International Congress of Meat Science and Technology. August 20-25, Copenhagen, Denmark.
32. Myhara, R.M., Naczk, M. and Shahidi, F. 1989. Effect of Methanol-Ammonia Processing on the soluble sugars of soybean. Canadian Institute of Food Science and Technology Annual Meeting. June 4-7, Québec City, PQ.
31. Shahidi, F. and Hong, C. 1989. Effect of natural phenolic compounds on the oxidation of cooked meats. Canadian Institute of Food Science and Technology Annual Meeting. June 4-7, Québec City, PQ.
30. Pegg, R.B., and Shahidi, F., 1989. Effect of light and storage time on the colour stability of processed meats. Canadian Institute of Food Science and Technology Annual Meeting. June 4-7, Québec City, PQ.
29. Naczk, M., Banfield, S., Hall, D. and Shahidi, F. 1989. Amino acid compositions and PER values of rapeseed meals as affected by methanol-ammonia. Canadian Institute of Food Science and Technology Annual Meeting. June 4-7, Québec City, PQ.
28. Shahidi, F. and Pegg, R.B. 1988. Synthesis of cooked cured-meat pigment, dinitrosyl ferrohemochrome and its colour characteristics. To be presented in the Thirty-Fourth International Congress of Meat Science and Technology, Brisbane, Australia. August 29-September 2.
27. Rubin, F. and Shahidi, F. 1988. Lipid oxidation and the flavour of meat products. To be presented in the Thirty-Fourth International Congress of Meat Science and Technology. August 29-September 2, Brisbane, Australia.
26. Shahidi, F. and Naczk, M. 1988. Effect of processing on the phenolic constituents of canola. Presented at the 1988 International Conference of Group Polyphenols. August 15-19, St. Catherine, ON.
25. Shahidi, F. and Brooker, J. 1988. Antioxidant activity of plant phenolics in meats. Presented at the 1988 International Conference of Group Polyphenols. August 15-19, St. Catherine, ON.
24. Shahidi, F. 1988. Elimination of antinutritional factors from canola. Presented at the Third Chemical Congress of North America. June 5-11, Toronto, ON.
23. Shahidi, F. 1988. Flavour of cooked meats. Presented at the Third Chemical Congress of North America. June 5-11, Toronto, ON.
22. Shahidi, F., Pegg, R.B. and Brooker, J. 1988. Role of metal ions in autoxidation of cooked meats. Presented in the Thirty-First Annual Meeting of the Canadian Institute of Food Science and Technology. May 29-June 2, Winnipeg, MB.
21. Shahidi, F. and Hong, C. 1988. Some benefits of polyphosphates in cooked ground chicken meat. Presented in the Thirty-First Annual Meeting of the Canadian Institute of Food Science and Technology. May 29-June 2, Winnipeg, MB.

20. Shahidi, F., 1987. Recent advances in meat-curing technology. Presented at the Food Processing in Newfoundland and Labrador: Producer to Consumer, November 18-20. By Invitation.
19. Shahidi, F., Gabon, J.E. and Rubin, L.J. 1987. A novel process for the removal of glucosinolates from canola. Presented at the Seventh World Congress of Food Science and Technology. September 28 - October 2, Singapore.
18. Shahidi, F., Gabon, J.E. and Rubin, L.J. 1987. The effect of methanol-ammonia-water treatment on the degradation of glucosinolates in canola and as isolated compounds. Presented at the Seventh International Rapeseed Congress. May 11-14, Poznan, Poland.
17. Shahidi, F., Naczk, M., Rubin, L.J. and Diosady, L.L. 1987. The alkanol-ammonia-water/ hexane treatment of canola - An overview. Presented at the Seventh International Rapeseed Congress. May 11-14, Poznan, Poland.
16. Pegg, R. and Shahidi, F. 1987. Single-step preparation of cooked cured-meat pigment and its application to meat. Presented at the Thirtieth Annual Meeting of the Canadian institute of Food Science Technology. May 17-20, Hamilton, ON.
15. Shahidi, F., Kassam, N. and Rubin, L.J. 1987. Effect of ammonia-alcohol extraction system on the properties of soy meal. Presented at the Thirtieth Annual Meeting of the Canadian Institute of Food Science and Technology. May 17-20, Hamilton, ON.
14. Shahidi, F., Gabon, J.E. and Rubin, L.J. 1987. Methanol-ammonia-water treatment of canola and isolated glucosinolates. Presented at the Thirtieth Annual Meeting of the Canadian Institute of Food Science and Technology. May 17-20, Hamilton, ON.
13. Gabon, J.E., Kassam, N., Rubin, L.J., and Shahidi, F. 1986. Fate of glucosinolates in $CH_3OH/ NH_3/H_2O$ treatment of rapeseed. Presented at the Twentieth-Ninth Annual Meeting of the Canadian Institute of Food Science and Technology. Calgary, AB.
12. Shahidi, F., Diosady, L.L., Naczk, M., and Rubin, L.J. 1985. Removal of glucosinolates from high-glucosinolate rapeseed and mustard seed. Presented at the Twenty-Eighth Annual Meeting of the Canadian Institute of Food Science and Technology. Toronto, ON.
11. Rubin, L.J., Shahidi, F., Diosady, L.L., And Wood, D.F. 1985. Control of lipid oxidation in cooked meats. Presented at the Thirty-First Meeting of Meat Research Workers Meeting. Bulgaria.
10. Shahidi, F. 1984. Alternative meat-curing systems. Presentation to the Industry-Government Committee on Nitrites and Nitrosamines. Ottawa, ON. By invitation.
9. Shahidi, F., Rubin, L.J., Diosady, L.L. and Wood, D.F. 1984. Alternative meat-curing system. Presented at the Twenty-Seventh Annual Meeting of the Canadian Institute of Food Science and Technology. Vancouver, BC.
8. Diosady, L.L., Rubin, L.J., Shahidi, F. and Yun, J.J. 1984. Alternative meat-curing system. Presented at the Twenty-Seventh Annual Meeting of the Canadian Institute of Food Science and Technology. Vancouver, BC.
7. Rubin, L.J., Shahidi, F., Diosady, L.L., and Wood, D.F. 1984. Synthesis of dinitrosyl ferrohemochrome and its characteristics. Presented at the Thirtieth European Congress of Meat Research Workers Meeting. Ireland.

6. Shahidi, F., Rubin, L.J. and Diosady, L.L. 1983. Alternative meat-curing systems. II. Control of oxidative rancidity. Presented at the Twenty-Sixth Annual Meeting of the Canadian Institute of Food Science and Technology. Ottawa, ON.
5. Rubin, L.J., Shahidi, F., and Diosady, L.L. 1983. Alternative meat-curing systems. I. cooked cured-meat pigment. Presented at the Twenty-Ninth European Congress of Meat Research Workers Meeting. Italy.
4. Shahidi, F., Thankachan, C. and Tidwell, T.T. 1982. Reactivity of di-tert-butyl-O-benzene-diperacetate. Presented at the Sixty-Fifth Annual Meeting of the Canadian Institute of Chemistry. Toronto, ON.
3. Shahidi F. and Tidwell, T.T. 1979. Cyclization and bond cleavage reactions of free radicals and peroxides. Presented at the International Symposium of Physical Organic Chemistry. Toronto, ON.
2. Shahidi, F., Farrell, P.G., and Edward, J.T. 1977. Partial molar volumes of hydrocarbons in CCl_4 Presented at the Second American Chemical Society/ Canadian Institute of Chemistry Conference. Montréal, PQ.
1. Edward, J.T., Farrell, P.G., and Shahidi, F. 1975. Les volumes molaires partial des composes organique dans l'eau. Presented at the Forty-Fourth Congress of Association Canadienne-Francaise pour l'Avancement des Sciences. Sherbrooke, PQ.

Post-doctoral Fellows/Research Assistants/Associates at Memorial:

Prof. Laura de La Rosa	2009 -			Visiting Professor		
Prof. Emilio Alvarez-Parrilla	2009 -			Visiting Professor		
Ms. Juarte Dougalaite	2009 -			Visiting Scholar		
Dr. Jenny Ann John	Nov. 2007		-			Research Assistant
Dr. Nadia Mahfooz	Aug.	2005	-	Dec.	2005	Visiting Professor
Dr. Min-Soo Heu	Aug.	2001	-	Aug.	2002	Visiting Professor
Dr. S.P.J. Senanayake	Jan.	2001	-	Oct.	2001	Post-doctoral Fellow
Mr. M.A. Khan	Aug.	1999	-	Jan.	2000	Research Assistant
Professor S-K. Kim	Feb.	1999	-	Aug.	2000	Visiting Professor
	June	2001	-	Aug.	2001	
	June	2005	-	Aug.	2005	
Dr. Y.J. Jeon	Dec.	1998	-	Jan.	2000	Post-doctoral Fellow
Dr. U.N. Wanasundara	Jan.	1997	-	Jan.	1999	Post-doctoral Fellow
Dr. P.K.J.P.D. Wanasundara	Mar.	1996	-	Jan.	1999	Post-doctoral Fellow
Ms. Yue Hua He	Mar.	1995	-	1997		Research Assistant
Dr. R.B. Pegg	June	1993	-	1997		Post-doctoral Fellow
Dr. R. Amarowicz	Oct.	1991	-	1998		Post-doctoral Fellow

Ms. M.X. Liu	Sept.	1992	-	Mar.	1994	Visiting Scholar
Dr. V. Venugopal	Mar.	1993	-	Oct.	1993	Post-doctoral Fellow
Prof. X. Zhao	Aug.	1991	-	Jan.	1992	Visiting Scholar
Dr. J. Balejko	Sept.	1991	-	Nov.	1992	Post-doctoral Fellow
Ms. X. Chong	June	1991	-	Feb.	1993	Research Assistant
Ms. N. Helbig	Jan.	1991	-	June	1991	Senior Research Assistant
Mr. Z. Yang	Nov.	1990	-	Aug.	1992	Visiting Scholar
Dr. E. Dunajski	Jan.	1990	-	July	1991	Post-doctoral Fellow
Dr. J. Synowiecki	May	1989	-	Oct.	1991	Post-doctoral Fellow
	Mar.	1992	-	Oct.	1992	
	Jan.	1993	-	Apr.	1993	
	Jan.	1995	-	June	1995	
Dr. M. Naczk	Sept.	1987	-	Aug.	1989	Research Associate

Theses Supervised:

a. Postgraduate:

T. Albishi, " Antioxidants in Potato and Onion Peels". M.Sc. in progress.

Y. Zhong, "Modification of Tea Catechins and their Health Effects", Ph.D. 2010.

Z. Tan, "Modification of Phytosterols and Production of Structured Lipids", Ph.D., in progress.

A. Chandrasekara, "Millet Phytochemicals", M.Sc. in progress.

N. Chandrasekara, "Lipid Biology and Biotechnology", M.Sc, 2011.

J. Wang, "Structural and Modified Lipids", M.Sc. in progress.

T. Madhujith, "Antioxidants in Barley", Ph.D., 2007.

H. Miraliakbari, "Antioxidants and Bioactives in Tree nut oils", 2005.

Y. Zhong, "Nutritional Implications of Dietary Oxidized Oil in Juvenile Cod", 2005.

F. Hamam, "Structured Lipids", Ph.D., 2007.

C. Liyanapathirana, "Phenolics in Cereals and Grains and their Biological Effects", Ph.D. 2005.

R. Abou-Zaytun, Lipids in DNA breakage, M.Sc., 2005.

F. Hamam, "Lipid Biotechnology, M.Sc., 2003.

A. Gomage, "Chitosan in Water Purification", M.Sc., 2003.

G. Whiteway, "Chitosan Oligomers", M.Sc. Transferred to Chemistry 2002.

M.A. Khan, "Algal Food and Bivalue Aquaculture". Ph.D., 2005.

T. Madhujith, "Antioxidants in Beans", M.Sc., 2003.

S. Siriwardhana, "Antioxidants of Almond", M.Sc., 2002.

X. Yu, "Preparation of concentrates of docosapentaenoic acid and studies on its absorption in an animal model", M.Sc., 2002.

C. Liyanapathirana, "Effect of Dietary Carotenoids on the Quality of Sea Urchin", M.Sc., 2001.

J. Kamil, "Marine Lipids, their Stability and Characteristics", M.Sc., 2000.

Metusalach, "Aquaculture Feed and Cultured Species". Ph.D., 2002.

N. Senanayake, "Lipids of Borage and Evening Primrose", Ph.D., 2001.

S.A. Spurvey, "Lipid Biotechnology of Seal Blubber Oil", M.Sc., 2002.

A. Khan, "Effects of Stripping on Quality of Medicinal Oils", M.Sc., 1999.

U. Chavan, "Beach Pea Characteristics and Utilization", Ph.D., 1999.

Y.H. Chen, "Beach Pea/Grass Pea - Chemistry and Detoxification", M.Sc., transferred to Auburn University.

E. Durnford, "Lipid Classes and Subclasses of Tissues of Harp Seal", M.Sc., 1999.

M. Wettasinghe, "Antioxidants from Borage and Evening Primrose", Ph.D., 1999.

A.C. Onodenalore, "The Chemistry and Modifications of Seafood Proteins, Flavourants and Antioxidants", Ph.D., 1999.

H.A.H. Abou Gharbia, "Enzyme and Processing Effects on Sesame Seed", Ph.D., 1997.

A. Campos, "Artemia Biomass in Aquaculture", M.Sc. 1997.

S. Lin, "Aquaculture of Arctic char: Effect of lipid content on pigmentation of Arctic char", M.Sc. 1997.

M. Wettasinghe, "Oxidative Stability and Texture of Meat as Affected by Salts and Haem Pigments", M.Sc., 1995.

X.Q. Han, "Modification of Seafood Proteins and Chemistry of Cold-Adapted Marine Enzymes", Ph.D., 1992- , transferred to the University of Wisconsin.

J. Synowiecki, "Marine Processing By-Products", Habilitions Doctorate (D.Sc.), Technical University of Gdansk, Gdansk, Poland, 1994.

X.Q. Han, "Marine Enzymes", M.Sc., 1993.

D.M. Power, "Tea Tannins", M.Sc., transferred.

M. Metusalach, "Effect of Stacking Density on Seafood Quality", M.Sc., 1996.

D. Lam, "Lipid Oxidation in Seafoods: Development and Prevention", M.Sc., 1992 - transferred to Medical School.

W.M.U.N. Wanasundara, "Further Processing of Marine Oils", Ph.D., 1995.

W.M.U.N. Wanasundara, "Stabilization of Canola Oil by Naturally-Occurring Antioxidants", M.Sc., 1993.

A.C. Onodenalore, "Mechanically Deboned Chicken Meat: Products and Properties", M.Sc., 1993.

R.B. Pegg, "Development of Nitrite-Free Meat Curing Systems", Ph.D., 1993.

P.K.J.P.D. Wanasundara, "Flaxseed Proteins", Ph.D. 1996.

P.K.J.P.D. Wanasundara, "Characteristics of Solvent Extracted Flaxseed (*Linum usitatissimum L.*) Meals", M.Sc., 1992.

R.B. Pegg, "One-Step Preparation of Nitrosyl Ferrohemochrome and Its Characteristics", 1989 transferred from M.Sc. to Ph.D.

J.E. Gabon, "Fate of Glucosinolates in Rapeseed", M.A.Sc., 1986.

N. Kassam, "Effect of Methanol-Ammonia Treatment on Soybean Protein", M. Eng., 1986.

J.J. Yun, "Flavour and Oxidative Stability of Meats", M.A.Sc., 1984.

L.A. D'Souza, "Meat Flavour Volatiles: A Review of the Composition, Techniques, and Sensory Evaluations", M. Eng., 1984.

b. Undergraduate, Honours:

H. Miraliakbari, "Wheats as Free Radical Scavengers", B.Sc. (Nutrition), 2002.
J. Farrell, APhytochemicals from Amaranth@, B.Sc. (Nutrition), 1999. Moved to Medical School.

M. Murrin, "Production and Characteristics of Structured Lipids involving Long-chain polyunsaturated and medium chain fatty acids", B.Sc. (Nutrition), 1999.

R. Saunders, AToxicological Studies on Cod Sperm and Eggs@, B.Sc. (Biology), 1997.

S.A. Spurvey, "Oxidative Stability of Fresh and Heat-Processed Dark and Light Muscles of Mackeral (*Scomber scombrus*)", B.Sc., 1995.

J.L. Lewis, "Effect of Processing on Meat Flavour", B.A.Sc., 1986.

J. Brito, "Sinigrin Breakdown Products", B.A.Sc.,1986.

A. O'Boyle, "Microencapsulation of Dinitrosyl Ferrohemochrome", B.A.Sc., 1986.

S. Joseph, "Dinitrosyl Ferrohemochrome and its Application to Meat", B.A.Sc., 1985.

T.G.M. Chiu, "Meat Flavour Volatiles", B.A.Sc., 1985.

P.I. Kawamura, "Preparation and Application of the Synthetic Pigment Dinitrosyl Ferrohemochrome", B.A.Sc., 1984.

M.T. Lau, "Detoxification of High-Glucosinolate Rapeseed by the Two-Phase Extraction Method@, B.A.Sc., 1984.

R.J. Goncza, "The Effect of Changes in Contact Time, Temperature, and Solvent Concentration on the Glucosinolate Content of Brassica Juncea (L22a)", B.A.Sc., 1984.

N.S. Lee, "Stabilization of Dinitrosyl Ferrohemochrome and its Application to Meat@, B.A.Sc., 1983.

A. Shimizu, "The Determination of Sulphur by Desulphurization with Raney Nickel", B.A.Sc., 1982.

Industrial Research Assistance Program (IRAP) Projects And Reports Supervised:

16. Saleemi, Z. Chicken Surimi. 1992.

15. Chong, X. Hot Filleting of Farmed Cod (*Gadus morhua*). 1991

14. Keats, M. Poultry Products and Modified Atmosphere Packaging. 1991.

13. O'Leary, R. Quality Management Program of Fish and Shellfish Processing. 1991.

12. Pegg, R. B. Colour Evaluation of Muscle Foods. 1990.

11. Hong, C. Studies of Drip Water, Gaping and Effect of Exercise on Farmed Cod Quality. 1990.

10. Murphy, G. Seafood Products Research and Development Handbook. 1990.

9. Harris, R. The Development of Secondary Pork and Poultry Products, 1990.

8. Hewitt, S. Product Enhancement and Production Control of Seafoods, 1990.

7. Walsh, K. Collection and Quality Assurance of Cod Livers. 1989.

6. Murphy, G. Evaluation of Feed and Quality of Wintered Cod. 1989.

5. Williams, L. Quality Enhancement and Production Control in Crab Processing. 1989.

4. Walsh, K. Storage-Life Study of Frozen Breaded Chicken Pieces and Mechanically Separated Chicken Meat. 1988.

3. Murphy, G. Some Quality Characteristics of Cod Fillet and Liver. 1988.

2. Harris, R. Upgrading of Crab Processing as the Utilization of Crab Shells. 1988.

1. Brooker, J. Development of Capelin Quality and Cod Rigour Mortis Indicators. 1988.

Teaching Duties at Memorial:

2009-Present	Bioenergetics (BC 4200)
1996-Present	Biochemical Techniques (BC 4211)
1987-Present	Food Chemistry (BC 3402)
1987-Present	Food Biochemistry (BC 6530)
1987-1998	Instrumental Methods of Food Analysis (BC 4400)
1988-1990	Food Topics (BC 4501)
1990-Present	Science and Technology of Marine Foods (BC 4650/BC 6650)
1992-Present	Marine Biochemistry (BC 6630)
1988-1992	Training of students on IRAP-H and NSERC projects

Other Activities:

36. Serving P & T Committee of the Department of Biochemistry, 2009-2010.
35. Serving P & T Committee of the Department of Biochemistry, 2007-2008.
34. Serving P & T Committee of the Department of Biochemistry, 2005-2006.
33. Serving on the University's Biosafety Committee, 1997- .
32. Elected to Senate, Memorial University of Newfoundland, 2002-2005.
31. Serving on Departmental Safety Committee, 1997-2001.
30. Serving on Departmental Promotion and Tenure Committee, 1998-1999.
29. Serving as a member of the Nomination Committee for the Academic Council of Graduate Studies, 1994-1995.
28. Serving as an International network coordinator for Meat Focus International Journal.
27. Serving as a Supervisory Committee Member for M.Sc. thesis of N. Senanayake.
26. Served as a member of Steering Committee of the Department of Fisheries and Oceans on seal meat research and developing of sealing industries (1990-92).
25. Served as external examiner for the Ph.D. thesis of C.A. Thompson, University of Alberta, 1994.
24. Served as external examiner for the Ph.D. thesis of A. Khamessan, McGill University, 1994.
23. Member of Senate Committee on Research, 1992-95. Served as a number of the sub-committee for evaluation of "A Sea Change" report and served as the chair of the "President's Awards" evaluation sub-committee (1993-94).

22. Served as the internal examiner for M. Sc. thesis of M. Ogbomo, Department of Chemistry, 1993.
21. Served as the representative of the Dean of graduate Studies for the Comprehensive Examination of Mr. Xiao Ping, Department of Physics, 1993.
20. Member of Academic Council of Graduate Studies, 1992-95. Also served in the subcommittee on admission of refugees and served as the Chairperson on the subcommittee on evaluation of M.Sc. and Ph.D. oral examination procedures.
19. Served as the Member of Search Committee for Biochemistry Headship, 1992.
18. Dean of Graduate Studies Representative for the Ph.D., comprehensive of Amgad Hossein in Engineering, 1992.
17. Served as a member of the Graduate Studies Committee in the Department 1987-1988, 1992-1993.
16. Served as a member of the Undergraduate Studies Committee in the Department 1988-89, 1989-90 and 1990-91 and 1993-94 as well as Undergraduate Food Science Advisor, 1993-94.
15. Served on the technical committee of the Eighth World Congress of Food Science and Technology, IUFoST, held in Toronto September 29-October 4, 1991 and organizing two symposia entitled "Flavour of Meat and Meat Products" and "Seafoods: Chemistry, Processing Technology and Quality" in that conference.
14. Reviewed grant applications for NSERC, Texas A and M University and MRC.
13. Organized a symposium on Canola Proteins and Co-Products for the American Oil Chemists' Society, held in Toronto May 10-14, 1991.
12. Served as a member of the supervisory committee of R. F. Omar (MSc.), 1989-91.
11. Was elected as the Canadian Chairman of the Pacific Basin 1989 Conference. Served as the Canadian Chairman of the Third Chemical Congress of North America, June 5-11, 1988, Toronto, Canada.
10. Elected to the National Office of Education Committee Chairman of the CIFST (1989-present). Organized two symposia in the Third Chemical Congress of North America, June 5-11, 1988, Toronto, Canada. They were entitled "New Trends and Developments in Flavour Chemistry" and "New Trends and Developments in Canola/Rapeseed Research".
9. Have been charged to form the Agricultural and food Chemistry Division of the Canadian Institute of Chemistry.
8. Was the reader of Mr. Tony Nakhla's M.Sc. thesis in the Biochemistry.
7. Was invited to give a presentation on the "Current Status of Meat Processing Industry" in the Conference on Food Processing in Newfoundland and Labrador - Producer to Consumer, Corner Brook, Nov. 18-20, 1987.
6. Have served as a member of the Advisory Group to the publishing recommendations of the CRC Publishing Company since 1986.
5. Was a member of Provincial/Federal Government delegations and Sealing Industry and Academia Delegations to visit interested industries in Japan.
4. Was a Member of Government, Industry and Academic Delegation to Singapore, Taiwan, Hong Kong and China to present the current status of underutilized fish species and seal to counterparts in those countries.

3. Presented seminars in the Departments of Chemistry and Biochemistry at Memorial University of Newfoundland and at the Agricultural University in Denmark. Supervised 16 IRAP-H projects funded jointly by the NRC and the industry.
2. Regularly reviewing papers for Canadian Inst. Food Sci. Technol. J. (now Food Research International), J. Food Sci., J. Agric. Food Chem., Food Quality, Food Chemistry J. Food Biochem. and J. Muscle Foods.
1. Reviewed promotion applications for candidates at several Universities including University of Kentucky, University of Georgia, Universitie Putra Malaysia, University of Karachi, University of Massachusetts.

Research Support at Memorial:

Since joining Memorial University in 1987, over $8,000,000 research support has been obtained. (Partial List Only). Other applications are in process.

72. Shahidi, F. EGCG Derivatives: Application areas and commercialization perspectives, DFA, 2011-2012 $ 62,125
71. Shahidi, F. Phenolics and polyphenolic compounds in food and as functional food ingredients:characterization, mechanism(s) of action, structure modification and process effects. 2010-2015 $210,000

70. Shahidi, F. Stabilization of Highly Unsaturated Lipids with Novel Compounds. AFMNet. 2009-2010 $22,000

69. Shahidi, F., Sun. G., Naczk, M. and Cao, R. Effect of Agricultural Products and By-products on Oxidative Stress in Animal Model, 2008-2012 $480,000

68. Shahidi, F., Sun, G., Muir, A. Clinical Studies on Flax Lignan And Protein Hydrolyzates Agriculture and Agri-Food Canada, 2008-2012 $428,000

67. Shahidi, F., Sun, G. and Cao, R. Role of Antioxidants in Cereals, Legume And Oilseed Products in Metabolic Syndrome and Oxidative Stress 2008-2011 $366,000

66. Rupasinghe, V., Shahidi, F. et al. Beyond Basic Nutrition: Healthy Functional Food Ingredients, Snacks and Beverages from Nova Scotia Apples AIF/ACOA 2008-2011 $1,900,000

65. Shahidi, F. Process Induced Changes in Antioxidants NSERC 2005-2010 $200,000

64. Shahidi, F. A member of team led by Dr. R. Yada of University of

Guelph for Canadian Advanced Foods and Biomaterials Network (CAFBN), 2003-2007 Shahidi's portion: $99,000

63. Shahidi, F. A member of team of applicants. Nutritional strategies to improve lipid utilization in diets for commercially important farm fish species, Aquanet, 2003-2006 $390,500

61. Shahidi, F. A member of team of applicants for AIF funding to establish a seafood by-product centre, and others 2003-2006 $1,430,000

60. Shahidi, F. Antioxidants and Prooxidants in Food Sources: Characteristics and Potential as Functional Food Ingredients in Health Promotion, NSERC, 2001-2005 $130,400

59. Shahidi, F. Centrifugal partition chromatographs, NSERC, 2002 $36,000

58. Shahidi, F. Lead applicant for CFI application for establishment of a seafood by-product centre, 2002 and associated contributions CFI: $890,600
Total: $2,240,000

57. Shahidi, F. A member of team of applicants for CFI funding to OSC and Chemistry $2,600,000

56. Shahidi, Y. Yield and Quality of Chitosan as Affected by Varying Raw Material Quality, Feasibility of use of Chitosans as Edible Invisible Films and Production of Chitosan Oligomers. ACOA, held 2000-2002. $125,000

55. Shahidi, F. Travel Grant. Department of Fisheries and Aquaculture, held 2000. $7,000

54. Shahidi, F. Phytochemicals in Almond. Almond Board of California, held 1999, 2000 $20,500

53. Thompson, R., Parish, C. and Shahidi, F., Algal Food Quality and the Enhancement of Bivalve Aquaculture. NSERC Strategic, held 1999-2002, $402, 310

52. Shahidi, F. Extraction of glycolipids from marine oils, DFO held 1999. $2,500

51. Shahidi, F. Travel Grant. Department of Fisheries and Aquaculture, held 1999. $6,170

50. Shahidi, F. (with G. Herzberg). Production of Human Milkfat Structural Lipids. Memorial University of Newfoundland, held 1998-2001. $55,000

49.	Shahidi, F. Several Small Contracts, held 1998.	$14,500
48.	Shahidi, F. Seal Protein Hydrolyzate Products, held 1997-98.	$186,000
47.	Shahidi, F. Seal Oil and Protein Capsules, Seal Oil-Based Soaps, NRC/CCFI/CAFID	$10,500
46.	Shahidi, F. Natural Antioxidants, NSERC, held 1997-2001.	$88,400
45.	Shahidi, F. Anti-yellow for Seal Oil. CCFI, held 1997.	$24,950
44.	Shahidi, F. Anti-yellow for Seal Pelt. CAFID, held 1997.	$26,000
43.	Shahidi, F. Natural Antioxidants. NSERC, held 1996-97.	$25,610
42.	Shahidi, F. Travel Grant. NSERC/JSPS, held 1996.	$9,800
41.	Shahidi F. (with A.K. Bal). Evaluation of Beach Pea (*Latyrus maritinus*) for Food and Feed Utilization. NSERC Strategic, held 1994-97.	$102,000
40.	Shahidi, F. Seal Paté and Gelatin. CAFID, held 1996-97.	$46,200
39.	Shahidi, F. Market Studies for Nitrite Alternative Meat Curing Systems. NRC, held 1995.	$10,000
38.	Shahidi, F. Cooking Cured-Meat Pigment (Pilot Studies). SID, held 1995.	$46,672
37.	Shahidi, F. Green Tea Catechins. NRC, held 1994-95.	$17,000
36	Shahidi, F. Sesame Seed Research. Foreign aid, held 1993-95.	$10,000
35.	Shahidi, F. Seal Protein Hydrolyzates. CAFID, held 1994-95.	$52,000
34.	Shahidi, F. (J. Brown, Co-investigator). Effect on Population Density on Pigmentation of Arctic Char. CFI, held 1994-95.	$19,050
33.	Shahidi, F. Isolation and Characterization of Glycolipids. DFO, held 1993-94.	$10,000
32.	Shahidi, F. Shellfish Components. DFO-NSERC, held 1994-95.	$12,000

31.	Shahidi, F. Equipment. NSERC, held 1994-95.	$31,106
30.	Shahidi, F. Shellfish Components. DFO-NSERC, held 1993-94.	$15,800
29.	Shahidi, F. Multifaceted Seal Research. NF Fisheries/CSA, held 1993-94.	$30,000
28.	Shahidi, F. Chicken Surimi. Schneider, held 1993-94.	$29,500
27.	Shahidi, F. Travel Grant. NIFDA/CFI, held 1992.	$8,340
26.	Shahidi, F. Quality of Salted and Smoked Seafoods. NIFDA, held 1992-93.	$29,500
25.	Shahidi, F. Fish Oil Capsules. NIFDA, held 1992-93.	$4,700
24.	Shahidi, F. Pigmentation of Arctic Char. NIFDA, held 1992-93.	$25,000
23.	Shahidi, F. GC/MS. CFI/NIFDA/NF Fisheries, held 1992-93.	$70,000
22.	Shahidi, F. Seal Meat and Blubber Research. CSA, ACOA, CFI, held 1992-94.	$107,000
21.	Shahidi, F. Stabilization of Meat Lipids. NSERC/held 1992-96.	$91,940
20.	Shahidi, F. Stability of Canola Oil. Canada Council of Canada, held 1992-93	$10,700
19.	Shahidi, F. Shellfish Components. DFO-NSERC, held 1992-93.	$14,600
18.	Shahidi, F. Travel Funds. DFO, held 1991-92.	$3,318
17.	Shahidi, F. Conference Funds. NSERC, held 1991-92.	$4,000
16.	Shahidi, F. Conference Funds. DFO, held 1991-92.	$11,000
15.	Shahidi, F. Farmed Cod Quality. DFO-NSERC, held 1991-92.	$17,400
14.	Shahidi, F. Capelin Proteins. DFO-NIFDA, held 1991-92.	$39,800
13.	Shahidi, F. Seal Meat and Lipids. Newfoundland Fisheries - NIFDA, held 1991-92.	$82,000
12.	Shahidi, F. Travel Funds. Newfoundland Fisheries, held 1990.	$2,000

11.	Shahidi, F. Utilization of Discards from Crustacean Offal and preparation of Value-Added Products, DFO-NIFDA, held 1990-91.	$43,900
10.	Shahidi, F. Farmed Cod: Quality Enhancement and Production/ Process Control, DFO-NSERC, held 1990-91.	$18,000
9.	Shahidi, F. Preparation and Quality Enhancement of Seal Meat/ Surimi and Seal-based Products, Newfoundland Fisheries-NIFDA, held 1990-91.	$49,980
8.	Shahidi, F. Effect of Heat Processing and Packaging on the Quality Characteristics of Seal Meat. Canadian Sealers Association, held 1990-91.	$25,000
7.	Shahidi, F. Quality of Farmed Cod, DFO-NSERC, held 1989-90.	$18,000
6.	Shahidi, F. Preparation of Seal Surimi and its Characteristics, Newfoundland Fisheries-NIFDA, held 1989-90.	$28,510
5.	Shahidi, F. Utilization of Discards from Crab and Shrimp Processing. DFO-NIFDA, held 1989-90.	$34,900
4.	Shahidi, F. Meat Processing-Role of Lipids in Flavour Development in Cured meats, NSERC Operating, held 1989-92.	$66,180
3.	Shahidi, F. IRAP-H Contracts (15 in total), NRC, held 1988-92.	$171,863
2.	Shahidi, F. Flavour of Muscle Foods, President's NSERC, held 1987-88.	$13,180
1.	Shahidi, F. Meat Processing: Alternatives to Nitrite, NSERC Operating, held 1987-89.	$42,010

Appendix B

Nutritional Labeling and Education Act (NLEA) Requirements (8/94 - 2/95), U.S. Food and Drug Administration (available at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114098.htm)

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

GUIDE TO NUTRITION LABELING AND EDUCATION ACT (NLEA) REQUIREMENTS-ATTACHMENT 6-8

ATTACHMENT 6

ROUNDING RULE TABLE FOR SERVING SIZE

MEASUREMENT TYPE	UNIT		INCREMENT ROUNDING
Discrete Units	Servings		< 50% of the Reference Amounts (RA): number of units closest to the RA = 1 serving > 50% to < 67% of RA: then 1 unit = 1 serving OR 2 units = 1 serving >or = 67% to < 200% of RA: then 1 unit = 1 serving >or = 200% of RA: then 1 unit = 1 serving, if it can reasonably be consumed at a single eating occasion
Common Household Measures	Volume:	Cup (cup) Tablespoon (Tbsp) Teaspoon (tsp) Fluid Ounce (fl oz)	Use "cup" in 1/3 or 1/4 cup increments, except may use "fl oz" for beverages >or = 2 Tbsp & < 1/4 cup = whole Tbsp Between 1 & 2 Tbsp, may use increments of: 1, 1 1/3, 1 «, 1 2/3, 2 >or = 1 tsp & < 1 Tbsp = whole tsp < 1 tsp = 1/4 tsp increments Ounce (oz) measures = 0.5 oz increments Fluid Ounce (fl oz) = whole number increments Serving sizes that fall half-way between two serving sizes, manufacturers shall round up to the next incremental size.
	Weight:	Ounce (oz)	
Metric Measures	Volume:	Milliliters (ml)	> 5 = nearest whole number >or = 2 and < 5 = nearest 0.5
	Weight:	Gram (g) Milligram (mg)	< 2 = nearest 0 1
Number of Servings/Container	Numbers		Round to the nearest whole number except for servings between 2 and 5 servings Between 2 and 5 servings = nearest 0.5 serving Rounding should be indicated by the term "about."

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ATTACHMENT 7

ROUNDING RULES FOR DECLARING NUTRIENTS

Per Technical amendments of mandatory nutrition labeling final rule, August, 1993

Nutrient/Serving	(M) (V) (*)	Core Nutrient	Units	Increment Rounding(**)
Calories	M	X	cal.	< 5 cal - express as zero < or = 50 cal - express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment
Calories from fat	M		cal	< 5 cal - express as zero < or = 50 cal - express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment
Calories from saturated fat	V		cal	< 5 cal - express as zero < or = express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment
Total fat	M	X	g	<0.5g - express as zero < 5g - express in nearest 0.5g increment > = 5g - express to nearest ig increment
Saturated fat	M		g	<0.5g - express as zero 5g - express to nearest 0.5g increment > or = 5g - express to nearest ig increment
Polyunsaturated & Monounsaturated fat	V		g < 5g -express to nearest 0.5g increment	<0.5g - express as zero > or = 5g - express to nearest lg increment
Cholesterol	M		mg	,2 mg - express as zero

				2 - 5 mg - express as "less than 5 mg" > 5 mg - express to nearest 5 mg increment
Sodium	M	X	mg	< 5 mg - express as zero 5 - 140 mg - express to nearest 5 mg increment > 140 mg - express to nearest 10 mg increment
Potassium	V		mg	< 5mg - express as zero 5 - 140 mg - express to nearest 5 mg increment > 140 mg - express to nearest 10 mg increment
Total carbohydrate	M	X	g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment
Dietary fiber	M		g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment

ATTACHMENT 7

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Nutrient/Serving	(M) (V) (*)	Core Nutrient	Units	Increment Rounding (**)	Insignificant Amount	
Soluble & Insoluble fiber	V		g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment	< 0.5 g	101.9(c)(6)(i)(A) & (B)
Sugars	M		g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment	< 0.5 g	101.9(c)(6)(ii)
Sugar alcohol	V		g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment	< 0.5 g	101.9(c)(8)(iii)
Other carbohydrate	V		g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment	< 0.5 g	101.9(c)(6)(iv)
Protein	M	X	g	< 0.5g - express as zero < 1g - express as "Contains less than 1g" OR "less than 1g" > or = 1g - express to nearest 1g increment	< 1 g	101.9(c)(7)
Vitamins & minerals	M		% DV	< 2% of RDI - may be expressed as (1) 2% if actual amount is 1.0% or more (2) zero (3) an asterisk that refers to statement "Contains less than 2% of the Daily Value of this (these) nutrient (nutrients) (4) for Vit A, C, calcium, iron: statement "Not a significant source of ___ (listing the vitamins or minerals omitted)" < or = 10% of RDI - express to nearest 2% increment\ > 10% - < or = 50% of RDI - express to nearest 5% increment > 50% of RDI - express to nearest 10% increment	< 2% RDI	Vitamins and minerals other than vit A, C, calcium and iron, listed (8)(iv), are mandatory if added as nutrient supplement is food or if claim is made 101.9(c)(8)(iii) & (iv)
Beta-carotene	V		% Vit A	< or = 10% of Vit. A - express to nearest 2% increment > 10% - < or = 50% of Vit A - express to nearest 5%increment > 50% of Vit A - express to nearest 10% increment		101.9(c)(8)(vi)

(M) = Mandatory and (V) = Voluntary

(**) To express to the nearest 1g increment, amounts exactly halfway between two whole number or higher (e.g., 2.50 to 2.66g) round up (e.g., 3g) and amounts less than halfway between two whole numbers (e.g., 2.01 to 2.49g) round down (e.g., 2g).

(***) NOTES FOR ROUNDING % Daily Value (DV):

(1) To calculate % DV, divide either the actual (unrounded) quantitative amount or the declared (rounded) amount by the appropriate RDI or DRV. Use whichever amount will provide the greatest consistency on the food label and prevent unnecessary consumer confusion 109.9(d)(7)(2).

(2) When %DV values fall between two whole numbers, rounding shall be as follows:
- for values exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.990 the values shall round up (e.g., 3%)
- for values less than halfway between two whole numbers (e.g., 2.01 to 2.49) the values shall round down (e.g., 2%).

ATTACHMENT 7

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ATTACHMENT B
DAILY VALUES FOR NUTRITION LABELING
(Based on 2,000 Calorie Intake for Adults and Children 4 or More Years of Age)

Nutrients in this table are listed in the order in which they are required to appear on a label in accordance with 101.9(c)

This list includes only those nutrients for which a Daily Reference Value (DRV) has been established in 101.9(c)(g) or a Reference Daily Intake (RDI) in 101.9(c)(8)(iv).

NUTRIENT	M or V	UNIT OF MEASURE	DAILY VALUE

Total Fat	M	grams (g)	65
Saturated Fatty Acids	M	grams (g)	20
Cholesterol	M	milligrams (mg)	300
Sodium	M	milligrams (mg)	2,400
Potassium	V	milligrams (mg)	3,500
Total Carbohydrate	M	grams (g)	300
Dietary Fiber	M	grams (g)	25
Protein	M	grams (g)	50
Vitamin A	M	International Unit (IU)	5,000
Vitamin C	M	milligram (mg)	60
Calcium	M	grams (g)	1
Iron	M	milligrams (mg)	18
Vitamin D	V	International Unit (IU)	400
Vitamin E	V	International Unit (IU)	30
Thiamin	V	milligrams (mg)	1.5
Riboflavin	V	milligrams (mg)	1.7
Niacin	V	milligrams (mg)	20
Vitamin B (sub) 6	V	milligrams (mg)	2.0
Folate	V	milligrams (mg)	0.4
Vitamin B (sub) 12	V	micrograms (ug)	6.0
Biotin	V	milligrams (mg)	0.3
Pantothenic acid	V	milligrams (mg)	10
Phosphorus	V	grams (g)	1.0
Iodine	V	micrograms (ug)	150
Magnesium	V	milligrams (mg)	400
Zinc	V	milligrams (mg)	15
Copper	V	milligrams (mg)	2.0

M = Mandatory
V = Voluntary

On January 4, 1994, FDA proposed values for seven additional nutrients: Vitamin K., Selenium, Chloride, Manganese, Fluoride, Chromium and Molybdenum.

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Appendix C

GRAS Notice for Aker Biomarine Antarctic AS, December 14, 2010.

GR

ORIGINAL SUBMISSION

000001

Soni & Associates Inc.

749 46th Square
Vero Beach, FL 32968, USA
Telephone: 772-299-0746
Facsimile: 772-299-5381
E-mail: sonim@bellsouth.net

December 14, 2010

Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: Notification of GRAS Determination for Krill Oil

Dear Sir/Madam:

In accordance with proposed 21 CFR 170.36 (Notice of a claim for exemption based on a GRAS determination) published in Federal Register (62 FR 18938-18964; April 17, 1997), I am submitting in triplicate, as the agent of the notifier, Aker Biomarine Antarctic AS, Norway, a Generally Recognized As Safe (GRAS) notification for Superba® Krill Oil.

Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba* is intended for use as a food ingredient in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods, at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba® Krill Oil is estimated to result in a maximum daily intake of 8.28 g/person.

If you have any questions or require additional information, please feel free to contact me by phone at 772-299-0746 or by email at sonim@bellsouth.net.

Sincerely,

(b) (6)

Madhu G. Soni, Ph.D.

Enclosures:

Soni & Associates Inc.

749 46th Square
Vero Beach, FL 32968, USA
Telephone: 772-299-0746
Facsimile: 772-299-5381
E-mail: sonim@bellsouth.net

GRAS NOTIFICATION

I. Claim of GRAS Status

A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

Aker Biomarine Antarctic AS, Norway, has determined that high phospholipid krill oil is Generally Recognized As Safe, and therefore, exempt from the requirement of premarket approval, under the conditions of its intended use. This determination is based on scientific procedures as described in the following sections, under the conditions of krill oil's intended use in food, among experts qualified by scientific training and expertise.

Sig (b) (6)

Date 12/14/10

Madhu G. Soni, Ph.D., FACN

Agent for:

Aker Biomarine Antarctic AS
Fjordalléen 16, 0115 Oslo
Norway

000003

B. Name and Address of Notifier:

Hogne Vik, M.D., Ph.D.
EVP Documentation
Aker Biomarine Antarctic AS
Fjordallèen 16, 0115 Oslo
Norway

Tel: +47 24 13 00 00
Fax: +47 24 13 01 10
Email: hogne.vik@akerbiomarine.com

C. Common or usual name of the notified substance:

The common name of the substance of this notification is high phospholipid krill oil. The specific substance of this GRAS determination is Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba*. Superba™ Krill Oil is rich in omega-3 fatty acids, most of which are attached to phospholipids. Superba™ Krill Oil also contains astaxanthin ester.

D. Conditions of use:

High phospholipid krill oil is intended for use as a substitute or alternative to fish oils in the following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods[1], at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba™ Krill Oil, in the above mentioned food categories, is estimated to result in a maximum daily intake of 8.28 g/person. The proposed use of Superba™ Krill Oil will provide a maximum daily consumption of up to 2.20 g/person/day of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

E. Basis for GRAS Determination:

In accordance with 21 CFR 170.30, high phospholipid krill oil has been determined to be Generally Recognized As Safe (GRAS) based on scientific procedures. A comprehensive search of the scientific literature was also utilized for this determination. There exists sufficient qualitative and quantitative scientific evidence, including human and animal data to determine safety-in-use for Superba™ Krill Oil. Recently, high phospholipid krill oil (GRN 000242) has been the subject of a GRAS notification, while two of its important component fatty acids, EPA and DHA as part of fish or algal oil, have been the subject of multiple GRAS notifications. In response to these notices, FDA did not question the conclusions that the use of high phospholipid krill oil or sources of fatty acids (EPA and DHA) is GRAS under the conditions described in the notices. The safety

[1] Under Section 5(b) of the Orphan Drug Act (ODA), a Medical Food is defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The intended use of krill oil in medical foods will be as per these and other applicable regulations.

determination of high phospholipid krill oil is based on the totality of available scientific evidence that includes human observations and a variety of preclinical and clinical studies. Based on the available safety-related information, the estimated daily intake, if ingested daily over a lifetime, is safe.

F. Availability of Information:

The data and information that forms the basis for this GRAS determination will be provided to the Food and Drug Administration upon request and are located at the offices of:

Madhu G. Soni, Ph.D., FACN,
Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968
Phone: (772) 299-0746; E-mail: sonim@bellsouth.net

II. Detailed Information About the Identity of the Notified Substance:

A. Trade Name:

The subject of this notification will be marketed as Superba™ Krill Oil

B. Physical Characteristics

Superba™ Krill Oil is dark red colored viscous oil

C. Chemical Abstract Registry Number:

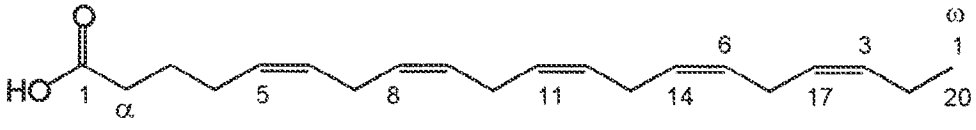
Not available

D. Chemical Formula:

Not applicable

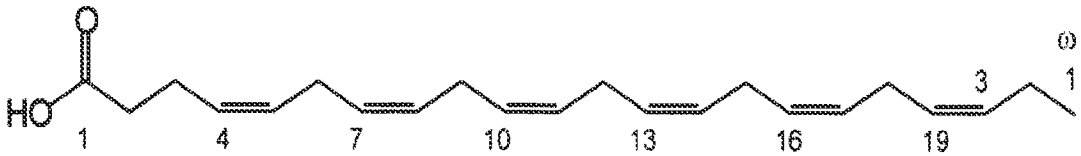
E. Structure:

The important constituents of high phospholipid krill oil are the fatty acids, EPA and DHA. The structures of these two fatty acids presented in Figure 1.



$CH_3CH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CH(CH_2)_3COOH$

Eicosapentaenoic acid (EPA)



$CH_3CH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CHCH_2CH{=}CH(CH_2)_2COOH$

Docosahexaenoic acid (DHA)

Figure 1. Chemical structures of EPA and DHA

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F. Typical Composition and Specifications

Typical compositional analysis and specifications of Superba™ Krill Oil are presented in Table 1. Analytical results of five lots from non-consecutive batches (Appendix I) indicate that the product consistently meets these specifications. The major components of Superba™ Krill Oil are triglycerides and phospholipids high in omega-3 fatty acids such as EPA (C 20:5 n-3 fatty acid) and DHA (C 22:6 n-3 fatty acid). The maximum amount of EPA + DHA present in Superba™ Krill Oil will be 23.5 ± 2 g/100 g of the oil. No processing aids or additives, with the exception of residual amounts of ethanol solvent, are included in the final Superba™ Krill Oil product. Likewise due to naturally occurring astaxanthin esters that aid in its preservation, addition of an exogenous antioxidant is not required. Based on an 18 month stability test at different storage temperatures, the shelf life of Superba Krill Oil is set to 18 months when stored at 2-8°C. The results of pesticides and other environmental contaminants including PCBs, dioxins, furans and dioxin like PCBs, organochlorine pesticides, PBDEs, PAHs, and elements and heavy metal analyses from multiple batches of the product are presented in Appendix II.

Table 1. Typical compositional analysis and specifications of Superba™ Krill Oil

Parameter	Limits	Assay method
Appearance	Dark red viscous oil	Visual
Lipid composition		
Total phospholipids (g/100 g)	43 ± 3	N A88[1]/AM-AKMB-012
- Omega-3 phospholipids of total PL[2] % (w/w)	>70	Calculation
Triglycerides (g/100 g)	<50	N A88[1]/AM-AKMB-012
Fatty acid profile		
Total omega-3 (expressed as g/100 g)	23.5 ± 2	AOCS Ce 1b-89/AM-ABM-013
-C 20:5 n-3 (EPA)(expressed as g/100 g)	14 ± 2	AOCS Ce 1b-89/AM-ABM-013
-C 22:6 n-3 (DHA)(expressed as g/100 g)	6.5 ±1	AOCS Ce 1b-89/AM-ABM-013
Total omega-6	<3.0	AOCS Ce 1b-89/AM-ABM-013
Stability index		
Peroxide value (mEq peroxide/kg)	<2	AOCS Cd 8b-90/AM-058
Antioxidants		
Astaxanthin[4] (mg/kg)	100 ± 20 (minimum)	N A23[3]/AM-ABM-011
Water and Ethanol		
Water activity at 25°C	<0.5	AOAC 978.18
Ethanol content (% w/w)	<3.0	GC
Microbiology		
Total plate count (cfu/g)	<2500	NF EN ISO 4833/CQ-MO-231
E. coli (1 sample at 10 g)	Negative	Petrifilm Select EC
Coliform bacteria, 37°C (cfu/g)	<10	NordVal Ref. No. 014
Salmonella negative (PCR) (1 sample at 10 g)	Negative	AES 10/4-025/04
Mold and Yeast (cfu/g)	<10	NordVal Ref. No. 016

[1]Based on Homan and Anderson (1998) and Moreau (2006)
[2]Omega-3 phospholipid: defined as phospholipid where on average one out of two possible positions is occupied by an omega-3 fatty acid.
[3]Based on Schierle J. & Härdi W. (1994); [4]Expressed as astaxanthin diols.

000006

As available research highlights the potential for seafood to contain substantial amounts of arsenic, an extensive chemical analysis of both organic and inorganic arsenic was undertaken from multiple batches (see Appendix II). These results show that while the total arsenic levels in krill oil ranged from 4 to 6 ppm, the vast majority of this arsenic was in organic form. The inorganic arsenic as measured in the form of arsenite and arsenate was below the level of quantification at 0.05 ppm.

G. Lipid and Fatty Acid Profile:

The lipid profile composition and fatty acid profile of krill oil is presented in Table 2 and 3, respectively. Analysis of *trans*-fatty acids from four different batches revealed the presence of total *trans*-fatty acids of <0.2% (Appendix III).

Table 2. Lipid profile, including phospholipids

Lipids	Percent Oil
Triacylglycerol	38
Diacylglycerol	0.8
Monoacylglycerol	<1
Free fatty acids	5.4
Cholesterol	1.1
Cholesterol ester	<0.5
Phosphatidylethanolamine	1.6
Phosphatidylinsotol	<1
Phosphatidylserine	<1
Phosphatidylcholine	39
Lysophosphatidylserine	3.7
Total polar lipids	44.7
Total neutral lipids	45.6

Table 3. Details of representative fatty acid profile

Fatty acid	Percent*	Fatty acid	Percent*
C14:0	7.7	C20:4 n-6	0.4
C16:0	15.4	C22:0	<0.1
C18:0	0.9	C22:4 n-6	0.5
C20:0	<0.1	C18:3 n-3	1.4
C22:0	0.1	C18:4 n-3	<0.1
C16:1 n-7	4.9	C20:4 n-3	0.5
C18:1 (n-9) + (n-7) + (n-5)	12.1	C20:5 n-3	14.7
C20:1 (n-9) + (n-7)	0.9	C21:5 n-3	0.4
C22:1 (n-11) + (n-9) + (n-7)	0.7	C22:5 n-3	0.3
C24:1 n-9	0.1	C22:6 n-3	6.2
C16:2 n-4	0.5		
C16:3 n-4	0.2	SFA	24.1
C18:2 n-6	1.2	MEFA	18.7
C18:3 n-6	0.2	PUFA (n-6)	1.9
C20:2 n-6	<0.1	PUFA (n-3)	24.0
C20:3 n-6	0.1	Total PUFA	26.6
		Total Fatty Acids	68.2

*Percent of total oil; Data from representative batch (A)-U301/006/A10

H. Manufacturing process

Superba™ Krill Oil is derived from shrimp-like, marine crustaceans of the order *Euphausiacea*, *Euphausia superba.* These organisms have a circumpolar distribution with the highest concentrations found in the Atlantic sector. Antarctic krill exist in large numbers in the open sea and are consumed as food by humans. The Antarctic krill used in the production of Superba™ Krill Oil are naturally occurring organisms fished from the wild. The harvested Antarctic krill is cooked and dried on the vessel to prepare krill meal. The steps involved in the manufacturing are summarized in Figure 1. The raw material that is extracted, krill meal, is a biomass composed of lipids, carbohydrates, and proteins. By using a solvent extraction process, the proteins and free carbohydrates are removed. Thus the oil is produced by subjecting the krill meal to ethanol extraction. The solvent used is food-grade quality and is removed from the product in accordance with current good manufacturing practice.

Following extraction, the defatted krill meal and the ethanol oil solution are separated. The ethanol-oil solution is then concentrated by evaporation and stored. The ethanol-oil solution is analyzed for ethanol, neutral and polar lipids, and astaxanthin content. Several batches are blended and the ethanol-oil solution is clarified by centrifugation. The ethanol is then evaporated from the oil solution and the final product is analyzed to verify the conformity with product specifications. The final product is filled into suitable containers and stored at 2-8°C and can be shipped by land, air, or boat. Processing aids, including solvents (which is removed by evaporation) used in the manufacturing process are food-grade quality as specified in the 5th Edition of Food Chemicals Codex. The Superba™ Krill Oil production process is controlled under the Hazard Analysis Critical Control Points (HACCP) system and points for likely contamination of the oil are strictly monitored. Additionally, the quality of the final product and production lots are routinely tested for specifications including solvent residue, microorganisms, heavy metals, and pesticides.

I. Manufacturing of Superba™ Krill Oil Process Diagram

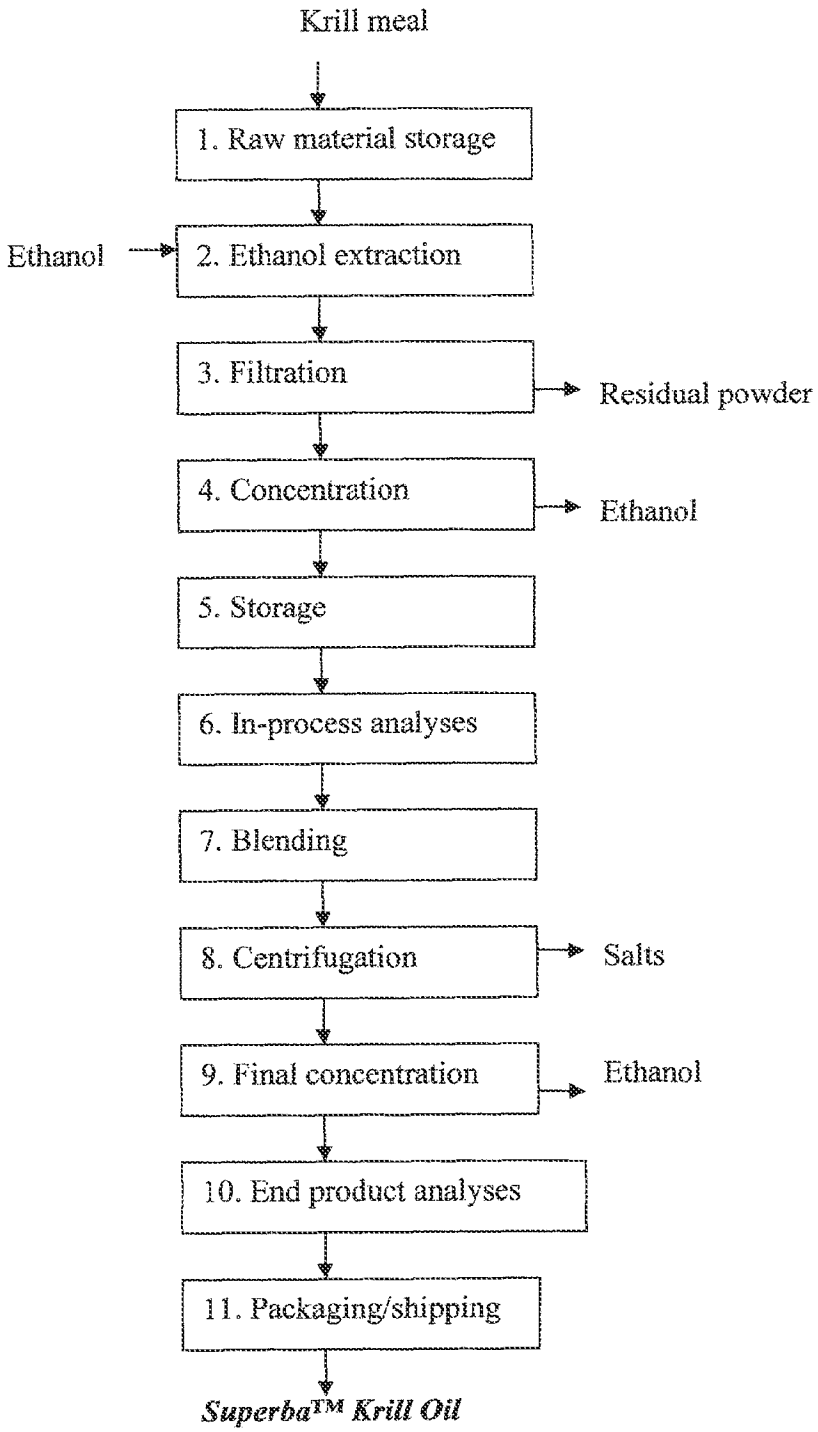

Figure 2. Manufacturing process of Superba™ Krill Oil

J. Intended Technical Effects

Superba™ Krill Oil is intended for use as a nutrient supplement as defined in 21 CFR 170.3(o)(20). It is intended for use by the general population at levels ranging from 0.05 to 0.50 g/serving for addition to the following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk products; processed fruit and fruit juices; and in medical foods. It is recognized that there are Standard of Identity requirements for some of these foods, located in Title 21 of the Code of Federal Regulations. If used in such foods, the name will be changed so as not to be confused with the standardized food. Available information indicates that use levels are self-limiting because of their strong taste that can be detected, depending on food type, at levels greater than 0.30-0.50 g/serving. It is intended to be used as a replacement for fish oil. The intended use of Superba™ Krill Oil is in the same foods and at the same levels of addition as those described in GRN 242 for krill oil. The use of Superba™ Krill Oil in foods is not intended to function as a color additive as defined in 21 CFR 70.3(f).

III. Summary of the Basis for the Notifier's Determination that Krill Oil is GRAS

An independent panel of recognized experts, qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was requested by Aker Biomarine Antarctic AS to determine the Generally Recognized As Safe (GRAS) status of high phospholipid krill oil. A comprehensive search of the scientific databases for safety and toxicity information on krill oil and its component omega-3 fatty acids (EPA and DHA) was conducted through August 2010 and was utilized for this assessment. Based on a critical evaluation of the pertinent data and information summarized here and employing scientific procedures, the Expert Panel members have individually and collectively determined by scientific procedures that the addition of high phospholipid krill oil to the foods (non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk; processed fruit and fruit juices) containing no other ingredients that are good sources of EPA or DHA, when not otherwise precluded by a Standard of Identity, and to Medical Foods, meeting the specification cited above and manufactured in according with current Good Manufacturing Practice, is Generally Recognized As Safe (GRAS) under the conditions of intended use, as specified herein.

In coming to this decision that krill oil is GRAS, the Expert Panelists relied upon the conclusions that neither high phospholipid krill oil nor any of its constituents pose any toxicological hazards or safety concerns at the intended use levels, as well as on published toxicology studies and other articles relating to the safety of the product. It is also the opinion of the Expert Panelists that other qualified and competent scientists, reviewing the same publicly available toxicological and safety information, would reach the same conclusion.

IV. Basis for a Conclusion that Superba™ Krill Oil is GRAS for its Intended Use.

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DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF KRILL OIL AS A NUTRIENT

1. INTRODUCTION

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel)[2], qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was convened by Soni & Associates Inc., at the request of Aker Biomarine Antarctic AS, Norway, to determine the Generally Recognized As Safe (GRAS) status of high phospholipid krill oil as a nutrient [21 CFR 170.3(o)(20)][3] in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and in medical foods at use levels ranging from 0.05 to 0.50 g/serving resulting in maximum estimated daily intake of 8.3 g/person/day. A comprehensive search of the scientific literature for safety and toxicity information on krill oil and omega-3 fatty acids was conducted through August 2010 and made available to the Expert Panel. The Expert Panel independently and critically evaluated materials submitted by Aker Biomarine Antarctic AS and other information deemed appropriate or necessary. Following an independent, critical evaluation, the Expert Panel conferred and unanimously agreed to the decision described herein.

1.1. Background

Krill is the common name given to the order Euphausiacea of shrimp-like marine crustaceans. The current taxonomic placement of *E. superba* is summarized in Table 4. These small invertebrates, also known as euphausiids, are found in oceans around the world. The name krill is a Norwegian word that means "young fry of fish", which is also often attributed to other species of fish. Krill is a vital component of the marine food chain for baleen whales, whale sharks, seals, and a few seabird species. In Japan and Russia, krill is also used for human consumption. Since the 19th century or may be even earlier, krill has been harvested as a food source for humans (*okiami*) in Japan. Antarctic krill is closely related to shrimp and are consumed as human food in a similar way. Commercially, krill is used for aquaculture and aquarium feeds, as bait in sport fishing, or in the pharmaceutical industry. In the Southern Ocean one species, *Euphausia superba* is abundant. Commercial fishing of krill is done primarily in the Southern Ocean and in the waters around Japan. Approximately 40% of the Japanese Antarctic krill catch is processed for human consumption, and Antarctic krill has been sold as a food for human consumption since the mid-1970s.

In recent years, krill has received considerable attention because it is a rich source of high-quality protein, with the advantage over other animal proteins of being low in fat and rich in omega-3 fatty acids (Tou *et al.*, 2007). Antioxidant levels in krill are higher than in fish, suggesting benefits against oxidative damage. Antarctic krill oil has been reported to contain high levels (30%) of EPA and DHA as well as astaxanthin esters in concentrations of 200 to 400 ppm (Zhu *et al.*, 2008; Kidd, 2007). Additionally, krill oil is also a rich source of phospholipids, vitamin A, and other nutrients (Ruben *et al.*, 2003).

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[2] See also attachments (curriculum vitae) documenting the expertise of the Panel members.

[3] "Nutrient supplements": Substances which are necessary for the body's nutritional and metabolic processes.

Table 4. Classification of *Euphausia superba*

Kingdom	Animalia
Phylum	Arthropoda
Subphylum	Crustcia
Class	Malacostrasa
Superorder	Eucarida
Order	Euphausiacea
Family	Euphausidae
Genus	Euphausia
Species	*Euphausia superba*

1.2. Chemistry and Biological Activity

The important constituents of krill oil, omega-3 fatty acids, also known as n-3 polyunsaturated fatty acids (PUFA) belong to an essential fatty acid family characterized by their first double bond at carbon atom number 3 counted from the methyl or omega end of the carbon chain constituting the backbone of fatty acids. Omega-3 fatty acids are chemically and biologically distinct from omega-6 fatty acids, where the first double bond is at carbon atom number 6. There are two subgroups of omega-3 fatty acids. One, α-linolenic acid (ALA), derived from plant oils such as canola oil, rapeseed oil and linseed oil, is composed of 18 carbon atoms with three double bonds (nomenclature; 18:3). The other group is derived from seafood, and the major marine omega-3 fatty acids are EPA (20:5) and DHA (22:6) (Figure 1). In humans, ALA can, to a limited extent, be elongated and desaturated to EPA and DHA. Otherwise, EPA and DHA are only acquired from seafood.

In a recent review article, Calder (2006) discussed the biological role and mechanism of action of long-chain omega-3 fatty acids. It is well known that the omega-6 fatty acid, arachidonic acid, gives rise to the eicosanoid family of mediators (prostaglandins, thromboxanes, leukotrienes, and related metabolites). These mediators have inflammatory actions in their own right and also regulate the production of other mediators including inflammatory cytokines. Consumption of long chain omega-3 fatty acids decreases the amount of arachidonic acid in cell membranes and the availability for eicosanoid production. Additionally, these fatty acids also decrease the production of the classic inflammatory cytokines, such as tumor necrosis factor, interleukin-1 and interleukin-6, and the expression of adhesion molecules involved in inflammatory interactions between leukocytes and endothelial cells. These latter effects may occur by eicosanoid-independent mechanisms including modulation of the activation of transcription factors involved in inflammatory processes. Because of their potential health benefits, omega-3 fatty acids have been commonly consumed and extensively studied for their physiological effects.

1.3. Description, Manufacturing Process and Specifications

Superba™ Krill Oil is a dark red colored viscous oil with a seafood odor. Typical food grade specification and composition of Superba™ Krill Oil produced by Aker Biomarine Antarctic AS are summarized in Tables 1, 2, and 3. The primary constituents of Superba™ Krill Oil are triglycerides and phospholipids which are rich in EPA and DHA fatty acid. Detailed information about the identity of krill oil along with specifications, composition, and manufacturing are described earlier in Section II. Analytical results of five different batches indicate that the product consistently meets the specifications (Appendix I). The results of

pesticide, PCBs and dioxins, and furans analyses are presented in Appendix II. The *trans*-fatty acid profile from four batches of Superba™ Krill is presented in Appendix III.

In an extensive study, Winther *et al.* (2010) used high performance liquid chromatography-electrospray tandem mass spectrometry to elucidate the phospholipids in Superba™ Krill Oil extracted from *Euphausia superba.* The study was carried out in order to map the species of the choline-containing phospholipid classes: phosphatidylcholine and lyso-phosphatidylcholine. A total of 69 choline-containing phospholipids were detected, whereof 60 phosphatidylcholine substances, among others seven with probable omega-3 fatty acids in both sn-1 and sn-2. The phosphatidylcholine concentration was estimated to be 34 ± 5 g/100 g oil (n = 5). The results of this study reveal the composition of phospholipids of Superba™ Krill Oil and the presence of long chained, heavily unsaturated fatty acids. This study also verifies previous findings and offer new insights into the composition of krill oil. In addition to EPA and DHA, the other major fatty acids present in krill oil are palmitic acid, myristic acid, oleic acid, and palmitoleic acid.

1.4. Similarity with Fish oils

The available information suggests a considerable similarity, particularly omega-3 fatty acids, between krill oil and fish oil from different fish sources. In response to a number of GRAS notices, the FDA has acknowledged the GRAS status of different forms of fish oil. As per 21 CFR 184.1472, menhaden oil has been affirmed as GRAS. Additionally, the FDA has not questioned GRAS notifications submitted on tuna oil (FDA, 2002), salmon oil (FDA, 2004a), and anchovy oil (FDA, 2004b). In FDA's review of tuna oil, the fatty acid content of tuna oil was compared to menhaden oil (FDA, 2002). The fatty acid composition of krill oil is compared with those of FDA's comparison of tuna and menhaden oil in Table 5. Krill oil contains a high level of the desirable n-3 unsaturated fatty acids that is comparable to other oils.

Table 5. Comparison of fatty acid profile of Superba™ Krill Oil with tuna oil and menhaden oil* (g/100g)

Fatty acid	Tuna oil	Menhaden oil	Krill oil
14:0	20.3	9.0	7.7
16:0	20.0	19.0	15.4
18:0	6.0	3.0	0.9
16:1	4.5	12.0	4.9
18:1	15.0	13.0	12.1
22:1	1.0	-	0.6
18:2	1.5	1.0	1.2
18:3	1.0	1.0	0.2
20:5 (EPA)	6.0	14.0	14.7
22:6 (DHA)	26.5	8.0	6.2

*Values for tuna and menhaden oils adapted from FDA response to GRN 109 (FDA, 2002)

1.5. Technical effects

Superba™ Krill Oil is intended for addition to a limited number of conventional foods as a nutritional ingredient. It is intended for use as a dietary ingredient as a source of omega-3 fatty acids, which are found in their phospholipid form. Supplementation with the omega-3-fatty acids EPA and DHA has been shown to have a wide variety of biological effects. The intended use is for the general population at levels ranging from 0.05 to 0.50 g/serving for addition to the

following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk products; processed fruit and fruit juices; and medical foods. It is recognized that there are Standard of Identity requirements for some of these foods, and as such, Aker Biomarine Antarctic AS does not intend to refer to them by the commonly recognized names such as milk, or yogurt.

The use of Superba™ Krill Oil in foods may impart a color to food products. However, the intended use of Superba™ Krill Oil would fall outside the definition of "color additive" because: the intended use levels are low enough to impart a significant color to food products, consistent with the "non-apparent color" Exemption [21 CFR 70.3(f)]; the intended use of Superba™ Krill Oil as a nutrient would contribute a color in a manner consistent with the "unimportant color" exemption addressed in 21 CFR 70.3(g); and the intended use of Superba™ Krill Oil is to provide consumers with an additional source of a nutrient in the diet and does not relate to any use of the ingredient as a color additive [21 CFR 70.3(f)].

1.6. Current Uses

Krill oil has been reportedly used in human food in Japan, Russia, Ukraine, and France since the 1970s. Based on information described in FDA dockets, in 2003 a New Dietary Ingredient Notification was submitted on the use of krill oil as a dietary supplement (FDA, 2003). The FDA filed the notice without any objections. The supplement is sold in 300 and 500 mg capsules with a recommended dose of 1 to 2 capsules/day. Krill oil has been available as a dietary supplement in North America for several years, European Union, Norway, and Taiwan. In the GRN 242 (FDA, 2008), it is stated that a total of 120,000 kg of krill oil has been consumed by customers as a dietary supplement without any reports of serious adverse effects.

Based on information from FDA's GRAS Notice Inventory[4] website, in February 2008 Neptune Technologies submitted a GRAS notification to the FDA on krill oil (FDA, 2008). The notice indicated that krill oil obtained from krill is intended to be added to a limited number of different food categories. The notice informed the FDA that krill oil is GRAS, through scientific procedures, for use as a food ingredient in non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, processed fruit and fruit juices, and medical foods at a use level to provide 150 to 500 mg of the oil per serving. On October 14, 2008,[5] the FDA issued a "No Questions" letter for the GRAS notice.

Recently, on October 12, 2009, the use of krill oil received an approval as a novel food ingredient in Europe, under Commission Regulation (EC) No 258/97 related to novel foods and novel food ingredients. On December 22, 2009, in response to a notification on behalf of Aker Biomarine Antarctic AS, the Novel Food Board found that Superba™ Krill Oil is substantially equivalent to the krill oil authorized by the commission with respect to composition, nutritional value, metabolism, intended use, and the levels of undesirable substances contained therein (Appendix IV).

1.7. Intended Use Levels and Food Categories

Aker Biomarine Antarctic AS intends to offer Superba™ Krill Oil for incorporation into a limited number of human food categories where krill oil would function as a nutrient

[4]Accessible at: www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true.
[5]Accessible at: http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000242.pdf

supplement as defined under 21 CFR 170.3(o)(20). Superba™ Krill Oil is intended for use in the same foods and at the same or lower use levels of addition as described in GRN 242 for krill oil. The proposed food uses as a dietary source of krill oil in foods include addition to: non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices. In addition to these categories, it is also intended for use in Medical Food at levels not to exceed 0.50 g/person/day.

1.7.1. Estimated Daily Intake from the Intended Uses

As Aker Biomarine Antarctic AS intends to use its Superba™ Krill Oil in the same foods and at the same use levels of addition as described in GRN 242, estimates of possible daily intake from the proposed use levels were adapted from GRN 242 (FDA, 2008). In the GRN 242, the use of krill oil was proposed at use levels of 0.15 to 0.50 g of the oil/serving (reference amounts customarily consumed, 21 CFR 101.12) of food. The specific food categories, the intended use levels of krill oil, and the resulting intake of krill oil are summarized in Table 5. In the GRN 242, the estimates of possible daily intake of krill oil were calculated using the FDA guidelines using serving size data and the mean consumption (50%) of each type of food of interest from the CSFII 1994-96 database (USDA, 2005). According to the FDA guidelines, a level twice the mean consumption was calculated to estimate use at the 90th percentile consumption level. A summary of dietary intake calculations from the intended food categories is also presented in Table 6.

The intended use levels of krill oil will result in an estimated daily intake at average (50th percentile) and high (90th percentile) consumption of 4.14 and 8.28 g/person, respectively. The resulting intake of total EPA and DHA from the exaggerated estimated daily intake of krill oil (8.30 g/person/day) would be 2.20 g/person/day. Thus the intended food uses for Superba™ Krill Oil are within the allowances FDA has accepted for the GRAS status use of menhaden oil. The acceptable menhaden oil food use does not exceed safe levels of consumption for total EPA and DHA. The maximum estimated consumption of astaxanthin ester, which is present in krill oil at 100 ppm would be 0.83 mg/person/day. The application of krill oil to the same foods and at the same use levels as those described in GRN 242 are unlikely to affect the dietary intake of krill oil from introduction into the market by another supplier who will have to compete in essentially the same market with the same foods. Hence, there is no need for a cumulative intake analysis.

Table 6. Intended Food Uses and Use Levels of Superba™ Krill Oil

Food category	Food subcategory	Use level per serving	Approximate serving size	Food intake (g/p/d) 50%-tile	Krill oil intake[a] (g/p/d) 50%-tile	Krill oil intake (g/p/d) 50%-tile X 2
Breakfast cereals	Cooked cereal	0.05-0.30 g	½ cup of cooked Oatmeal = 117 g	233	0.60	1.19
	Ready-to-eat cereal	0.05-0.30 g	1 cup of corn flakes = 25 g	48	0.60	1.15
Cheeses	Total cheese other than cream or cottage	0.05-0.30 g	1/2 oz. of cheese = 43 g	26	0.18	0.36
	Total cottage cheese	0.05-0.30 g	1/2 cup of cottage cheese = 105 g	50	0.14	0.29
Beverages, Nonalcoholic	Fruit drinks	0.05-0.25 g	8 oz. = 248 g	360	0.22-0.36	0.44-0.73
Milk, whole & skim	Total milk	0.05-0.50 g	1 cup of fluid whole milk = 244 g	216	0.27-0.45	0.53-0.89
Milk products	Sour cream	0.05-0.50 g	1 tablespoon of sour cream = 14 g	6	0.13-0.21	0.26-0.43
	Creams	0.05-0.50 g	1 tablespoon of cream = 15 g	3	0.06-0.10	0.12-0.20
	Yogurt[b]	0.05-0.50 g	No data in USDA survey	0.17 servings	0.05-0.085	0.10-0.17
Frozen dairy desserts	Ice cream, Ice milk	0.05-0.50 g	1/2 cup of hard ice cream = 67 g	132	0.59-0.98	1.18-1.97
Processed fruits/fruit juices	Total orange juice	0.05-0.25 g	6 fl. oz. of orange juice = 187 g	186	0.15-0.25	0.30-0.50
	Total lemon juice	0.05-0.25 g	1 fl. oz. of lemon juice = 30 g	<0.05	0.00	0.00
	Total apple juice	0.05-0.25 g	6 fl. oz. of apple juice = 186 g	150	0.12-0.20	0.24-0.41
Medical foods		0.05-0.50 g[c]	No data in USDA survey			
				Sum of all categories	**3.08-4.14**	**6.16-8.28**

[a] Dietary intake of krill oil for each food type is calculated by multiplying ,g/serving by grams of food consumed divided by grams of food per serving;

[b] Yogurt consumption in the US has been estimated by Neptune to average 60 servings per year or 0.17 servings per day, with a high consumer exposure at 250 servings per year. This estimate is based on sales data with a per capita consumption of 5-6 kg/person;

[c] It is envisioned that these foods would be meal replacements for patients whose diets would consist of these foods entirely for 3 meals per data and therefore, total krill oil consumption in these patients would be 0.90-1.50 g/day.

Adapted from GRN 000242 (FDA, 2008); note that values for low proposed intake are not calculated but the low values from GRN 000242 were considered.

2. DATA PERTAINING TO SAFETY

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The safety of krill oil and its biologically important constituents such as omega-3 fatty acids is supported by human observations and clinical trials as well as animal experimental

studies. Because of the physiological role of omega-3 fatty acids in human health, there have been considerable efforts to elucidate the mechanism and biological role of these fatty acids in human nutrition. As a result, the literature is full of information on omega-3 fatty acids. Relevant biological and toxicological studies on krill oil and its constituents (omega-3 fatty acids) are included in the following section in support of the safety conclusions determined in this assessment.

2.1. Absorption and Metabolism

Krill oil consists primarily of phospholipids that are commonly consumed via diet. It is well established and recognized that dietary phospholipids and fatty acids from either plant or animal sources are handled the same metabolically. The composition of Superba™ Krill Oil is well characterized and from this perspective there is nothing unusual that is not found in a commonly consumed diet. The components of krill oil have been extensively studied for their biological and physiological properties. Despite krill oil's complex composition, available information suggest that the major phospholipids and fatty acids are consistent with other lipid sources with differences noted in proportions of phospholipids, minor constituents, and fatty acid content. Given the metabolic sequelae of different dietary lipids, there is no reason to believe that the Superba™ Krill Oil would pose any different health hazards.

In two separate unpublished pharmacokinetics studies, bioavailability of EPA and DHA was investigated from different oils (Meyer, 2009a, 2009b). The first study was a single centre, open-label, randomized four-way crossover study designed to evaluate the 24 hour pharmacokinetic profiles of EPA, DHA, and astaxanthin after single doses of A: Superba™ Krill Oil (8 g), B: Neptune krill oil (8 g), C: Omega-3 enriched fish oil (8 g), and D: Krill powder (8 g). The doses were separated by 72 hours wash-out periods. In this study, 36 healthy male subjects (age 25 - 45 years) were randomized (1:1:1:1) to one of four treatment sequences. Blood samples were collected pre-dose, and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 10, 12, 16, and 24 hours after the dosing. A general trend to increases in levels of EPA, DHA, and astaxanthin across the four study periods was observed in the majority of subjects. This trend to continuous increase was confirmed by regression analysis for EPA and DHA in plasma and in phospholipid fractions. The median t_{max} for EPA in plasma was 12 hours for all products. With regards to DHA in plasma, the median absolute t_{max} was longest after Superba™ krill oil (10 hours), shortest after omega-3 enriched fish oil (6 hours), and in between after Neptune krill oil (7 hours) and krill powder (8 hours). All study products were safe and well tolerated (Meyer, 2009a).

In another unpublished open-label, randomized two-way crossover study, changes in EPA and DHA in phospholipid membranes were determined following eight weeks of daily intake of 2 g Superba™ Krill Oil or 2 g omega-3 enriched fish oil in healthy male and female subjects (Meyer, 2009b). A total of 28 healthy male and female subjects (14/sex; aged 25-45 years) took part in this study. Blood for the pharmacokinetic analysis was collected on Day 1 (pre-dose) and on Days 14, 28, 42 and 56 (± 2 days) of each treatment period for the analysis of EPA and DHA in phospholipid fractions and of omega-3 index in RBCs. In addition to daily enquiry of adverse events, a 12-lead ECG, and a standard clinical laboratory assessment (urinalysis, hematology, clinical chemistry) at screening and on Day 56 of period 2 was performed. Steady state in EPA levels and omega-3 index was attained earlier after Superba™ Krill Oil (Day 14) as compared to omega-3 enriched fish oil (Day 28). Steady state in DHA levels was attained later after Superba™ Krill Oil (Day 42) than after omega-3 enriched fish oil (Day 28).

In female subjects, the bioavailability of EPA in plasma (after dose adjustment) in krill oil administered subject was higher compared to fish oil (Meyer, 2009b). Similarly, across males and females, DHA in plasma (after dose adjustment) was higher in subjects receiving krill oil. Statistically significant differences between the treatments could not be demonstrated with respect to omega-3 index in RBCs (after dose adjustment). In subjects receiving krill oil, overall $AUC_{(0\text{-}56D)}$ of EPA and DHA in plasma and omega-3 index in RBCs was determined as 97908, 98261, 4208 ng*h/(mg*ml), respectively. Overall, there were no trends related to the study products in the adverse event reports, in clinical laboratory, ECG, and physical examinations. There were no withdrawals due to adverse effects. Krill oil ingestion decreased the mean serum insulin level, whereas the mean adiponectin level increased. Following omega-3 enriched fish oil administration, both the mean serum insulin level and the mean adiponectin level decreased. No statistically significant treatment effects were seen in the analysis of platelet aggregation, lipid parameters and the other selected clinical chemistry parameters (glucose, CRP, insulin TNF alpha, and adiponectin). The investigator concluded that both krill oil and fish oil were safe and well-tolerated (Meyer, 2009b).

2.2. Human Studies

In a randomized, double-blind parallel arm trial, overweight and obese subjects (n=76; 13 men, 63 women) were randomly assigned to receive double-blind capsules containing 2 g/day of krill oil (n=25), menhaden oil (n=26), or control (olive) oil (n=25) for four weeks (Maki *et al.*, 2009). The objective of this study was to examine the effects of krill oil supplementation on plasma EPA and DHA concentrations, indicators of safety, tolerability, and selected metabolic parameters. The krill oil used in this study was Superba™ Krill Oil, the subject of this GRAS determination. In addition to physical examination, clinical laboratory measurements (plasma chemistry, hematology, urine, and lipids) were performed. At baseline and at the end of week 4, subjects completed a gastrointestinal (GI) tolerability questionnaire, which assessed the presence and severity (on a scale of 0 to 5) of GI symptoms such as gas, bloating, nausea, flatulence, diarrhea, constipation, and cramping over the period of seven days. Subjects also completed a symptom checklist at the end of week 4, which assessed the incidence of or changes in a variety of symptoms (e.g., irritability, nervousness, mood, blurred vision, drowsiness, mental sharpness, and hair and skin changes) in the previous four weeks on a scale of 1 (a lot less) to 5 (a lot more). Adverse events were assessed from the time subjects signed the informed consent form at screening (week -1) and continued through the end of the study.

The changes from baseline to week 4 did not differ significantly among the treatment groups for hematology values or for plasma concentrations of albumin, electrolytes, creatinine, or liver enzymes. Responses for measures of glucose homeostasis, lipoprotein lipids, hs-CRP (high-sensitivity C-reactive protein), and F2-isoprostanes did not vary significantly by treatment group. The results revealed that compared to the control group, plasma EPA and DHA concentrations increased in the krill oil and menhaden oil groups. Blood urea nitrogen declined in the krill oil group as compared with the menhaden oil group. The frequencies of adverse events were similar in the three treatment groups. At week 4, significant differences were observed among the treatment groups in the number of subjects with scores of 4 or higher for gas or bloating ($P = 0.05$) and flatulence ($P = 0.034$). The number of subjects with gas or bloating increased from 2 (8%) at baseline to 5 (20%) at week 4 in the krill oil group and from 1 (4%) at baseline to 5 (20%) in the control group. No significant differences were observed among the treatment groups in the frequencies of any symptoms assessed with the symptom checklist. The

investigators concluded that compared with both menhaden oil and olive oil, krill oil was generally well tolerated and showed no indication of adverse effects on safety parameters (Maki *et al.*, 2009).

Ulven *et al.* (2010) investigated the effects of krill oil (Superba™ Krill Oil) and fish oil on serum lipids and markers of oxidative stress and inflammation. The objective of this study was to evaluate if different molecular forms, triacylglycerol and phospholipids, of omega-3 polyunsaturated fatty acids (PUFAs) influence the plasma level of EPA and DHA differently. In this study, 113 subjects with normal or slightly elevated total blood cholesterol and/or triglyceride levels were randomized into three groups and given either six capsules of krill oil (n = 36; 3.0 g/day, EPA + DHA = 543 mg) or three capsules of fish oil (n = 40; 1.8 g/day, EPA + DHA = 864 mg) daily for 7 weeks. The third group did not receive any supplementation and served as controls (n = 37). Safety was evaluated by assessment of hematology and biochemistry parameters, and by reported adverse events.

Compared to control group, a significant increase in plasma EPA, DHA, and DPA was noted in the subjects supplemented with n-3 PUFAs. However, there were no significant differences in the changes in any of these fatty acids between the fish oil and the krill oil groups. The serum lipids or the markers of oxidative stress and inflammation did not reveal any statistically significant differences between the study groups. The safety assessment did not reveal any patterns in the changes in any of the hematological or serum biochemical variables, vital signs or weight that might indicate a relation with administration of any of the studied products. Clinical symptoms registered during the study included mainly symptoms of common cold or gastrointestinal symptoms. One subject in the fish oil group experienced moderate bruises, and one subject in the krill oil group withdrew from the study because of an outbreak of rash that was possibly related to intake of the study products. There were no apparent differences in the rate of adverse events or blood safety parameters between the krill oil, fish oil or control groups. These observations indicate that krill oil was well tolerated. The results of this study show that krill oil and fish oil are comparable dietary sources of n-3 PUFAs, even if the EPA + DHA dose in the krill oil was 62.8% of that in the fish oil (Ulven *et al.*, 2010).

Sampalis *et al.* (2003) investigated the effects of krill oil on premenstrual syndrome (PMS) and dysmenorrhoea in 70 female adults of reproductive age. The females were randomized to receive either krill oil or fish oil. The subjects consumed two 1 g capsules once per day with meals during the first month. Subsequently, the subjects consumed same dose during the second and third months but for eight days prior to menstruation and for two days during menstruation. During the course of study, no serious adverse effects were reported. Three subjects reported a reduction in the duration of the menstrual cycle during the first month of treatment. In subjects receiving krill oil, a slight increase in the oiliness of the facial skin was noted. No subjects reported gastrointestinal disturbances. However, in fish oil group 64% of the participants reported "unpleasant" reflux following consumption. The results of this study suggest that krill oil softgels were well tolerated.

In another study, Deutsch (2007) investigated the effects of krill oil on markers of chronic inflammation in 90 subjects (age 50 to 68 years) recruited from primary care physicians. The subjects recruited had been diagnosed with cardiovascular disease, rheumatoid arthritis, or osteoarthritis, and were reported to have C-reactive protein levels greater than 1.0 mg/dL. Except for acetaminophen, the subjects were asked not to consume any other pain medication. The

subjects were administered either 100 mg of placebo or 300 mg krill oil/day and were followed for 30 days. C-reactive protein levels and pain and functional impairment scores were assessed during the experimental period on a weekly basis. Compared to baseline, a significant decrease in C-reactive protein levels was observed in subjects consuming krill oil at the end of 7, 14, and 30 days. No adverse effects were associated with the consumption of krill oil.

Bunea *et al.* (2004) evaluated the effects of krill oil on the clinical course of hyperlipidemia in 120 patients (mean age 51 years). The patients were randomized into four groups which were further subdivided according to their body mass index (BMI) (Bunea *et al.*, 2004; FDA 2008). Group 1 was administered either 2 g krill oil/day (BMI<30) or 3 g krill oil/day (BMI>30). Group 2 was administered either 1 or 1.5 g krill oil/day (BMI< or >30, respectively). Group 3 was administered a fish oil capsule that provided 180 mg EPA and 120 mg DHA, and Group 4 was the placebo group. The experimental period was 12 weeks while Group 2 consumed 500 mg krill oil/day for an additional 90 days. No adverse effects were noted in any of the groups.

In an unpublished study described in GRN 242 (FDA, 2008), the safety of krill oil was examined in 25 healthy male and female subjects between the ages of 25 and 53 years. The volunteers consumed two krill oil gelcaps, three times a day for two months. Each gelcap contained 1 g of krill oil that provided 386 mg of omega-3 fatty acids, 416 mg phospholipids, and 0.16 mg of astaxanthin. As described in GRN 242, complete blood counts and biochemical blood tests, medical histories, and vital signs were collected at baseline, one month, and two months. The volunteers were asked about the occurrence of adverse effects and if there was any regurgitation effects of the capsules. The subjects were also asked to stop consuming the gelcaps if they had the following symptoms: low or high blood pressure, difficulty breathing, bleeding, loss of consciousness, unusual migraines or body pain, weight gain, or significant alterations in blood test results. Biochemical parameters examined included cell counts, PTT, creatinine, glucose, alkaline phosphatase, albumin, amylase, total bilirubin, total cholesterol, HDL and LDL cholesterol, triglycerides, urea, and TSH levels. As described in GRN 242, no serious side effects were reported in volunteers consuming 6 g krill oil throughout the experimental period. No regurgitative effects were reported or any unpleasant aftertaste. Of the 25 volunteers, three withdrew for reasons associated with consuming krill oil. One female withdrew due to a known salt tolerance for which consumption of krill oil resulted in a moderate increase in water retention. Two females withdrew because they felt an increasing greasiness of their facial skin which was attributed to consuming krill oil. In the remaining volunteers, no noticeable physical or biochemical changes were observed. A significant decrease in serum total cholesterol, triglycerides, LDL cholesterol, the ratio of total cholesterol to HDL cholesterol, albumin, and amylase were observed. A significant increase in HDL cholesterol was also observed. These effects were not considered adverse effects but beneficial changes in blood lipids and pancreatic function. While a decrease in albumin levels might be indicative of underlying disease processes, their occurrence in the absence of other biochemical abnormalities suggested they were not adverse effects (FDA, 2008).

2.3. Animal Studies

Batetta *et al.* (2009) compared the effects of dietary (n-3) LC-PUFA, in the form of either fish oil or krill oil (Superba™ Krill Oil) balanced for EPA and DHA content, with a control diet containing no EPA and DHA and similar contents of oleic, linoleic, and α-linolenic acids, on ectopic fat and inflammation in Zucker rats, a model of obesity and related metabolic

dysfunction. In this study, male Zucker rats (Harlan) four weeks of age, with an initial weight of 250±30 g, were equally divided into three groups and were fed either a control diet or diets containing krill oil or fish oil for four weeks. The amount of 0.5 g of EPA + DHA per 100 g of diet, equivalent to 0.8% by energy in the rat diet, was chosen. Effects on lipid metabolism, ectopic fat deposition, and susceptibility to inflammation was measured. The investigators concluded that diets rich in (n-3) LCPUFA, and a krill oil-based diet in particular, exert beneficial effects on several metabolic dysfunctions in Zucker rats, which was associated with lower endocannabinoid concentrations in several peripheral tissues. Although the objective of the study was to investigate the efficacy of krill oil, growth and food intake was not affected by krill oil diet. Additionally, the investigators also reported that none of the rats exhibited adverse effects.

In another study, Di Marzo *et al.* (2010) investigated whether in Zucker rats, under the same conditions as described above by Batetta *et al.* (2009), fish and krill oil are also able to influence LC-PUFA and endocannabinoid profiles in the brain. The study design and protocol of this study was identical to the above described study. In this study, only krill oil was able to significantly increase DHA levels in brain phospholipids, with no changes in arachidonic acid. Based on the results of this study, the investigators claimed the beneficial effect of krill oil on the metabolic syndrome is mostly exerted by modifying endocannabinoid levels in peripheral tissues. Similar to the above described study, feeding krill oil in the diet for four weeks did not affect growth and food intake. No differences in growth and food intake among groups, nor any adverse effects of the diets, were observed.

Ruggiero-Lopez *et al.* (1994) investigated the effect of krill oil, as compared to fish and corn oil, on the rat intestinal fucosylation process at weaning, a very sensitive model of the influence of nutritional factors. In this study, the effects of oil were studied over a three-day period immediately after weaning. All the oils were well-tolerated by pups at a level of 10% of the diet. The use of krill oil was not reflected in the enzymatic activities involved in the fucosylation pathway. The investigators concluded that the results of their study confirm the harmlessness of krill derived products and their possible use in human nutrition.

A repeat-dose toxicity study described in GRN 242 (FDA, 2008) was conducted to examine the safety of krill oil in mice for six months. In this study, 96 C57BL6 nude congenic mice (B6NU-T heterozygotes) were fed a diet containing 16.6% krill oil (equivalent to 28.3 g krill oil/kg body weight/day. The animals were examined weekly by a certified veterinarian. At the end of the experiment, all the animals were euthanized by gas exposure and subjected to histopathological examinations. No adverse effects were noted over the experimental period and no histopathological abnormalities were observed in the brain, lungs, heart, stomach, pancreas, liver, kidneys, uterus or prostate, intestines, or skin.

In a follow up investigation to the above described study, also described in GRN 242, the development of UVB-Radiation Induced Skin Cancer in mice was investigated (FDA, 2008). In this study, C57BL6 Nude Congenic mice (B6NU-T heterozygotes) were randomized into two groups (48/sex/group). One group was administered oral, topical, or oral and topical treatments of krill oil. The second group was administered soya oil. In the oral dosing regime, mice were administered diets where 10% of the daily dietary intake consisted of either krill oil or soya oil (equivalent to 17.1 g/kg body weigh/day). In the topical treatment regime, krill oil or soya oil was applied to the skin. The mice were exposed for 30 minutes to UVB radiation, at a distance of 30 cm, daily for 20 weeks. After 20 weeks, the animals were euthanized and subjected to

histological examinations. The occurrence of cancers and pre-malignant tumors in mice administered topical treatments was 12.5% and 31.3%, respectively, as compared to 37.5% and 31.3%, respectively, in the soya oil group. In mice administered both oral and topical treatments, the occurrence of cancers and pre-malignant tumors was reported to be 18.8% and 31.3%, respectively in the krill oil group and 37.5% and 12.5% respectively, in the soya oil group. As compared to the soya oil group, a significant reduction in the incidence of cancers was noted in mice administered krill oil.

2.4. Safety of Omega-3 fatty acids- EPA and DHA

The principal fatty acid constituents of krill oil, EPA, and DHA are typically contained in oily fish, such as salmon, lake trout, tuna, and herring. The composition of EPA and DHA in krill oil, which is the subject of this notification ranges from 14±2 and 6.5 ±1% w/w, respectively. The total of EPA+DHA in krill oil is 23.5 ± 2%. In the 1997 final rule on the GRAS affirmed use of menhaden oil as a direct food ingredient (FDA, 1997) and also regarding the use of omega-3 fatty acids as a dietary supplement in 2005 (FDA, 2005), FDA has critically evaluated the safety of DHA and EPA. The FDA (1997) has affirmed menhaden oil as GRAS in 1997, as a direct human food ingredient with specific limitations of use to ensure that the total daily intake of EPA and DHA would not exceed 3 g/person/day (62 FR 30751; June 5, 1997; 21 CFR 184.1472). In these regulations, the FDA established maximum use levels of menhaden oil in certain foods (62 FR 30751 at 30757; June 5, 1997; amended March 23, 2005) because of concerns over possible adverse effects of consumption of fish oil on bleeding coagulation time, glycemic control, and LDL cholesterol,. The FDA reaffirmed the maximum intake of DHA and EPA to 3.0 g/day from all fish oil sources. To ensure the consumption remains below 3.0 g/day, the agency placed specific limitations, including the category of foods, the functional use of the ingredient, and the level of use.

Besides the menhaden oil GRAS affirmation, the FDA has not questioned multiple GRAS notices for additional sources of EPA and DHA as food ingredients. These notices include GRN 000102, GRN 000105, GRN 000109, GRN 000138; GRN 000146; GRN 000193; GRN 000200; GRN 000217[6]. In these GRAS Notifications, the intended maximum use levels were consistent with those specified in the final rule affirming GRAS status of menhaden oil as a direct human food ingredient with specific limitations of use. Furthermore, the FDA did not object to a GRAS notification for high DHA algal oil (GRAS Notice No. GRN 000137). In this case the notifier estimated that the use of algal oil in a number of food categories at the maximum proposed use levels would result in a mean exposure of no more than 1.5 g DHA/day.

In order to support the safety in use of DHA and EPA, the composition of principal krill oil fatty acids was compared with menhaden oil and tuna oil (Table 5). As noted in Table 5, menhaden oil contains 8% DHA and 14% EPA. The total of DHA+EPA (22%) in menhaden oil is essentially similar to that in krill oil (23%). Similarly, the individual levels of DHA (8% vs 6.5%) and EPA (14% vs 14%) are also essentially similar between menhaden and krill oil. In different FDA GRAS Notifications, the total amount of DHA+EPA ranged from 20 to 41% and was reported as follows: GRN 000105 = 38%, GRN 000109 = 28%, GRN 000138 = 29%, GRN 000146 = 20%, GRN 000200 = 41%, and GRN 000279 = 22%. In all of these notices, the

[6] The FDA response to all these and other GRAS notices is assessable at GRAS Notice Inventory: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true

maximum levels of use in food categories were adjusted such that the resulting intake of DHA+EPA was similar to or lower than what is currently permitted for menhaden oil under 21 CFR 184.1472. As krill oil is proposed for use as a substitute or alternative to fish oils, the intended use of krill oil will not add to the existing intake of DHA and EPA.

2.5. Astaxanthin

In addition to lipids, one of the minor components of biological importance of the oil is astaxanthin. In Krill, either one or both of the alcoholic hydroxyl functional groups of astaxanthin may be esterified to fatty acids. Thus astaxanthin from krill are found almost exclusively in esterified form. Takaichi *et al.* (2003) determined that only five kinds of fatty acids, dodecanoate, tetradecanoate, hexadecanoate, hexadecenoate, and octadecenoate were esterified to astaxanthin in krill. Assuming one C16 fatty acids in each position gives a molecular weight of the esterified molecule of 1110 or approximately twice as much as astaxanthin alone. Hence to specify the astaxanthin content of krill oil, one can consider the molar concentration or the amount of astaxanthin diol. Because of the general unfamiliarity with molar concentrations, Aker Biomarine declares its product on the basis of astaxanthin diol. Thus the levels presented in Table 1 for astaxanthin of 100 ppm means the product contains 100 µg/g of the diols, regardless of fatty acids that may be esterified.

As mentioned earlier, the intended use of the krill oil will result in a maximum estimated consumption of 0.83 mg astaxanthin/person/day. Although there is no recommended daily allowance (RDA) for astaxanthin, available safety-related information suggests that the estimated daily intake of astaxanthin (0.83 mg) from the intended uses of Superba™ Krill Oil is lower than the generally considered safe levels of 6 mg/day. It has been reported that in consumers with a high intake of fish and seafood, the estimated daily intake of astaxanthin ranges from 1.6 to 4.1 mg/day. Recently, in response to a GRAS notice on *Haematococcus pluvialis* extract containing astaxanthin esters (GRN 000294)[7], the FDA did not question the safety of astaxanthin intake at levels of 1.08 mg/person/day.

2.6. *Trans*-Fatty acids

As shown in Appendix III, high phospholipid krill oil contains only small amount of *trans*-fatty acids (<0.3%). Accordingly, one of the fatty acids vaccenic acid (C18:1, n-7) in Superba™ Krill Oil is almost exclusively present in the *cis*-isomeric form. The vaccenic acid content of high phospholipid krill oil in GRN 243 was reported as about 10% (FDA, 2008). From more common sources such as fat from ruminants and in diary products, vaccenic acid is present naturally as *trans*-fatty acid in the fat of ruminants and in dairy products such as milk and yogurt. In krill oil, the vaccenic acid (C18:1, n-7) primarily occurs in the *cis*-isomeric form. The fatty acid profile presented in Table 3 provides values for C18.1 that includes n-5, n-7, n-9 and n-11. Among these, n-7 represents vaccenic acid, while n-9 represents oleic acid. Additional analysis of C18:1 fatty acids revealed that Superba™ Krill Oil primarily contains C18:1 n-9 + n-11 in *cis* configuration at levels of ~11%, while the levels of vaccenic acid are below 1%. As compared to these low levels, the vaccenic acid content (10%) reported in GRN 243 (FDA, 2008) is significantly higher. It is possible that the differences in manufacturing method may affect the levels of vaccenic acid.

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[7] The FDA response is assessable at GRAS Notice Inventory:
http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true

The presence of vaccenic acid is also reported in edible fats and oils (Wasowicz and Hougen, 1976; Sauer *et al.*, 1997). Several vegetable and animal oils are known to contain lower levels of vaccenic acid, while butter contains higher amounts of various isomers of 18:1 fatty acids in the *trans* configuration. These fatty acids are not believed to exhibit the same clot-forming potential as saturated fatty acids or other *trans*-fatty acids formed by partial hydrogenation of vegetable oils. In a critical review on the health benefits of vaccenic acid, Field *et al.* (2009) noted that epidemiological, clinical, and rodent studies to date have not demonstrated a relationship of vaccenic acid with heart or cardiovascular disease, insulin resistance, or inflammation. Available evidence does not indicate that dietary vaccenic acid poses any safety concerns and levels of this fatty acid in Superba® Krill Oil are very low.

2.7. Other Safety Considerations

As krill oil, the subject of this GRAS determination, is derived from marine organism, it is important to characterize the nature and quantity of impurities/contaminants that might be stored in marine lipids that may pose a health hazard. The potential impurities and incidental constituents present in krill oil arise largely from environmental exposure of the Antarctic Krill. As krill oil is derived from the lipid fraction of krill biomass, Aker Biomarine Antarctic AS routinely analyzes production lots of Superba™ Krill Oil for the presence of dioxins, furans, organochlorine pesticides, PBDEs, PAHs, heavy metals and PCBs. Likely contaminants were analyzed from multiple representative batches. These results, presented in Appendix II, demonstrate the levels of contaminants are low and consistent with levels of other food ingredients.

It is well recognized that arsenic especially in seafood is present in an organic form that is less toxic (EFSA, 2009). Hence, there is a need for speciation data for arsenic. As presented in Appendix II, an extensive chemical analysis of both organic and inorganic arsenic was undertaken from multiple batches of krill oil. These results of eleven different forms of arsenic show that the total arsenic levels in krill oil ranged from 4 to 6 ppm, the majority of which was in organic form. The organic arsenic was found to be primarily in the form of dimethylarsinate, arsenobetaine, and trimethylarsine oxide (Appendix II). The inorganic arsenic as measured by the levels of arsenite and arsenate was below the level of quantification at 0.05 ppm. In a critical scientific opinion on arsenic in food, the European Food Safety Authority (EFSA, 2009) panel reported that on the basis of limited data on inorganic arsenic in foods, fixed values for inorganic arsenic of 0.03 mg/kg in fish and 0.1 mg/kg in seafood were considered realistic for calculating human dietary exposure. The levels of inorganic arsenic in krill oil are lower than these assumptions, particularly for seafood. The EFSA panel also stated that the organic forms of arsenic, arsenobetaine, which is the major form in fish and most seafood, is widely assumed to be of no toxicological concern. The available evidence suggests that arsenic levels in krill oil are similar to other sea-foods. Considering that krill oil contains maximum total arsenic levels of 6 ppm, the intended use Superba™ Krill Oil will result in maximum daily intake of 48 µg/person or 0.08 µg/kg body weight/day. The WHO/FAO (1989) has suggested a provisional maximum tolerable weekly adult intake (PTWI) for inorganic arsenic of 0.015 mg/kg of body weight. Thus, the WHO/FAO provisional maximum tolerable intake is about 130 µg inorganic As/day for a 60 kg individual (15 µg/kg/week x 60 kg / 7 days/week = 128.6 µg/day). The above reported total arsenic intake of 0.08 µg/kg body weight/day is negligible compared to the tolerable daily intake of inorganic arsenic. This also suggests that krill oil consumption does not represent a major increase in the expected total daily arsenic exposure, and especially with regards to inorganic

arsenic. Thus the intended use of Superba™ Krill Oil is unlikely to present any safety hazards to human health.

2.8. Allergenicity and Other Related Concerns

As krill oil is prepared by the separation of lipids from protein of krill meal, consumption of krill oil by individuals allergic to shellfish may trigger an allergic response. Generally, krill oil is contraindicated for individuals who are allergic to crustacean. There is a lack of allergic responses based on the use of krill oil as a dietary supplement. While krill is known to contain allergens, its processing in the production of oil results in a reduction of its protein content to typically less than 1% which is an order of magnitude lower than in krill (about 10-15% protein). While this does not eliminate a risk, the risk is certainly no greater and possibly lower than that naturally contained in the starting materials. Aker Biomarine Antarctic AS will market krill oil in full compliance with the Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282) (FDA, 2004). Aker Biomarine Antarctic AS intends to include a warning on food products containing Superba™ Krill Oil to suggest that individuals with seafood allergies, coagulopathy or who are taking anticoagulants or other medications should consult their situation with their physician before taking Superba™ Krill Oil as an ingredient in conventional foods or as nutritional supplements.

3. COMMON KNOWLEDGE ELEMENT

The compositional similarity of krill oil with fish oils from multiple sources that already have GRAS status supports the common knowledge element. The composition of krill oil and common fish oils are published and the similarity in compositions is readily ascertainable in the cited public documents (FDA, 2002, 2004a, 2004b, 2008). As described in GRN 242 (FDA, 2008) documentation exists in the Federal Register for the GRAS status of menhaden oil and on the FDA website for tuna oil, salmon oil, and sardine oil. These documents cite and support the consumption of fish oil resulting in total daily consumption of EPA plus DHA of less than 3 g/person. This GRAS determination is based on the totality of the available evidence, particularly from human observations, in concert with animal experimental studies. Majority of this information as described above, particularly in Sections 2.2 and 2.3 is available in public domain. Furthermore, safety documentation for food uses of krill oil is found in GRN 242, which also constitutes information that is generally available for review and evaluation. The composite information noted thereby fulfills the common knowledge element required for GRAS determination.

4. SUMMARY

Krill, a vital component of the marine food chain, is also consumed by humans, particularly in Japan and Russia. Because it is a rich source of high-quality protein as well as omega-3 fatty acids, krill has received considerable attention in recent years. Two fatty acids, EPA and DHA, that have received considerable attention for their potential health benefits have been reported to be present at high levels (30%) in krill oil. Aker Biomarine intends to use standardized krill oil (Superba™ Krill Oil) as a nutrient at levels of 0.05 to 0.50 g of the oil per serving in non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices. In addition to the above categories, krill oil is also intended for use in Medical Food at levels not to exceed 0.50 g/person/day. The intended use of krill oil will result in an estimated daily mean and high (90th percentile) intake of 4.1 and 8.3

g/person/day. The resulting high intake of EPA+DHA is estimated as 2.2 g/person/day. Krill oil has been the subject of a GRAS Notice submitted to the FDA for use as a nutrient. In this case, the FDA responded that they had no questions on the proposed use and did not object to the GRAS determination. The composition of Superba™ Krill Oil is well characterized and is substantially equivalent to the European Commission approved krill oil.

It is well established and recognized that dietary phospholipids and fatty acids from either plant or animal sources are handled the same metabolically. Given the metabolic sequelae, there is no reason to believe that the minor variations in the levels of lipids including phospholipids or fatty acids between these oils would pose any different health hazards. Similar to other phospholipids from other sources, phospholipids from krill oil will be absorbed, transported, and converted into endogenous constituents. The fatty acids present in krill oil are typical components of the diet and are not anticipated to pose any risk at the levels consumed. Furthermore, the different fatty acid chains are unlikely to affect the overall oral toxicity, as the fatty acid portions of molecules are largely cleaved prior to absorption by mucosal cells.

Among the fatty acids of krill oil, there is a potential safety concern for EPA and DHA at high levels of intake. The safety of these two fatty acids has been extensively evaluated by the US FDA in the final rule on the approved use of menhaden oil as a direct food ingredient and subsequently in 2005, regarding the use of omega-3 fatty acids as a dietary supplement. The FDA affirmed the GRAS status of menhaden oil for use in foods provided daily intakes of DHA and EPA did not exceed 3 g/person/day from all fish oil sources. The FDA also permitted the use of a Qualified Health Claim on dietary supplements containing EPA and DHA as well as for conventional foods. The FDA concluded that the use of EPA and DHA omega-3 fatty acids as dietary supplements is safe, provided that daily intakes of EPA and DHA do not exceed 3 g/person/day from conventional food and dietary supplement sources. For the food uses of menhaden oil, the FDA imposed specific limitations in its use in different food categories to ensure that total intake of EPA and or DHA is safe. Further, the FDA concluded that in order to help ensure that a consumer does not exceed an intake of 3 g/person/day of EPA and DHA omega-3 fatty acids from consumption of a dietary supplement with the qualified claim, an EPA and DHA omega-3 fatty acid dietary supplement bearing a qualified claim should not recommend or suggest in its labeling, or under ordinary conditions of use, an intake exceeding 2 g EPA and DHA/day. Given the substitutional (for substances with DHA and EPA) uses of krill oil, the resulting intake of DHA and EPA is unlikely to exceed 2.2 g/person/day and is considered as safe.

The safety of krill oil has been investigated in human clinical and animal experimental studies. Although the majority of these studies were designed to investigate the potential health benefits of krill oil, no adverse effects were noted. These studies support the safety of krill oil. Of the five clinical studies on krill oil, three were more significant with regard to dose and duration. In one clinical trial conducted to examine the safety, krill oil was well tolerated at a dose of 2 g/day for four weeks. In the second study, no adverse effects were noted following the consumption of 6 g krill oil/day for two months. In the third clinical study, participants tolerated krill oil at doses of up to 3 g/day for a period of 12 weeks, followed by an additional 0.5 g/day by some participants for 90 days. In these studies no significant adverse effects of krill oil consumption were noted.

There is sufficient qualitative and quantitative scientific evidence, including human and animal data, to determine safety-in-use for krill oil. The safety of krill oil is based on several

factors that include the inherent safety of the fatty acid, phospholipids and other components in the oil, the compositional similarity of the krill oil with fish oils, extensive knowledge of their metabolism, the expected levels in the diet of EPA and DHA fatty acids, and astaxanthin from the intended use of krill oil, the safety of krill oil as demonstrated in pre-clinical and clinical trials, and the absence of reports of toxicity. Additionally, Antarctic krill also has some history of consumption by humans in Japan and Russia. On the basis of scientific procedures[8], the consumption of krill oil as an added food ingredient is considered safe at levels up to 8.3 g/person/day. The intended uses are compatible with current regulations, *i.e.,* krill oil is used in non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices, and Medical Foods.

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[8] 21 CFR §170.3 Definitions. (h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

5. CONCLUSION

Based on a critical evaluation of the publicly available data summarized above, the Expert Panel members whose signatures appear below, have individually and collectively concluded that krill oil (Superba™ Krill Oil), meeting the specifications cited above, and when used as a food ingredient in selected food products (non-alcoholic beverages, breakfast cereals, cheeses, frozen dairy desserts, milk products, and processed fruit and fruit juices, and Medical Foods) at levels of 0.05 to 0.50 g krill oil/serving (reference amounts customarily consumed, 21CFR 101.12) when not otherwise precluded by a Standard of Identity as described in this monograph and resulting in the 90th percentile (high) estimated intake of 8.3 g krill oil/person/day is Generally Recognized As Safe (GRAS).

It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, we have also concluded that Superba™ Krill Oil, when used as described, is GRAS, based on scientific procedures.

Signatures

(b) (6)

John A. Thomas, Ph.D., F.A.C.T., D.A.T.S. — 12/8/10 Date

(b) (6)

Stanley T. Omaye, Ph.D., D.A.T.S. — 12/07/10 Date

(b) (6)

Madhusudan G. Soni, Ph.D., F.A.C.N. — Dec. 10, 2010 Date

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7. APPENDIX I

Analytical data from different manufacturing lots of Superba™ Krill Oil (Aker Biomarine, 2010)

Parameter	Limits	U133 002 A10	U176 004 A10	U141 001 A10	U141 003 A10	U141 002 A10
Appearance	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil	Dark red viscous oil
Lipid composition						
Total phospholipids (g/100g)	43 ± 3	40.3	44.8	40.8	45.3	42.7
-Omega-3 phospholipids[1] of total PL % (w/w)	>70	>70	>70	>70	>70	>70
Triglycerides (g/100g)	<50	39	36	32	32	32
Fatty acid profile						
Total omega-3 (expressed as g/100g)	23.5 ± 2	22.9	22.4	24.5	26.2	25.5
-C 20:5 n-3 (EPA)(expressed as g/100g)	14 ± 2	13.4	14.3	14.7	16.7	16.3
-C 22:6 n-3 (DHA)(expressed as g/100g)	6.5 ± 1	6.5	5.8	6.7	6.7	6.5
Total omega-6	<3.0	1.9	2.0	2.2	2.4	2.4
Stability index						
Peroxide value (mEq peroxide/kg)	<2	<1	<1	<1	<1	<1
Antioxidants						
Astaxanthin (mg/kg)	100 ± 20 (minimum)	164	125	144	96	92
Water and Ethanol						
Water activity at 25°C	<0.5	0.116	0.149	0.143	0.115	0.139
Ethanol content (% w/w)	<3.0	1.8	1.52	1.58	1.37	1.21
Microbiology						
Total plate count (cfu/g)	<2500	<100	<100	<100	<100	<100
E. coli (1 sample at 10 g)	Negative	Negative	Negative	Negative	Negative	Negative
Coliform bacteria, 37°C (cfu/g)	<10	<10	<10	<10	<10	<10
Salmonella negative (PCR) (1 sample at 10 g)	Negative	Negative	Negative	Negative	Negative	Negative
Mold and Yeast (cfu/g)	<10	<10	<10	<10	<10	<10

[1]Omega-3 phospholipid: defined as phospholipid where on average one out of two possible positions is occupied by an omega-3 fatty acid.

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Additional Specification and compositional analysis data of Superba™ Krill Oil from five different batches Adapted from Superba™ Krill oil substantial equivalence notification

Parameter	Unit	Batch 233/34/A 8	Batch 234/42/A 8	Batch 234/43/A8	Batch 235/24/A 8	Batch 280/42/A 9	Batch 279/22/ A9
1. Saponification value	Mg KOH/g	N.D	N.D	N.D	N.D	149	160
2. Peroxide value*	eEq/kg	<2	<2	<2	<2	<2	<2
3. Moisture**		0.19	0.251	0.27	0.339	N.D	N.D
4. Total phospholipids	g/100g	46.0	44.3	45.7	44.5	N.D	N.D
5. *Trans*-fatty acids	% of lipids	0.23	0.23	0.23	0.24	N.D	N.D
6. EPA (20:5)		14.8	14.9	14.3	14.9	N.D	N.D
7. DHA (22:6)		8.6	8.7	8.4	8.7	N.D	N.D

Analysis 3-7 was performed by validated methods at an accredited laboratory (NOFIMA). Analysis number 1 was performed at NOFIMA. Adapted from Superba™ Krill Oil substantial equivalence notification.

* As assayed by the relevant AOCS method.

** Moisture expressed as water activity at 25°C. N.D. = not determined.

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8. APPENDIX II

Analytical Results of Dioxins, Furans, Organochlorine Pesticides, PBDEs, PAHs, and Heavy Metals from Five Batches, and Marker PCBs from Four Batches of Superba™ Krill Oil

Parameter	Unit	Method	233/34/A8 (262/72/A8)	234/42/A8	234/43/A8	235/24/A8	341/78/A9	average
Dioxins, furans and dioxine like PCBs								
Total PCDDs/PCDFs	ng/kg	EN 1948 modified, HRMS	0.16	0.16	0.17	0.15	0.294	0.187
PCDDs/PCDFs and dioxine like PCBs	ng/kg	EN 1948 modified, HRMS	0.27	0.26	0.26	0.26	0.436	0.297
Organochlorine pesticides								
DDTs/DDDs/DDEs	ug/kg	Internal method, HRGC-HRMS	<1.7	<1.37	<1.43	<1.45	<1.2	
Aldrin	ug/kg	Internal method, HRGC-HRMS	<0.5	<0.5	<0.5	<0.5	<0.5	
Dieldrin	ug/kg	Internal method, HRGC-HRMS	0.72	0.65	0.64	0.57	0.42	
Toxaphen	ug/kg	Internal method, HRGC-HRMS	<3.3	<2.1	<2.2	<2.1	<1.8	
PBDEs								
PBDE #17	ng/g	LRMS	<0.02	<0.01	<0.01	<0.01	<0.02	<0.014
PBDE #28	ng/g	LRMS	<0.02	<0.01	<0.01	<0.01	<0.019	<0.0138
PBDE #49	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #71	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #47	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #66	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #77	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #100	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #119	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #99	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #85	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #126	ng/g	LRMS	<0.04	<0.03	<0.03	<0.03	<0.048	<0.036
PBDE #154	ng/g	LRMS	<0.06	<0.04	<0.04	<0.04	<0.077	<0.051

PBDE #153	ng/g	LRMS	<0.06	<0.04	<0.04	<0.04	<0.077	<0.051
PBDE #138	ng/g	LRMS	<0.06	<0.04	<0.04	<0.04	<0.077	<0.051
PBDE #183	ng/g	LRMS	<0.07	<0.06	<0.06	<0.06	<0.096	<0.069
PBDE #190	ng/g	LRMS	<0.07	<0.06	<0.06	<0.06		
PBDE #203	ng/g	LRMS	<0.15	<0.15	<0.15	<0.15		
PBDE #207	ng/g	LRMS	<0.15	<0.12	<0.11	<0.12	<0.479	<0.196
PBDE #209	ng/g	LRMS	<1.48	<1.19	<1.14	<1.16	<1.91	<1.38
PAHs								
Benzo(a)anthracene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Chrysene/triphenylene	ug/kg	GC-MS	0.7		ND	0.6	<0.5	<0.6
Benzo(b)fluoranthene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Benzo(k/j)fluoranthene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Benzo(a)pyrene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Indeno(1,2,3-cd)pyrene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Dibenzo(a,h)anthracene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.5	<0.5
Benzo(ghi)perylene	ug/kg	GC-MS	<0.5		ND	<0.5	<0.6	<0.53
Dibenzo(a,l)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Dibenzo(a,i)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Dibenzo(a,h)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Dibenzo(a,e)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Cyclopenta(c,d)pyrene	ug/kg	GC-MS	<1		ND	<1	<1	<1
5-methylchrysene	ug/kg	GC-MS	<1		ND	<1	<1	<1
Benzo-(o)-fluorene	µg/kg	GC-MS					<1	<1
Benzo(a)pyrene	µg/kg	GC-MS					<0.5	<0.5
Arsenic								
Arsenite	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0,005	0.015	0.007
Arsenate	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	0.005

Monomethylarsonate	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.075	0.041	0.057	0.062	0.042	
Dimethylarsinate	mg/kg	Extraction/digestion, HPLC-ICP-MS	3.18	3.18	3.3	3.29	3.64	
Arsenobetaine	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.91	0.771	0.886	0.914	0.723	
Arsenocholine	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	
Trimethylarsine oxide	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.399	0.42	0.417	0.431	0.519	
Tetramethylarsonium ion	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.063	0.062	0.062	0.064	<0.005	
Arsenosugar a	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	
Arsenosugar b	mg/kg	Extraction/digestion, HPLC-ICP-MS	<0.005	<0.005	<0.005	<0.005	<0.005	
Arsenosugar c	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.011	0.008	0.011	0.01	0.02	
Arsenosugar d	mg/kg	Extraction/digestion, HPLC-ICP-MS	0.038	0.036	0.041	0.037	0.022	
Arsenic (As)	mg/kg	Microwave assisted digestion, ICP-MS	5.5	4.9	5.5	5.2	5.6	
Heavy metals								
Pb	mg/kg	§64 LFGB L00.00-19/3, AAS-Gr.	<0.05	<0.1	<0.05	<0.05	<0.04	<0.058
Cd	mg/kg	§64 LFGB L00.00-19/3, AAS-Gr.	<0.01	<0.01	<0.01	<0.01	<0.02	<0.012
Hg	mg/kg	§64 LFGB L00.00-19/4, AAS-cold vapour	<0.005	<0.005	<0.005	<0.005	<0.02	<0.008
Cu	mg/kg	EN ISO 11885, mod., ICP-OES	6.3	7.7	7.2	5.8	10	7.4
Fe	mg/kg	EN ISO 11885, mod., ICP-OES	0.4	0.21	0.18	0.2	<2	0.598
Zn	mg/kg	EN ISO 11885, mod., ICP-OES	2.9	2.5	2.8	2.9	2.5	2.72

Data information provided by Aker Biomarine.

Analytical Results on Marker PCBs from four representative batches of Superba™ Krill Oil are presented separately (see below)

Levels of Marker PCBs from four representative batches of Superba™ Krill Oil

Marker PCBS	Unit	341 70 A9	A112/011/A10	U194/001/A10	U232/002/A10
PCB 28	pg/g	<54.6	<89.7	<92.8	<90.7
PCB 52	pg/g	<43.1	<46.2	<47.7	56.8
PCB 101	pg/g	<54.6	<66.7	<69.0	<67.4
PCB 118	pg/g	<21.6	<24.1	62.7	36.2
PCB 138	pg/g	<63.2	<79.5	<82.2	<80.3
PCB 153	pg/g	<66.1	<84.6	<87.5	<85.5
PCB 180	pg/g	<26.4	<61.5	<63.7	<62.2
Total 7 indicator PCBs	pg/g	330	452	506	479

9. APPENDIX III

trans-Fatty acid profile from four batches of Superba™ Krill Oil

Fatty acids	Batch 235-24-A8	Batch 234-33-A8	Batch 02925-01	Batch 234-43-A8
trans 16:1	<0.1	<0.1	<0.1	<0.1
trans 18:1	<0.1	<0.1	<0.1	<0.1
trans 18:2	<0.1	<0.1	<0.1	<0.1
trans 18:3	<0.1	<0.1	<0.1	<0.1
trans 20:1	<0.1	<0.1	<0.1	<0.1
trans 20:2	<0.1	<0.1	<0.1	<0.1
trans 20:3	<0.1	<0.1	<0.1	<0.1
trans 20:4	<0.1	<0.1	<0.1	<0.1
trans 20:5	0.1	0.1	0.1	0.1
trans 22:1	<0.1	<0.1	<0.1	<0.1
trans 22:6	<0.1	0.1	0.1	0.1
Total *trans*-fatty acids	0.2	0.2	0.2	0.2

Values are expressed as g/100 g of fatty acids; Method: AOCS Ce 1h-05; Data information provided by Aker Biomarine

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10. APPENDIX IV

Novel Food Ingredient approval for Superba™ Krill Oil

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Safety of the Food chain
Food law, nutrition and labelling

SANCO
22. 12. 2009

Brussels,
SANCO/E4/AK/bs (2009) D/540876

Note to the Permanent Representations of

Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

Subject: **Regulation (EC) N° 258/97 concerning novel foods and novel food ingredients**
Notification pursuant to Article 5 of the above mentioned Regulation
Lipid extract from Antarctic Krill

Pursuant to Article 5 of Regulation (EC) N° 258/97, the Commission has received a notification for the placing of the above-mentioned product on the Community market on 17 December 2009.

Notifier: **Aker BioMarine Antarctic AS**
Fjordalléen 16
P.O.Box 1423 Vika
NO – 0115 Oslo
Norway.

The Novel Food Board (FIN) has delivered an opinion that the Krill oil to be placed on the market by the company Aker BioMarine Antarctic AS is substantially equivalent to the Krill oil authorised by Commission Decision 2009/752/EC with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein (Article 3.4 of Regulation (EC) N° 258/97).

Pursuant to Article 5 of Regulation (EC) N° 258/97 you are now receiving a copy of the notification with its enclosures.

(b) (6)

Andreas Klepsch

Enclosures
cc: Competent authorities, EFTA Secretariat, Mr Hogne Vik

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11
Office: F101 8/22. Telephone: direct line (32-2) 2953210. Fax: (32-2) 2951735

Soni & Associates Inc.

749 46th Square
Vero Beach, FL 32968, USA
Telephone: 772-299-0746

E-mail: msoni@soniassociates.net

January 28, 2011

Dr. Paulette Gaynor
Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: GRAS Notification for Kril

Dear Dr. Gaynor:

This has reference to our discussion about Superba™ Krill Oil GRAS notification submitted on behalf of Aker Biomarine Antarctic AS, Norway. As discussed, please find attached three copies of the revised Availability of Information statement (page 3).

If you have any questions or require additional information, please feel free to contact me at 772-299-0746 by phone or at msoni@soniassociates.net by email.

Sincerely,
(b) (6)

Madhu G. Soni, Ph.D.

Enclosure:

determination of high phospholipid krill oil is based on the totality of available scientific evidence that includes human observations and a variety of preclinical and clinical studies. Based on the available safety-related information, the estimated daily intake, if ingested daily over a lifetime, is safe.

F. Availability of Information:

The data and information that forms the basis of Aker Biomarine's Superba™ Krill Oil GRAS determination will be available for the Food and Drug Administration's review and copying at the following address or will be provided to the FDA upon request:

Madhu G. Soni, Ph.D., FACN,
Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968
Phone: (772) 299-0746; E-mail: sonim@bellsouth.net

II. Detailed Information About the Identity of the Notified Substance:

A. Trade Name:

The subject of this notification will be marketed as Superba™ Krill Oil

B. Physical Characteristics

Superba™ Krill Oil is dark red colored viscous oil

C. Chemical Abstract Registry Number:

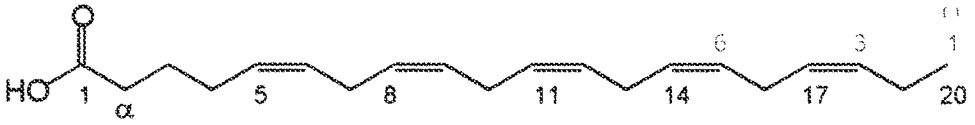
Not available

D. Chemical Formula:

Not applicable

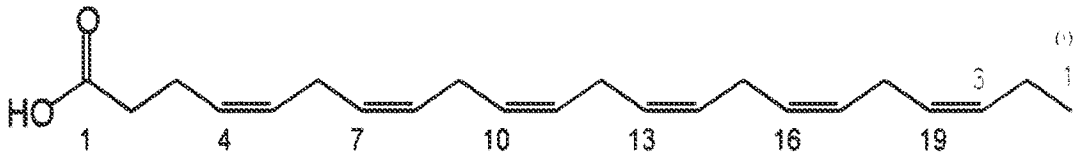
E. Structure:

The important constituents of high phospholipid krill oil are the fatty acids, EPA and DHA. The structures of these two fatty acids presented in Figure 1.



$CH_3CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}(CH_2)_3COOH$

Eicosapentaenoic acid (EPA)



$CH_3CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}CH_2\mathbf{CH}{=}\mathbf{CH}(CH_2)_2COOH$

Docosahexaenoic acid (DHA)

Figure 1. Chemical structures of EPA and DHA