

From: [Morissette, Rachel](#)
To: [Katrina Emmel](#)
Subject: RE: GRN 735 2'-Fucosyllactose
Date: Wednesday, December 13, 2017 11:16:00 AM
Attachments: [image001.png](#)

Dear Katrina,

I received your email regarding the confidential information for GRN 735. Our review team is meeting on Monday to discuss your notice. I will be in contact shortly after the meeting to discuss the next steps for this notice.

Best regards,

Rachel

Rachel Morissette, Ph.D.

Consumer Safety Officer

Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov



From: Katrina Emmel [mailto:emmel@gras-associates.com]
Sent: Tuesday, December 12, 2017 2:02 PM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>
Cc: Steven Overgaard <smovergaard@gras-associates.com>; Richard Kraska <kraska@gras-associates.com>; robert mcquate <mcquate@gras-associates.com>
Subject: GRN 735 2'-Fucosyllactose

Dear Dr. Morissette,

GRAS Associates, acting as the agent for Glycosyn and FrieslandCampina Domo, submitted to you a GRAS Notification (GRN 735) for 2'-Fucosyllactose (2'-FL), on September 29, 2017. Our clients had retained Intertek to prepare an intake assessment of 2'-FL based on its intended uses, and a copy of the report was included in the submission as Appendix 8.

Intertek has recently contacted us indicating that the final report that was issued to our client is marked "confidential" and as such, they are expecting that it would not be part of the releasable information on the FDA website and wanted us to confirm this point with you.

In the event that the report's contents must be included on the website, they have provided an "unbranded" version that is not marked "confidential," which can be submitted for the one that we filed initially. I have attached a copy of this version, should that be the case.

I apologize for any issues this may cause, and I appreciate your help with this matter.

Thank you,

Katrina

Katrina Emmel, Ph.D.
Senior Scientist/Project Manager/Associate
GRAS Associates, LLC.

emmel@gras-associates.com

From: [Richard Kraska](#)
To: [Morissette, Rachel](#)
Subject: Response on GRN 737
Date: Friday, January 05, 2018 10:57:05 AM
Attachments: [Response Ltr to FDA GRN 735.pdf](#)
[Emmel CV.pdf](#)
[Lonnerdal CV .pdf](#)
[Kraska CV.pdf](#)
[Archer CV.pdf](#)
[Expert Panel Qualifications.pdf](#)
[U.S. Intakes Report 2"-FL NHANES.pdf](#)
[2"-FL Table 10 Updated .pdf](#)

Hi Rachel

Attached please find our letter responding to your questions. Please confirm your receipt of this message.

In response to FDA comments, we have added Dr. Bo Lönnerdal to the expert panel. Dr. Lönnerdal is a recognized expert in pediatric nutrition.

Other attachments included are:

- CVs for all four members of the expert panel
- A short statement of qualification for the members of the expert panel
- A correction of Table 10 in the dossier
- A corrected, non-confidential report for the dietary intake estimate to be used to correct Appendix 8

Thank you for your help and we hope these responses are useful in the review.

Regards

Rich

Richard Kraska, Ph.D., DABT

Chief Scientific Officer and Executive Vice President

Co-Founder

GRAS Associates, LLC

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January 5, 2018

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety (HFS-255)
5001 Campus Drive
College Park, MD 20740-3835
Attention: Dr. Rachel Morissette
Re: GRN 735 –2'-fucosyllactose (2'-FL) –Response to Questions Posed in an Email Dated 12/20/17

Dear Dr. Morissette:

Per your request, GRAS Associates, LLC, acting as the agent for Glycosyn and Friesland Campina, is providing a response to complete FDA's request for additional information as denoted in the attachment to your email dated December 20, 2017, as follows:

1) *Substitution of Corrected Version of Appendix 8*

We have attached a correction of the report that constitutes Appendix 8. It removes unintended confidential markings and corrects Table 3-1 in response to FDA questions 4 and 5.

2) *Questions on composition of Expert Panel*

We appreciate FDA's questions in light of the publication FDA's recent draft guidance on convening a GRAS Panel. We can assure you that Dr. Emmel and Dr. Kraska are sensitive to questions of bias and have the highest regard for scientific integrity and conflict of interest. We are providing a short statement of the qualifications of all the panelists and a current curriculum vitae for each member. We did not include a panel member with expertise in infant nutrition or a medical background in pediatrics because Friesland Campina experts in these area provided technical support in construction of the notice. We also noted that in previous GRAS notices for 2'-FL, there was favorable review by these experts. We felt that the main needs of expertise for the panel were chemistry—to link the composition of a new source of 2'-FL to the test materials used in previous published studies, microbiology --- to review the safety questions that might arise from the new organism and toxicology—to review the new unpublished studies provided with the notice. However, in view of FDA's comments we have contracted with Dr. Bo Lönnnerdal from the University of California at Davis to review the dossier and the panel report and join the expert panel. We are including a letter from Dr. Lönnnerdal indicating his agreement with the panel findings.

3) *Please clarify if 2'-FL is intended for milk-based infant formulas only or also for soy-based infant formulas*

• • •

The intended use of 2'-FL in infant formula is for all types of non-exempt infant formula.

4) *Table 10 indicates a proposed use of 2'-FL in "infant meal replacement products such as Pediasure." Pediasure and similar products are for children older than 12 months of age, not for infants. Please clarify that these are meal replacement products for children older than 12 months of age.*

We confirm these meal replacement products are for children older than 12 months of age. A corrected version of Table 10 is included to reflect that.

5) *In Table 10, it is unclear what the intended use level of 2'-FL is going to be infant formula –2.4 g/L or 0.40 g/kcal. Please provide the conversion used between these two use levels.*

We have corrected Table 10 to indicate that these levels are equivalent and included a footnote showing the conversion.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via email.

We look forward to your feedback.

Sincerely,



Richard Kraska, Ph.D., DABT
Chief Scientific Officer
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KATRINA EMMEL, Ph.D.

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Corona, CA 92879
(847) 436-2598

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EMPLOYMENT

- April 2016-Current Independent Contractor-Senior Associate & Project Manager, GRAS Associates, Bonita Springs, FL
- Coordinate GRAS evaluations, while interfacing with both colleagues and clients
 - Prepare, review, and edit technical documents and GRAS evaluations
 - Review chemical analysis and recommend specifications
 - Serve as an Expert Panelist and/or as Chair of the Expert Panel for GRAS evaluations
- Jan. 2013-Mar. 2016 Independent Contractor/Consultant, GRAS Associates, Bonita Springs, FL
- Prepare, review, and edit technical documents
 - Review chemical analysis and recommend future direction
- Oct. 2012-July 2014 Analytical Scientist II (On-Call), NOW Foods, Bloomingdale, IL
- Prepare, review and edit technical documents, SOPs, posters and literature for publication.
 - Research and recommend technology to develop cutting-edge analytical techniques.
 - Provide guidance on analytical methodology and testing
- Jan. 2012- Sept. 2012 Analytical Scientist II, NOW Foods, Bloomingdale, IL
- Sept. 2008- Dec. 2011 Analytical Scientist I, NOW Foods, Bloomingdale, IL
- GRAS Project Leader: GRN 337
 - Prepare technical documents, SOPs, posters and literature for publication.
 - Work closely with chemists to develop and/or improve methods, including adulteration testing, rancidity, fatty acids, and vitamins as well as modify current methods to improve throughput and efficiency.
 - Research, recommend, and integrate new technology to develop cutting-edge analytical techniques.
 - Apply traditional methodology and instrumentation in a non-traditional manner to develop novel analysis techniques.
 - Review QC data packages and release documentation.
 - Support International, R&D, and Private Label divisions with customer questions and technical assistance.

- GC-FID, Reaction Pyrolysis (RxPy-GC-FID), HPLC, uHPLC, LC-MS, FTIR, UV-Vis

Fall 2008 – Fall 2010 Adjunct Chemistry Professor, Waubensee Community College, Sugar Grove, IL

2007- 2008 Chemist/Chromatographer, Doctor's Data, Inc., St. Charles, IL

EDUCATION

Ph.D., Analytical Chemistry, Northern Illinois University, DeKalb, IL, 2007

Thesis title: "Using Ion-Molecule Reactions to Probe the Structure and Reactivity of Amino Acids in the Gas Phase"

Advisor: Professor Victor Ryzhov

M.S., Biochemistry, Worcester Polytechnic Institute, Worcester, MA, 2003

Thesis title: "The Genetics of TCV Resistance"

Advisor: Professor Kristin K. Wobbe

PUBLICATIONS AND PRESENTATIONS

- Michael Lelah and Katrina Emmel. "The Science of Enzyme-Treated Stevia." *Vitamin Retailer*, May 2011.
- A.B. Champagne; K.V. Emmel. "Rapid Screening Test for Adulteration in Raw Materials of Dietary Supplements," *Vibrational Spectroscopy* (2010).
- Oral Presentation, Katrina Emmel and Andrea Champagne, PerkinElmer Open House, April 19, 2012
"Keeping it Clean: FTIR as a Screening Tool for Adulteration in Raw Materials of Dietary Supplements"
- Oral Presentation, Chicago IFT Suppliers' Night 2011 Innovation NOW! Forum, 2011
"Enzyme-treated Stevia Extract – A Better Way to Beat the Bitterness"
- Poster Presentation, 10th Annual Oxford International Conference on the Science of Botanicals, Mississippi, 2011
Champagne, AC; Emmel, KV; Lelah, MD
"Rapid Screening Test for Adulteration of Herbal Supplements"
- Poster Presentation, AOAC Meeting, Philadelphia, PA, 2009
Ted Waszkuc, Susan Berkman, Katrina Emmel, Sandra Jordan and Felicia Mohammed
"High Performance Thin Layer Chromatography (HPTLC) Characterization of the Enzymatic Glycosylation of *Stevia rebaudiana*: A Comparison of Enzyme Treated and Non-Enzyme Treated Stevia Extracts"
- Poster Presentation, ASMS Meeting, Philadelphia, PA, 2009
Katrina Emmel, Ted Waszkuc, Susan Kraemer-Berkman, Andre Szczesniewski and Sue D'Antonio
"High-Resolution TOF LC/MS Characterization of the Enzymatic Glycosylation of *Stevia rebaudiana*: A Comparison of Natural and Enzyme-Treated Stevia Extracts"
- Poster Presentation, ACS Meeting, Lincolnshire, IL 2009
Ted Waszkuc, Susan Berkman, Katrina Emmel and Felicia Mohammed
"High Performance Liquid Chromatography (HPLC) Characterization of the Enzymatic Glycosylation of *Stevia rebaudiana*: A Comparison of Enzyme Treated and Non-Enzyme Treated Stevia Extracts"

- Poster Presentation, ASMS Meeting, Seattle, WA, 2006
Katrina Vaitkunas, Victor Ryzhov, Andrea Weinecke, and Robert Sobel
“Characterization of Reaction Products and Kinetics of Maillard Reactions of Dark Malts with Amino Acids by Chromatography and Mass Spectrometry”
- Poster Presentation, ASMS Meeting, San Antonio, TX, 2005
Katrina Vaitkunas and Victor Ryzhov
“Using Ion-Molecule Reactions to Probe the Structure of Amino Acid-Alkali Metal Ion Complexes in the Gas Phase”

CURRICULUM VITAE

BO L.G. LÖNNERDAL

Office Address:

Department of Nutrition
University of California
Davis, CA 95616
Telephone: (530) 752-8347/8438
Fax: (530) 752-3564

Home Address:

230 Guaymas Place
Davis, CA 95616
Telephone: (530) 756-8791

Personal:

Born: March 5, 1948, in Linköping, Sweden
Citizenship: U.S. (and Swedish)
Marital Status: Married, 1974 to Inger C. Lindsten, B.S.
Four children (Jacob, born 1974; Ida, born 1975; Jan, born 1978; Daniel, born 1981)

Education:

S:t Lars High School, 1963-1966

University of Uppsala, Uppsala, Sweden, B.S. (Fil. kand.), 1969 (Biochemistry, chemistry, genetics and mathematics)

University of Uppsala, Uppsala, Sweden, M.S. (Fil. lic.), 1972 (Biochemistry, minor in organic chemistry)

University of Uppsala, Uppsala, Sweden, Ph.D., 1973 (Biochemistry; minor in Nutrition)

Languages:

Fluent English, German (French)

Professional Positions:

Research Assistant in Biochemistry, University of Uppsala, Uppsala, Sweden, 1969-1974

Post-doctoral Fellow in Nutrition, University of Uppsala, Uppsala, Sweden, 1974-1976

Assistant Professor of Nutrition, University of Uppsala, Uppsala, Sweden, 1976-1978

Visiting Assistant Research Nutritionist, University of California, Davis, California, 1978-1980

Assistant Research Nutritionist, University of California, Davis, California, 1980-1981

Assistant Professor of Nutrition, University of California, Davis, California, 1981-1983

Associate Professor of Nutrition, University of California, Davis, California, 1983-1985

Professor of Nutrition, University of California, Davis, California, 1985-1986

Professor of Nutrition and Internal Medicine, University of California, Davis, California, 1986-

Distinguished Professor of Nutrition and Internal Medicine, University of California, Davis, 2003-

Honors:

Henning Throne-Holst's Award for Research in Nutritional Physiology, 1977
St. Göran's Annual Lecture in Nutritional Physiology, Karolinska Institute, 1986
Underwood Memorial Lecture in Trace Element Research, 1987
Borden Award, 1990
International Award for Modern Nutrition, 1991
Doctor Honoris Causa (Honorary Doctor) in Medicine, University of Uppsala, Sweden, 2000
Macy-György Award (for research on human milk and its components), International Society for Research on Human Milk and Lactation (ISRHML), 2002
Gabriel Bertrand Prize and Medal for research on trace element metabolism, 2004
Lucille Hurley Lectureship 2012

Society Memberships:

American Society of Nutrition (ASN)
European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)
Society for International Nutrition Research (SINR)
International Society for Research on Human Milk and Lactation (ISRHML)

Editorial Boards:

Journal of Nutritional Biochemistry
Biological Trace Element Research
Journal of Trace Elements in Medicine and Biology

PUBLICATIONS

1. 1969 Lönnerdal, B. Synthesis of imino carbonates and isothiocyanates-two methods of coupling to dextran gels. Filosofie kandidatexamen (B.S. Thesis), University of Uppsala, Sweden.
2. 1972 Lönnerdal, B. The low molecular weight proteins in rapeseed (Brassica napus). Licentiatavhandling (M.S. Thesis), University of Uppsala, Sweden.
3. 1972 Lönnerdal, B. and J.-C. Janson. Studies on Brassica seed proteins. I. The low molecular weight proteins in rapeseed. Isolation and characterization. *Biochimica et Biophysica Acta* 278:175-183.
4. 1973 Lönnerdal, B. and J.-C. Janson. Studies on myrosinases. II. Purification and characterization of a myrosinase from rapeseed (Brassica napus L.). *Biochimica et Biophysica Acta* 315:421-429.
5. 1973 Björkman, R. and B. Lönnerdal. Studies on myrosinases. III. Enzymatic properties of myrosinases from *Sinapis alba* and *Brassica napus* seeds. *Biochimica et Biophysica Acta* 327:121-131.
6. 1973 Lönnerdal, B. Studies on myrosinases and a group of low molecular weight proteins in rapeseed. Ph.D. Thesis, University of Uppsala, Sweden.
7. 1975 Callmer, E., R. Kihlberg, B. Lönnerdal and P. Omstedt. Report from Xth International Congress of Nutrition. *Näringsforskning (Nutrition Research, SW)* 19:241-256.
8. 1976 Lönnerdal, B., E. Forsum and L. Hambraeus. The protein content of human milk. I. A transversal study of Swedish normal material. *Nutrition Reports International* 13:125-134.
9. 1976 Lönnerdal, B., E. Forsum and L. Hambraeus. A longitudinal study of the protein, nitrogen and lactose contents of human milk from Swedish well-nourished mothers. *American Journal of Clinical Nutrition* 29:1127-1133.
10. 1976 Lönnerdal, B., E. Forsum, M. Gebre-Medhin and L. Hambraeus. Breast milk composition in Ethiopian and Swedish mothers. II. Lactose, nitrogen, and protein contents. *American Journal of Clinical Nutrition* 29:1134-1141.
11. 1976 Hambraeus, L., E. Forsum, L. Abrahamsson and B. Lönnerdal. Automatic total nitrogen analysis in nutritional evaluations using a block digester. *Analytical Biochemistry* 72:78-85.
12. 1976 Lönnerdal, B. and T. Låås. Improved agarose for immunoelectrophoresis. *Analytical Biochemistry* 72:527-532.

13. 1977 Lönnerdal, B., L. Gillberg and B. Törnell. Preparation of rapeseed protein isolates: A study of rapeseed protein isolates by molecular sieve chromatography. *Journal of Food Science* 42:75-78.
14. 1977 Hambraeus, L., E. Forsum and B. Lönnerdal. Nutritional aspects of breast milk versus cow's milk formula. In: *Food and Immunology. Swedish Nutrition Foundation Symposium No. XIII*, Almkvist and Wilksell Tryckeri AB, Uppsala, Sweden, pp. 116-124.
15. 1977 Lönnerdal, B., E. Forsum and L. Hambraeus. A longitudinal study of the protein content of human milk from well-nourished Swedish mothers. In: *Proceedings of the Second European Nutrition Conference. Nutrition Metabolism* 21(Suppl. 1):106-109.
16. 1977 Abrahamsson, L., E. Forsum, M. Gebre-Medhin and B. Lönnerdal. Rapport fran Second European Nutrition Congress, Munich, 1976. *Naringsforskning (Nutrition Research, SW)* 21:117-123.
17. 1977 Lönnerdal, B., J. Carlsson and J. Porath. Isolation of lactoferrin from human milk by metal-chelate affinity chromatography. *Federation of European Biochemical Societies Letters* 75:89-92.
18. 1977 Appelqvist, L.-Å. and B. Lönnerdal. Naturligt forekommande antinutritionella substanser i livsmedels- och foderproteiner. *Naringsforskning (Nutrition Research, SW)* 21:241-253.
19. 1977 Anjou, K., B. Lönnerdal, B. Uppstrom and P. Åman. Composition of seeds from Brassica cultivars. *Swedish Journal of Agricultural Research* 7:169-178.
20. 1978 Hambraeus, L., B. Lönnerdal, E. Forsum and M. Gebre-Medhin. Nitrogen and protein components of human milk. *Acta Paediatrica Scandinavica* 67:561-565.
21. 1978 Hambraeus, L. and B. Lönnerdal. A report from Western Hemisphere Nutrition Congress V, Quebec, 1977. *Naringsforskning (Nutrition Research, SW)* 22:1-9.
22. 1979 Forsum, E. and B. Lönnerdal. Protein evaluation in growing rats of breast milk and breast milk substitutes with special reference to the content of non-protein nitrogen. *Journal of Nutrition* 109:185-192.
23. 1979 Hurley, L. S., B. Lönnerdal and A. G. Stanislawski. Zinc citrate, human milk and acrodermatitis enteropathica. *Lancet* i:677-678.
24. 1979 Forsum, E. and B. Lönnerdal. Variation in the contents of nutrients of breast milk during one feeding. *Nutrition Reports International* 19:815-820.
25. 1979 Lönnerdal, B. Brostmjolkens kemi. *Kemisk Tidskrift (Journal of Chemistry, SW)* 91:47-48.

26. 1979 Forsum, E. and B. Lönnerdal. Evaluation of breast milk and breast milk substitutes in growing rats. *Pediatrics* 64:536-538.
27. 1979 Lönnerdal, B., C. L. Keen and L. S. Hurley. Isoelectric focusing of superoxide dismutase isoenzymes. *Federation of European Biochemical Societies Letters* 108:51-55.
28. 1979 Lönnerdal, B. The chemistry of breast milk. *Naringsforskning (Nutrition Research, SW)*.
29. 1980 Lönnerdal, B., A. G. Stanislawski and L. S. Hurley. Isolation of a low molecular weight zinc binding ligand from human milk. *Journal of Inorganic Biochemistry* 12:71-78.
30. 1980 Keen, C. L., B. Lönnerdal, M. V. Sloan and L. S. Hurley. Effect of dietary iron, copper, and zinc chelates of nitrilotriacetic acid (NTA) on trace metal concentrations in rat milk and maternal and pup tissues. *Journal of Nutrition* 110:897-906.
31. 1980 Lönnerdal, B., E. Forsum and L. Hambraeus. Effect of oral contraceptives on composition and volume of breast milk. *American Journal of Clinical Nutrition* 33:816-824.
32. 1980 Lönnerdal, B., C. L. Keen, G.-B. Fransson, L. Hambraeus and L. S. Hurley. New perspectives on iron supplementation of milk. *Journal of Pediatrics* 96:242.
33. 1980 Forsum, E. and B. Lönnerdal. Effect of protein intake on protein and nitrogen composition of breast milk. *American Journal of Clinical Nutrition* 33:1809-1813.
34. 1980 Fransson, G.-B and B. Lönnerdal. Iron in human milk. *Journal of Pediatrics* 96:380-384.
35. 1980 Keen, C. L., B. Lönnerdal, M. V. Sloan and L. S. Hurley. Effects of milking procedure on rat milk composition. *Physiology and Behavior* 24:613-615.
36. 1980 Lönnerdal, B., B. O. Schneeman, C. L. Keen and L. S. Hurley. Molecular distribution of zinc in biliary and pancreatic secretions. *Biological Trace Element Research* 2:149-158.
37. 1980 Lönnerdal, B., C. L. Keen, B. Hoffman and L. S. Hurley. Copper ligands in human milk: A vehicle for copper supplementation in the treatment of Menkes' Disease? *American Journal of Disease of Children* 134:802-803.
38. 1980 Keen, C. L., B. Lönnerdal, T. N. Stein and L. S. Hurley. Superoxide dismutase isoenzymes in bovine and human milk. *Biological Trace Element Research* 2:221-227.
39. 1980 Hurley, L. S., C. L. Keen and B. Lönnerdal. Copper in fetal and neonatal development. In: *The Biological Roles of Copper, Ciba Foundation Symposium, London, England, 1980, Excerpta Medica* pp. 227-245.
40. 1980 Hurley, L. S. and B. Lönnerdal. Zinc absorption and tryptophan metabolism. Letter to the Editor. *Nutrition Reviews* 38:295.

41. 1980 Lönnerdal, B., C. L. Keen, M. V. Sloan and L. S. Hurley. Molecular localization of zinc in rat milk and neonatal intestine. *Journal of Nutrition* 110:2414-2419.
42. 1980 Lönnerdal, B., M. Clegg, C. L. Keen and L. S. Hurley. Effects of wet ashing techniques on the determinations of trace element concentrations in biological samples. In: *Trace Element Analytical Chemistry in Medicine and Biology* (Schramel, P and P. Bratter, eds.), Walter de Gruyter and Co., New York, pp. 619-629.
43. 1980 Lönnerdal, B. Chemical modification of dextran gels for gel filtration of trace element ligands. In: *Trace Element Analytical Chemistry in Medicine and Biology, Proceedings of the First International Workshop*, pp. 439-446.
44. 1980 Hurley, L. S. and B. Lönnerdal. Tryptophan, picolinic acid, and zinc absorption: an unconvincing case. Letter to the Editor. *Journal of Nutrition* 110:2536-2538.
45. 1981 Hurley, L. S. and B. Lönnerdal. Picolinic acid as a zinc binding ligand in human milk: An unconvincing case. Letter to the Editor. *Pediatric Research* 15:166-167.
46. 1981 Keen, C. L., B. Lönnerdal and G. L. Fisher. Seasonal variations and the effects of age on serum copper and zinc values in the dog. *American Journal of Veterinary Research* 42:347-350.
47. 1981 Keen, C. L., B. Lönnerdal, M. Clegg and L. S. Hurley. Developmental changes in composition of rat milk: trace elements, minerals, protein, carbohydrate and fat. *Journal of Nutrition* 111:226-236.
48. 1981 Keen, C. L., B. Lönnerdal and G. L. Fisher. Age-related variations in hepatic iron, copper, zinc and selenium concentrations in beagles. *American Journal of Veterinary Research* 42:1884-1887.
49. 1981 Clegg, M. S., C. L. Keen, B. Lönnerdal and L. S. Hurley. Influence of ashing techniques on the analysis of trace elements in animal tissue. I. Wet ashing. *Biological Trace Element Research* 3:107-115.
50. 1981 Lönnerdal, B., C. L. Keen, L. S. Hurley and G. L. Fisher. Developmental changes in the composition of beagle dog milk. *American Journal of Veterinary Research* 42:662-666.
51. 1981 Lönnerdal, B., C. L. Keen and L. S. Hurley. Iron, copper, zinc and manganese in milk. *Annual Review of Nutrition* 1:149-174.
52. 1981 Hurley, L. S. and B. Lönnerdal. Zinc-binding ligands in Viokase and role in zinc absorption. Letter to the Editor. *Journal of Pediatrics* 99:328-330.
53. 1981 Borrebaeck, C. A. K., B. Lönnerdal and M. E. Etzler. Metal ion content of the *Dolichos*

biflorus lectin and effect of divalent cations on lectin activity. *Biochemistry* 20:4119-4122.

54. 1981 Clegg, M. S., C. L. Keen, B. Lönnerdal and L. S. Hurley. Influence of ashing techniques on the analysis of trace elements in biological samples. II. Dry ashing. *Biological Trace Element Research* 3:237-244.
55. 1981 Lönnerdal, B. and B. Hoffman. Alkaline reduction of dextran gels and crosslinked agarose to overcome nonspecific binding of trace elements. *Biological Trace Element Research* 3:301-307.
56. 1981 Hurley, L. S., C. L. Keen, B. Lönnerdal, P. Mark-Savage and R. Hackman. Trace elements, genetic factors, and drugs in developmental abnormalities. In: *Trace Element Metabolism in Man and Animals (TEMA)-4* (Howell, J. McC., J. N. Gawthorne and C. L. White, eds.), Griffin Press Limited, Netly, South Australia, pp. 283-286.
57. 1981 Lönnerdal, B., C. L. Keen and L. S. Hurley. Trace elements in milk from various species. In: *Trace Element Metabolism in Man and Animals (TEMA)-4* (Howell, J. McC., J. M. Gawthorne and C. L. White, eds.), Griffin Press Limited, Netly, South Australia, pp. 249-252.
58. 1981 Keen, C. L., B. Lönnerdal and L. S. Hurley. Developmental changes in zinc and copper in mouse and rat tissues. In: *Trace Element Metabolism in Man and Animals (TEMA)-4* (Howell, J. McC., J. M. Gawthorne and C. L. White, eds.), Griffin Press Limited, Netly, South Australia, pp. 187-290.
59. 1981 Borrebaeck, C. A. K., B. Lönnerdal and M. E. Etzler. Metal chelate affinity chromatography of the *Dolichos biflorus* seed lectin and its subunits. *Federation of European Biochemical Societies Letter* 130:194-196.
60. 1982 Rebello, T., B. Lönnerdal and L. S. Hurley. Picolinic acid in milk, pancreatic juice, and intestine: inadequate for role in zinc absorption. *American Journal of Clinical Nutrition* 35:1-5.
61. 1982 Hurley, L. S. and B. Lönnerdal. Zinc binding in human milk: citrate versus picolinate. *Nutrition Reviews* 40:65-71.
62. 1982 Keen, C. L., B. Lönnerdal and L. S. Hurley. Comparative aspects of postnatal changes in iron metabolism. In: *The Biochemistry and Physiology of Iron* (Saltman, P and J. Hegenauer, eds.), Elsevier Press, North Holland, New York, pp. 603-604.
63. 1982 Fransson, G.-B. and B. Lönnerdal. The role of lactoferrin in human milk. In: *The Biochemistry and Physiology of Iron* (Saltman, P. and J. Hegenauer, eds.), Elsevier Press, North Holland, New York, pp. 305-307.
64. 1982 Lönnerdal, B., C. L. Keen and L. S. Hurley. Increases of iron in maternal milk and tissues of the suckling rat by supplementation with Fe NTA. In: *The Biochemistry and Physiology of Iron* (Saltman, P. and J. Hegenauer, eds.), Elsevier Press, North Holland, New York, pp. 231-

- 232.
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693. 2016 Donovan SM, Lönnerdal B. Introduction: Emerging roles of bioactive components in pediatric nutrition. *J Pediatr* 173:Suppl:S1-3.
694. 2016 Lönnerdal B. Bioactive proteins in human milk: Health, nutrition, and implications for infant formulas. *J Pediatr* 173:Suppl:S4-9.
695. 2016 Hernell O, Timby N, Domellöf M, Lönnerdal B. Clinical benefits of milk fat globule membranes for infants and children. *J Pediatr* 173:Suppl:S60-5.
696. 2016 Zhang M, Liao Y, Lönnerdal B. EGR-1 is an active transcription factor in TGF- β 2-mediated small intestinal cell differentiation. *J Nutr Biochem* 37:101-108.
697. 2016 Jiang R, Lönnerdal B. Biological roles of milk osteopontin. *Curr Opin Clin Nutr Metab Care* 19:214-9.
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700. 2016 Lönnerdal B, Erdmann P, Thakkar SK, Sauser J, Destailats F. Longitudinal evolution of true protein, amino acids and bioactive proteins in breast milk: a developmental perspective. *J Nutr Biochem* 41:1-11.
701. 2016 Ziaei S, Rahman A, Raqib R, Lönnerdal B, Ekström EC. A prenatal multiple micronutrient supplement produces higher maternal vitamin B-12 concentrations and similar folate, ferritin, and zinc concentrations as the standard 60-mg iron plus 400- μ g folic acid supplement in rural Bangladeshi women. *J Nutr* 146:2520-29.

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703. 2016 Jorgensen JM, Yang Z, Lönnerdal B, Chantry CJ, Dewey KG. Effect of iron supplementation during lactation on maternal iron status and oxidative stress: a randomized controlled trial. *Matern Child Nutr* Nov 29. doi: 10.1111/mcn.12394. [Epub ahead of print]
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706. 2017 Timby N, Domellöf M, Holgerson PL, West CE, Lönnerdal B, Hernell O, Johansson I. Oral microbiota in infants fed a formula supplemented with bovine milk fat globule membranes - A randomized controlled trial. *PLoS One* 12(1):e0169831.
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712. 2017 Jorgensen JM, Yang Z, Lönnerdal B, Chantry CJ, Dewey KG. Plasma ferritin and hepcidin are lower at 4 months postpartum among women with elevated C-reactive protein or α 1-acid glycoprotein. *J Nutr* 147:1194-99.
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716. 2017 Demmelmair H, Prell C, Timby N, Lönnerdal B. Benefits of lactoferrin, osteopontin and milk fat globule membranes for infants. *Nutrients* 9(8).
717. 2017 Liao Y, Weber D, Xu W, Durbin-Johnson BP, Phinney BS, Lönnerdal B. Absolute quantification of human milk caseins and the whey/casein ratio during the first year of lactation. *J Proteome Res* Sep 19. doi: 10.1021/acs.jproteome.7b00486. [Epub ahead of print]

**Richard Kraska
Chief Scientific Officer
GRAS Associates, LLC
27499 Riverview Center Parkway
Bonita Springs, FL 34134**

Curriculum Vitae

EDUCATION B.S., Chemistry; Providence College
Ph.D., Pharmacology; University of Minnesota

**PROFESSIONAL
CERTIFICATION** Diplomate, American Board of Toxicology

EXPERIENCE 40 years' experience in toxicology and regulatory affairs for industry and government in broad aspects of the food and chemical industries including food additives, foods, food contact materials, cosmetics, lubricants and fuels, coatings, defoamers, anti-microbial pesticides and pharmaceuticals.

**GRAS ASSOCIATES, LLC
Bonita Springs, FL (2006 to Present)**

Chief Scientific Officer and Co Founder

- Serve as Lead Scientist and Panel Chair for GRAS determinations.
- Lead consultant for food contact regulations and preparation of Food Contact Notifications.
- Coordinate drafting and report review by chemists, toxicologists and scientists of other disciplines as needed.
- Ingredients reviewed include stevia-derived sweeteners, natural antioxidants, novel sources of dietary fiber, fats and oils and extracts from vegetables, fruit and herbs.
- Speaker at several scientific sessions relating to GRAS determinations, safety of stevia-derived sweeteners and food contact compliance.

**KRASKA CONSULTANTS, INC.
Bonita Springs, FL (2004 to 2014)**

Vice President and Principal

- Toxicology and Regulatory Consultant for a variety of lubricant, chemical, food processing and food packaging companies and trade associations
- Offer services in Toxicology and Product Safety including FDCA, TSCA and FIFRA regulations and filings, Food Contact Notifications, MSDS Authoring and International Hazard Communication Support, REACH Preparation and Support, Product Stewardship, Expert Witness and Litigation Support
- Founder and Technical Consultant for the Defoamer Industry Trade Association
- Speaker on TSCA and OSHA regulations, lubricant toxicology and safety, food contact regulations

**Richard Kraska
Curriculum Vitae**

**THE LUBRIZOL CORPORATION
Wickliffe, OH (1987 to 2004)**

MANAGER OF SPECIAL TOXICOLOGY AND REGULATORY PROJECTS (2001 to 2004)

- Toxicology and regulatory consultant for organic growth initiatives and new acquisitions. Regulatory consultation topics included TSCA, FDA and OSHA Hazard Communication Standard
- Coordinating \$2.8 million inhalation toxicology program on engines emissions with a novel diesel fuel formulation for registration with EPA under the Clean Air Act.
- Coordinating world wide implementation of compliance with revised European hazard communication regulations
- Consultant to Lubrizol defoamer, coating, process chemical, metalworking and lubricant businesses on regulations and toxicology
- Team member studying and planning implementation of sustainable development at Lubrizol.

MANAGER OF TOXICOLOGY AND RISK ASSESSMENT (1987 – 2001)

- Provided leadership and management for corporate toxicologists and product safety specialists.
- Direct responsibility for toxicology testing and evaluation of all Company specialty chemicals and products.
- Manage \$1 million annual toxicology and environmental testing budget for regulatory approvals and product stewardship.
- Lead consultant for business units on novel regulatory approvals, product stewardship and risk evaluation. Wrote and coordinated PMNs and FCNs.
- Lead consultant for TSCA Inspection Team
- Developed and implemented automated TSCA 12(b) compliance system
- Developed and institutionalized product risk assessment process for all Lubrizol businesses.
- Provide leadership role representing Company on trade association task groups involved in legislative and regulatory advocacy.
- Co-team leader for development and implementation of award -winning expert system for writing MSDSs from a product safety database.

**BP AMERICA INC (formerly THE STANDARD OIL CO)
Cleveland, OH (1985-1987)**

MANAGER OF PRODUCT SAFETY AND REGULATORY COMPLIANCE

- Assumed responsibility for assuring all Company products complied with federal regulations (TSCA, FIFRA, FDCA, USDA).
- Coordinated and expedited all regulatory submissions for premarket approval including TSCA PMNs, reporting rules and rulemaking comment.
- Conscientiously developed Company Product Safety Policies and Manual.
- Critically evaluated Corporate Hazard Communication Program in a decentralizing company.
- Successfully initiated labeling program to comply with OSHA Hazard Communication Standard.

**AMERICAN CYANAMID COMPANY, CHEMICALS GROUP
Wayne, NJ (1983-1985)**

MANAGER OF TOXICOLOGY PROGRAMS

- Wide range of responsibility for recommending, contracting, monitoring and evaluating mammalian, genetic and aquatic toxicology studies for chemical products.

Richard Kraska
Curriculum Vitae

- Responsible for \$250,000 total contract value for testing, quality assurance and consultants.
- Effectively guided regulatory staff in strategy and data requirements for premarket approvals.
- Successfully orchestrated targeted research programs for mechanistic studies on key chemicals for aquatic and mammalian toxicity.
- Actively represented Company in a wide spectrum of trade association activities.

FOOD AND DRUG ADMINISTRATION
Washington, DC (1977-1983)

GRAS Review Branch
Division of Food and Color Additives

SUPERVISORY CONSUMER SAFETY OFFICER
(1981-1983)

- Successfully managed group of 3-4 professionals in regulatory program to implement expert panel reviews of GRAS list food ingredients.
- Projects of responsibility included salt, caffeine, BHA, BHT, cellulose, enzymes, rapeseed oil, vitamins, iron, manganese and zinc salts.
- Co-directed agency expertise on toxicology, chemistry, law and policy to propose regulatory action on food uses of DSS. Negotiated consistency with Bureau of Drugs proposal on OTC and Rx uses.
- Advised Branch Chief in matters of policy, consistency and personnel.
- Interacted with industry regarding regulatory opinions and new product approvals.

Petitions Control Branch
Division of Food and Color Additives

CONSUMER SAFETY OFFICER (1977-1981)

- Coordinated scientific review and regulatory response to review food additive petitions submitted by industry for direct additives and food packaging materials.
- Scientific and historical expert for General Counsel, U. S. Attorney and Department of Justice for legal proceedings on cyclamate.
- Expert on food/drug interface of vitamins and dietary supplements.
- Analyzed quality of critical studies on aspartame and served on GLP review committee
- Served as Bureau representative in Interagency Regulatory Liaison Group on phthalate plasticizers.
- Assistant to Bureau Director on advocacy activities on behalf of U.S. industry for WHO programs

PUBLICATIONS

Reed, MD, Blair LF, Burling K, Daly I, Gigliotti AP, Gudi R, Mercieca MD. McDonald JD, O'callaghan JP, Seilkop, SK, Ronsko NL, Wagner VO, Kraska RC Health effects of subchronic exposure to diesel-water-methanol emulsion emissions *Toxicology & Industrial Health* Vol 22: 65-85 (2006)

Reed, MD, Blair LF, Burling K, Daly I, Gigliotti AP, Gudi R, Mercieca MD. McDonald JD, Naas DJ, O'callaghan JP, Seilkop, SK, Ronsko NL, Wagner VO, Kraska RC Health effects of subchronic exposure to diesel-water emulsion emissions. *Inhal Toxicol* 17: 851-70 (2005)

Kraska, RC , Industrial Chemicals. Regulation of new and existing chemicals. In: Gad S.C. editor. *Regulatory Toxicology*. Taylor and Francis Ltd. London 2001.

Kraska, RC . and Hooper DH, Industrial Chemicals. Hazard Communication, exposure limits, labeling and other workplace and transportation requirements under OSHA, DOT, and similar

Richard Kraska
Curriculum Vitae

authorities around the world. In: Gad S.C. editor. *Regulatory Toxicology*. Taylor and Francis Ltd. London 2001.

Strother, DE, Mast RW, Kraska RC, Frankos V Acrylonitrile as a carcinogen. Research needs for better risk assessment. *Ann NY Acad Sci* 534:169-78 (1988)

Petersen DW, Kleinow KM, Kraska RC, Lech JJ Uptake, disposition and elimination of acrylamide in rainbow trout *Toxicol Appl Pharmacol* 80: 58-65 (1985)

Mast RW, Jeffcoat AR, Sadler BM, Kraska RC and Friedman MA Metabolism, disposition and excretion of [C14] melamine in male Fischer 344 rats. *Food Chem Toxicol* 21: 807-810 (1983)

SERVED AS EXPERT PANEL CHAIRMAN FOR THE FOLLOWING GRAS NOTIFICATIONS

- GRN 242 Krill Oil
- GRN 245 Menaquinone-7
- GRN 278 Rebaudioside A
- GRN 287 Purified Steviol Glycosides with Rebaudioside A and Stevioside
- GRN 303 Rebaudioside A
- GRN 304 Purified Steviol Glycosides with Rebaudioside A and Stevioside
- GRN 318 Rebaudioside A
- GRN 323 Purified Steviol Glycosides with Rebaudioside A and Stevioside
- GRN 337 Steviol Glycosides
- GRN 338 L-theanine
- GRN 348 Stevioside
- GRN 349 Purified Steviol Glycosides with Rebaudioside A and Stevioside
- GRN 351 *Dunaliella bardawil*
- GRN 366 Oat Hull Fiber
- GRN 367 Purified Steviol Glycosides with Rebaudioside A and Stevioside
- GRN 368 Corn Hull Fiber
- GRN 380 Purified Rebaudioside A
- GRN 388 Purified Rebaudioside A
- GRN 389 Purified Steviol Glycosides with Stevioside
- GRN 393 Purified Rebaudioside A
- GRN 395 Purified Steviol Glycosides with Rebaudioside A and Stevioside
- GRN 401 Erythritol
- GRN 403 Double Salt of Magnesium and Potassium Chloride Hexahydrate
- GRN 425 Canola Oil Use in Infant Formula
- GRN 427 Corn Fiber
- GRN 437 Beta-Glucans Derived from Oat Bran
- GRN 443 Shrimp-Derived Chitosan
- GRN 448 Glucosylated Steviol Glycosides
- GRN 452 Glucosylated Rebaudioside A
- GRN 456 High Purity Rebaudioside D
- GRN 461 High Purity Rebaudioside A
- GRN 467 High Purity Rebaudioside A
- GRN 493 High Purity Steviol Glycosides
- GRN 512 High Purity Rebaudioside M
- GRN 522 Luo Han Guo Fruit Extracts
- GRN 536 High Purity Rebaudioside C
- GRN 548 High Purity Rebaudioside D
- GRN 644 Goat Milk Powder and Goat Milk Whey
- GRN 654 Cocoa Butter Substitute

Richard Kraska
Curriculum Vitae

- GRN 656 Enzyme Modified Steviol Glycosides
- GRN 715 Rebaudioside D
- GRN 735 2'-Fucosyl Lactose

SPEAKER Talks given on following topics at national meetings, seminars and workshops
GRAS Criteria
FDA Food Contact Regulations
REACH and GHS Regulations
HPV Toxicology Testing
TSCA 12(b) Compliance
Product Deselection Lists
MSDS Expert Systems
Confidential Business Information under TSCA
TSCA Section 12(b) Compliance
Risk Assessment and Risk Management
Lubricant Additive Safety

TRAINING COURSES Training courses given to business, research and legal groups at Lubrizol
General Regulatory Overview
TSCA New Chemicals
FDA Food Additive Requirements
Product Regulatory Law Course (TSCA, FDCA, OSHA)

Trainer, Toxicology Module, Metalworking Fluids Certificate Course (2005-2007)

**TRADE
ASSOCIATION
ACTIVITIES**

Chemical Reporting Task Group (1983-1998)
Chemical Manufacturers Association
Chairperson (1997-1998)

Safety, Health, Environmental and Regulatory Affairs Committee, Independent
Lubricant Manufacturers Association (1997 to 2012)
Vice chairperson (2001-2002)
Chairperson (2003-2004)
Toxicology consultant (2006-2012)

Oversight Committee, Metalworking Fluid Product Stewardship Group, Independent
Lubricant Manufacturers Association (1997-2004)

Health Environmental and Regulatory Task Group, Petroleum Additives Panel
(1997-2002)
Chairperson, Sensitization Work Group (1999 to 2002)

Biocides Panel, AEATF II Protocol Committee and Technical Committee (2003-
2006) Team Leader for Metalworking Study (2005-2010)

Defoamer Industry Trade Association, Founder and Technical Consultant (2005-
2014)

**PROFESSIONAL
SOCIETY
MEMBERSHIPS**

Society of Toxicology (SOT)
Regulatory Affairs Professionals Society (RAPS)

CURRICULUM VITAE

DOUGLAS L. ARCHER, PH.D.
INTERIM DEAN FOR RESEARCH AND PROFESSOR
Interim Director, Florida Agricultural Experiment Station
Assistant Surgeon General, USPHS (ret)

I. PERSONAL DATA

Home Address: 2916 SW 98th Way
Gainesville, FL 32608
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PO Box 110200
Gainesville, FL 32611-0200
Telephone: 352/332-2243 (Home)
352/392-1784 (Work)
Facsimile: 352/392-4965 (24 Hours)
E-Mail: dlrcher@ufl.edu
dlarcher149@yahoo.com

II. EDUCATION

B.A. - Zoology (1968)
University of Maine, Orono, ME

M.S. - Bacteriology (1970)
University of Maine, Orono, ME

Ph.D. - Microbiology (1973)
University of Maryland, College Park, MD

III. SERVICE US Army Reserve, 1968-1973; honorable discharge, rank 1st Lieut.

Commissioned Officer, U. S. Public Health Service - Retired 1/1/94:
Rank: Assistant Surgeon General (O7, Rear Admiral)

IV. EXPERIENCE

March, 2016 – Present: Professor of Food Science and Human Nutrition, U of Florida

February, 2006 – Present:

Associate Dean for Research, Institute for Food and Agricultural Sciences, University of Florida

January 2, 2001 – Present:

Professor of Food Science and Human Nutrition, University of Florida.

January 3, 1994 – January 1, 2001:

Professor and Chair, Food Science and Human Nutrition Department, University of Florida, Institute of Food and Agricultural Sciences

November 6, 1992 - December 31, 1993:

Deputy Director for Programs, Center for Food Safety and Applied Nutrition, FDA.

December, 1989 - November 6, 1992

Deputy Director, Center for Food Safety and Applied Nutrition, FDA.

February, 1991 – July, 1991

Acting Director, Office of Seafood, Center for Food Safety and Applied Nutrition, FDA

February, 1986 - December, 1989:

Director, Division of Microbiology, Center for Food Safety and Applied Nutrition, FDA

1983 - 1986: Deputy Director, Division of Microbiology, Center for Food Safety and Applied Nutrition, FDA.

1975 - 1983: Research Team Leader, Immunobiology, Division of Microbiology, FDA, Cincinnati, Ohio.

1979 - 1983: Adjunct Assistant Professor of Toxicology, University of Cincinnati College of Medicine.

1973 - 1975: Research Microbiologist, Division of Microbiology, Bureau of Foods, Washington, DC.

1970 - 1973: Graduate Teaching Assistant, Department of Microbiology, University of Maryland, College Park, Maryland.

1968 - 1970: Graduate Teaching Assistant, Department of Microbiology, University of Maine, Orono, Maine.

V. AWARDS

2005: **Distinguished Alumnus Award** – US Food and Drug Administration

2005: **Ivan Parkin Lecturer** – International Association for Food Protection annual Meeting, Baltimore, MD – August 14, 2005

2000: **Advancement of Industry Award**-American Meat Institute. “For outstanding service to the industry and consumers by defending sodium nitrite safety.”

1993: **Public Service Fellow**, Woodrow Wilson National Foundation Fellowship, 1993 academic year – Rocky Mountain College, Billings, MT.

1993: **U.S. Public Health Service Distinguished Service Medal**

1992: **J.C. Frazier Memorial Award**, Food Research Institute, "In recognition of outstanding achievements in the field of food Microbiology." Madison, WI.

1992: **U.S. Public Health Service Outstanding Unit Citation** for Exemplary performance of duty - For leadership demonstrated during the implementation of the Nutrition Labeling and Education Act of 1990.

1991: **Appointed Assistant Surgeon General, United States Public Health Service.**

1989: **U.S. Public Health Service Citation** for “outstanding leadership of the microbiological programs of the Center for Food Safety and Applied Nutrition.”

1988: **Tanner Memorial Award** - Institute of Food Technologists – Outstanding Individual in Food Technology and Related Sciences. Award Lecture: "The True Health Impact of Foodborne Disease".

- 1987: **Commissioner's Special Citation** "In recognition of sustained superior management performance and national and international recognition as an expert in the area of food safety and microbiology."
- 1986, 87, 88, 89: **U.S. Public Health Service Citation** for Outstanding Performance.
- 1984: **U.S. Public Health Service Meritorious Service Medal** for "sustained high-quality leadership and professional accomplishments in microbiological toxicology research and providing research direction for the Division of Microbiology, FDA."
- 1979: **U.S. Public Health Service Commendation Medal** for "development of in vitro immunological systems."

VI. ORGANIZATIONS

International Association for Food Protection – 2001 – present
Florida Association for Food Protection – 2001 - present
National Meat Association, Member, 1997 – present.
American Frozen Foods Institute, Affiliate Member, 1997 - present
Institute of Food Technologists (IFT), elected professional member, 1989 - Present.
Commissioned Officers Association, USPHS, 1973 - Present.

VII. PROFESSIONAL ACTIVITIES

International

U.S. Representative, WHO Expert Advisory Panel on Food Safety, January 1990 – February 2006.
U.S. Delegate to WHO Strategic Planning Meeting, March, 2001, Geneva, Switzerland
International Meat and Poultry HACCP Alliance, Scientific Advisory Committee Member, 1994 - Present.
Consultant to United Fresh Fruit and Vegetable Association, Produce Microbiology Committee; Allied Trade Associations, International Trade Council; 1994–1998.
Advisor to Australian Government on formation of the Australian National Food Authority, April, 1991.
Chairman, Codex Alimentarius Food Hygiene Committee, FAO/WHO, 1985-1994.
Consultant to WHO Committee on Listeria in Foods, 1988.
Chairman, ILSI Europe/WHO Workshop on a Scientific Basis for Regulations on Pathogenic Microorganisms in Foods. 1993, Brussels, Belgium.
Member and U.S. Delegation Chairman, 1986 -1990. U.S. (AOAC) Representative to International Standards Organization, Helsinki, Finland, 1984
International Dairy Federation meeting and Chairman, dilutions methodology, Helsinki, Finland, 1984.

Editorial Boards

Editorial Board Member, Food Control, 1989 - Present.

Contributing Editor, Food Technology, IFT, 2001 - 2003

North American Editor, Food Control, Elsevier, Ltd.

October 1994 – 1999.

Editorial Board Member, Journal of Natural Toxins, 1991 - 1995.

Advisory Board Member, Academic Press Nutrition and Food Science Publications, 1987 - 2000.

Member, Board of Publications of Fundamental and Applied Toxicology, Society of Toxicology, May 1983 - 1986.

Professional Society Related

IFT Nominations and Elections Task Force - 2011

IFT Board of Directors – Elected – 2005-2008.

IFT Global Policy and Regulation Committee – Subject expert on the Codex Committee on Food Hygiene – 2005 - present

IFT Committee on Mentoring, 2003

IFT Planning Committee for 3rd Food Safety and Quality Conference, 2003

IFT Committee on Global Regulations and Policy, 2003 -2005

IFT, Elizabeth Stier Award jury member, 2003

IFT Task Force on Sound Science Advocacy, 2002 – Present

IFT Distinguished Lecturer, 2002

IFT/AAAS Congressional Science Fellow Selection Panel member, 2002.

IFT Contributing Editor, Food Technology, 2001 – 2003

IFT Science, Communications and Government Relations Committee, Member, 2001-2002.

IFT Expert Panel on Emerging Pathogens, 2000

IFT Task Force Steering Committee on Food Safety Initiatives, October 1997 – Present

IFT Florida Section, Member, 1994 - Present.

IFT Committee on Education, September 1, 1994 - August 31, 1997; Appointed Secretary, March 1996 - 1997.

IFT Toxicology and Safety Evaluation Division, Appointed to the Executive Committee, August 1995 - August 1998.

IFT Florida Section, Elected Councilor, September 1995 - August 1997.

Domestic & Government-Related

Standing Committee Member – National Academy of Sciences, Division of Earth and Life Studies – Review of Food Safety and Defense Risk Assessments, Analyses, and Data. April, 2011- April, 2012.

Florida Food Safety and Food Defense Advisory Council – first Chair and member, 1997-present

Committee Member, National Academy of Sciences/Institute of Medicine and National Research Council: Review of the Food and Drug Administration's Role in Ensuring Safe Food – 2009-2011

Advisory Board Member – Produce Safety Project – Pew Charitable Trusts at Georgetown University (grant ended August, 2010)

Member, Outback Steakhouse Inc. Science Advisory Board – 2008 – present.

Panel Member – Assuring Safety of Imported Foods – FSRC, Washington, DC 2010.

Small Farms Subcommittee Member, Food Safety and Food Defense Advisory Council, DACS – attended two public hearings, edited final report. 2010.

Chair, American Frozen Food Institute Scientific Advisory Board- 2005 – 2010.

International Food Information Council, Media Expert Resource, 2004-Present.

Board of Directors, National Institute for Agricultural Security, 2003 - present

Food Advisory Committee, US Food and Drug Administration, voting member of general committee, 2002 – 2005

Chair, Subcommittee on Biotechnology and Member – FDA Food Advisory Committee, 2002 – present.

Member, Food Safety Advisory Council, American Meat Institute, 2000-2001

Board of Directors, International Life Sciences Research Office (LSRO) for the American Society for Nutritional Sciences, 1999 - 2003.

Member, Cyclospora Advisory Panel, California Strawberry Commission, June 1996

Consultant to the FDA Food Advisory Committee on the Safety of Calgene Tomatoes, Washington, DC, April 7-9, 1994.

Consultant, Centers for Disease Control, Review of Draft Plan for the Detection, Prevention, and Control of New, Re-emerging, and Drug Resistant Infectious Diseases, March 22-23, 1993.

Member, Advisory Committee to the Center for Veterinary Medicine, Safety of Somatotrope (bovine somatotropin), March 31, 1993.

National Advisory Committee on Microbiological Criteria for Foods, Voting Member, 1989 - November 1994.

Chairman, National Advisory Committee on Microbiological Criteria for Foods, Subcommittee on Risk Assessment, January 1993 - November 1994.

Food Update Board of Governors, Food and Drug Law Institute Food Update, 1991 - 1993.

Public Health Service Overall Coordinator, L-Tryptophan/Eosinophilia-Myalgia Syndrome Crisis, October, 1989 - 1994.

Member, Government Steering Committee to Institute of Food Technology Research. Committee, 1987 - 1994

US Food and Drug Administration, Commissioner's Advisory Group on Women's Health Issues: Infectious Diseases, 1987 - 1988.

Consultant, Centers for Disease Control, writing of the "Recommendations for Preventing Transmission of Infection with HTLV-III/LAV in the Workplace, November 1985.

**University of Florida (UF)
Institute of Food and Agricultural Sciences (IFAS),
and Academic Related Activities**

Member, UF Crisis Management Committee, 2010-present.
Emerging Pathogens Institute, Planning Committee, 2006-2009
Emerging Pathogens Institute, Search and Screen Committee for Director, 2007.
Emerging Pathogens Institute, Internal Advisory Board member, 2009-present.
UF Animal Research Committee, 2009-present.
Chair – IFAS Faculty Advisory Committee – Elected Sept. 2004 – 1 year
IFAS Genetics Institute Committee, 2004
Elected Member, IFAS Faculty Advisory Committee, 2003-2005
Co-Chair, IFAS Task Force for On-Campus Re-structuring, 2002.
IFAS representative to Florida Food Safety and Food Security Advisory
Council, 2002 - present
Co-Director (and establisher) of the UF/IFAS Center for Juice and Beverage Research,
2001 - present
Chairperson, Plant Product Safety Center (elected), National Alliance for Food Safety,
2001-2003.
ESCOP/ECOP Food Safety Subcommittee, 2000 - present.
Screening Committee, position of Coordinator, Florida Sea Grant Extension. 2009.
Search and Screen Committee, Dean, College of Agriculture, Aug. 1998 – January 1999.
IFAS Long Range Planning Committee, Oct. 1998-Feb. 1999.
IFAS representative to National Alliance for Food Safety (NAFS) April 1998 – 2009.
IFAS representative to NAFS Operations Committee (elected) June 1998-June 2000, and
July 2002-present.
IFAS Institutional Marketing Committee – May 1997-June 1998
Facilitator - UF's Workshop on Academic Management, Maximizing Your Leadership
Potential, "Dealing with Institutional Conflict/Small Group Discussion",
Camp Weed, FL, May 19, 1997.
Industry Representative - West Palm Beach Town Meeting, regarding Florida's needs of
minimizing microbiological food safety risks for produce, West Palm
Beach, FL, December 5, 1997.
Chair - Committee for the Aquatic Food Products Laboratory Building Dedication, August
1996 - April 1997.
Discussion Leader at the Institute for Academic Leadership, Department Chairs Workshop,
Howey-in-the-Hills, FL, October 6-9, 1996.
Member - Search and Screen Committee for the UF Associate Director of Development
and Alumni Affairs Position, August 1996.
Chair - Program Committee and Steering Committee for the October 28-30, 1996, UF/IFAS
Statewide Faculty Meeting, March 8, 1996.
Member - IFAS Chairs' Subcommittee to Review the Task Force 1995 Recommendations
for the Annual Faculty Achievement, Planning, and Evaluation Requirements
and Forms, May 1995.

Member - UF, College of Veterinary Medicine, Center for Environmental and Human Toxicology (CEHT) Search Committee for the position of Director, CEHT, Member, October 1994.
UF World Food Day Committee, Member, 1994.

Service to Other Schools

Review Team Member, CSREES Comprehensive Review, Department of Food Microbiology and Toxicology, University of Wisconsin, Sept. 2004.
In-depth Reviewer for University of Wisconsin, Department of Food Microbiology & Toxicology, Dr. Charles Kasper, Professor. 2002
Review Team Member, CSREES Comprehensive Review, Department of Nutrition and Food Science, University of Vermont, March, 2001.
In-depth Reviewer for University of California, Davis – Dr. Linda Harris, Extension Specialist. 2001
In-depth Reviewer for Rutgers University – Dr. Donald Schaffner, Extension Specialist. 2001
Review Team Member, CSREES Comprehensive Review, Department of Food Science and Human Nutrition, Michigan State University, December, 1998.

Teaching and Mentoring

Primary Instructor – FOS 6915 - Research Planning (2 cr) – Required course for all incoming graduate students – 2003 – present.

Guest Lecturer in FOS 3042, Introduction to Food Science, "Food Safety Laws and Regulations, 1994.

Guest Lecturer in FOS 6915, Research Planning, "An Overview of Graduate Student Responsibilities and Expectations," September 6, 1994; August 29, 1995.

Team teach (33%) in Fall, Spring, and Summer terms, FOS 2001, Man's Food, 3 Credit Course, January 1995 – 2000 – 1,600 students per year.

Guest Lecturer in FOS 4731, Government Regulations and the Food Industry.

Guest Lecturer in AGG 4932/5932, Hazard Analysis Critical Control Point (HACCP) Systems, "Microbial Concerns in the Food Industry"

Instructor, US Army Veterinary Medical Command College, Fort Sam Houston, TX. Food safety – Presented 4 hours of lectures on risk assessment and food safety. 2001.

Student Mentoring

Past Committees:

Lisa Wojciechowski	Ph.D.	1995	Member
Lori D. Stephens	MS	1996	Member
Andreas M. Keller	Ph.D.	1997	Member
Morgan A. Wallace	Ph.D.	1997	Member
Erica Malnati	MS	1998	Member
Robin Ellison	MS	1998	Member
Margaret Farley	MS	1999	Member
Michael Bradley	Ph.D.	2000	Co-chair
Samir Assar	Ph.D.	2000	Member
Roger A. Young	MS	2000	Member
Ronald A. Benner	Ph.D.	2001	Co-chair
Kelly D. Felkey	MS	2002	Member
Mark S. Campbell	MS	2003	Co-Chair
Raina L. Allen	MS	2003	Member
Gabriella A. Calero	MS	2003	Member
Maria Chatzidaki	Ph.D.	2004	Member
Benjamin R. Warren	Ph.D.	2006	Member
Masoumeh Rajabi	Ph.D.	2005	Member
April M. Elston	MS	2005	Member
Crystal L. Jackson	MS	2005	Member
Margaret Richards	MS	2005	Co-Chair
Jennifer Joy	MS	2005	Member
Melissa M. Kolsch	Ph.D.	2006	Member
Amber Scarlatos	Ph.D.	2007	Member (ABE)
Matthew Jeletic	Ph.D.	2010	Member (Chem)

THESIS

M.S. Degree: A comparison of swarming and motility in Proteus mirabilis and a variant.

Ph.D. Degree: Control of interferon, virus capsid antigens, and migration inhibitory factor in Burkitt's Lymphoma-derived cell lines: Role of L-arginine.

BIBLIOGRAPHY**A. BOOKS**

Marshall, M. and Archer, D. Your Food and Health: A Study Guide for Man's Food. Second Edition. Kendall/Hunt Publishing Company, Dubuque, IA, 352 pages. Sixth Edition, 2004.

Archer, DL, Schneider, KR, Schmidt, RL, Otwell, WS, Goodrich, RM, Thomas, C. The Food Recall Manual. Copyright, 2004. University of Florida, Gainesville, FL, 174 pp.

B. MONOGRAPHS

Archer, D.L. (co-author with 16 experts). 2002. Emerging Microbiological Food Safety Issues: Implications for Control in the 21st century. Institute of Food Technologists, Chicago. 139 pages

C. REFEREED PUBLICATIONS

1. Archer, D. L. and Young, B. G. Control of interferon, migration inhibitory factory, and virus capsid antigens in Burkitt's Lymphoma-derived cell lines: Role of L-arginine. *Infect. & Immun.* 9:684, 1974.
2. Archer, D. L., Bukovic-Wess, J. A., and Smith, B. G. Gallic acid: A potential chemical tool for studying cellular interactions involved in the in vitro immune response. *IRCS Med. Sci.* 4:553, 1976.
3. Archer, D. L., Bukovic-Wess, J. A., and Smith, B.G. Inhibitory effect of an antioxidant, butylated hydroxyanisole, on the primary in vitro immune response. *Proc. Soc. Exp. Biol. Med.* 154:289, 1977.
4. Archer, D. L., Bukovic-Wess, J. A., and Smith, B.G. Suppression of macrophage-dependent T-lymphocyte functions by gallic acid, a food additive metabolite. *Proc. Soc. Exp. Biol. Med.* 156:465, 1977.
5. Archer, D. L., Smith, B.G. and Bukovic-Wess, J. A. Use of an in vitro antibody-producing system for recognizing potentially immunosuppressive compounds. *Int. Arch. All. Appl. Immunol.* 56:90, 1978.
6. Archer, D. L. and Johnson, H. M. Blockade of mitogen induction of the interferon lymphokine by a phenolic food additive metabolite. *Proc. Soc. Exp. Biol. Med.* 157:684, 1978.
7. Archer, D. L., Smith, B. G. and Wess, J. A. Evidence for helper T-cell participation in the antibody response to thymus-independent antigens. *IRCS Med. Sci.* 6:76, 1978.
8. Archer, D. L. Immunotoxicology of foodborne substances: An overview. *J. Food Prot.* 41:983-988, 1978.
9. Archer, D. L. and Wess, J. A. Chemical dissection of the primary and secondary in vitro antibody response with gallic acid and butylated hydroxyanisole. *Drug and Chem. Toxicol.* 2:155-166, 1979.

10. Archer, D. L., Smith, B. G., Ulrich, J. T. and Johnson, H. M. Immune interferon induction by T-cell mitogens involves different T-cell subpopulations. *Cell Immunol.* 48:420-426, 1979.
11. Archer, D. L. Antioxidants and the immune response. *Proc. of the Fourth FDA Science Symposium: Inadvertent modification of the immune response.* pp. 99-103, 1980.
12. Archer, D. L., Smith, B. G. and Johnson, H. M. Effects of toxicants on T-cell subpopulations as determined by lymphokine activity. *Arch. Toxicol. Suppl.* 4:138-142, 1980.
13. Chen, S. E., Tse, C. S., Bernstein, I. L. and Archer, D. L. In vivo suppression and enhancement of the murine homocytotropic antibody response by staphylococcal enterotoxin A. *Int. Arch. Allergy Appl. Immunol.* 63:470-472, 1980.
14. Stelma, G. N. and Archer, D. L. Detection of low levels of staphylococcal enterotoxin A in foods by mitogenesis. *IRCS Med. Sci.* 8:347, 1980.
15. Bernstein, I. L., Gallagher, J. S., Johnson, H. M., Archer, D. L. and Splansky, G. L. Evaluation of reactions to tartrazine. *Proc. IV FDA Science Symposium: Inadvertent modification of the immune response.* pp. 258-260, 1980.
16. Archer, D. L., Smith, G. G. and Peeler, J. T. Activation of murine T-lymphocyte DNA synthesis in vivo by staphylococcal enterotoxin A: Applicability to immunotoxicity testing. *IRCS Med. Sci.* 8:457, 1980.
17. Osborne, L. C. and Archer D. L. The antiviral effect of human fibroblast interferon is blocked by gallic acid. *IRCS Med. Sci.* 8:756, 1980.
18. Stelma, G. N., Bradshaw, J. G., Kauffman, P. E. and Archer, D. L. Thermal inactivation of mitogenic activities of staphy-lococcal enterotoxin A at 121~C. *IRCS Med. Sci.* 8:629, 1980.
19. Archer, D. L., Smith, B. V. and Johnson, H. M. Direct and induced suppression of in vitro antibody production by selected phenols: A comparison to virus-type interferon. In *Biological Relevance of Immune Suppression* (Dean, J. and Padarathsingh, M., eds.) Van Nostrand, NY, pp. 199-212, 1981.
20. Archer, D. L., Wess, J. A., and Johnson, H. M. Inverse relationship between immune interferon induction and mitogen effects on the maturation of the primary antibody response. *Immunopharmacology* 3:71-81, 1981.
21. Archer, D. L. and Smith, B. G. Immunotoxic and immunosuppressive effects of food chemicals: Focus on diethylstilbestrol. *Proceedings of the 33rd Annual Reciprocal Meat Conference of the American Meat Science Association*, pp. 143-146, 1981.
22. Luster, M. I., Dean, J. H., Boorman, G. A., Archer, D. L., Lauer, L., Lawson, L. D., and Wilson, R. A. The immunotoxicity of orthophenyphenol, Tris (2,3-dichloropropyl) phosphate and cyclophosphamide following acute exposure in mice. *Toxicol. and Appl. Pharmacol.* 58:252-261, 1981.
23. Blalock, J. E., Archer, D. L., and Johnson, H. M. Anticellular and immunosuppressive activities of foodborne phenolic compounds. *Proc. Soc. Exp. Biol. Med.* 167:391-393, 1981.
24. Osborne, L. C., Peeler, J. T. and Archer, D. L. Reduction in the antiviral activity of human fibroblast interferon by gallic acid. *Infect. & Immun.* 33:769-774, 1981.
25. Archer, D. L., Wess, J. A. and Smith, B. G. Location of specific lesions in the immune response using in vitro tests. *Proc. Soc. Toxicol. Can.* pp. 137-149, 1981.

26. Wess, J. A. and Archer, D. L. Restoration by cyclic guanosine monophosphate and extracellular calcium of butylated hydroxyanisole-suppressed primary murine thymus-dependent antibody response. *Immunopharmacology* 3:71-81, 1981.
27. Buxser, S. E., Boventre, P. F. and Archer, D. L. Specific receptor binding of staphylococcal enterotoxin by murine splenic lymphocytes. *Infect. & Immun.* 33:827-833, 1981.
28. Blakley, B. and Archer, D. L. The effect of lead acetate on the immune response of BDF1 mice. *Tox. and Appl. Pharm.* 61:18-27, 1981.
29. Archer, D. L. and Smith, B. G. Immunotoxicity testing of food chemicals: Different results may be obtained with in vitro and in vivo exposure to gallic acid. *Proc. AOAC Symposium on Analytical Methodology for Determining Immunotoxicity of Chemicals Including Pesticides*, 1982.
30. Archer, D. L. New approaches to immunotoxicity testing. *Env. Hlth. Persp.* 43:109-113, 1982.
31. Blakley, B., Archer, D. L. and Osborne, L. C. The effect of lead on immune and viral interferon production. *Canad. J. Comp. Med.* 46:43-46, 1982.
32. Wess, J. A. and Archer, D. L. Disparate in vivo and in vitro immunomodulatory activities of Rhodamine B. *Food and Chem. Toxicol.* 20:9-14, 1982.
33. Blakley, B. R. and Archer, D. L. Mitogen stimulation of lymphocytes exposed to lead. *Toxicol. and Appl. Pharmacol.* 62:183-189, 1982.
34. Buxser, S. E., Bonventre, P. F. and Archer, D. L. Staphylococcal enterotoxin induced mitogenesis: Toxin binding and cell-cell interactions. *Microbiologica* 6:181-190, 1982.
35. Wess, J. A. and Archer, D. L. Evidence from in vitro murine immunologic assays that some phenolic food additives may function as antipromoters by lowering intracellular cyclic GMP levels. *Proc. Soc. Exp. Biol. Med.* 170:427-430, 1982.
36. Johnson, H. M., Archer, D. L. and Torres, B. A. Cyclic GMP as the second messenger in helper cell requirement for gamma interferon production. *J. Immunol.* 129:2570-2572, 1982.
37. Archer, D. L. Assays for cell-mediated and humoral immunity. *Proc. 13th Annual Conference on Environ. Toxicol. NTIS*, 11-14, 1983.
38. Johnson, H. M., Torres, B. A. and Archer, D. L. Vasopressin and Phorbol Ester replacement of interleukin 2 requirement in gamma interferon production: Cyclic GMP as the common second messenger. *Interleukins, Lymphokines and Cytokines. Proc. 3rd Intl. Workshop.* (J. J. Oppenheim, S. Cohen and M. Landy, eds.) Academic Press, NY, 1:51-61, 1983.
39. Wess, J. A. and Archer, D. L. Differential effects of Nordihydroguaiaretic acid (NDGA) on B-cell subsets: Reversal of NDGA-induced antibody suppression by cyclic GMP is subset specific. *Int. J. Immunopharmacol.* 6:27-34, 1984.
40. Osborne, L. C., Peeler, J. T., and Archer, D. L. 1984. Effects of a strong and a weak carcinogen on murine alpha/beta interferon production in vivo. *Fundamental and Appl. Toxicol.* 4:210-215.
41. Archer, D. L. 1984. Diarrheal episodes and diarrheal disease: Acute disease with chronic implications. *J. Food Prot.* 47:321-327.

42. Bonventre, P. F., Linnemann, C., Ritz, H., Smith, B. G. and Archer, D. L. 1984. Antibody responses to toxic shock syndrome toxin: Serum antitoxin levels in normal women and TSS cases. *J. Infect. Dis.* 150:662-666.
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44. Archer, D. L. and Wess, J. A. 1985. Cyclic nucleotides; in: Prostaglandins, Leukotrienes and Cancer, Vol. I. Basic Biochemical Processes. (Lands, W. E. M., ed.) Martinus Nijhoff, Boston, pp. 287-296.
45. Archer, D. L. and Glinsmann, W. H. 1985. Intestinal infection and malnutrition initiate acquired immune deficiency syndrome (AIDS). *Nutr. Res.* 5:9-19.
46. Archer, D. L. 1985. Enteric microorganisms in rheumatoid disease: Causative agents and possible mechanisms. *J. Food Prot.* 48:538-545.
47. Archer, D. L. and Glinsmann, W. H. 1985. Enteric infections and other cofactors in AIDS: Possible intervention points from a historical perspective. *Immunology Today* 6:292-295.
48. Archer, D. L. and Kvenberg, J. E. 1985. Incidence and cost of foodborne diarrheal disease in the United States. *J. Food Prot.* 48:887-894.
49. Madden, J. M., McCardell, B. A., Archer, D. L. 1986. Virulence assessment of foodborne microbes. In (Pierson and Stern, Eds.) *Foodborne Microorganisms and Their Toxins*. Marcel Dekker, Inc., N.Y. pp. 291-315.
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51. Archer, D. L. 1987. Foodborne gram-negative bacteria and atherosclerosis: is there a connection? *J. Food. Prot.* 50:783-787.
52. Kvenberg, J. E. and Archer, D. L. 1987. Colonization of livestock to prevent pathogens from entering the food supply: potential impact on economics and foodborne disease. *Food Technol.* 41:77-81.
53. Archer, D. L. 1988. Disease in day care. *J. Env. Health.* 51:143-147.
54. Bunning, V. K., Raybourne, R. R. and Archer, D. L. 1988. Foodborne enterobacterial pathogens and rheumatoid disease. *Appl. Bacteriol.* 65 (Suppl.): 87S-107S.
55. Archer, D. L. and J. E. Kvenberg. 1988. Regulatory significance of Aeromonas in foods. *J. Food Safety.* 9:53-58.
56. Garthright, W. E., Archer, D. L., and Kvenberg, J. E. 1988. Incidence of acute episodes of intestinal infectious diseases and costs of medical care and lost productivity. *Public Health Service Reports* 103:107-115.
57. Archer D. L., and Young F. E. 1988. Contemporary Issues: Diseases with a food vector. *Clin. Microbiol. Rev.* 1:377-398.
58. Archer, D. L. 1988. The true impact of foodborne infections. *Food Technol.* 42:53-58.
59. Bennett, R. W., Archer, D. L., and Lancette, G. 1988. Modified procedure to eliminate elution of food proteins during seroassay for staphylococcal enterotoxin. *J. Food Safety* 9:135-143.
60. Archer, D. L. 1989. Food counseling for persons infected with HIV-1: one strategy for defensive living. *Public Health Rep.* 104:196-198.

61. Archer, D. L. 1989. Listeria monocytogenes: what is its ecological niche? In: Foodborne Listeriosis. (Eds. Miller, A. J., Smith, J. L., and Somkuti, G. A. Society for Industrial Microbiology. pp. 5-8.
62. Archer, D. L. 1989. Food Safety: a scientific viewpoint. Proc. 37th Annual Meeting Agri. Res. Inst. p.77-82.
63. Archer, D. L. 1989. The new foodborne pathogens. J. Assoc. Food Drug Offic. 52:5-9.
64. Archer, D. L. 1989. Response to Listeria deserves a fair trial. Food Microbiol. 6:191-193.
65. Archer, D. L. 1990. Future challenges to the HACCP approach: the need for flexibility. Food Technol. 44:174-178.
66. Archer, D. L. 1990. Food counseling should be given to all persons infected with the human immunodeficiency virus (HIV). J. Infect. Dis. 161:358-9.
67. Klontz, K. C., Cawley, J. F., Archer, D. L., and White, G. L. 1990. L-tryptophan and the eosinophilia-myalgia syndrome: a new clinical entity. Physicians Assistant, July, 31-38.
68. Levine, W., Smart, J. F., Archer, D. L., Bean, N. H., and Tauxe, R. V. 1991. Foodborne disease outbreaks in nursing homes: 1975-1987. J. Amer. Med. Assoc., Vol. 266, No. 15:2105-2109.
69. Thompson, P., Salisbury, P. A., Adams, C. E., and Archer, D. L. 1991. U.S. Food Legislation. Lancet i:1557-1559.
70. Jackson, G. J., Langford, C. F., and Archer, D. L. 1991. Control of salmonellosis and similar foodborne infections. Food Control 2:26-34.
71. Archer, Douglas L. 1995. Food Control - The Challenges Ahead From the Lessons of the Past. Food Control, Vol. 6, No. 2:69-70.
72. Archer, Douglas L. 1996. The Validation of Rapid Methods in Food Microbiology. Food Control, Vol. 7, No. 1:3-4.
73. Archer, Douglas L. 1996. Bad Bugs and Good Bugs: The Changing Perceptions. Food Control, Vol. 7, No. 2:61-62.
74. Archer, D.L. 1996. Preservation microbiology and Safety: Evidence that Stress Enhances Virulence and Triggers Adaptive Mutations. Trends in Food Science and Technology, Vol. 7, No. 3:91-95.
75. Archer, Douglas L. 1996. Listeria: The Science and the Politics. Food Control. Vol. 7, No. 4/5:181-182.
76. Bunning, V. K., Lindsay, J. A., Archer, D. L. 1997. Chronic Health Effects of Microbial Foodborne Disease. World Health Statistics Quarterly 50:51-56
77. Archer, D.L. 2002. Evidence that nitrate and nitrite are beneficial to health. J. Food Prot. 65:872-875.
78. Archer, D.L., Schneider, K.R., and Schmidt, R.H. 2002. Can HACCP and other systems assure protection from terrorism against the food supply? AFDO J. 66(3):94-102.
79. Archer, D.L. 2004. Freezing: An underutilized food safety technology? International Journal of Food Microbiology 90:127-138
80. Allen, R.L.[†], Warren, B.R.[†], Archer, D.L., Sargent, S.A. and Schneider, K.R. 2005. Survival of *Salmonella* spp. on the Surfaces of Tomatoes and Packing Line Materials. Hort Tech. Hort Tech. 15: 831-836

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Chlorine Disinfection of Tomato Surface Wounds Contaminated with *Salmonella* spp.
Hort. Technol. 16:253-256.
82. Turner, R.E., Degnan, F.H., and Archer, D.L. 2005. Label claims for foods and
supplements: a review of the regulations. Nutrition in Clinical Practice. 20:21-32.
83. Scarlatos, A., Welt, B.A., Cooper, B.Y., Archer, D.L., DeMarse, T., and Chau, K.V.
2005. Methods for detecting botulinum toxin with applicability to screening foods
against biological terrorist attacks. J. Food Sci. 70:R121-R130.
84. Jackson, C., Archer, D.L., Goodrich, R.M., Gravani, R.B., and Schneider, K.R. 2007.
Testing the effectiveness of Good Agricultural Practices (GAPs): a multi-state
survey. Food Protection Trends. 27(9):684-693.
85. Raies A. Mir, Thomas A. Weppelmann, Judith A. Johnson, Douglas L. Archer, J.
Glenn Morris Jr, Kwang Cheoi Casey Jeong. 2016. Identification and
characterization of cefotaxime resistant bacteria in beef cattle. PLOS ONE DOI:
10.1371/journal.pone.01

D. MISCELLANEOUS PUBLICATION

1. Archer, D. 1994. Controlling Bacteria in Food Through Temperature, Fine Cooking
Magazine, June/July Issue, 12-13.
2. Archer, D. 1996. Should All Juices be Pasteurized? Food
Protection Inside Report, 2 pages.
3. Archer, D. 2000. E. coli O157:H7 – Searching for Solutions. Food Technology
54:142.
4. Archer, D. 2001. WHO Holds Food Safety Strategic Planning Meeting. Food
Technology 55(5):22.
5. Archer, D. 2001. Nitrite and the Impact of Advisory Groups. Food Technology
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F. EXTRAMURAL FUNDING

USDA. Facility Study. Aquatic Food Product Pilot Plant Facility. \$1,455,000. Role: PI

UF Athletic Association. 1999. Nutrition for athletes. \$13,500. Role: PI

Department of Homeland Security, Homeland Security National Center for Post-Harvest Food Protection and Defense. (10/05 – 10/09) University of Minnesota is Lead Institution. Role: Collaborating Researcher.

USDA – CSREES, Reducing microbial risks in fruits and vegetables. (1/01 – 12/02) Principle Investigator: R. Gravani, Cornell University. University of Florida Co-PIs: D.L. Archer, R.H. Schmidt. \$20,000. Role: Co-PI

USDA - IFAFS, Improving the Safety of Fruits and Vegetables: A Tri-state Consortium. (January 2001 – December 2005). Principle Investigators: E.A. Murano, D. Archer and L.J. Harris. Co-principle Investigators (University of Florida): K.R. Schneider and R. Goodrich. \$1,289,000. Role: UF Project Director and PI

U.S. Department of Defense. Developing Guidance to Expedite Food Product Recalls to Mitigate or Contain a Purposeful Contamination of Commercially Distributed Food. (10/02 to 10/04) Principle Investigators: D.L. Archer, K.R. Schneider, W.S. Otwell, R.M. Goodrich, and R.H. Schmidt. \$95,986. Role: PI

USDA – NIFSI. Risk assessment of tanker truck sanitation as related to the secure transport of juice and dairy products. (09/03 to 09/06). This is a research/Extension grant. Principle Investigators: M.E. Parish, R.M. Goodrich, K.R. Schneider and R.H. Schmidt, DL Archer. Role: Investigator

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XI PRESENTATIONS

2005

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2004

Archer, D.L. Use of zero tolerance for Salmonella in seafoods. July 2004. IFT Annual Meeting and Expo. Las Vegas, NV. Invited

2003

Archer, D. L.. *How can I make my farm more secure?*. Jan. 10-12, 2003. SE regional F&V Assn - Savannah, GA. Invited.

Archer, D. L.. *Homeland security and agriculture*. 1/29/03. SE Regional Partnership Conf. – Atlanta, GA. Invited.

Archer, D. L.. *Food safety on the farm*. 3/7/03. US Potato Board (CHIP) - Jacksonville, FL. Invited.

Archer, D. L.. *Introduction to bioterrorism and the threat to the food supply*. -1/1/03. Florida. Environmental Health Association - Tallahassee, FL., Invited

Archer, D. L.. *Bioterrorism and Agroterrorism: are we prepared?* 4/3/03. Florida Assn Food Protection - Melbourne, FL. Invited.

Archer, D. L.. *Session II - Microbial Genetics*. Feb. 17-19, 2003. ABC Research 29th Technical Seminar - Orlando, FL. Descriptors: Moderator

Archer, D. L.. *Food Security Issues*. 7/21/03. Florida Pathogen Analysis Conf. (FL DACS) – St. Petersburg, FL. Invited.

2002

Archer, Douglas L.. *The politics and science of assuring biosecurity*. 3/12/02. St. Petersburg, FL. 2002 Division Meeting - North American Millers Association. Invited.

Archer, Douglas L.. *Can HACCP be a useful tool in assuring food security?*. 2/19/02. Gainesville, FL. ABC Research 28th Annual Technical Seminar. Invited.

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Archer, Douglas L.. *General considerations about bio- and agri-terrorism*. 1/9/02. Coral

Gables, FL. Farm Foundation -Bennett Agricultural Round Table. Invited.
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Archer, Douglas L., Clemens, Roger A.. *Probiotics:regulatory and marketing claims issues*.. Jun, 2001. IFT Annual Meeting. New Orleans, LA. Invited
Archer, Douglas L.. *Food Safety Management and Regulation*. Jun, 2001. Presentation to the Chief Research Officers of the Institute of Food Technologists. IFT Annual Meeting, New Orleans, LA. Invited.

Over 150 PRESENTATIONS PRIOR TO 2000 (available on request)

GRN 735

Expert Panel Qualifications

Dr. Douglas Archer, Assistant Surgeon General, USPHS (ret) – Prior to his career at the University of Florida, Dr. Archer served with CFSAN, FDA in various capacities beginning with bench scientist, to Director, Division of Microbiology, and ultimately as Deputy Director, CFSAN. During his career at CFSAN, Dr. Archer was involved all aspects of CFSAN activities, including the safety of foods, dietary supplements, infant formula, and cosmetics. He retired from CFSAN in 1993 to accept a faculty and administrative position in the Food Science and Human Nutrition Department at UF. He has been involved as a frequent consultant on matters involving the safety of pre- and probiotics, and served on the FDA Ad Hoc Advisory Committee on Probiotics. Dr. Archer remains active as a consultant to many companies on pre- and probiotic safety matters, and is also involved in clinical studies at UF on probiotics and prebiotics. At UF he holds the rank of Professor, and has served as Associate Dean for Research and Interim Dean for Research.

Dr. Katrina V. Emmel, Ph.D., Senior Associate & Project Manager- Dr. Emmel started her career as an analytical chemist in the private sector, performing routine LC-MS analysis at a clinical laboratory, and then developing analytical methods for a dietary supplement and food manufacturer. While in the private sector, she was involved in preparing the first GRAS Notification for enzyme modified steviol glycosides on behalf of NOW Foods. As an independent consultant since 2013, Katrina has been involved in a number of GRAS evaluations as a chemist, technical writer, project manager, Expert Panelist, and as Chair of the Expert Panel.

Dr. Richard Kraska, Ph.D., DABT, Chief Scientific Officer and Executive Vice President- Dr. Kraska has had a 40 year career in toxicology and regulatory affairs for industry and government in broad aspects of the food and chemical industries including food additives, foods, food contact materials, cosmetics, lubricants and fuels, coatings, defoamers and anti-microbial pesticides. He is a cofounder of GRAS Associates, LLC and has chaired expert panels for over 50 GRAS assessments on various food ingredients such as stevia-derived sweeteners, natural antioxidants, novel sources of dietary fiber, fats and oils and extracts from vegetables, fruit and herbs.

Dr. Bo Lönnerdal, Ph.D. Distinguished Professor Emeritus, Department of Nutrition and Department of Internal Medicine- Dr. Lönnerdal has an active research program which is focused on infant/pediatric nutrition. Current research topics include: bioactive factors in milk, studies on factors affecting breast milk composition, including maternal nutrition, hormones and stage of lactation and trace element metabolism.

ESTIMATED DAILY INTAKE OF 2'-FL BY THE U.S. POPULATION FROM PROPOSED FOOD- USES (2013-2014 NHANES)

PREPARED FOR:

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DATE:

21 September 2017

Estimated Daily Intake of 2'-FL by the U.S. Population from Proposed Food-Uses (2013-2014 NHANES)

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Estimated Daily Intake of 2'-FL by the U.S. Population from Proposed Food-Uses (2013-2014 NHANES)

1.0 INTRODUCTION

Glycosyn LLC proposes to use 2'-fucosyllactose (2'-FL) as an ingredient in foods marketed in the United States (U.S.). Such foods include products falling under the following food categories: beverages and beverage bases, breakfast cereals, dairy product analogs, frozen dairy desserts and mixes, gelatins, puddings, and fillings, grain products and pastas, commercial jams and jellies, whole and skim milk, milk products, processed fruits and fruit juices, sweet sauces, toppings, and syrups, non-exempt infant and follow-on formula, and baby foods.

Estimates for the intake of 2'-FL from foods were based on the proposed food-uses and use levels for 2'-FL in conjunction with food consumption data included in the U.S. National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Surveys (NHANES) 2013-2014 (CDC, 2015, 2016; USDA, 2016). Calculations for the mean and 90th percentile *per capita* and consumer-only intakes were performed for all proposed food-uses of 2'-FL and the percentage of consumers were determined. Similar calculations were used to estimate the intake of 2'-FL resulting from each individual proposed food-use, including the calculations of percent consumers. In both cases, the per person and per kilogram body weight intakes were reported for the following population groups:

- Infants, ages 0 to 5 months;
- Infants, ages 6 to 11 months;
- Toddlers, ages 12 to 35 months;
- Children, ages 3 to 11 years;
- Female teenagers, ages 12 to 19 years;
- Male teenagers, ages 12 to 19 years;
- Women of child-bearing age, ages 16 to 45 years;
- Female adults, ages 20 years and up;
- Male adults, ages 20 years and up;
- Elderly, ages 65 years and up; and
- Total population (all age and gender groups combined).

In addition to the NHANES-based assessment of exposures from proposed food uses, exposure estimates of 2'-FL from proposed uses in medical foods were considered independently, based on the intended dosages for target populations for which these products were intended.

2.0 FOOD CONSUMPTION SURVEY DATA

2.1 Survey Description

NHANES for the years 2013-2014 are available for public use (CDC, 2015). NHANES are conducted as continuous, annual surveys, and are released in 2-year cycles. During each year of the ongoing NHANES program, individuals from the United States are sampled from up to 30 different study locations in a complex multi-stage probability design intended to ensure the data are a nationally representative sample of the U.S. population.

NHANES 2013-2014 dietary survey data were collected from individuals and households *via* 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2) throughout all 4 seasons of the year. Day 1 data were collected in-person, and Day 2 data were collected by telephone in the following 3 to 10 days, on different days of the week, to achieve the desired degree of statistical independence. The data were collected by first selecting Primary Sampling Units (PSUs), which were counties throughout the U.S., of which 30 PSUs are visited per year. Smaller contiguous counties were combined to attain a minimum population size. These PSUs were segmented and households were chosen within each segment. One or more participants within a household were interviewed. For NHANES 2013-2014, 14,332 individuals were selected for the sample, 10,175 were interviewed (71.0%) and 9,813 were examined (68.5%).

In addition to collecting information on the types and quantities of foods being consumed, NHANES 2013-2014 collected socio-economic, physiological and demographic information from individual participants in the survey, such as sex, age, body weight, and other variables (such as height and race-ethnicity) that may be useful in characterizing consumption. The inclusion of this information allows for further assessment of food intake based on consumption by specific population groups of interest within the total population. The primary sample design for NHANES 2013-2014 includes an oversample of Non-Hispanic Asian persons, Hispanic persons, non-Hispanic black persons, older adults, and “low income whites/others”, however sample weights were incorporated to allow estimates from these subgroups to be combined to obtain national estimates that reflect the relative proportions of these groups in the population as a whole (CDC, 2015).

2.2 Statistical Methods

For the intake assessment, consumption data from individual dietary records, detailing food items ingested by each survey participant, were collated by computer and used to generate estimates for the intake of 2'-FL by the U.S. population¹. Estimates for the daily intake of 2'-FL represent projected 2-day averages for each individual from Day 1 and Day 2 of NHANES 2013-2014; these average amounts comprised the distribution from which mean and percentile intake estimates were determined. Mean and percentile estimates were generated incorporating survey weights in order to provide representative intakes for the entire U.S. population. “*Per capita*” intake refers to the estimated intake of 2'-FL averaged over all individuals surveyed, regardless of whether they consumed food products in which 2'-FL is proposed for use, and therefore includes individuals with “zero” intakes (*i.e.* those who reported no intake of food products containing 2'-FL during the 2 survey days). “Consumer-only” intake refers to the estimated intake of 2'-FL by those individuals who reported consuming food products in which the use of 2'-FL is currently under consideration. Individuals were considered “consumers” if they reported consumption of 1 or more food products in which 2'-FL is proposed for use on either Day 1 or Day 2 of the survey.

Mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size (CDC, 2013). As such, the reliability of estimates for the intake of 2'-FL based on consumption estimates derived from individual population groups of a limited sample size should be interpreted with caution. These values are marked with an asterisk in the relevant data tables.

¹ Statistical analysis and data management were conducted in DaDiet Software (Dazult Ltd., 2017). DaDiet Software is a web-based software tool that allows accurate estimate of exposure to nutrients and to substances added to foods, including contaminants, food additives and novel ingredients. The main input components are concentration (use level) data and food consumption data. Data sets are combined in the software to provide accurate and efficient exposure assessments.

3.0 FOOD USAGE DATA

The individual proposed food-uses and use-levels for 2'-FL employed in the current intake analysis are summarized in Table 3-1. Food codes representative of each proposed food-use were chosen from the NHANES 2013-2014 (CDC, 2016). Food codes were grouped in food-use categories according to Title 21, Section §170.3 of the Code of Federal Regulations (CFR, 2017a). If necessary, adjustment factors were developed for composite foods/mixtures based on data provided in the Food and Nutrition Database for Dietary Studies (FNDDS) (USDA, 2016). All food codes included in the current intake assessment are listed in Appendix C.

Table 3-1 Summary of the Individual Proposed Food-Uses and Use-Levels for 2'-FL in the U.S.

Food Category (21 CFR 170.3)	Food-Uses	Maximum 2'-FL Level (g/serving)	RACC ^a (g or mL)	Maximum 2'-FL Use-Levels (g/100 g)
Beverages and Beverage Bases	Energy drinks	0.28	360	0.08
	Fitness water and third quenchers, sports and isotonic drinks	0.28	360	0.08
Breakfast Cereals	Ready-to-eat breakfast cereals for adults and children	1.2	15 (puffed) 40 (high-fiber) 60 (biscuit-types)	8.0 3.0 2.0
	Hot cereals for adults and children	1.2	40 (dry) ~ 250 (prepared)	0.48 (as consumed)
Dairy Product Analogs	Milk substitutes such as soy milk and imitation milks	0.28	240	0.12
Frozen Dairy Desserts and Mixes	Frozen desserts including ice creams* and frozen yogurts, frozen novelties	1.2	~ 70	1.7
Gelatins, puddings, and fillings	Dairy-based puddings, custards, and mousses	1.2	~ 70	1.7
	Fruit pie filling	1.2	85	1.41
	"Fruit prep" such as fruit filling in bars, cookies, yogurt, cakes	1.2	~ 40	3.0
Grain Products and Pastas	Bars, including snack bars, meal-replacement bars, breakfast bars	0.48	40	1.20
Jams and Jellies, Commercial	Jellies and jams, fruit preserves*, fruit butters	1.2	~ 20	6.0
Milk, Whole and Skim	All <i>acidophilus</i> or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder*	0.28	240	0.12
Milk Products	Flavored milks, including chocolate milk, coffee drinks, cocoa, smoothies (dairy and fruit-based), other fruit and dairy combinations, yogurt drinks fermented milk drinks including kefir**	0.28	240	0.12
	Milk-based meal replacement beverages or diet beverages**	0.28	240	0.12
	Yogurt*, **	1.2	225	0.53
	Formula intended for pregnant women ("mum" formulas; -9 to 0 months)	1.2	200 ^b	0.6
Processed Fruits and Fruit Juices	Fruit drinks, including vitamin and mineral-fortified products	0.28	240	0.12
	Fruit juices*	0.28	240	0.12

Table 3-1 Summary of the Individual Proposed Food-Uses and Use-Levels for 2'-FL in the U.S.

Food Category (21 CFR 170.3)	Food-Uses	Maximum 2'-FL Level (g/serving)	RACC ^a (g or mL)	Maximum 2'-FL Use-Levels (g/100 g)
Sweet Sauces, Toppings, and Syrups	Syrups used to flavor milk beverages	0.28	40	0.70
Other Categories				
Non-Exempt Infant and Follow-On Formula	Infant Formula (0 to 6 months), including ready-to-drink formula or formula prepared from powder	0.24	100 ^b	0.24 (0.40 g/100 kcal) ^c
	Follow-On Formula (6 to 12 months), including ready-to-drink formula or formula prepared from powder	0.24	100 ^b	0.24 (0.40 g/100 kcal) ^c
Baby Foods	Meal replacement products such as Pediasure	0.24	120 ^b	0.2
	Growing-Up (Toddler) Milks (12 to 36 months)	0.24	120 ^b	0.2
	Ready-to-eat, ready-to-serve, hot cereals	1.2	15 (dry) 110 (ready-to-serve)	1.09 (as consumed)
	Yogurt and juice beverages identified as "baby" drinks	1.2	120	1.0
	Desserts including fruit desserts, cobblers, yogurt / fruit combinations ("junior type" desserts)	1.2	110	1.09
	Baby crackers, pretzels, cookies, and snack items	0.4	7	5.7
Medical Foods	Oral nutritional supplements and enteral tube feeding (11 years and older)	4.0	200 ^b	2.0

2'-FL = 2'-fucosyllactose; CFR = Code of Federal Regulations; RACC = Reference Amounts Customarily Consumed per Eating Occasion; U.S. = United States.

^a RACC based on values established in 21 CFR §101.12 (U.S. FDA, 2016, CFR, 2017b). When a range of values is reported for a proposed food-use, particular foods within that food-use may differ with respect to their RACC.

^b No RACC value exists; therefore, approximate serving sizes are provided according to the food manufacturer instructions.

^c The intended use level in infant formula and baby meal replacement products is 2.4 g per L (0.24 g per 100 mL), or 0.40 g per 100 kcal. For a 100 mL formula that contains 60 kcal, the conversion is as follows:

$$\frac{100 \text{ mL}}{60 \text{ kcal}} \times \frac{0.24 \text{ g}}{100 \text{ mL}} = 0.004 \frac{\text{g}}{\text{kcal}} \text{ or } 0.40 \frac{\text{g}}{100 \text{ kcal}}$$

* 2'-FL is intended for use in unstandardized products when standards of identity do not permit its addition.

** Includes ready-to-drink and powder forms.

It is further noted that 2'-FL is intended for use in medical foods (oral nutritional supplements and enteral tube feeding) at maximum dosages of 4.0 g per product. The dietary exposures from these intended uses are considered separately from the NHANES-based assessment, as the conventional food consumption database would not adequately capture these target uses.

4.0 FOOD SURVEY RESULTS

Estimates for the total daily intakes of 2'-FL from proposed food-uses are provided in Tables 4.1-1 and 4.1-2. Estimates for the daily intake of 2'-FL from individual proposed food-uses in the U.S. are summarized in Tables A-1 to A-10 and B-1 to B-10 of Appendices A and B, respectively. Tables A-1 to A-10 provide estimates for the daily intake of 2'-FL on an absolute basis (g/person/day), whereas Tables B-1 to B-10 provide estimates for the daily intake of 2'-FL on a per kilogram body weight basis (mg/kg body weight/day).

4.1 Estimated Daily Intake of 2'-FL from All Proposed Food-Uses in the U.S.

Table 4.1-1 summarizes the estimated total intake of 2'-FL (g/person/day) from all proposed food-uses in the U.S. population group. Table 4.1-2 presents this data on a per kilogram body weight basis (mg/kg body weight/day). The percentage of consumers was high among all age groups evaluated in the current intake assessment; greater than 57.5% of the infant population and greater than 86.8% of the other population groups consisted of consumers of food products in which 2'-FL is currently proposed for use (Table 4.1-1). Owing to the proposed uses of 2'-FL in milks, juices, cereals, yogurts which are popular food items among toddlers, 100% of individuals aged 12 to 35 months simulated to consume foods in which 2'-FL is proposed for use. The consumer-only estimates are more relevant to risk assessments as they represent exposures in the target population; consequently, only the consumer-only intake results are discussed in detail herein.

Among the total population (all ages), the mean and 90th percentile consumer-only intakes of 2'-FL were determined to be 1.70 and 3.54 g/person/day, respectively. Of the individual population groups, older infants aged 6 to 11 months were determined to have the greatest mean consumer-only intakes of 2'-FL on an absolute basis, at 2.28 g/person/day, whereas male teenagers were estimated to have the highest 90th percentile intake of 2'-FL at 4.29 g/day. Females of childbearing age (16 to 45 years old) had the lowest estimated mean and 90th percentile consumer-only intakes of 1.36 and 2.87 g/person/day, respectively (Table 4.1-1).

Table 4.1-1 Summary of the Estimated Daily Intake of 2'-FL from Proposed Food-Uses in the U.S. by Population Group (2013-2014 NHANES Data)

Population Group	Age Group (Years)	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infants	0 to 5 (months)	1.10	2.75	57.5	107	1.91	3.00
Infants	6 to 11 (months)	2.14	3.86	94.1	160	2.28	3.86
Toddlers	12 to 35 (months)	1.83	2.97	100.0	348	1.83	2.97
Children	3 to 11	1.96	3.53	99.7	1,277	1.97	3.53
Female Teenagers	12 to 19	1.47	2.95	94.7	544	1.55	2.95
Male Teenagers	12 to 19	1.85	4.16	92.5	526	2.00	4.29
Women of Child-Bearing Age	16 to 45	1.22	2.82	89.9	1,219	1.36	2.87
Female Adults	20 and up	1.32	2.96	91.9	2,169	1.44	3.05
Male Adults	20 and up	1.59	3.81	86.8	1,842	1.84	3.97
Elderly	65 and up	1.76	3.74	92.8	939	1.90	3.91
Total Population	All Ages	1.55	3.41	91.2	6,973	1.70	3.54

2'-FL = 2'-fucosyllactose; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

On a body weight basis, the total population (all ages) mean and 90th percentile consumer-only intakes of 2'-FL were determined to be 36 and 80 mg/kg body weight/day, respectively. Among the individual population groups, younger infants aged 0 to 5 months were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 315 and 532 mg/kg body weight/day, respectively. Female adults and females of childbearing age were predicted to have the lowest mean and 90th percentile intakes at 20 and 43 mg/kg body weight/day, respectively (Table 4.1-2).

Table 4.1-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Proposed Food-Uses in the U.S. by Population Group (2013-2014 NHANES Data)

Population Group	Age Group (Years)	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infants	0 to 5 (months)	181	477	57.5	107	315	532
Infants	6 to 11 (months)	244	441	94.1	160	259	447
Toddlers	12 to 35 (months)	148	243	100.0	346	148	243
Children	3 to 11	75	147	99.7	1,268	76	147
Female Teenagers	12 to 19	24	52	94.7	536	26	52
Male Teenagers	12 to 19	29	67	92.5	524	31	67
Women of Child-Bearing Age	16 to 45	18	42	89.9	1,209	20	43
Female Adults	20 and up	19	42	91.9	2,156	20	43
Male Adults	20 and up	19	46	86.7	1,833	22	48
Elderly	65 and up	24	53	92.6	928	26	54
Total Population	All Ages	32	76	91.1	6,930	36	80

2'-FL = 2'-fucosyllactose; bw = body weight; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

4.2 Estimated Daily Intake of 2'-FL from Specific Food Categories

4.2.1 Intake of 2'-FL from Infant and Follow-On Formula Among Non-Breastfeeding Infants and Toddlers

In order to consider the intake of 2'-FL from formula products, an additional assessment was undertaken in which the subpopulation of breastfed infants/toddlers were removed, and the intakes were examined by the remaining non-breastfed infants and toddlers to investigate whether 2'-FL intake was greater among this group. This reflected the intake models included under GRN 546 and GRN 571 (Glycom A/S, 2014; Environ International Corp., 2015). The anticipated intake of 2'-FL from (non-exempt) infant formula products among infants and toddlers who are not breastfed are presented in the table below on an absolute (g/day) and per kilogram body weight basis (mg/kg body weight/day). Mean intakes decreased with age from 2.14 to 0.39 g/day, or 354 to 40 mg/kg body weight/day, which is anticipated as children move on to a more varied diet over 6 months of age. Due to the low sample size, the 90th percentile results are only statistically reliable for infants aged 6 to 11 months, at 2.56 g/day or 311 mg/kg body weight/day.

Table 4.2.1-1 Estimated Daily Intake of 2'-FL from Non-Exempt Infant Formula Among Non-Breastfed Infants (2013-2014 NHANES Data)

Population Group	Age Group (Months)	Consumer-Only Intake of 2'-FL [‡]					
		%	n	g/day		mg/kg body weight/day	
				Mean	90 th Percentile	Mean	90 th Percentile
Infants	0 to 5	43.0	79	2.14	2.88*	354	498*
Infants	6 to 11	56.6	100	1.67	2.56	192	311
Toddlers	12 to 35	11.7	39	0.39	1.14*	40	101*

2'-FL = 2'-fucosyllactose; NHANES = National Health and Nutrition Examination Survey.

[‡] Infants and toddlers recording a breastmilk consumption event in NHANES were removed from these analyses. The results represent intake of 2'-FL from non-exempt infant and follow-on formula among consumers of formula, by age group.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

4.2.2 Intake of 2'-FL from Other Food Categories

Estimates for the mean and 90th percentile daily intakes of 2'-FL from each individual food category are summarized in Tables A-1 to A-10 and B-1 to B-10 on a g/day and mg/kg body weight/day basis, respectively. Among the non-infant population, individuals were identified as being significant consumers of milk products (46.2 to 89.1% consumers among the individual demographics), fruit juices (25.3 to 64.0% consumers), and ready-to-eat breakfast cereals (28.5 to 61.1% consumers).

In terms of contribution to total mean intake of 2'-FL among the non-infant population, ready-to-eat breakfast cereal accounted for 18.5 to 32.3% of total intakes, which were followed by frozen desserts (contributed 5.7 to 29.0% to total intakes) and milks (contributed 8.1 to 26.2% to total mean intakes). The other food categories accounted for less than 8.8% of the total 2'-FL intake (see Tables A-1 to A-10 and/or B-1 to B-10 for further details).

4.2.3 Intake of 2'-FL from Proposed Uses in Medical Foods

As noted in the introduction, 2'-FL is proposed for use in medical foods at maximum dosage levels of 4 g/serving, intended to be consumed by patients aged 11 years and older at no more than 3 servings per day. Medical foods containing 2'-FL will be used under the supervision of a physician for the dietary management of a disease or condition and therefore will not be combined with a diet containing 2'-FL from its conventional food uses described under Table 3-1. Therefore, the anticipated daily intake of 2'-FL from its proposed uses in medical foods is expected to be at a maximum of 12 g/person/day² among the target population. Using default body weight values for adolescents and adults as established in the U.S. Environmental Protection Agency's Exposure Factors Handbook (U.S. EPA, 2011), dosages are equivalent to 211 mg/kg body weight/day in a 56.8 kg adolescent and 150 mg/kg body weight/day in an 80.0 kg adult.

5.0 SUMMARY AND CONCLUSIONS

Consumption data and information pertaining to the individual proposed food-uses of 2'-FL were used to estimate the *per capita* and consumer-only intakes of 2'-FL for specific demographic groups and for the total U.S. population. There were a number of assumptions included in the assessment which render exposure estimates that may be considered suitably conservative. For example, it has been assumed in both exposure assessments that all food products within a food category contain 2'-FL at the maximum specified level of use. In reality, the levels added to specific foods will vary depending on the nature of the food product and it is unlikely that 2'-FL will have 100% market penetration in all identified food categories.

In summary, on consumer-only basis, the resulting mean and 90th percentile intakes of 2'-FL by the total (all ages) U.S. population from all proposed food-uses, were estimated to be 1.70 g/person/day (36 mg/kg body weight/day) and 3.54 g/person/day (80 mg/kg body weight/day), respectively. Among the individual population groups, older infants aged 6 to 11 months were determined to have the greatest mean consumer-only intakes of 2'-FL on an absolute basis, at 2.28 g/person/day (259 mg/kg body weight/day), whereas male teenagers were estimated to have the highest 90th percentile intake of 2'-FL at 4.29 g/day (67 mg/kg body weight/day). When intakes were expressed on a body weight basis, younger infants aged 0 to 5 months were identified as having the highest mean and 90th percentile consumer-only intakes of any population group, of 315 and 532 mg/kg body weight/day, respectively. When considering predicted intake of 2'-FL from formula products among non-breastfed infants, estimates of mean consumer-only intake

² Calculated as 4.0 g/serving x 3 servings/day = 12 g/day.

ranged from 0.39 g/day (40 mg/kg body weight/day) among toddlers, up to 2.14 g/day (354 mg/kg body weight/day) among young infants aged 0 to 5 months.

Uses of 2'-FL in medical foods at a dosage of 4 g/serving are expected to result in a maximum daily intake of 12 g/day of 2'-FL among its intended target patient population of individuals aged 11 years and older (equivalent to approximately 211 mg/kg body weight/day in adolescents and 150 mg/kg body weight/day in adults).

6.0 REFERENCES

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Appendix A
Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by
Different Population Groups Within the U.S. (2013-2014 NHANES DATA)

Table A-1 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Infants Aged 0 to 5 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.10	2.75	57.5	107	1.91	3.00
<u>Beverages and Beverage Bases</u>							
Energy drinks	0	na	na	0	0	na	na
Fitness water and third quenchers, sports and isotonic drinks	0	na	na	0	0	na	na
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	<0.1	<0.01*	na	0.2	1	0.01*	0.01*
Hot cereals for adults and children	0.1	<0.01*	na	0.9	1	0.15*	0.15*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0	na	na	0	0	na	na
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	0.3	<0.01*	na	0.9	1	0.32*	0.32*
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	0	na	na	0	0	na	na
Fruit pie filling	0	na	na	0	0	na	na
"Fruit prep"	0	na	na	0	0	na	na
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	0	na	na	0	0	na	na
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	0	na	na	0	0	na	na
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	<0.1	<0.01*	na	0.2	1	0.10*	0.09*
<u>Milk Products</u>							
Flavored milks	0	na	na	0	0	na	na
Milk-based meal replacement beverages or diet beverages	0	na	na	0	0	na	na
Yogurt	0	na	na	0	0	na	na
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	0	na	na	0	0	na	na
Fruit juices	0.3	<0.01*	na	2.1	5	0.16*	0.26*
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0	na	na	0	0	na	na
<u>Other</u>							

Table A-1 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Infants Aged 0 to 5 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant formula	92.3	1.02	2.63	52.4	102	1.94	2.78
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0.8	0.01*	na	2.4	4	0.37*	0.66*
Yogurt and juice beverages identified as "baby" drinks	3.0	0.03*	na	4.5	8	0.74*	1.79*
"Junior type" desserts	1.2	0.01*	na	6.5	6	0.20*	0.33*
Baby crackers, pretzels, cookies, and snack items	2.1	0.02*	na	2.6	6	0.86*	1.61*

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-2 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Older Infants Aged 6 to 11 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	2.14	3.86	94.1	160	2.28	3.86
<u>Beverages and Beverage Bases</u>							
Energy drinks	0	na	na	0	0	na	na
Fitness water and third quenchers, sports and isotonic drinks	0.1	<0.01*	na	2.7	6	0.11*	0.10*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	1.4	0.03*	0.12	15.9	22	0.19*	0.33*
Hot cereals for adults and children	1.5	0.03*	0.06	11.3	13	0.29*	0.48*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.1	<0.01*	na	1.6	2	0.17*	0.17*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	0.2	<0.01*	na	4.3	8	0.10*	0.25*
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	0.6	0.01*	na	2.9	4	0.45*	0.56*
Fruit pie filling	0.2	0.01*	na	1.7	1	0.31*	0.31*
"Fruit prep"	0	na	na	0	0	na	na
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	0.5	0.01*	na	1.7	1	0.68*	0.68*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	0	na	na	0	0	na	na
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	3.2	0.07	0.29*	15.9	33	0.43	0.73*
<u>Milk Products</u>							
Flavored milks	0.1	<0.01*	na	2.0	4	0.12*	0.19*
Milk-based meal replacement beverages or diet beverages	0	na	na	0	0	na	na
Yogurt	1.8	0.04*	0.02	10.6	18	0.37*	0.65*
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	0.1	<0.01*	na	2.1	5	0.08*	0.10*
Fruit juices	0.8	0.02*	0.06	14.0	29	0.12*	0.19*
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages		na	na	0	0	na	na
<u>Other</u>							

Table A-2 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Older Infants Aged 6 to 11 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	46.6	1.00	2.38	63.0	107	1.58	2.56
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-Up (Toddler) Milks	3.0	0.06*	na	6.5	7	0.98*	1.43*
Ready-to-eat, ready-to-serve, hot cereals for babies	1.7	0.04*	na	5.0	9	0.74*	0.92*
Yogurt and juice beverages identified as "baby" drinks	18.6	0.40	1.24*	40.5	59	0.98	2.17*
"Junior Type" Desserts	11.2	0.24	0.62*	36.3	55	0.66	1.29*
Baby crackers, pretzels, cookies, and snack items	8.1	0.17	0.60	46.5	82	0.37	0.82

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-3 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Toddlers Aged 12 to 35 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.83	2.97	100	348	1.83	2.97
<u>Beverages and Beverage Bases</u>							
Energy drinks	0	0	na	0	0	na	na
Fitness water and third quenchers, sports and isotonic drinks	0.8	0.01*	na	7.0	20	0.21*	0.40*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	18.5	0.34	0.90	61.1	203	0.55	1.07
Hot cereals for adults and children	5.2	0.09	0.40*	17.7	66	0.53	0.87*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	1.4	0.03*	na	7.5	22	0.35*	0.91*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	5.7	0.10	0.49*	17.1	69	0.61	1.21*
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	2.0	0.04*	na	5.6	24	0.64*	1.02*
Fruit pie filling	<0.1	<0.01*	na	0.5	1	0.16*	0.16*
"Fruit prep"	0.5	0.01*	na	5.6	14	0.17*	0.33*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	1.5	0.03*	na	7.7	25	0.35*	0.58*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	5.4	0.10	0.38*	19.9	51	0.50	0.90*
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	26.2	0.48	0.99	89.1	305	0.54	1.04
<u>Milk Products</u>							
Flavored milks	1.5	0.03	0.10*	15.9	59	0.17	0.34*
Milk-based meal replacement beverages or diet beverages	0.9	0.02*	na	4.6	7	0.37*	0.68*
Yogurt	6.9	0.13	0.41	29.3	95	0.43	0.90
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	3.7	0.07	0.22	30.1	128	0.23	0.43
Fruit juices	7.0	0.13	0.34	64.0	213	0.20	0.41
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<0.01*	na	3.2	8	0.09*	0.12*
<u>Other</u>							

Table A-3 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Toddlers Aged 12 to 35 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant formula	1.6	0.03*	na	4.0	13	0.75*	1.21*
Follow-on formula	<0.1	<0.01*	na	<0.1	1	0.58*	0.58*
Meal replacement products	0.9	0.02*	na	2.9	6	0.55*	1.22*
Growing-up (toddler) milks	0.5	0.01*	na	1.1	3	0.79*	0.92*
Ready-to-eat, ready-to-serve, hot cereals for babies	0.7	0.01*	na	1.9	5	0.69*	0.93*
Yogurt and juice beverages identified as "baby" drinks	3.6	0.07*	na	6.0	20	1.11*	2.02*
"Junior type" desserts	1.3	0.02*	na	4.1	12	0.58*	1.20*
Baby crackers, pretzels, cookies, and snack items	4.0	0.07	0.02*	11.5	31	0.65	1.63*

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
 * Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-4 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Children Aged 3 to 11 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.96	3.53	99.7	1,277	1.97	3.53
<u>Beverages and Beverage Bases</u>							
Energy drinks	<0.1	<0.01*	na	0.1	1	0.15*	0.15*
Fitness water and third quenchers, sports and isotonic drinks	1.4	0.03	0.07	12.2	128	0.22	0.43
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	27.1	0.53	1.47	59.0	777	0.90	1.74
Hot cereals for adults and children	2.4	0.05	na	8.3	117	0.57	1.19
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.2	<0.01	na	2.5	33	0.18	0.33*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	21.9	0.43	1.29	35.2	388	1.22	2.41
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	3.9	0.08	na	5.0	67	1.53	3.09*
Fruit pie filling	0.2	<0.01*	na	1.0	15	0.31*	0.42*
"Fruit prep"	0.2	<0.01	na	3.4	46	0.14	0.38*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	1.5	0.03	0.13	11.9	128	0.24	0.45
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.9	0.10	0.38	17.2	224	0.56	1.13
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	13.2	0.26	0.57	80.7	1,041	0.32	0.63
<u>Milk Products</u>							
Flavored milks	3.8	0.08	0.26	35.1	473	0.22	0.44
Milk-based meal replacement beverages or diet beverages	0.1	<0.01*	na	1.4	10	0.21*	0.29*
Yogurt	5.6	0.11	0.45	23.3	260	0.47	0.90
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	6.2	0.12	0.34	50.6	665	0.24	0.44
Fruit juices	6.7	0.13	0.34	56.9	759	0.23	0.45
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.4	0.01	na	4.9	55	0.15	0.30*
<u>Other</u>							

Table A-4 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Children Aged 3 to 11 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	<0.1	<0.01*	na	<0.1	1	0.44*	0.44*
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0.1	<0.01*	na	0.4	11	0.42*	0.99*
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0.1	<0.01*	na	0.3	3	0.77*	0.90*
"Junior Type" Desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	0.1	<0.01*	na	0.2	2	0.82*	0.98*

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-5 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Female Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.47	2.95	94.7	544	1.55	2.95
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.3	<0.01*	na	1.9	7	0.25*	0.38*
Fitness water and third quenchers, sports and isotonic drinks	1.6	0.02	na	9.2	55	0.26	0.47*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	32.3	0.47	1.49	43.0	230	1.10	1.99
Hot cereals for adults and children	2.3	0.03	na	4.9	38	0.69	1.22*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.3	<0.01*	na	2.0	22	0.18*	0.40*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	21.3	0.31	1.21	24.3	125	1.29	2.04
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	3.9	0.06*	na	4.1	20	1.39*	1.85*
Fruit pie filling	0.3	<0.01*	na	0.7	10	0.60*	1.02*
"Fruit prep"	0.5	0.01*	na	3.0	23	0.24*	0.49*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	3.7	0.05	0.26*	17.0	68	0.32	0.50*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.2	0.06	na	9.7	44	0.63	0.84*
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	10.6	0.16	0.41	59.6	320	0.26	0.50
<u>Milk Products</u>							
Flavored milks	2.8	0.04	0.19	18.9	107	0.22	0.38
Milk-based meal replacement beverages or diet beverages	0.1	<0.01*	na	0.5	6	0.23*	0.29*
Yogurt	4.8	0.07	0.24*	12.8	53	0.54	1.01*
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	7.5	0.11	0.34	37.1	235	0.30	0.70
Fruit juices	3.6	0.05	0.20	25.3	189	0.21	0.42
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<0.01*	na	1.9	6	0.13*	0.15*
<u>Other</u>							

Table A-5 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Female Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	0	na	na	0	0	na	na
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	<0.1	<0.01*	na	<0.1	1	1.51*	1.51*
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior Type" Desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	<0.1	<0.01*	na	<0.1	1	1.14*	1.14*

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-6 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Male Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.85	4.16	92.5	526	2.00	4.29
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.7	0.01*	na	4.0	8	0.31*	0.41*
Fitness water and third quenchers, sports and isotonic drinks	6.0	0.11	0.30	19.9	93	0.56	0.79
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	31.4	0.58	1.61	45.5	252	1.27	2.80
Hot cereals for adults and children	1.8	0.03*	na	3.9	28	0.86*	1.92*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.1	<0.01*	na	0.9	11	0.25*	0.55*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	19.4	0.36	1.34	19.8	109	1.82	3.22
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	1.7	0.03*	na	2.5	12	1.26*	2.22*
Fruit pie filling	0.4	0.01*	na	2.2	6	0.34*	0.41*
"Fruit prep"	0.6	0.01*	na	2.0	14	0.52*	0.98*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.1	0.04	0.14*	12.3	52	0.32	0.82*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.4	0.08	na	6.8	50	1.21	2.25*
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	14.4	0.27	0.71	65.3	360	0.41	0.85
<u>Milk Products</u>							
Flavored milks	3.2	0.06	0.21	23.9	140	0.24	0.53
Milk-based meal replacement beverages or diet beverages	0.8	0.02*	na	1.8	9	0.84*	1.19*
Yogurt	1.3	0.02*	na	4.4	27	0.55*	0.92*
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	5.6	0.10	0.29	30.2	209	0.34	0.75
Fruit juices	5.8	0.11	0.30	40.6	224	0.27	0.54
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.3	0.01*	na	1.4	4	0.40*	0.48*
<u>Other</u>							

Table A-6 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Male Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	0	na	na	0	0	na	na
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior Type" Desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-7 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Women of Childbearing Age, 16 to 45 Years, Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.22	2.82	89.9	1,219	1.36	2.87
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.5	0.01	na	2.5	31	0.22	0.41*
Fitness water and third quenchers, sports and isotonic drinks	1.3	0.02	na	5.8	72	0.27	0.50*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	25.8	0.32	1.09	31.0	410	1.02	2.10
Hot cereals for adults and children	5.1	0.06	na	9.1	141	0.69	1.23
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.7	0.01	na	6.2	86	0.15	0.29
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	23.0	0.28	0.96	21.8	261	1.28	2.94
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	2.9	0.04	na	3.6	54	1.00	1.68*
Fruit pie filling	0.7	0.01	na	2.0	31	0.42	0.65*
"Fruit prep"	1.1	0.01	na	4.2	62	0.32	1.10*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	3.7	0.05	0.21	14.1	154	0.32	0.54
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	3.5	0.04	na	7.8	93	0.54	1.13
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	8.7	0.11	0.35	46.2	644	0.23	0.50
<u>Milk Products</u>							
Flavored milks	2.9	0.04	0.15	12.1	172	0.29	0.57
Milk-based meal replacement beverages or diet beverages	0.6	0.01*	na	2.4	27	0.32*	0.44*
Yogurt	7.2	0.09	0.38	15.1	178	0.58	1.05
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	7.0	0.09	0.30	27.4	395	0.31	0.65
Fruit juices	5.1	0.06	0.22	27.8	409	0.22	0.39
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<0.01*	na	1.0	7	0.20*	0.25*
<u>Other</u>							

Table A-7 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Women of Childbearing Age, 16 to 45 Years, Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	0	na	na	0	0	na	na
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior Type" Desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	<0.1	<0.01*	na	<0.1	1	1.14*	1.14*

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-8 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Female Adults Aged 20 and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.32	2.96	91.9	2,169	1.44	3.05
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.2	<0.01	na	1.4	32	0.21	0.40*
Fitness water and third quenchers, sports and isotonic drinks	0.9	0.01	na	3.7	78	0.31	0.50*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	22.3	0.30	1.03	31.0	711	0.95	1.85
Hot cereals for adults and children	7.3	0.10	0.42	13.6	394	0.71	1.20
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	1.1	0.01	na	7.5	176	0.20	0.48
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	22.7	0.30	1.21	24.9	547	1.20	2.56
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	5.2	0.07	na	5.5	133	1.26	2.26
Fruit pie filling	2.0	0.03	na	5.1	101	0.51	1.17
"Fruit prep"	1.3	0.02	na	6.3	150	0.28	0.56
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.7	0.04	0.14	10.7	211	0.34	0.60
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.4	0.06	0.09	10.7	243	0.55	1.13
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	8.1	0.11	0.35	48.9	1,179	0.22	0.47
<u>Milk Products</u>							
Flavored milks	1.9	0.03	na	9.3	243	0.28	0.52
Milk-based meal replacement beverages or diet beverages	1.1	0.01	na	4.2	77	0.34	0.60*
Yogurt	8.8	0.12	0.45	19.1	379	0.61	1.05
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	5.4	0.07	0.24	22.3	558	0.32	0.63
Fruit juices	4.5	0.06	0.21	28.4	727	0.21	0.39
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	<0.1	<0.01*	na	0.6	12	0.25*	0.36*
<u>Other</u>							

Table A-8 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Female Adults Aged 20 and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	0	na	na	0	0	na	na
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior Type" Desserts	<0.1	<0.01*	na	<0.1	1	1.85*	1.85*
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-9 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Male Adults Aged 20 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.59	3.81	86.8	1,842	1.84	3.97
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.7	0.01	na	4.2	90	0.28	0.40
Fitness water and third quenchers, sports and isotonic drinks	2.0	0.03	na	8.1	163	0.40	0.77
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	25.0	0.40	1.29	28.5	574	1.40	2.55
Hot cereals for adults and children	6.3	0.10	0.28	10.4	292	0.97	1.94
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.6	0.01	na	4.2	95	0.22	0.44
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	24.0	0.38	1.57	24.5	448	1.56	2.96
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	4.9	0.08	na	4.7	97	1.64	3.06
Fruit pie filling	1.4	0.02	na	4.5	86	0.51	0.97
"Fruit prep"	1.3	0.02	na	7.0	134	0.29	0.53
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.5	0.04	0.14	12.3	186	0.32	0.67
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	5.9	0.09	0.38	12.2	253	0.77	1.26
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	9.6	0.15	0.44	48.3	1,019	0.32	0.67
<u>Milk Products</u>							
Flavored milks	1.6	0.03	na	8.6	177	0.30	0.54
Milk-based meal replacement beverages or diet beverages	1.1	0.02	na	3.6	65	0.50	1.16*
Yogurt	4.4	0.07	0.28	11.0	201	0.65	1.30
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	4.3	0.07	0.26	18.9	448	0.36	0.67
Fruit juices	4.4	0.07	0.27	26.1	615	0.27	0.48
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	<0.1	<0.01*	na	0.6	9	0.12*	0.17*
<u>Other</u>							

Table A-9 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by Male Adults Aged 20 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	0	na	na	0	0	na	na
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior Type" Desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-10 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by the Elderly Aged 65 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.76	3.74	92.8	939	1.90	3.91
<u>Beverages and Beverage Bases</u>							
Energy drinks	<0.1	<0.01*	na	0.1	3	0.18*	0.19*
Fitness water and third quenchers, sports and isotonic drinks	0.3	0.01*	na	2.1	21	0.27*	0.39*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	22.5	0.40	1.28	39.7	359	1.00	1.81
Hot cereals for adults and children	8.1	0.14	0.58	17.1	224	0.83	1.69
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.7	0.01	na	5.8	63	0.21	0.49*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	29.0	0.51	1.65	35.5	306	1.44	2.70
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	5.9	0.10	na	8.0	78	1.30	2.07*
Fruit pie filling	2.9	0.05	na	7.9	68	0.64	1.17*
"Fruit prep"	1.8	0.03	0.05	11.3	88	0.28	0.67
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	1.0	0.02	na	7.0	51	0.24	0.32*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.9	0.09	0.30	13.8	138	0.62	1.20
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	8.6	0.15	0.45	59.7	574	0.25	0.55
<u>Milk Products</u>							
Flavored milks	1.0	0.02	na	6.4	74	0.27	0.49*
Milk-based meal replacement beverages or diet beverages	1.4	0.02	na	6.1	45	0.40	0.68*
Yogurt	4.9	0.09	0.45	15.9	136	0.55	0.90
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	2.9	0.05	0.20	19.2	198	0.27	0.55
Fruit juices	4.1	0.07	0.25	34.1	360	0.21	0.39
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.1	<0.01*	na	0.7	7	0.26*	0.42*
<u>Other</u>							

Table A-10 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by the Elderly Aged 65 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	0	na	na	0	0	na	na
Follow-On Formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-Up (Toddler) Milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior Type" Desserts	0.1	<0.01*	na	0.1	1	1.85*	1.85*
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table A-11 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by the Total U.S. Population (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	1.55	3.41	91.2	6,973	1.70	3.54
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.4	0.01	na	2.4	138	0.26	0.41
Fitness water and third quenchers, sports and isotonic drinks	1.7	0.03	na	7.5	543	0.36	0.62
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	24.6	0.38	1.21	35.2	2,770	1.08	2.08
Hot cereals for adults and children	5.5	0.08	0.25	10.9	949	0.78	1.36
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.7	0.01	na	5.0	361	0.21	0.44
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	21.9	0.34	1.26	25.1	1,695	1.35	2.75
<u>Gelatins, puddings, and fillings</u>							
Dairy-based puddings, custards, and mousses	4.4	0.07	na	4.9	357	1.41	2.83
Fruit pie filling	1.2	0.02	na	3.9	220	0.50	0.99
"Fruit prep"	1.0	0.02	na	5.7	381	0.27	0.53
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.4	0.04	0.14	11.6	671	0.32	0.60
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	5.0	0.08	0.19	11.8	865	0.65	1.20
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	10.4	0.16	0.46	54.3	4,258	0.30	0.61
<u>Milk Products</u>							
Flavored milks	2.2	0.03	0.15	13.4	1,203	0.25	0.47
Milk-based meal replacement beverages or diet beverages	0.9	0.01	na	3.3	174	0.41	0.87
Yogurt	5.9	0.09	0.41	15.6	1,033	0.58	1.05
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	5.1	0.08	0.28	25.5	2,248	0.31	0.61
Fruit juices	4.8	0.07	0.26	32.0	2,761	0.23	0.45
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.1	0.00	na	1.3	94	0.17	0.42
<u>Other</u>							

Table A-11 Estimated Daily Intake of 2'-FL from Individual Proposed Food-Uses by the Total U.S. Population (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant Formula	1.0	0.02	na	0.9	223	1.62	2.64
Follow-On Formula	<0.1	<0.01*	na	<0.1	1	0.58*	0.58*
Meal replacement products	<0.1	<0.01*	na	0.1	18	0.52*	1.41*
Growing-Up (Toddler) Milks	<0.1	<0.01*	na	0.1	10	0.91*	1.04*
Ready-to-eat, ready-to-serve, hot cereals for babies	<0.1	<0.01*	na	0.1	18	0.66*	0.93*
Yogurt and juice beverages identified as "baby" drinks	0.3	0.01	na	0.5	90	0.99	2.07
"Junior Type" Desserts	0.2	<0.01	na	0.4	74	0.63	1.25*
Baby crackers, pretzels, cookies, and snack items	0.2	<0.01	na	0.7	122	0.52	1.62

2'-FL = 2'-fucosyllactose; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.
 * Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Appendix B
Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from
Individual Proposed Food-Uses by Different Population Groups Within
the U.S. (2013-2014 NHANES Data)

Table B-1 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Infants Aged 0 to 5 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	181	477	57.5	107	315	532
<u>Beverages and Beverage Bases</u>							
Energy drinks	0	na	na	0	0	na	na
Fitness water and third quenchers, sports and isotonic drinks	0	na	na	0	0	na	na
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	<0.1	<1*	na	0.2	1	<1*	1*
Hot cereals for adults and children	0.1	<1*	na	0.9	1	25*	25*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0	na	na	0	0	na	na
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	0.3	<1*	na	0.9	1	54*	54*
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	0	na	na	0	0	na	na
Fruit pie filling	0	na	na	0	0	na	na
"Fruit prep"	0	na	na	0	0	na	na
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	0	na	na	0	0	na	na
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	0	na	na	0	0	na	na
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	<0.1	<1*	na	0.2	1	12*	10*
<u>Milk Products</u>							
Flavored milks	0	na	na	0	0	na	na
Milk-based meal replacement beverages or diet beverages	0	na	na	0	0	na	na
Yogurt	0	na	na	0	0	na	na
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	0	na	na	0	0	na	na
Fruit juices	0.3	<1*	na	2.1	5	22*	37*
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0	na	na	0	0	na	na
<u>Other</u>							

Table B-1 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Infants Aged 0 to 5 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant formula	92.3	167	441	52.4	102	319	482
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0.6	1*	na	2.4	4	45*	76*
Yogurt and juice beverages identified as "baby" drinks	3.5	6*	na	4.5	8	141*	315*
"Junior type" desserts	0.9	2*	na	6.5	6	26*	40*
Baby crackers, pretzels, cookies, and snack items	2.0	4*	na	2.6	6	138*	263*

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-2 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Older Infants Aged 6 to 11 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	244	441	94.1	160	259	447
<u>Beverages and Beverage Bases</u>							
Energy drinks	0	na	na	0	0	na	na
Fitness water and third quenchers, sports and isotonic drinks	0.1	<1*	na	2.7	6	11*	11*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	1.4	3*	14*	15.9	22	21*	47*
Hot cereals for adults and children	1.5	4*	8*	11.3	13	33*	54*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.1	<1*	na	1.6	2	22*	22*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	0.2	<1*	na	4.3	8	11*	30*
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	0.6	2*	na	2.9	4	53*	73*
Fruit pie filling	0.3	<1*	na	1.7	1	40*	40*
"Fruit prep"	0	na	na	0	0	na	na
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	0.6	1*	na	1.7	1	87*	87*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	0	na	na	0	0	na	na
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	3.1	7	30*	15.9	33	47	85*
<u>Milk Products</u>							
Flavored milks	0.1	<1*	na	2.0	4	14*	23*
Milk-based meal replacement beverages or diet beverages	0	na	na	0	0	na	na
Yogurt	1.9	5*	2*	10.6	18	43*	81*
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	0.1	<1*	na	2.1	5	9*	11*
Fruit juices	0.8	2*	6*	14	29	13*	19*
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0	na	na	0	0	na	na

Table B-2 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Older Infants Aged 6 to 11 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	47.1	115	284	63	107	183	307
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	3.0	7*	na	6.5	7	113*	163*
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	1.8	4*	na	5.0	9	87*	116*
Yogurt and juice beverages identified as "baby" drinks	18.7	46	141*	40.5	59	113	240*
"Junior type" desserts	10.9	27	76*	36.3	55	73	152*
Baby crackers, pretzels, cookies, and snack items	7.7	19	64	46.5	82	41	91

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-3 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Toddlers Aged 12 to 35 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	148	243	100	346	148	243
<u>Beverages and Beverage Bases</u>							
Energy drinks	0	na	na	0	0	na	na
Fitness water and third quenchers, sports and isotonic drinks	0.8	1*	na	7.0	20	17*	31*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	18.2	27	69	60.7	201	44	88
Hot cereals for adults and children	5.3	8	33*	17.9	66	44	75*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	1.5	2*	na	7.6	22	30*	81*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	4.7	7	28*	16.6	68	42	92*
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	2.0	3*	na	5.6	24	52*	83*
Fruit pie filling	<0.1	<1*	na	0.5	1	15*	15*
"Fruit prep"	0.5	1*	na	5.7	14	14*	32*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	1.4	2*	na	7.8	25	27*	49*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.5	7	22*	19.4	50	34	63*
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	26.7	40	83	89.0	303	44	85
<u>Milk Products</u>							
Flavored milks	1.4	2	7*	15.9	58	13	23*
Milk-based meal replacement beverages or diet beverages	0.9	1*	na	4.7	7	30*	52*
Yogurt	7.1	11	32	29.5	95	35	78
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	3.8	6	16	30.4	128	19	34
Fruit juices	6.8	10	26	63.7	211	16	34
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<1*	na	3.2	8	8*	9*
<u>Other</u>							

Table B-3 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Toddlers Aged 12 to 35 Months Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant formula	1.9	3*	na	4.0	13	71*	111*
Follow-on formula	<0.1	<1*	na	<0.1	1	48*	48*
Meal replacement products	1.3	2*	na	3.0	6	64*	203*
Growing-up (toddler) milks	0.6	1*	na	1.1	3	85*	102*
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	1.0	1*	na	1.9	5	77*	122*
Yogurt and juice beverages identified as "baby" drinks	3.9	6*	na	6.1	20	96*	195*
"Junior type" desserts	1.4	2*	na	4.2	12	50*	104*
Baby crackers, pretzels, cookies, and snack items	4.3	6	2*	11.4	30	56	112*

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-4 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Children Aged 3 to 11 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	75	147	99.7	1,268	76	147
<u>Beverages and Beverage Bases</u>							
Energy drinks	<0.1	<1*	na	0.1	1	4*	4*
Fitness water and third quenchers, sports and isotonic drinks	1.2	1	3	12.4	128	8	16
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	27.7	21	59	59.0	771	36	73
Hot cereals for adults and children	2.9	2	na	8.4	117	27	59
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.3	<1	na	2.6	33	8	15*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	19.9	15	48	35.3	386	42	90
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	4.2	3	na	5.1	67	63	127*
Fruit pie filling	0.2	<1*	na	1.0	15	12*	17*
"Fruit prep"	0.2	<1	na	3.4	45	5	12*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	1.4	1	4	12.1	128	9	14
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.9	4	14	16.9	221	22	49
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	13.5	10	23	80.6	1,034	13	25
<u>Milk Products</u>							
Flavored milks	3.8	3	10	35.5	472	8	16
Milk-based meal replacement beverages or diet beverages	0.1	<1*	na	1.4	10	6*	8*
Yogurt	6.2	5	18	23.6	258	20	46
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	5.8	4	13	50.4	660	9	17
Fruit juices	6.8	5	14	56.8	753	9	18
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.5	<1	na	4.9	54	7	14*
<u>Other</u>							

Table B-4 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Children Aged 3 to 11 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant formula	<0.1	<1*	na	<0.1	1	22*	22*
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0.1	<1*	na	0.4	11	21*	60*
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0.1	<1*	na	0.3	3	36*	44*
"Junior type" desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	0.1	<1*	na	0.2	2	50*	69*

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-5 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Female Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	24	52	94.7	536	26	52
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.3	<1*	na	1.9	7	4*	7*
Fitness water and third quenchers, sports and isotonic drinks	1.4	<1	na	9.0	53	4	6*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	32.4	8*	24	43.3	228	18*	30*
Hot cereals for adults and children	2.4	1	na	5.0	38	12	21*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.3	<1*	na	2.1	22	3*	6*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	21.1	5	19	24.3	122	21	40
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	4.0	1*	na	4.1	20	24*	32*
Fruit pie filling	0.3	<1*	na	0.7	10	12*	20*
"Fruit prep"	0.5	<1*	na	3.0	23	4*	10*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	3.7	1	4*	17.2	68	5	9*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.3	1	na	9.7	42	11	21*
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	10.8	3	7	59.4	315	4	8
<u>Milk Products</u>							
Flavored milks	2.6	1	3	18.9	106	3	6
Milk-based meal replacement beverages or diet beverages	0.1	<1*	na	0.5	6	4*	6*
Yogurt	4.7	1	4*	12.8	52	9	18*
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	7.6	2	5	37.0	231	5	13
Fruit juices	3.4	1	3	25.3	188	3	6
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<1*	na	1.7	5	2*	3*

Table B-5 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Female Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	0	na	na	0	0	na	na
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior type" desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	<0.1	<1*	na	<0.1	1	15*	15*

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-6 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Male Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	29	67	92.5	524	31	67
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.4	<1*	na	4.0	8	3*	4*
Fitness water and third quenchers, sports and isotonic drinks	5.2	1	3	20.1	93	7	14
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	32.2	9	27	45.9	252	20	42
Hot cereals for adults and children	2.0	1*	na	3.9	28	15*	36*
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.1	<1*	na	0.9	11	3*	7*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	18.4	5	22	19.1	107	28	48
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	2.3	1*	na	2.5	12	26*	56*
Fruit pie filling	0.3	<1*	na	2.3	6	4*	9*
"Fruit prep"	0.6	<1*	na	2.0	14	9*	20*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.1	1	2*	12.4	52	5	9*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.1	1	na	6.9	50	17	32*
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	14.8	4	11	65.8	359	6	14
<u>Milk Products</u>							
Flavored milks	3.3	1	4	24.1	140	4	7
Milk-based meal replacement beverages or diet beverages	0.7	<1*	na	1.8	9	11*	15*
Yogurt	1.6	<1*	na	4.5	27	10*	20*
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	5.6	2	5	30.4	208	5	11
Fruit juices	5.8	2	5	40.9	223	4	9
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.3	<1*	na	1.4	4	6*	7*

Table B-6 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Male Teenagers Aged 12 to 19 Years Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	0	na	na	0	0	na	na
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior type" desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-7 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Women of Childbearing Age, 16 to 45 Years, Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	18	42	89.9	1,209	20	43
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.5	<1	na	2.6	31	4	7*
Fitness water and third quenchers, sports and isotonic drinks	1.2	<1	na	5.8	70	4	7*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	26.1	5	16	31.1	407	15	30
Hot cereals for adults and children	5.0	1	na	9.0	140	10	19
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.8	<1	na	6.2	86	2	5
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	23.2	4	13	21.9	258	19	40
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	2.9	1	na	3.5	53	15	30*
Fruit pie filling	0.7	<1	na	2.0	30	6	12*
"Fruit prep"	1.0	<1	na	4.1	61	4	16*
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	3.9	1	3	14.2	153	5	9
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	3.3	1	na	7.8	91	8	12
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	8.9	2	5	46.1	637	3	7
<u>Milk Products</u>							
Flavored milks	2.9	1	2	12.2	172	4	9
Milk-based meal replacement beverages or diet beverages	0.6	<1*	na	2.4	27	5*	8*
Yogurt	7.0	1	5	15.1	177	8	18
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	6.8	1	4	27.4	392	4	9
Fruit juices	5.1	1	3	27.8	407	3	6
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<1*	na	1.1	7	4*	5*

Table B-7 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Women of Childbearing Age, 16 to 45 Years, Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	0	na	na	0	0	na	na
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior type" desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	<0.1	<1*	na	<0.1	1	15*	15*

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-8 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Female Adults Aged 20 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	19	42	91.9	2,156	20	43
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.2	<1	na	1.4	32	3	6*
Fitness water and third quenchers, sports and isotonic drinks	0.9	<1	na	3.8	78	4	7*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	22.2	4	14	31.0	707	13	25
Hot cereals for adults and children	7.2	1	5	13.4	389	10	19
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	1.2	<1	na	7.5	175	3	7
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	22.9	4	14	24.9	544	17	38
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	5.0	1	na	5.4	132	17	32
Fruit pie filling	2.1	<1	na	5.1	99	8	17
"Fruit prep"	1.3	<1	na	6.3	149	4	9
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.8	1	2	10.7	209	5	10
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.5	1	1	10.7	242	8	14
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	8.3	2	5	48.8	1,172	3	7
<u>Milk Products</u>							
Flavored milks	1.9	<1	na	9.3	243	4	8
Milk-based meal replacement beverages or diet beverages	1.1	<1	na	4.2	77	5	11*
Yogurt	8.5	2	7	19.1	378	8	15
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	5.0	1	3	22.3	556	4	8
Fruit juices	4.5	1	3	28.4	724	3	6
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.1	<1*	na	0.6	12	4*	5*

Table B-8 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Female Adults Aged 20 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	0	na	na	0	0	na	na
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior type" desserts	<0.1	<1*	na	<0.1	1	51*	51*
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-9 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Male Adults Aged 20 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	19	46	86.7	1,833	22	48
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.7	<1	na	4.3	90	3	5
Fitness water and third quenchers, sports and isotonic drinks	2.0	<1	na	8.0	161	5	9
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	25.2	5	16	28.6	569	17	30
Hot cereals for adults and children	6.8	1	3	10.5	291	12	28
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.6	<1	0	4.3	95	3	6
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	23.3	4	17	24.1	443	18	33
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	5.0	1	na	4.8	97	20	38
Fruit pie filling	1.4	<1	na	4.4	85	6	10
"Fruit prep"	1.3	<1	na	7.1	133	3	7
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.5	<1	2	12.4	186	4	7
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	5.6	1	4	12.3	253	9	15
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	9.8	2	5	48.6	1,015	4	8
<u>Milk Products</u>							
Flavored milks	1.6	<1	na	8.7	176	3	6
Milk-based meal replacement beverages or diet beverages	1.0	<1	na	3.2	64	6	15*
Yogurt	4.6	1	3	11.1	201	8	15
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	4.1	1	3	19.1	448	4	8
Fruit juices	4.3	1	3	25.7	611	3	7
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	<0.1	<1*	na	0.6	9	1*	2*

Table B-9 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by Male Adults Aged 20 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	0	na	na	0	0	na	na
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior type" desserts	0	na	na	0	0	na	na
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-10 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by the Elderly Aged 65 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	24	53	92.6	928	26	54
<u>Beverages and Beverage Bases</u>							
Energy drinks	<0.1	<1*	na	0.1	3	3*	3*
Fitness water and third quenchers, sports and isotonic drinks	0.3	<1*	na	1.7	19	4*	6*
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	22.4	5	18	40.3	356	14	23
Hot cereals for adults and children	8.3	2	8	17.2	220	12	25
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.7	<1	na	5.9	62	3	7*
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	28.9	7	22	35.0	304	20	38
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	6.0	1	na	8.2	78	18	33*
Fruit pie filling	2.9	1	na	7.6	66	9	17*
"Fruit prep"	1.7	<1	1	11.4	87	4	10
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	1.0	<1	na	7.1	50	3	5*
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.9	1	4	14.1	138	9	16
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	8.9	2	6	60.6	570	4	8
<u>Milk Products</u>							
Flavored milks	0.9	<1	na	6.5	73	4	7*
Milk-based meal replacement beverages or diet beverages	1.1	<1	na	5.0	44	5	14*
Yogurt	5.0	1	6	16.1	135	8	13
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	2.7	1	3	19.5	196	3	7
Fruit juices	4.0	1	3	33.4	355	3	6
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.1	<1*	na	0.7	7	4*	5*

Table B-10 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by the Elderly Aged 65 Years and Over Within the U.S. (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
<u>Other</u>							
Infant formula	0	na	na	0	0	na	na
Follow-on formula	0	na	na	0	0	na	na
Meal replacement products	0	na	na	0	0	na	na
Growing-up (toddler) milks	0	na	na	0	0	na	na
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0	na	na	0	0	na	na
Yogurt and juice beverages identified as "baby" drinks	0	na	na	0	0	na	na
"Junior type" desserts	<0.1	<1*	na	0.1	1	51*	51*
Baby crackers, pretzels, cookies, and snack items	0	na	na	0	0	na	na

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Table B-11 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by the Total U.S. Population (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
All	100	32	76	91.1	6,930	36	80
<u>Beverages and Beverage Bases</u>							
Energy drinks	0.2	<1	na	2.4	138	3	6
Fitness water and third quenchers, sports and isotonic drinks	1.3	<1	na	7.5	539	6	12
<u>Breakfast Cereals</u>							
Ready-to-eat breakfast cereals for adults and children	22.7	7	23	35.3	2,751	21	45
Hot cereals for adults and children	4.7	2	3	10.9	943	14	30
<u>Dairy Product Analogs</u>							
Milk substitutes such as soy milk and imitation milks	0.7	<1	na	5.1	360	4	8
<u>Frozen Dairy Desserts and Mixes</u>							
Frozen desserts including ice creams and frozen yogurts, frozen novelties	17.5	6	20	24.9	1,679	23	47
<u>Gelatins, Puddings, and Fillings</u>							
Dairy-based puddings, custards, and mousses	3.8	1	na	4.9	356	25	57
Fruit pie filling	0.8	<1	na	3.8	217	7	15
"Fruit prep"	0.7	<1	na	5.7	378	4	10
<u>Grain Products and Pastas</u>							
Snack, breakfast, and meal replacement bars	2.0	1	2	11.7	669	5	11
<u>Jams and Jellies, Commercial</u>							
Jellies and jams, fruit preserves, fruit butters	4.4	1	3	11.8	858	12	26
<u>Milk, Whole and Skim</u>							
All acidophilus or fortified milks, non-fat and low-fat fluid milks, including fluid milk and reconstituted milk powder	12.1	4	9	54.3	4,232	7	15
<u>Milk Products</u>							
Flavored milks	2.2	1	2	13.4	1,199	5	10
Milk-based meal replacement beverages or diet beverages	0.6	<1	na	3.2	173	7	15
Yogurt	5.7	2	6	15.7	1,029	12	23
<u>Processed Fruits and Fruit Juices</u>							
Fruit drinks, including vitamin and mineral-fortified products	4.6	1	5	25.5	2,236	6	13
Fruit juices	5.0	2	5	31.9	2,744	5	11
<u>Sweet Sauces, Toppings, and Syrups</u>							
Syrups used to flavor milk beverages	0.2	<1	na	1.3	92	5	9
<u>Other</u>							

Table B-11 Estimated Daily Per Kilogram Body Weight Intake of 2'-FL from Individual Proposed Food-Uses by the Total U.S. Population (2013-2014 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90 th Percentile	%	n	Mean	90 th Percentile
Infant formula	6.5	2	na	1.0	223	222	401
Follow-on formula	<0.1	<1*	na	<0.1	1	48*	48*
Meal replacement products	0.2	<1*	na	0.1	17	48*	185*
Growing-up (toddler) milks	0.2	<1*	na	0.1	10	103*	122*
Ready-to-eat, ready-to-serve, hot cereals for babies for babies	0.2	<1*	na	0.1	18	76*	133*
Yogurt and juice beverages identified as "baby" drinks	1.7	1	na	0.5	90	104	204
"Junior type" desserts	0.8	<1	na	0.4	74	62	106*
Baby crackers, pretzels, cookies, and snack items	1.1	<1	na	0.7	121	50	110

2'-FL = 2'-fucosyllactose; bw = body weight; na = not available; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements.

Appendix C
Representative Food Codes for Proposed Food-Uses of 2'-FL in the U.S.
(2013-2014 NHANES Data)

Representative Food Codes for Proposed Food and Beverage-Uses of 2'-FL in the U.S. (U.S. NHANES 2013-2014)

Beverages and Beverage Bases

Energy Drinks

[2'-FL] = 0.08 g/100 g

93301216	Vodka and energy drink
95310200	Full Throttle Energy Drink
95310400	Monster Energy Drink
95310500	Mountain Dew AMP Energy Drink
95310550	No Fear Energy Drink
95310555	No Fear Motherload Energy Drink
95310560	NOS Energy Drink
95310600	Red Bull Energy Drink
95310700	Rockstar Energy Drink
95310750	SoBe Energize Energy Juice Drink
95310800	Vault Energy Drink
95311000	Energy Drink
95312400	Monster Energy Drink, Lo Carb
95312500	Mountain Dew AMP Energy Drink, sugar-free
95312550	No Fear Energy Drink, sugar-free
95312555	NOS Energy Drink, sugar-free
95312560	Ocean Spray Cran-Energy Cranberry Energy Juice Drink
95312600	Red Bull Energy Drink, sugar-free
95312700	Rockstar Energy Drink, sugar-free
95312800	Vault Zero Energy Drink
95312900	XS Energy Drink
95312905	XS Gold Plus Energy Drink
95313200	Energy drink, sugar free

Sports Drinks

[2'-FL] = 0.08 g/100 g

94210100	Propel Water
94220100	Propel Zero Water
94220110	Propel Zero Calcium Water
95320200	Gatorade G sports drink
95320500	Powerade sports drink
95321000	Sports drink, not further specified (NFS)
95322200	Gatorade G2 sports drink, low calorie
95322500	Powerade Zero sports drink, low calorie
95323000	Sports drink, low calorie
95330100	Fluid replacement, electrolyte solution
95330500	Fluid replacement, 5% glucose in water

Not Reconstituted Sports Drinks

(Adjusted for not being reconstituted, 16 g of powder to 240 mL of water)

[2'-FL] = 1.28 g/100 g

92900300	Sports drink, dry concentrate, not reconstituted
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Breakfast Cereals

Ready-to-Eat Breakfast Cereals for Adults and Children

[2'-FL] = 2.0 to 8.0 g/100 g

57000000	Cereal, NFS
57000050	Kashi cereal, not specified (NS) as to ready to eat or cooked
57000100	Oat cereal, NFS
57100100	Cereal, ready-to-eat, NFS
57101000	All-Bran
57102000	Alpen
57103000	Alpha-Bits
57103020	Alpha-bits with marshmallows
57103100	Apple Cinnamon Cheerios
57104000	Apple Jacks
57106050	Banana Nut Crunch Cereal (Post)
57106060	Banana Nut Cheerios
57106100	Basic 4
57106250	Berry Berry Kix
57106260	Berry Burst Cheerios
57106530	Blueberry Morning, Post
57107000	Booberry
57110000	All-Bran Bran Buds, Kellogg's (formerly Bran Buds)
57117000	Cap'n Crunch
57117500	Cap'n Crunch's Christmas Crunch
57119000	Cap'n Crunch's Crunch Berries
57120000	Cap'n Crunch's Peanut Butter Crunch
57123000	Cheerios
57124000	Chex cereal, NFS
57124030	Chex Chocolate
57124050	Chex Cinnamon
57124100	Chocolate Cheerios
57124200	Chocolate flavored frosted puffed corn cereal
57124300	Chocolate Lucky Charms
57124900	Cinnabon cereal
57125000	Cinnamon Toast Crunch
57125010	Cinnamon Toast Crunch Reduced Sugar
57125900	Honey Nut Clusters (formerly called Clusters)
57126000	Cocoa Krispies
57127000	Cocoa Pebbles
57128000	Cocoa Puffs
57128005	Cocoa Puffs, reduced sugar
57130000	Cookie-Crisp
57131000	Crunchy Corn Bran, Quaker
57132000	Corn Chex
57134000	Corn flakes, NFS
57135000	Corn flakes, Kellogg's
57137000	Corn Puffs
57139000	Count Chocula
57143000	Cracklin' Oat Bran
57143500	Cranberry Almond Crunch, Post
57144000	Crisp Crunch
57148000	Crispix
57148500	Crispy Brown Rice Cereal
57151000	Crispy Rice
57201900	Dora the Explorer Cereal

57206000	Familia
57206700	Fiber One
57206705	Fiber One Caramel Delight
57206710	Fiber One Honey Clusters
57206715	Fiber One Raisin Bran Clusters
57206800	Fiber 7 Flakes, Health Valley
57207000	Bran Flakes, NFS (formerly 40% Bran Flakes, NFS)
57208000	All-Bran Complete Wheat Flakes, Kellogg's
57209000	Natural Bran Flakes, Post (formerly called 40% Bran Flakes, Post)
57211000	Frankenberry
57213000	Froot Loops
57213010	Froot Loops Marshmallow
57213850	Frosted Cheerios
57214000	Frosted Mini-Wheats
57214100	Frosted Wheat Bites
57215000	Frosty O's
57216000	Frosted rice, NFS
57218000	Frosted Rice Krispies, Kellogg's
57219000	Fruit & Fibre (fiber), NFS
57221000	Fruit & Fibre (fiber) with dates, raisins, and walnuts
57221700	Fruit Rings, NFS
57221800	Fruit Whirls
57221810	Fruity Cheerios
57223000	Fruity Pebbles
57224000	Golden Grahams
57227000	Granola, NFS
57228000	Granola, homemade
57229000	Granola, lowfat, Kellogg's
57229500	Granola with Raisins, lowfat, Kellogg's
57230000	Grape-Nuts
57231000	Grape-Nuts Flakes
57231100	Grape-Nuts Trail Mix Crunch
57231200	Great Grains, Raisin, Date, and Pecan Whole Grain Cereal, Post
57231250	Great Grains Double Pecan Whole Grain Cereal, Post
57237100	Honey Bunches of Oats Honey Roasted Cereal
57237200	Honey Bunches of Oats with Vanilla Clusters, Post
57237300	Honey Bunches of Oats with Almonds, Post
57237310	Honey Bunches of Oats with Pecan Bunches
57237900	Honey Bunches of Oats Just Bunches
57238000	Honeycomb, plain
57239000	Honeycomb, strawberry
57239100	Honey Crunch Corn Flakes, Kellogg's
57240100	Honey Nut Chex
57241000	Honey Nut Cheerios
57241200	Honey Nut Shredded Wheat, Post
57243000	Honey Smacks, Kellogg's (formerly Smacks; Honey Smacks)
57301500	Kashi, Puffed
57301505	Kashi Autumn Wheat
57301510	Kashi GOLEAN
57301511	Kashi GOLEAN Crunch
57301512	Kashi GOLEAN Crunch Honey Almond Flax
57301520	Kashi Good Friends
57301530	Kashi Heart to Heart Honey Toasted Oat
57301535	Kashi Heart to Heart Oat Flakes and Blueberry Clusters

57301540	Kashi Honey Sunshine
57302100	King Vitaman
57303100	Kix
57303105	Honey Kix
57304100	Life (plain and cinnamon)
57305100	Lucky Charms
57305150	Frosted oat cereal with marshmallows
57305160	Malt-O-Meal Blueberry Muffin Tops
57305165	Malt-O-Meal Cinnamon Toasters
57305170	Malt-O-Meal Coco-Roos
57305174	Malt-O-Meal Colossal Crunch
57305175	Malt-O-Meal Cocoa Dyno-Bites
57305180	Malt-O-Meal Corn Bursts
57305200	Malt-O-Meal Crispy Rice
57305210	Malt-O-Meal Frosted Flakes
57305215	Malt-O-Meal Frosted Mini Spooners
57305300	Malt-O-Meal Fruity Dyno-Bites
57305400	Malt-O-Meal Honey Graham Squares
57305500	Malt-O-Meal Honey and Nut Toasty O's
57305600	Malt-O-Meal Marshmallow Mateys
57306100	Malt-O-Meal Puffed Rice
57306120	Malt-O-Meal Puffed Wheat
57306130	Malt-O-Meal Raisin Bran
57306500	Malt-O-Meal Golden Puffs (formerly Sugar Puffs)
57306700	Malt-O-Meal Toasted Oat Cereal
57306800	Malt-O-meal Tootie Fruities
57307010	Maple Pecan Crunch Cereal, Post
57307500	Millet, puffed
57308150	Mueslix cereal, NFS
57308190	Muesli, dried fruit and nuts (formerly Muesli with raisins, dates, and almonds)
57308400	MultiGrain Cheerios
57309100	Nature Valley Granola, with fruit and nuts
57316200	Nutty Nuggets, Ralston Purina
57316300	Oat Bran Flakes, Health Valley
57316380	Oat Cluster Cheerios Crunch
57316450	Oatmeal Crisp with Almonds
57316500	Oatmeal Crisp, Raisin (formerly Oatmeal Raisin Crisp)
57316710	Oh's, Honey Graham
57319000	100% Natural Cereal, plain, Quaker
57320500	100 % Natural Cereal, with oats, honey and raisins, Quaker
57321500	100 % Natural Wholegrain Cereal with raisins, lowfat, Quaker
57321900	Organic Flax Plus, Nature's Path
57321905	Organic Flax Plus, Pumpkin Granola, Nature's Path
57323000	Sweet Crunch, Quaker (formerly called Popeye)
57325000	Product 19
57326000	Puffins Cereal
57327450	Quaker Oat Bran Cereal
57327500	Quaker Oatmeal Squares (formerly Quaker Oat Squares)
57328000	Quisp
57329000	Raisin bran, NFS
57330000	Raisin Bran, Kellogg's
57330010	Raisin Bran Crunch, Kellogg's
57331000	Raisin Bran, Post
57332050	Raisin Bran, Total

57332100	Raisin Nut Bran
57335550	Reese's Peanut Butter Puffs cereal
57336000	Rice Chex
57337000	Rice Flakes, NFS
57339000	Rice Krispies, Kellogg's
57339500	Rice Krispies Treats Cereal, Kellogg's
57340000	Rice, puffed
57341000	Shredded Wheat'N Bran
57341200	Smart Start Strong Heart Antioxidants Cereal, Kellogg's
57344000	Special K
57344001	Special K Blueberry
57344005	Special K Chocolatey Delight
57344007	Special K Low Fat Granola
57344010	Special K Red Berries
57344015	Special K Fruit & Yogurt
57344020	Special K Vanilla Almond
57344025	Special K Cinnamon Pecan, Kellogg's
57346500	Oatmeal Honey Nut Heaven, Quaker (formerly Toasted Oatmeal, Honey Nut)
57347000	Corn Pops
57348000	Frosted corn flakes, NFS
57349000	Frosted Flakes, Kellogg's
57349020	Reduced Sugar Frosted Flakes Cereal, Kellogg's
57355000	Golden Crisp (Formerly called Super Golden Crisp)
57401100	Toasted oat cereal
57406100	Total
57407100	Trix
57407110	Trix, reduced sugar
57408100	Uncle Sam Cereal (formerly Uncle Sam's Hi Fiber Cereal)
57409100	Waffle Crisp, Post
57410000	Weetabix Whole Wheat Cereal
57411000	Wheat Chex
57412000	Wheat germ, plain
57413000	Wheat germ, with sugar and honey
57416000	Wheat, puffed, plain
57416010	Wheat, puffed, presweetened with sugar
57417000	Shredded Wheat, 100%
57418000	Wheaties
57419000	Yogurt Burst Cheerios

Hot Cereals for Adults and Children

[2'-FL] = 0.48 g/100 g

56200300	Cereal, cooked, NFS
56200350	Cereal, cooked, instant, NS as to grain
56200390	Barley, cooked, NS as to fat added in cooking
56200400	Barley, cooked, fat not added in cooking
56200490	Buckwheat groats, cooked, NS as to fat added in cooking
56200500	Buckwheat groats, cooked, fat not added in cooking
56200510	Buckwheat groats, cooked, fat added in cooking
56200990	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, NS as to fat added in cooking
56201000	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat not added in cooking
56201010	Grits, cooked, corn or hominy, regular, fat not added in cooking
56201020	Grits, cooked, corn or hominy, regular, fat added in cooking
56201030	Grits, cooked, corn or hominy, regular, NS as to fat added in cooking
56201040	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat added in cooking

56201060 Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, NS as to fat added in cooking

56201061 Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, fat not added in cooking

56201062 Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, fat added in cooking

56201070 Grits, cooked, corn or hominy, with cheese, regular, NS as to fat added in cooking

56201071 Grits, cooked, corn or hominy, with cheese, regular, fat not added in cooking

56201072 Grits, cooked, corn or hominy, with cheese, regular, fat added in cooking

56201080 Grits, cooked, corn or hominy, with cheese, quick, NS as to fat added in cooking

56201081 Grits, cooked, corn or hominy, with cheese, quick, fat not added in cooking

56201082 Grits, cooked, corn or hominy, with cheese, quick, fat added in cooking

56201090 Grits, cooked, corn or hominy, with cheese, instant, NS as to fat added in cooking

56201091 Grits, cooked, corn or hominy, with cheese, instant, fat not added in cooking

56201092 Grits, cooked, corn or hominy, with cheese, instant, fat added in cooking

56201110 Grits, cooked, corn or hominy, quick, fat not added in cooking

56201120 Grits, cooked, corn or hominy, quick, fat added in cooking

56201130 Grits, cooked, corn or hominy, quick, NS as to fat added in cooking

56201210 Grits, cooked, corn or hominy, instant, fat not added in cooking

56201220 Grits, cooked, corn or hominy, instant, fat added in cooking

56201230 Grits, cooked, corn or hominy, instant, NS as to fat added in cooking

56201240 Grits, cooked, flavored, corn or hominy, instant, fat not added in cooking

56201250 Grits, cooked, flavored, corn or hominy, instant, fat added in cooking

56201260 Grits, cooked, flavored, corn or hominy, instant, NS as to fat added in cooking

56201296 Grits, cooked, corn or hominy, NS as to regular, quick, or instant, made with milk, fat added in cooking

56201298 Grits, cooked, corn or hominy, NS as to regular, quick, or instant, made with milk, fat not added in cooking

56201300 Grits, cooked, corn or hominy, NS as to regular, quick, or instant, made with milk, NS as to fat added in cooking

56201320 Grits, cooked, corn or hominy, regular, made with milk, fat added in cooking

56201322 Grits, cooked, corn or hominy, regular, made with milk, fat not added in cooking

56201324 Grits, cooked, corn or hominy, regular, made with milk, NS as to fat added in cooking

56201330 Grits, cooked, corn or hominy, quick, made with milk, fat added in cooking

56201332 Grits, cooked, corn or hominy, quick, made with milk, fat not added in cooking

56201334 Grits, cooked, corn or hominy, quick, made with milk, NS as to fat added in cooking

56201340 Grits, cooked, corn or hominy, instant, made with milk, fat added in cooking

56201342 Grits, cooked, corn or hominy, instant, made with milk, fat not added in cooking

56201344 Grits, cooked, corn or hominy, instant, made with milk, NS as to fat added in cooking

56201510 Cornmeal mush, made with water

56201520 Cornmeal mush, fried

56201530 Cornmeal mush, made with milk

56201540 Cornmeal, made with milk and sugar, Puerto Rican Style (Harina de maiz)

56201600 Cornmeal, lime-treated, cooked (Masa harina)

56201700 Cornstarch with milk, eaten as a cereal (2 tbsp cornstarch in 2-1/2 cups milk)

56201990 Millet, cooked, NS as to fat added in cooking

56202000 Millet, cooked, fat not added in cooking

56202100 Millet, cooked, fat added in cooking

56202900 Oatmeal, cooked, from fast food

56202960 Oatmeal, cooked, NS as to regular, quick or instant; NS as to fat added in cooking

56202970 Oatmeal, cooked, quick (1 or 3 minutes), NS as to fat added in cooking

56202980 Oatmeal, cooked, regular, NS as to fat added in cooking

56203000 Oatmeal, cooked, NS as to regular, quick or instant, fat not added in cooking

56203010 Oatmeal, cooked, regular, fat not added in cooking

56203020 Oatmeal, cooked, quick (1 or 3 minutes), fat not added in cooking

56203030 Oatmeal, cooked, instant, fat not added in cooking
 56203040 Oatmeal, cooked, NS as to regular, quick, or instant, fat added in cooking
 56203050 Oatmeal, cooked, regular, fat added in cooking
 56203060 Oatmeal, cooked, quick (1 or 3 minutes), fat added in cooking
 56203070 Oatmeal, cooked, instant, fat added in cooking
 56203080 Oatmeal, cooked, instant, NS as to fat added in cooking
 56203110 Oatmeal with maple flavor, cooked
 56203200 Oatmeal with fruit, cooked
 56203210 Oatmeal, NS as to regular, quick, or instant, made with milk, fat not added in cooking
 56203211 Oatmeal, cooked, regular, made with milk, fat not added in cooking
 56203212 Oatmeal, cooked, quick (1 or 3 minutes), made with milk, fat not added in cooking
 56203213 Oatmeal, cooked, instant, made with milk, fat not added in cooking
 56203220 Oatmeal, NS as to regular, quick, or instant, made with milk, fat added in cooking
 56203221 Oatmeal, cooked, regular, made with milk, fat added in cooking
 56203222 Oatmeal, cooked, quick (1 or 3 minutes), made with milk, fat added in cooking
 56203223 Oatmeal, cooked, instant, made with milk, fat added in cooking
 56203230 Oatmeal, NS as to regular, quick, or instant, made with milk, NS as to fat added in cooking
 56203231 Oatmeal, cooked, regular, made with milk, NS as to fat added in cooking
 56203232 Oatmeal, cooked, quick (1 or 3 minutes), made with milk, NS as to fat added in cooking
 56203233 Oatmeal, cooked, instant, made with milk, NS as to fat added in cooking
 56203540 Oatmeal, made with milk and sugar, Puerto Rican style
 56203600 Oatmeal, multigrain, cooked, NS as to fat added in cooking
 56203610 Oatmeal, multigrain, cooked, fat not added in cooking
 56203620 Oatmeal, multigrain, cooked, fat added in cooking
 56206970 Wheat, cream of, cooked, quick, NS as to fat added in cooking
 56206980 Wheat, cream of, cooked, regular, NS as to fat added in cooking
 56206990 Wheat, cream of, cooked, NS as to regular, quick, or instant, NS as to fat added in cooking
 56207000 Wheat, cream of, cooked, NS as to regular, quick, or instant, fat not added in cooking
 56207010 Wheat, cream of, cooked, regular, fat not added in cooking
 56207020 Wheat, cream of, cooked, quick, fat not added in cooking
 56207030 Wheat, cream of, cooked, instant, fat not added in cooking
 56207050 Wheat, cream of, cooked, made with milk and sugar, Puerto Rican style
 56207060 Wheat, cream of, cooked, instant, fat added in cooking
 56207070 Wheat, cream of, cooked, instant, NS as to fat added in cooking
 56207080 Wheat, cream of, cooked, NS as to regular, quick, or instant, fat added in cooking
 56207082 Wheat, cream of, cooked, NS as to regular, quick, or instant, made with milk, fat added in cooking
 56207083 Wheat, cream of, cooked, NS as to regular, quick, or instant, made with milk, fat not added in cooking
 56207084 Wheat, cream of, cooked, NS as to regular, quick, or instant, made with milk, NS as to fat added in cooking
 56207086 Wheat, cream of, cooked, regular, made with milk, fat added in cooking
 56207087 Wheat, cream of, cooked, regular, made with milk, fat not added in cooking
 56207088 Wheat, cream of, cooked, regular, made with milk, NS as to fat added in cooking
 56207091 Wheat, cream of, cooked, quick, made with milk, fat added in cooking
 56207092 Wheat, cream of, cooked, quick, made with milk, fat not added in cooking
 56207093 Wheat, cream of, cooked, quick, made with milk, NS as to fat added in cooking
 56207094 Wheat, cream of, cooked, instant, made with milk, fat added in cooking
 56207095 Wheat, cream of, cooked, instant, made with milk, fat not added in cooking
 56207096 Wheat, cream of, cooked, instant, made with milk, NS as to fat added in cooking
 56207100 Wheat, rolled, cooked, fat not added in cooking
 56207110 Bulgur, cooked or canned, fat not added in cooking
 56207120 Bulgur, cooked or canned, fat added in cooking
 56207130 Bulgur, cooked or canned, NS as to fat added in cooking
 56207140 Wheat, rolled, cooked, NS as to fat added in cooking
 56207190 Whole wheat cereal, cooked, NS as to fat added in cooking

56207200	Whole wheat cereal, cooked, fat not added in cooking
56207210	Whole wheat cereal, cooked, fat added in cooking
56207212	Whole wheat cereal, cooked, made with milk
56207220	Wheat, cream of, cooked, regular, fat added in cooking
56207230	Wheat, cream of, cooked, quick, fat added in cooking
56207300	Whole wheat cereal, wheat and barley, cooked, fat not added in cooking
56207330	Whole wheat cereal, wheat and barley, cooked, fat added in cooking
56207340	Whole wheat cereal, wheat and barley, cooked, NS as to fat added in cooking
56207342	Whole wheat cereal, wheat and barley, cooked, made with milk
56207350	Wheat cereal, chocolate flavored, cooked, made with milk
56207360	Wheat cereal, chocolate flavored, cooked, fat not added in cooking
56207365	Wheat cereal, chocolate flavored, cooked, fat added in cooking
56207370	Wheat cereal, chocolate flavored, cooked, NS as to fat added in cooking
56208500	Oat bran cereal, cooked, fat not added in cooking
56208510	Oat bran cereal, cooked, fat added in cooking
56208520	Oat bran cereal, cooked, NS as to fat added in cooking
56208530	Oat bran cereal, cooked, made with milk, fat not added in cooking
56208540	Oat bran cereal, cooked, made with milk, fat added in cooking
56208550	Oat bran cereal, cooked, made with milk, NS as to fat added in cooking
56209000	Rye, cream of, cooked
56210000	Nestum cereal

Uncooked Hot Cereals

{Adjusted for not being cooked, approximately 15 g uncooked oats or bran into 150 mL of milk}

[2'-FL] = 4.8 g/100 g

57601100	Wheat bran, unprocessed
57602100	Oats, raw
57602500	Oat bran, uncooked

Dairy Product Analogs

Milk Substitutes

[2'-FL] = 0.12 g/100 g

11320000	Soy milk
11320100	Soy milk, light
11320200	Soy milk, nonfat
11321000	Soy milk, chocolate
11321100	Soy milk, light, chocolate
11321200	Soy milk, nonfat, chocolate
11340000	Imitation milk, non-soy, sweetened
11350000	Almond milk, sweetened
11350010	Almond milk, sweetened, chocolate
11350020	Almond milk, unsweetened
11350030	Almond milk, unsweetened, chocolate
11360000	Rice milk
11370000	Coconut milk

Mixtures Containing Milk Substitutes

(Adjusted for a Milk Substitute content ranging from 42.2 to 95.7%)

[2'-FL] = 0.05 to 0.11 g/100 g

11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk
11512120	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk and whipped cream

11513310	Chocolate milk, made from dry mix with non-dairy milk
11513375	Chocolate milk, made from reduced sugar mix with non-dairy milk
11513385	Nesquik, chocolate milk, made from dry mix with non-dairy milk
11513395	Nesquik, chocolate milk, made from no sugar added dry mix with non-dairy milk
11514150	Hot chocolate / Cocoa, made with dry mix and non-dairy milk
11514360	Hot chocolate / Cocoa, made with no sugar added dry mix and non-dairy milk
11519215	Strawberry milk, non-dairy
92101903	Coffee, Latte, with non-dairy milk
92101906	Coffee, Latte, with non-dairy milk, flavored
92101913	Coffee, Latte, decaffeinated, with non-dairy milk
92101919	Coffee, Latte, decaffeinated, with non-dairy milk, flavored
92101923	Frozen coffee drink, with non-dairy milk
92101928	Frozen coffee drink, with non-dairy milk and whipped cream
92101933	Frozen coffee drink, decaffeinated, with non-dairy milk
92101938	Frozen coffee drink, decaffeinated, with non-dairy milk and whipped cream
92101960	Coffee, Cafe Mocha, with non-dairy milk
92101975	Coffee, Cafe Mocha, decaffeinated, with non-dairy milk
92102020	Frozen mocha coffee drink, with non-dairy milk
92102050	Frozen mocha coffee drink, with non-dairy milk and whipped cream
92102080	Frozen mocha coffee drink, decaffeinated, with non-dairy milk
92102110	Frozen mocha coffee drink, decaffeinated, with non-dairy milk and whipped cream
92102502	Coffee, Iced Latte, with non-dairy milk
92102505	Coffee, Iced Latte, with non-dairy milk, flavored
92102512	Coffee, Iced Latte, decaffeinated, with non-dairy milk
92102515	Coffee, Iced Latte, decaffeinated, with non-dairy milk, flavored
92102602	Coffee, Iced Caf� Mocha, with non-dairy milk
92102612	Coffee, Iced Caf� Mocha, decaffeinated, with non-dairy milk
92161002	Coffee, Cappuccino, with non-dairy milk
92162002	Coffee, Cappuccino, decaffeinated, with non-dairy milk
11513750	Chocolate milk, made from syrup with non-dairy milk
11513805	Chocolate milk, made from light syrup with non-dairy milk
11513855	Chocolate milk, made from sugar free syrup with non-dairy milk

Frozen Dairy Desserts and Mixes

Frozen Desserts

[2'-FL] = 1.7 g/100 g

11459990	Yogurt, frozen, NS as to flavor, NS as to type of milk
11460000	Yogurt, frozen, flavors other than chocolate, NS as to type of milk
11460100	Yogurt, frozen, chocolate, NS as to type of milk
11460150	Yogurt, frozen, NS as to flavor, lowfat milk
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460190	Yogurt, frozen, NS as to flavor, nonfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low-calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11460420	Yogurt, frozen, NS as to flavor, whole milk
11460430	Yogurt, frozen, chocolate, whole milk
11460440	Yogurt, frozen, flavors other than chocolate, whole milk

11461000 Yogurt, frozen, chocolate-coated
 11461200 Yogurt, frozen, sandwich
 11461250 Yogurt, frozen, cone, chocolate
 11461260 Yogurt, frozen, cone, flavors other than chocolate
 11461270 Yogurt, frozen, cone, flavors other than chocolate, lowfat milk
 11461280 Yogurt, frozen, cone, chocolate, lowfat milk
 13110000 Ice cream, NFS
 13110100 Ice cream, regular, flavors other than chocolate
 13110110 Ice cream, regular, chocolate
 13110120 Ice cream, rich, flavors other than chocolate
 13110130 Ice cream, rich, chocolate
 13110140 Ice cream, rich, NS as to flavor
 13110200 Ice cream, soft serve, flavors other than chocolate
 13110210 Ice cream, soft serve, chocolate
 13110220 Ice cream, soft serve, NS as to flavor
 13110310 Ice cream, no sugar added, NS as to flavor
 13110320 Ice cream, no sugar added, flavors other than chocolate
 13110330 Ice cream, no sugar added, chocolate
 13120050 Ice cream bar or stick, not chocolate covered or cake covered
 13120100 Ice cream bar or stick, chocolate covered
 13120110 Ice cream bar or stick, chocolate or caramel covered, with nuts
 13120120 Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering
 13120121 Ice cream bar or stick, rich ice cream, thick chocolate covering
 13120130 Ice cream bar or stick, rich ice cream, chocolate covered, with nuts
 13120140 Ice cream bar or stick, chocolate ice cream, chocolate covered
 13120300 Ice cream bar, cake covered
 13120310 Ice cream bar, stick or nugget, with crunch coating
 13120400 Ice cream bar or stick with fruit
 13120500 Ice cream sandwich
 13120550 Ice cream cookie sandwich
 13120700 Ice cream cone with nuts, flavors other than chocolate
 13120710 Ice cream cone, chocolate covered, with nuts, flavors other than chocolate
 13120720 Ice cream cone, chocolate covered or dipped, flavors other than chocolate
 13120730 Ice cream cone, no topping, flavors other than chocolate
 13120740 Ice cream cone, no topping, NS as to flavor
 13120750 Ice cream cone with nuts, chocolate ice cream
 13120760 Ice cream cone, chocolate covered or dipped, chocolate ice cream
 13120770 Ice cream cone, no topping, chocolate ice cream
 13120780 Ice cream cone, chocolate covered, with nuts, chocolate ice cream
 13120790 Ice cream sundae cone
 13120800 Ice cream soda, flavors other than chocolate
 13120810 Ice cream soda, chocolate
 13121000 Ice cream sundae, NS as to topping, with whipped cream
 13121100 Ice cream sundae, fruit topping, with whipped cream
 13121200 Ice cream sundae, prepackaged type, flavors other than chocolate
 13121300 Ice cream sundae, chocolate or fudge topping, with whipped cream
 13121400 Ice cream sundae, not fruit or chocolate topping, with whipped cream
 13121500 Ice cream sundae, fudge topping, with cake, with whipped cream
 13122100 Ice cream pie, no crust
 13122500 Ice cream pie, with cookie crust, fudge topping, and whipped cream
 13126000 Ice cream, fried
 13127000 Dippin' Dots, flash frozen ice cream snacks, flavors other than chocolate
 13127010 Dippin' Dots, flash frozen ice cream snacks, chocolate
 13130100 Light ice cream, NS as to flavor (formerly ice milk)

13130300	Light ice cream, flavors other than chocolate (formerly ice milk)
13130310	Light ice cream, chocolate (formerly ice milk)
13130320	Light ice cream, no sugar added, NS as to flavor
13130330	Light ice cream, no sugar added, flavors other than chocolate
13130340	Light ice cream, no sugar added, chocolate
13130590	Light ice cream, soft serve, NS as to flavor (formerly ice milk)
13130600	Light ice cream, soft serve, flavors other than chocolate (formerly ice milk)
13130610	Light ice cream, soft serve, chocolate (formerly ice milk)
13130620	Light ice cream, soft serve cone, flavors other than chocolate (formerly ice milk)
13130630	Light ice cream, soft serve cone, chocolate (formerly ice milk)
13130640	Light ice cream, soft serve cone, NS as to flavor (formerly ice milk)
13130700	Light ice cream, soft serve, blended with candy or cookies
13135000	Ice cream sandwich, made with light ice cream, flavors other than chocolate
13135010	Ice cream sandwich, made with light chocolate ice cream
13136000	Ice cream sandwich, made with light, no sugar added ice cream
13140100	Light ice cream, bar or stick, chocolate-coated (formerly ice milk)
13140110	Light ice cream, bar or stick, chocolate covered, with nuts (formerly ice milk)
13140450	Light ice cream, cone, NFS (formerly ice milk)
13140500	Light ice cream, cone, flavors other than chocolate (formerly ice milk)
13140550	Light ice cream, cone, chocolate (formerly ice milk)
13140570	Light ice cream, no sugar added, cone, NS as to flavor
13140575	Light ice cream, no sugar added, cone, flavors other than chocolate
13140580	Light ice cream, no sugar added, cone, chocolate
13140600	Light ice cream, sundae, soft serve, chocolate or fudge topping, with whipped cream (formerly ice milk)
13140630	Light ice cream, sundae, soft serve, fruit topping, with whipped cream (formerly ice milk)
13140650	Light ice cream, sundae, soft serve, not fruit or chocolate topping, with whipped cream (formerly ice milk)
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping (without whipped cream) (formerly ice milk)
13140670	Light ice cream, sundae, soft serve, fruit topping (without whipped cream) (formerly ice milk)
13140680	Light ice cream, sundae, soft serve, not fruit or chocolate topping (without whipped cream) (formerly ice milk)
13140700	Light ice cream, creamsicle or dreamsicle (formerly ice milk)
13140710	Light ice cream, creamsicle or dreamsicle, no sugar added
13140900	Light ice cream, fudgesicle (formerly ice milk)
13142000	Milk dessert bar or stick, frozen, with coconut
13150000	Sherbet, all flavors
13160150	Fat free ice cream, no sugar added, chocolate
13160160	Fat free ice cream, no sugar added, flavors other than chocolate
13160400	Fat free ice cream, flavors other than chocolate
13160410	Fat free ice cream, chocolate
13160420	Fat free ice cream, NS as to flavor
13161000	Milk dessert bar, frozen, made from lowfat milk
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk
13161520	Milk dessert sandwich bar, frozen, with low-calorie sweetener, made from lowfat milk
13161600	Milk dessert bar, frozen, made from lowfat milk and low calorie sweetener
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate-coated (formerly ice milk)
13170000	Baked Alaska
91611050	Ice pop filled with ice cream, all flavor varieties

Gelatins, Puddings, and Fillings

Dairy-Based Puddings, Custards, and Mousses

[2'-FL] = 1.7 g/100 g

13200110	Pudding, NFS
13210110	Pudding, bread
13210150	Puerto Rican bread pudding made with evaporated milk
13210160	Diplomat pudding, Puerto Rican style (Budin Diplomatico)
13210180	Pudding, Mexican bread (Capirotada)
13210190	Pudding, Mexican bread (Capirotada), lower fat
13210220	Pudding, chocolate, NS as to from dry mix or ready-to-eat
13210250	Pudding, chocolate, low calorie, containing artificial sweetener, NS as to from dry mix or ready-to-eat
13210260	Rice flour cream, Puerto Rican style (manjar blanco)
13210270	Custard, Puerto Rican style (Maicena, Natilla)
13210280	Pudding, flavors other than chocolate, NS as to from dry mix or ready-to-eat
13210290	Pudding, flavors other than chocolate, low calorie, containing artificial sweetener, NS as to from dry mix or ready-to-eat
13210300	Custard
13210350	Flan
13210410	Pudding, rice
13210450	Pudding, rice flour, with nuts (Indian dessert)
13210520	Pudding, tapioca, made from dry mix, made with milk
13210530	Pudding, tapioca, chocolate, made with milk
13210610	Pudding, coconut
13210710	Pudding, Indian (milk, molasses and cornmeal-based pudding)
13210750	Pudding, pumpkin
13210810	Puerto Rican pumpkin pudding (Flan de calabaza)
13210820	Fresh corn custard, Puerto Rican style (Mazamorra, Mundo Nuevo)
13220110	Pudding, flavors other than chocolate, prepared from dry mix, milk added
13220120	Pudding, chocolate, prepared from dry mix, milk added
13220210	Pudding, flavors other than chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added
13220220	Pudding, chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added
13220230	Pudding, ready-to-eat, chocolate, reduced fat
13220235	Pudding, ready-to-eat, chocolate, fat free
13220240	Pudding, ready-to-eat, flavors other than chocolate, reduced fat
13220245	Pudding, ready-to-eat, flavors other than chocolate, fat free
13230110	Pudding, ready-to-eat, flavors other than chocolate
13230120	Pudding, ready-to-eat, low calorie, containing artificial sweetener, flavors other than chocolate
13230130	Pudding, ready-to-eat, chocolate
13230140	Pudding, ready-to-eat, low calorie, containing artificial sweetener, chocolate
13230200	Pudding, ready-to-eat, chocolate and non-chocolate flavors combined
13230500	Pudding, ready-to-eat, tapioca
13230510	Pudding, ready-to-eat, tapioca, fat free
13241000	Pudding, with fruit and vanilla wafers
13250000	Mousse, chocolate
13250100	Mousse, not chocolate
13250200	Mousse, chocolate, lowfat, reduced calorie, prepared from dry mix, water added
13252100	Coconut custard, Puerto Rican style (Flan de coco)
13252200	Milk dessert or milk candy, Puerto Rican style (Dulce de leche)
13252500	Barfi or Burfi, Indian dessert, made from milk and/or cream and/or Ricotta cheese
13252600	Tiramisu
91501010	Gelatin dessert
91501015	Gelatin snacks
91501020	Gelatin dessert with fruit

91501030	Gelatin dessert with whipped cream
91501040	Gelatin dessert with fruit and whipped cream
91501050	Gelatin dessert with cream cheese
91501060	Gelatin dessert with sour cream
91501070	Gelatin dessert with fruit and sour cream
91501080	Gelatin dessert with fruit and cream cheese
91501090	Gelatin dessert with fruit, vegetable, and nuts
91501100	Gelatin salad with vegetables
91501110	Gelatin dessert with fruit and whipped topping
91501120	Gelatin dessert with fruit and vegetables
91511010	Gelatin dessert, dietetic, sweetened with low calorie sweetener
91511020	Gelatin dessert, dietetic, with fruit, sweetened with low calorie sweetener
91511030	Gelatin dessert, dietetic, with whipped topping, sweetened with low calorie sweetener
91511050	Gelatin dessert, dietetic, with cream cheese, sweetened with low calorie sweetener
91511060	Gelatin dessert, dietetic, with sour cream, sweetened with low calorie sweetener
91511070	Gelatin dessert, dietetic, with fruit and sour cream, sweetened with low calorie sweetener
91511080	Gelatin dessert, dietetic, with fruit and cream cheese, sweetened with low calorie sweetener
91511090	Gelatin dessert, dietetic, with fruit and vegetable(s), sweetened with low calorie sweetener
91511100	Gelatin salad, dietetic, with vegetables, sweetened with low calorie sweetener
91511110	Gelatin dessert, dietetic, with fruit and whipped topping, sweetened with low calorie sweetener
91512010	Danish dessert pudding
91520100	Yookan (Yokan), a Japanese dessert made with bean paste and sugar
91550100	Coconut cream cake, Puerto Rican style (Bien me sabe, "Tastes good to me")
91550300	Pineapple custard, Puerto Rican style (Flan de pina)
91560100	Haupia (coconut pudding)
91580000	Gelatin, frozen, whipped, on a stick

**Mixtures Containing Dairy-Based Puddings, Custards, and Mousses
(Adjusted for a Gelatin Dessert Content of 9.5 to 42.9%)**

[2'-FL] = 0.16 to 0.73 g/100 g

14610200	Cheese, cottage cheese, with gelatin dessert
14610210	Cheese, cottage cheese, with gelatin dessert and fruit
14610250	Cheese, cottage cheese, with gelatin dessert and vegetables

Fruit Pie Filling

[2'-FL] = 1.4 g/100 g

61113500	Lemon pie filling
63113030	Cherry pie filling
63113050	Cherry pie filling, low calorie
63203700	Blueberry pie filling

**Mixtures Containing Fruit Pie Filling
(Adjusted for a Pie Filling Content of 35.7% to 61.2%)**

[2'-FL] = 0.50 to 0.86 g/100 g

53300100	Pie, NFS
53300170	Pie, individual size or tart, NFS
53300180	Pie, fried, NFS
53301000	Pie, apple, two crust
53301070	Pie, apple, individual size or tart
53301080	Pie, apple, fried pie
53301500	Pie, apple, one crust
53301750	Pie, apple, diet
53302000	Pie, apricot, two crust
53302070	Pie, apricot, individual size or tart

53302080 Pie, apricot, fried pie
 53303000 Pie, blackberry, two crust
 53303070 Pie, blackberry, individual size or tart
 53303500 Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; two crust
 53303510 Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; one crust
 53303570 Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry, individual size or tart

 53304000 Pie, blueberry, two crust
 53304050 Pie, blueberry, one crust
 53304070 Pie, blueberry, individual size or tart
 53305000 Pie, cherry, two crust
 53305010 Pie, cherry, one crust
 53305070 Pie, cherry, individual size or tart
 53305080 Pie, cherry, fried pie
 53305700 Pie, lemon (not cream or meringue)
 53305720 Pie, lemon (not cream or meringue), individual size or tart
 53305750 Pie, lemon, fried pie
 53306000 Pie, mince, two crust
 53306070 Pie, mince, individual size or tart
 53307000 Pie, peach, two crust
 53307050 Pie, peach, one crust
 53307070 Pie, peach, individual size or tart
 53307080 Pie, peach, fried pie
 53307500 Pie, pear, two crust
 53307570 Pie, pear, individual size or tart
 53308000 Pie, pineapple, two crust
 53308070 Pie, pineapple, individual size or tart
 53308300 Pie, plum, two crust
 53308500 Pie, prune, one crust
 53309000 Pie, raisin, two crust
 53309070 Pie, raisin, individual size or tart
 53310000 Pie, raspberry, one crust
 53310050 Pie, raspberry, two crust
 53311000 Pie, rhubarb, two crust
 53311050 Pie, rhubarb, one crust
 53311070 Pie, rhubarb, individual size or tart
 53312000 Pie, strawberry, one crust
 53313000 Pie, strawberry-rhubarb, two crust
 53314000 Pie, strawberry, individual size or tart
 53340000 Pie, apple-sour cream
 53340500 Pie, cherry, made with cream cheese and sour cream
 53341000 Pie, banana cream
 53341070 Pie, banana cream, individual size or tart
 53345000 Pie, lemon cream
 53345070 Pie, lemon cream, individual size or tart
 53346500 Pie, pineapple cream
 53347000 Pie, pumpkin
 53347070 Pie, pumpkin, individual size or tart
 53347100 Pie, raspberry cream
 53348000 Pie, strawberry cream
 53348070 Pie, strawberry cream, individual size or tart
 53381000 Pie, lemon meringue
 53381070 Pie, lemon meringue, individual size or tart
 53410100 Cobbler, apple

53410200	Cobbler, apricot
53410300	Cobbler, berry
53410500	Cobbler, cherry
53410800	Cobbler, peach
53410850	Cobbler, pear
53410860	Cobbler, pineapple
53410880	Cobbler, plum
53410900	Cobbler, rhubarb

“Fruit Prep”

(Adjusted for a Fruit Prep Content of 40% to 67.3%)

[2'-FL] = 1.2 to 2.0 g/100 g

53415100	Crisp, apple, apple dessert
53415200	Fritter, banana
53415220	Fritter, berry
53415300	Crisp, blueberry
53415400	Crisp, cherry
53415500	Crisp, peach
53415600	Crisp, rhubarb
53440000	Strudel, apple
53440300	Strudel, berry
53440500	Strudel, cherry
53440700	Strudel, peach
53440750	Strudel, pineapple
53440800	Strudel, cheese and fruit
53450000	Turnover or dumpling, apple
53450300	Turnover or dumpling, berry
53450500	Turnover or dumpling, cherry
53450800	Turnover or dumpling, lemon
53451000	Turnover or dumpling, peach
53451500	Turnover, guava
53451750	Turnover, pumpkin
53452100	Pastry, fruit-filled
63402010	Banana whip
63402030	Prune whip

(Adjusted for a Fruit Prep Content of <1% to 38.6%)

[2'-FL] = 0.01 to 1.16 g/100 g

53101250	Cake, angel food, with fruit and icing or filling
53102100	Cake or cupcake, applesauce, without icing or filling
53102200	Cake or cupcake, applesauce, with icing or filling
53102600	Cake or cupcake, banana, without icing or filling
53102700	Cake or cupcake, banana, with icing or filling
53104550	Cheesecake with fruit
53113000	Cake, jelly roll
53118500	Cake, torte
53122070	Cake, shortcake, biscuit type, with whipped cream and fruit
53122080	Cake, shortcake, biscuit type, with fruit
53123070	Cake, shortcake, sponge type, with whipped cream and fruit
53123080	Cake, shortcake, sponge type, with fruit
53123500	Cake, shortcake, with whipped topping and fruit, diet
53220000	Cookie, fruit-filled bar
53220010	Cookie, fruit-filled bar, fat free
53220030	Cookie, fig bar

53220040	Cookie, fig bar, fat free
53224250	Cookie, lemon bar
53233010	Cookie, oatmeal, with raisins
53233080	Cookie, oatmeal sandwich, with peanut butter and jelly filling
53237000	Cookie, raisin
53237010	Cookie, raisin sandwich, cream-filled
53241600	Cookie, butter or sugar, with fruit and/or nuts
53415120	Fritter, apple
53430200	Crepe, dessert type, fruit-filled
53453150	Empanada, Mexican turnover, fruit-filled
53453170	Empanada, Mexican turnover, pumpkin
53510100	Danish pastry, with fruit
53521140	Doughnut, jelly
53610170	Coffee cake, crumb or quick-bread type, with fruit
55801010	Funnel cake with sugar and fruit

Grain Products and Pastas

Bars, Including Snack Bars, Meal-Replacement Bars, Breakfast Bars

[2'-FL] = 1.20 g/100 g

53710400	Fiber One Chewy Bar
53710500	Kellogg's Nutri-Grain Cereal Bar
53710502	Kellogg's Nutri-Grain Yogurt Bar
53710504	Kellogg's Nutri-Grain Fruit and Nut Bar
53710600	Milk 'n Cereal bar
53710700	Kellogg's Special K bar
53710800	Kashi GOLEAN Chewy Bars
53710802	Kashi TLC Chewy Granola Bar
53710804	Kashi GOLEAN Crunchy Bars
53710806	Kashi TLC Crunchy Granola Bar
53710900	Nature Valley Chewy Trail Mix Granola Bar
53710902	Nature Valley Chewy Granola Bar with Yogurt Coating
53710904	Nature Valley Sweet and Salty Granola Bar
53710906	Nature Valley Crunchy Granola Bar
53711000	Quaker Chewy Granola Bar
53711002	Quaker Chewy 90 Calorie Granola Bar
53711004	Quaker Chewy 25% Less Sugar Granola Bar
53711006	Quaker Chewy Dipps Granola Bar
53711100	Quaker Granola Bites
53712000	Snack bar, oatmeal
53712100	Granola bar, NFS
53712200	Granola bar, lowfat, NFS
53712210	Granola bar, nonfat
53713000	Granola bar, reduced sugar, NFS
53713100	Granola bar, peanuts, oats, sugar, wheat germ
53714200	Granola bar, chocolate-coated, NFS
53714210	Granola bar, with coconut, chocolate-coated
53714220	Granola bar with nuts, chocolate-coated
53714230	Granola bar, oats, nuts, coated with non-chocolate coating
53714250	Granola bar, coated with non-chocolate coating
53714300	Granola bar, high fiber, coated with non-chocolate yogurt coating
53714400	Granola bar, with rice cereal

53714500	Breakfast bar, NFS
53720100	Balance Original Bar
53720200	Clif Bar
53720210	Clif Kids Organic Zbar
53720300	PowerBar
53720400	Slim Fast Original Meal Bar
53720500	Snickers Marathon Protein bar
53720600	South Beach Living Meal Bar
53720610	South Beach Living High Protein Bar
53720700	Tiger's Milk bar
53720800	Zone Perfect Classic Crunch nutrition bar
53729000	Nutrition bar or meal replacement bar, NFS
53714510	Breakfast bar, date, with yogurt coating
53714520	Breakfast bar, cereal crust with fruit filling, lowfat

Jams and Jellies, Commercial

Jellies and Jams, Fruit Preserves, Fruit Butters

[2'-FL] = 6.0 g/100 g

63307010	Cranberry-orange relish, uncooked
63307100	Cranberry-raspberry sauce
91401000	Jelly, all flavors
91402000	Jam, preserves, all flavors
91403000	Fruit butter, all flavors
91404000	Marmalade, all flavors
91405000	Jelly, dietetic, all flavors, sweetened with artificial sweetener
91405500	Jelly, reduced sugar, all flavors
91406000	Jams, preserves, marmalades, dietetic, all flavors, sweetened with artificial sweetener
91406500	Jams, preserves, marmalades, sweetened with fruit juice concentrates, all flavors
91406600	Jams, preserves, marmalades, low sugar (all flavors)
91407100	Guava paste
91407120	Sweet potato paste
91407150	Bean paste, sweetened

Milk, Whole and Skim

Acidophilus or Fortified Milks, Fluid Milks, Reconstituted Milk Powders

[2'-FL] = 0.12 g/100 g

11100000	Milk, NFS
11111000	Milk, whole
11111100	Milk, low sodium, whole
11111150	Milk, calcium fortified, whole
11111160	Milk, calcium fortified, low fat (1%)
11111170	Milk, calcium fortified, fat free (skim)
11112110	Milk, reduced fat (2%)
11112120	Milk, acidophilus, low fat (1%)
11112130	Milk, acidophilus, reduced fat (2%)
11112210	Milk, low fat (1%)
11113000	Milk, fat free (skim)
11114300	Milk, lactose free, low fat (1%)
11114320	Milk, lactose free, fat free (skim)

11114330	Milk, lactose free, reduced fat (2%)
11114350	Milk, lactose free, whole
11120000	Milk, dry, reconstituted, NS as to fat content
11121100	Milk, dry, reconstituted, whole
11121210	Milk, dry, reconstituted, low fat (1%)
11121300	Milk, dry, reconstituted, fat free (skim)

Dry Milks

(Adjusted for being reconstituted at 24 g powder to 240 mL water)

[2'-FL] = 1.32 g/100 g

11810000	Milk, dry, not reconstituted, NS as to fat content
11811000	Milk, dry, not reconstituted, whole
11812000	Milk, dry, not reconstituted, low fat (1%)
11813000	Milk, dry, not reconstituted, fat free (skim)

Mixtures Containing Milk

(Adjusted for a Milk Content of 50.3% to 87.5%)

[2'-FL] = 0.06 to 0.11 g/100 g

11513400	Chocolate milk, made from syrup, NS as to type of milk
11513500	Chocolate milk, made from syrup with whole milk
11513550	Chocolate milk, made from syrup with reduced fat milk (2%)
11513600	Chocolate milk, made from syrup with low fat milk (1%)
11513700	Chocolate milk, made from syrup with fat free milk (skim)
11513800	Chocolate milk, made from light syrup, NS as to type of milk
11513801	Chocolate milk, made from light syrup with whole milk
11513802	Chocolate milk, made from light syrup with reduced fat milk (2%)
11513803	Chocolate milk, made from light syrup with low fat milk (1%)
11513804	Chocolate milk, made from light syrup with fat free milk (skim)
11513850	Chocolate milk, made from sugar free syrup, NS as to type of milk
11513851	Chocolate milk, made from sugar free syrup with whole milk
11513852	Chocolate milk, made from sugar free syrup with reduced fat milk (2%)
11513853	Chocolate milk, made from sugar free syrup with low fat milk (1%)
11513854	Chocolate milk, made from sugar free syrup with fat free milk (skim)
92101900	Coffee, Latte
92101901	Coffee, Latte, nonfat
92101904	Coffee, Latte, flavored
92101905	Coffee, Latte, nonfat, flavored
92101910	Coffee, Latte, decaffeinated
92101911	Coffee, Latte, decaffeinated, nonfat
92101917	Coffee, Latte, decaffeinated, flavored
92101918	Coffee, Latte, decaffeinated, nonfat, flavored
92101950	Coffee, Cafe Mocha
92101955	Coffee, Cafe Mocha, nonfat
92101965	Coffee, Cafe Mocha, decaffeinated
92101970	Coffee, Cafe Mocha, decaffeinated, nonfat
92102500	Coffee, Iced Latte
92102501	Coffee, Iced Latte, nonfat
92102510	Coffee, Iced Latte, decaffeinated
92102511	Coffee, Iced Latte, decaffeinated, nonfat
92161000	Coffee, Cappuccino
92161001	Coffee, Cappuccino, nonfat
92162000	Coffee, Cappuccino, decaffeinated
92162001	Coffee, Cappuccino, decaffeinated, nonfat

Mixtures Containing Milk

(Adjusted for a Milk Content of 16.1 to 49.9%)

[2'-FL] = 0.02 to 0.06 g/100 g

92101810	Coffee, macchiato
92101820	Coffee, macchiato, sweetened
92101850	Coffee, cafe con leche
92101851	Coffee, cafe con leche, decaffeinated
92101920	Frozen coffee drink
92101921	Frozen coffee drink, nonfat
92101925	Frozen coffee drink, with whipped cream
92101926	Frozen coffee drink, nonfat, with whipped cream
92101930	Frozen coffee drink, decaffeinated
92101931	Frozen coffee drink, decaffeinated, nonfat
92101935	Frozen coffee drink, decaffeinated, with whipped cream
92101936	Frozen coffee drink, decaffeinated, nonfat, with whipped cream
92102000	Frozen mocha coffee drink
92102010	Frozen mocha coffee drink, nonfat
92102030	Frozen mocha coffee drink, with whipped cream
92102040	Frozen mocha coffee drink, nonfat, with whipped cream
92102060	Frozen mocha coffee drink, decaffeinated
92102070	Frozen mocha coffee drink, decaffeinated, nonfat
92102090	Frozen mocha coffee drink, decaffeinated, with whipped cream
92102100	Frozen mocha coffee drink, decaffeinated, nonfat, with whipped cream
92102503	Coffee, Iced Latte, flavored
92102504	Coffee, Iced Latte, nonfat, flavored
92102513	Coffee, Iced Latte, decaffeinated, flavored
92102514	Coffee, Iced Latte, decaffeinated, nonfat, flavored
92102600	Coffee, Iced Cafe Mocha
92102601	Coffee, Iced Cafe Mocha, nonfat
92102610	Coffee, Iced Cafe Mocha, decaffeinated
92102611	Coffee, Iced Cafe Mocha, decaffeinated, nonfat
92306800	Tea, hot, chai, with milk
92610030	Horchata beverage, made with milk
92611100	Atole de avena (oatmeal beverage with milk)
92613010	Atole (corn meal beverage)
92613510	Atole de chocolate / Champurrado (cornmeal beverage with chocolate and milk)

Milk Products

Flavored Milks

[2'-FL] = 0.12 g/100 g

11115000	Buttermilk, fat free (skim)
11115100	Buttermilk, low fat (1%)
11115200	Buttermilk, reduced fat (2%)
11115300	Buttermilk, whole
11115400	Kefir, NS as to fat content
11511000	Chocolate milk, NFS
11511100	Chocolate milk, ready to drink, whole
11511200	Chocolate milk, ready to drink, reduced fat (2%)
11511300	Chocolate milk, ready to drink, fat free (skim)
11511400	Chocolate milk, ready to drink, low fat (1%)
11511550	Chocolate milk, ready to drink, reduced sugar, NS as to milk

11511600 Nesquik, chocolate milk, ready to drink, low fat (1%)
 11511610 Nesquik, chocolate milk, ready to drink, fat free (skim)
 11511700 Nesquik, chocolate milk, ready to drink, low fat (1%), no sugar added
 11512010 Hot chocolate / Cocoa, ready to drink
 11512020 Hot chocolate / Cocoa, ready to drink, made with nonfat milk
 11512100 Hot chocolate / Cocoa, ready to drink, with whipped cream
 11512110 Hot chocolate / Cocoa, ready to drink, made with nonfat milk and whipped cream
 11513000 Chocolate milk, made from dry mix, NS as to type of milk
 11513100 Chocolate milk, made from dry mix with whole milk
 11513150 Chocolate milk, made from dry mix with reduced fat milk (2%)
 11513200 Chocolate milk, made from dry mix with low fat milk (1%)
 11513300 Chocolate milk, made from dry mix with fat free milk (skim)
 11513350 Chocolate milk, made from reduced sugar mix, NS as to type of milk
 11513355 Chocolate milk, made from reduced sugar mix with whole milk
 11513360 Chocolate milk, made from reduced sugar mix with reduced fat milk (2%)
 11513365 Chocolate milk, made from reduced sugar mix with low fat milk (1%)
 11513370 Chocolate milk, made from reduced sugar mix with fat free milk (skim)
 11513380 Nesquik, chocolate milk, made from dry mix, NS as to type of milk
 11513381 Nesquik, chocolate milk, made from dry mix with whole milk
 11513382 Nesquik, chocolate milk, made from dry mix with reduced fat milk (2%)
 11513383 Nesquik, chocolate milk, made from dry mix with low fat milk (1%)
 11513384 Nesquik, chocolate milk, made from dry mix with fat free milk (skim)
 11513390 Nesquik, chocolate milk, made from no sugar added dry mix, NS as to type of milk
 11513391 Nesquik, chocolate milk, made from no sugar added dry mix with whole milk
 11513392 Nesquik, chocolate milk, made from no sugar added dry mix with reduced fat milk (2%)
 11513393 Nesquik, chocolate milk, made from no sugar added dry mix with low fat milk (1%)
 11513394 Nesquik, chocolate milk, made from no sugar added dry mix with fat free milk (skim)
 11514110 Hot chocolate / Cocoa, made with dry mix and whole milk
 11514120 Hot chocolate / Cocoa, made with dry mix and reduced fat milk (2%)
 11514130 Hot chocolate / Cocoa, made with dry mix and low fat milk (1%)
 11514140 Hot chocolate / Cocoa, made with dry mix and fat free milk (skim)
 11514320 Hot chocolate / Cocoa, made with no sugar added dry mix and whole milk
 11514330 Hot chocolate / Cocoa, made with no sugar added dry mix and reduced fat milk (2%)
 11514340 Hot chocolate / Cocoa, made with no sugar added dry mix and low fat milk (1%)
 11514350 Hot chocolate / Cocoa, made with no sugar added dry mix and fat free milk (skim)
 11519040 Strawberry milk, NFS
 11519050 Strawberry milk, whole
 11519105 Strawberry milk, reduced fat (2%)
 11519200 Strawberry milk, low fat (1%)
 11519205 Strawberry milk, fat free (skim)
 11525000 Milk, malted, natural flavor, made with milk
 11526000 Milk, malted, chocolate, made with milk
 11541400 Milk shake with malt
 11542100 Milk shake, fast food, chocolate
 11542200 Milk shake, fast food, flavors other than chocolate
 11543000 Milk shake, bottled, chocolate
 11543010 Milk shake, bottled, flavors other than chocolate
 11551050 Licuado / Batido (milk fruit drink)
 11553100 Fruit smoothie, NFS
 11553110 Fruit smoothie, with whole fruit and dairy
 11553120 Fruit smoothie, with whole fruit and dairy, added protein
 11553130 Fruit smoothie juice drink, with dairy
 11560000 Yoo-hoo, chocolate milk drink
 78101100 Fruit and vegetable smoothie

78101110	Fruit and vegetable smoothie, added protein
78101120	Fruit and vegetable smoothie, bottled
92171000	Coffee, bottled/canned
92171010	Coffee, bottled/canned, light

Dry Mixtures of Flavored Milks, Cocoa

(Adjusted for Not Being Reconstituted, 28 g powder to 240 mL of water)

[2'-FL] = 1.15 g/100 g

11830100	Hot chocolate / Cocoa, dry mix, not reconstituted
11830115	Hot chocolate / Cocoa, dry mix, no sugar added, not reconstituted
11830150	Cocoa powder, not reconstituted (no dry milk)
11830160	Chocolate beverage powder, dry mix, not reconstituted
11830165	Chocolate beverage powder, reduced sugar, dry mix, not reconstituted
11830260	Milk, malted, dry mix, not reconstituted
11830400	Strawberry beverage powder, dry mix, not reconstituted

Milk-Based Meal Replacement Beverages or Diet beverages

[2'-FL] = 0.12 g/100 g

95101000	Boost, nutritional drink, ready-to-drink
95101010	Boost Plus, nutritional drink, ready-to-drink
95102000	Carnation Instant Breakfast, nutritional drink, regular, ready-to-drink
95103000	Ensure, nutritional shake, ready-to-drink
95103010	Ensure Plus, nutritional shake, ready-to-drink
95104000	Glucerna, nutritional shake, ready-to-drink
95105000	Kellogg's Special K Protein Shake
95106000	Muscle Milk, ready-to-drink
95106010	Muscle Milk, light, ready-to-drink
95110000	Slim Fast Shake, meal replacement, regular, ready-to-drink
95110010	Slim Fast Shake, meal replacement, sugar free, ready-to-drink
95110020	Slim Fast Shake, meal replacement, high protein, ready-to-drink
95120000	Nutritional drink or meal replacement, ready-to-drink, NFS
95120010	Nutritional drink or meal replacement, high protein, ready-to-drink, NFS
95120020	Nutritional drink or meal replacement, high protein, light, ready-to-drink, NFS

Powdered Milk-Based Meal Replacement Beverages

(Adjusted for Not Being Reconstituted, 16 g powder to 240 mL of water or milk)

[2'-FL] = 1.92 g/100 g

95220000	Nutritional drink mix or meal replacement, powder, NFS
95220010	Nutritional drink mix or meal replacement, high protein, powder, NFS

Not Reconstituted Milk-Based Meal Replacement Beverages

(Adjusted for Not Being Reconstituted, 20 g powder to 240 mL of milk)

[2'-FL] = 1.56 g/100 g

95201000	Carnation Instant Breakfast, nutritional drink mix, regular, powder
95201010	Carnation Instant Breakfast, nutritional drink mix, sugar free, powder

Not Reconstituted Milk-Based Meal Replacement Beverages

(Adjusted for not being reconstituted, 26 g powder to 227 mL of water)

[2'-FL] = 1.20 g/100 g

95202010	Muscle Milk, light, powder
95210000	Slim Fast Shake Mix, powder
95210010	Slim Fast Shake Mix, sugar free, powder
95210020	Slim Fast Shake Mix, high protein, powder

Not Reconstituted Milk-Based Meal Replacement Beverages
(Adjusted for not being reconstituted, 70 g powder to 454 mL of water)

[2'-FL] = 0.90 g/100 g

95202000 Muscle Milk, regular, powder

Yogurt

[2'-FL] = 0.53 g/100 g

11410000 Yogurt, NS as to type of milk or flavor
11411010 Yogurt, plain, NS as to type of milk
11411100 Yogurt, plain, whole milk
11411200 Yogurt, plain, low fat milk
11411300 Yogurt, plain, nonfat milk
11411400 Yogurt, Greek, plain, whole milk
11411410 Yogurt, Greek, plain, low fat
11411420 Yogurt, Greek, plain, nonfat milk
11420000 Yogurt, vanilla, NS as to type of milk
11421000 Yogurt, vanilla, whole milk
11422000 Yogurt, vanilla, low fat milk
11422100 Yogurt, vanilla, low fat milk, light
11423000 Yogurt, vanilla, nonfat milk
11424000 Yogurt, vanilla, nonfat milk, light
11424500 Yogurt, Greek, vanilla, whole milk
11424510 Yogurt, Greek, vanilla, low fat
11424520 Yogurt, Greek, vanilla, nonfat
11425000 Yogurt, chocolate, NS as to type of milk
11426000 Yogurt, chocolate, whole milk
11427000 Yogurt, chocolate, nonfat milk
11428000 Yogurt, Greek, chocolate, nonfat
11430000 Yogurt, fruit, NS as to type of milk
11431000 Yogurt, fruit, whole milk
11432000 Yogurt, fruit, low fat milk
11432500 Yogurt, fruit, low fat milk, light
11433000 Yogurt, fruit, nonfat milk
11433500 Yogurt, fruit, nonfat milk, light
11434000 Yogurt, Greek, fruit, whole milk
11434010 Yogurt, Greek, fruit, low fat
11434020 Yogurt, Greek, fruit, nonfat

Mixtures Containing Yogurt

(Adjusted for a Yogurt Content of 34.6% to 93.2%)

[2'-FL] = 0.18 to 0.49 g/100 g

11446000 Fruit and low fat yogurt parfait
83115000 Yogurt dressing

Processed Fruits and Fruit Juices

Fruit Drinks

[2'-FL] = 0.12 g/100 g

64134015 Fruit smoothie, with whole fruit (no dairy)
64134020 Fruit smoothie, with whole fruit (no dairy), added protein
64134030 Fruit smoothie juice drink (no dairy)
64134100 Fruit smoothie, light

64134200	Fruit smoothie, bottled
64200100	Fruit nectar, NFS
64201010	Apricot nectar
64201500	Banana nectar
64202010	Cantaloupe nectar
64203020	Guava nectar
64204010	Mango nectar
64205010	Peach nectar
64210010	Papaya nectar
64213010	Passion fruit nectar
64215010	Pear nectar
64221010	Soursop (Guanabana) nectar
92307500	Iced Tea / Lemonade juice drink
92307510	Iced Tea / Lemonade juice drink, light
92307520	Iced Tea / Lemonade juice drink, diet
92432000	Fruit juice drink, citrus, carbonated
92433000	Fruit juice drink, noncitrus, carbonated
92510610	Fruit juice drink
92510650	Tamarind drink (Refresco de tamarindo)
92510720	Fruit punch, made with fruit juice and soda
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream
92510955	Lemonade, fruit juice drink
92510960	Lemonade, fruit flavored drink
92511015	Fruit flavored drink
92511250	Fruit juice beverage, 40-50% juice, citrus
92512090	Pina Colada, nonalcoholic
92512110	Margarita mix, nonalcoholic
92513000	Fruit flavored smoothie drink, frozen (no dairy)
92513010	Fruit flavored smoothie drink, frozen, light (no dairy)
92530410	Fruit flavored drink, with high vitamin C
92530510	Cranberry juice drink, with high vitamin C
92530610	Fruit juice drink, with high vitamin C
92531030	Sunny D
92541010	Fruit flavored drink, powdered, reconstituted
92542000	Fruit flavored drink, with high vitamin C, powdered, reconstituted
92550030	Fruit juice drink, with high vitamin C, light
92550035	Fruit juice drink, light
92550040	Fruit juice drink, diet
92550110	Cranberry juice drink, with high vitamin C, light
92550200	Grape juice drink, light
92550350	Orange juice beverage, 40-50% juice, light
92550360	Apple juice beverage, 40-50% juice, light
92550370	Lemonade, fruit juice drink, light
92550380	Pomegranate juice beverage, 40-50% juice, light
92550610	Fruit flavored drink, with high vitamin C, diet
92550620	Fruit flavored drink, diet
92552000	Fruit flavored drink, with high vitamin C, powdered, reconstituted, diet
92552010	Fruit flavored drink, powdered, reconstituted, diet
92552020	Sunny D, reduced sugar
92552030	Capri Sun, fruit juice drink
92582100	Fruit juice drink, with high vitamin C, plus added calcium
92582110	Sunny D, added calcium

Frozen Fruit Drinks

(Adjusted for Not Being Reconstituted, 1 Cup Juice Mix to 3 Cups Water)

[2'-FL] = 0.48 g/100 g

92511000 Lemonade, frozen concentrate, not reconstituted

Concentrated Fruit Drinks

(Adjusted for Not Being Reconstituted, 55 mL of Frozen Concentrate to Produce a 240 mL Beverage)

[2'-FL] = 0.64 g/100 g

92512040 Frozen daiquiri mix, frozen concentrate, not reconstituted

92512050 Frozen daiquiri mix, from frozen concentrate, reconstituted

Powdered Fruit Drinks

(Adjusted for Not Being Reconstituted, 16 g Powder to 240 mL of Water)

[2'-FL] = 1.92 g/100 g

92900100 Fruit flavored drink, with high vitamin C, powdered, not reconstituted

92900110 Fruit flavored drink, powdered, not reconstituted

92900200 Fruit flavored drink, powdered, not reconstituted, diet

Mixtures Containing Fruit Drinks

(Adjusted for a Fruit Drink Content of 50% to 74.7%)

[2'-FL] = 0.06 to 0.09 g/100 g

92530950 Vegetable and fruit juice drink, with high vitamin C

92550400 Vegetable and fruit juice drink, with high vitamin C, diet

92550405 Vegetable and fruit juice drink, with high vitamin C, light

93301213 Vodka and lemonade

Fruit Juices

[2'-FL] = 0.12 g/100 g

61201020 Grapefruit juice, 100%, NS as to form

61201220 Grapefruit juice, 100%, canned, bottled or in a carton

61201225 Grapefruit juice, 100%, with calcium added

61201620 Grapefruit juice, 100%, frozen, reconstituted

61204000 Lemon juice, 100%, NS as to form

61204200 Lemon juice, 100%, canned or bottled

61207000 Lime juice, 100%, NS as to form

61207200 Lime juice, 100%, canned or bottled

61210000 Orange juice, 100%, NFS

61210220 Orange juice, 100%, canned, bottled or in a carton

61210250 Orange juice, 100%, with calcium added, canned, bottled or in a carton

61210620 Orange juice, 100%, frozen, reconstituted

61210820 Orange juice, 100%, with calcium added, frozen, reconstituted

61213220 Tangerine juice, 100%

61213800 Fruit juice blend, citrus, 100% juice

61213900 Fruit juice blend, citrus, 100% juice, with calcium added

64100100 Fruit juice, NFS

64100110 Fruit juice blend, 100% juice

64100200 Cranberry juice blend, 100% juice

64100220 Cranberry juice blend, 100% juice, with calcium added

64101010 Apple cider

64104010 Apple juice, 100%

64104030 Apple juice, 100%, with calcium added

64104600 Blackberry juice, 100%

64105400 Cranberry juice, 100%, not a blend

64116020 Grape juice, 100%

64116060	Grape juice, 100%, with calcium added
64120010	Papaya juice, 100%
64121000	Passion fruit juice, 100%
64124020	Pineapple juice, 100%
64126000	Pomegranate juice, 100%
64132010	Prune juice, 100%
64132500	Strawberry juice, 100%
64133100	Watermelon juice, 100%

Frozen Fruit Juices

(Adjusted for Not Being Reconstituted, 1 Cup Juice Mix to 3 Cups Water)

[2'-FL] = 0.48 g/100 g

61210720	Orange juice, 100%, frozen, not reconstituted
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Mixtures Containing Fruit Juices

(Adjusted for a Fruit Juice Content of 3.6% to 75.3%)

[2'-FL] = <0.01 to 0.09 g/100 g

78101000	Vegetable and fruit juice, 100% juice, with high vitamin C
93301032	Cape Cod
93301040	Daiquiri
93301075	Greyhound
93301085	Kamikaze
93301111	Martini, flavored
93301115	Mimosa
93301132	Orange Blossom
93301139	Salty Dog
93301140	Screwdriver
93301141	Seabreeze
93301200	Pina Colada
93301230	Sloe gin fizz
93301270	Fruit punch, alcoholic
93301275	Champagne punch
93301280	Singapore Sling
93301310	Mai Tai
93301320	Tequila Sunrise
93301330	Gin Rickey
93301370	Fuzzy Navel
93301600	Gin fizz
93302100	Zombie

Sweet Sauces, Toppings, and Syrups

Syrups Used to Flavor Milk Beverages

(Adjusted for a Syrup Content of 12.5 to 13.3%)

[2'-FL] = 0.09 g/100 g

11513400	Chocolate milk, made from syrup, NS as to type of milk
11513500	Chocolate milk, made from syrup with whole milk
11513550	Chocolate milk, made from syrup with reduced fat milk (2%)
11513600	Chocolate milk, made from syrup with low fat milk (1%)
11513700	Chocolate milk, made from syrup with fat free milk (skim)
11513750	Chocolate milk, made from syrup with non-dairy milk
11513800	Chocolate milk, made from light syrup, NS as to type of milk
11513801	Chocolate milk, made from light syrup with whole milk

11513802	Chocolate milk, made from light syrup with reduced fat milk (2%)
11513803	Chocolate milk, made from light syrup with low fat milk (1%)
11513804	Chocolate milk, made from light syrup with fat free milk (skim)
11513805	Chocolate milk, made from light syrup with non-dairy milk
11513850	Chocolate milk, made from sugar free syrup, NS as to type of milk
11513851	Chocolate milk, made from sugar free syrup with whole milk
11513852	Chocolate milk, made from sugar free syrup with reduced fat milk (2%)
11513853	Chocolate milk, made from sugar free syrup with low fat milk (1%)
11513854	Chocolate milk, made from sugar free syrup with fat free milk (skim)
11513855	Chocolate milk, made from sugar free syrup with non-dairy milk
91301130	Fruit flavored syrup used for milk beverages

Non-Exempt Infant and Follow-On Formula

Infant Formula

[2'-FL] = 0.24 g/100 g

11710000	Infant formula, NFS
11710050	Similac Expert Care Alimentum, infant formula, NS as to form
11710051	Similac Expert Care Alimentum, infant formula, ready-to-feed
11710053	Similac Expert Care Alimentum, infant formula, prepared from powder, made with water, NFS
11710054	Similac Expert Care Alimentum, infant formula, prepared from powder, made with tap water
11710055	Similac Expert Care Alimentum, infant formula, prepared from powder, made with plain bottled water
11710056	Similac Expert Care Alimentum, infant formula, prepared from powder, made with baby water
11710350	Similac Advance, infant formula, NS as to form
11710351	Similac Advance, infant formula, ready-to-feed
11710352	Similac Advance, infant formula, prepared from liquid concentrate, made with water, NFS
11710353	Similac Advance, infant formula, prepared from powder, made with water, NFS
11710354	Similac Advance, infant formula, prepared from liquid concentrate, made with tap water
11710355	Similac Advance, infant formula, prepared from liquid concentrate, made with plain bottled water
11710356	Similac Advance, infant formula, prepared from liquid concentrate, made with baby water
11710357	Similac Advance, infant formula, prepared from powder, made with tap water
11710358	Similac Advance, infant formula, prepared from powder, made with plain bottled water
11710359	Similac Advance, infant formula, prepared from powder, made with baby water
11710360	Similac Advance Organic, infant formula, NS as to form
11710361	Similac Advance Organic, infant formula, ready-to-feed
11710363	Similac Advance Organic, infant formula, prepared from powder, made with water, NFS
11710367	Similac Advance Organic, infant formula, prepared from powder, made with tap water
11710368	Similac Advance Organic, infant formula, prepared from powder, made with plain bottled water
11710369	Similac Advance Organic, infant formula, prepared from powder, made with baby water
11710370	Similac Sensitive, infant formula, NS as to form
11710371	Similac Sensitive, infant formula, ready-to-feed
11710372	Similac Sensitive, infant formula, prepared from liquid concentrate, made with water, NFS
11710373	Similac Sensitive, infant formula, prepared from powder, made with water, NFS
11710374	Similac Sensitive, infant formula, prepared from liquid concentrate, made with tap water
11710375	Similac Sensitive, infant formula, prepared from liquid concentrate, made with plain bottled water
11710376	Similac Sensitive, infant formula, prepared from liquid concentrate, made with baby water
11710377	Similac Sensitive, infant formula, prepared from powder, made with tap water
11710378	Similac Sensitive, infant formula, prepared from powder, made with plain bottled water
11710379	Similac Sensitive, infant formula, prepared from powder, made with baby water
11710380	Similac Sensitive for Spit-Up, infant formula, NS as to form
11710381	Similac Sensitive for Spit-Up, infant formula, ready-to-feed

11710383 Similac Sensitive for Spit-Up, infant formula, prepared from powder, made with water, NFS
 11710387 Similac Sensitive for Spit-Up, infant formula, prepared from powder, made with tap water
 11710388 Similac Sensitive for Spit-Up, infant formula, prepared from powder, made with plain bottled water
 11710389 Similac Sensitive for Spit-Up, infant formula, prepared from powder, made with baby water
 11710620 Enfamil PREMIUM Newborn, infant formula, NS as to form
 11710621 Enfamil PREMIUM Newborn, infant formula, ready-to-feed
 11710626 Enfamil PREMIUM Newborn, infant formula, prepared from powder, made with water, NFS
 11710627 Enfamil PREMIUM Newborn, infant formula, prepared from powder, made with tap water
 11710628 Enfamil PREMIUM Newborn, infant formula, prepared from powder, made with plain bottled water
 11710629 Enfamil PREMIUM Newborn, infant formula, prepared from powder, made with baby water
 11710630 Enfamil PREMIUM Infant, infant formula, NS as to form
 11710631 Enfamil PREMIUM Infant, infant formula, ready-to-feed
 11710632 Enfamil PREMIUM Infant, infant formula, prepared from liquid concentrate, made with water, NFS
 11710633 Enfamil PREMIUM Infant, infant formula, prepared from liquid concentrate, made with tap water
 11710634 Enfamil PREMIUM Infant, infant formula, prepared from liquid concentrate, made with plain bottled water
 11710635 Enfamil PREMIUM Infant, infant formula, prepared from liquid concentrate, made with baby water
 11710636 Enfamil PREMIUM Infant, infant formula, prepared from powder, made with water, NFS
 11710637 Enfamil PREMIUM Infant, infant formula, prepared from powder, made with tap water
 11710638 Enfamil PREMIUM Infant, infant formula, prepared from powder, made with plain bottled water
 11710639 Enfamil PREMIUM Infant, infant formula, prepared from powder, made with baby water
 11710640 Enfamil PREMIUM LIPIL, infant formula, NS as to form
 11710642 Enfamil PREMIUM LIPIL, infant formula, prepared from liquid concentrate, made with water, NFS
 11710643 Enfamil PREMIUM LIPIL, infant formula, prepared from powder, made with water, NFS
 11710644 Enfamil PREMIUM LIPIL, infant formula, prepared from liquid concentrate, made with tap water
 11710645 Enfamil PREMIUM LIPIL, infant formula, prepared from liquid concentrate, made with plain bottled water
 11710646 Enfamil PREMIUM LIPIL, infant formula, prepared from liquid concentrate, made with baby water
 11710647 Enfamil PREMIUM LIPIL, infant formula, prepared from powder, made with tap water
 11710648 Enfamil PREMIUM LIPIL, infant formula, prepared from powder, made with plain bottled water
 11710649 Enfamil PREMIUM LIPIL, infant formula, prepared from powder, made with baby water
 11710650 Enfamil LIPIL, infant formula, NS as to form
 11710651 Enfamil LIPIL, infant formula, ready-to-feed
 11710652 Enfamil LIPIL, infant formula, prepared from liquid concentrate, made with water, NFS
 11710653 Enfamil LIPIL, infant formula, prepared from powder, made with water, NFS
 11710654 Enfamil LIPIL, infant formula, prepared from liquid concentrate, made with tap water
 11710655 Enfamil LIPIL, infant formula, prepared from liquid concentrate, made with plain bottled water
 11710656 Enfamil LIPIL, infant formula, prepared from liquid concentrate, made with baby water
 11710657 Enfamil LIPIL, infant formula, prepared from powder, made with tap water
 11710658 Enfamil LIPIL, infant formula, prepared from powder, made with plain bottled water
 11710659 Enfamil LIPIL, infant formula, prepared from powder, made with baby water
 11710660 Enfamil A.R. Lipil, infant formula, NS as to form
 11710661 Enfamil A.R. Lipil, infant formula, ready-to-feed
 11710663 Enfamil A.R. LIPIL, infant formula, prepared from powder, made with water, NFS
 11710664 Enfamil A.R. LIPIL, infant formula, prepared from powder, made with tap water
 11710670 Enfamil Gentlease LIPIL, infant formula, NS as to form
 11710671 Enfamil Gentlease LIPIL, infant formula, ready-to-feed
 11710673 Enfamil Gentlease LIPIL, infant formula, prepared from powder, made with water, NFS
 11710677 Enfamil Gentlease LIPIL, infant formula, prepared from powder, made with tap water
 11710678 Enfamil Gentlease LIPIL, infant formula, prepared from powder, made with plain bottled water
 11710679 Enfamil Gentlease LIPIL, infant formula, prepared from powder, made with baby water
 11710910 Gerber Good Start Gentle Plus, infant formula, NS as to form
 11710911 Gerber Good Start Gentle Plus, infant formula, ready-to-feed

11710912	Gerber Good Start Gentle Plus, infant formula, prepared from liquid concentrate, made with water, NFS
11710913	Gerber Good Start Gentle Plus, infant formula, prepared from powder, made with water, NFS
11710914	Gerber Good Start Gentle Plus, infant formula, prepared from liquid concentrate, made with tap water
11710915	Gerber Good Start Gentle Plus, infant formula, prepared from liquid concentrate, made with plain bottled water
11710916	Gerber Good Start Gentle Plus, infant formula, prepared from liquid concentrate, made with baby water
11710917	Gerber Good Start Gentle Plus, infant formula, prepared from powder, made with tap water
11710918	Gerber Good Start Gentle Plus, infant formula, prepared from powder, made with plain bottled water
11710919	Gerber Good Start Gentle Plus, infant formula, prepared from powder, made with baby water
11710920	Gerber Good Start Protect Plus, infant formula, NS as to form
11710923	Gerber Good Start Protect Plus, infant formula, prepared from powder, made with water, NFS
11710927	Gerber Good Start Protect Plus, infant formula, prepared from powder, made with tap water
11710928	Gerber Good Start Protect Plus, infant formula, prepared from powder, made with plain bottled water
11710929	Gerber Good Start Protect Plus, infant formula, prepared from powder, made with baby water
11710960	America's Store Brand, infant formula, NS as to form
11710961	America's Store Brand, infant formula, prepared from liquid concentrate, made with water, NFS
11710962	America's Store Brand, infant formula, prepared from powder, made with water, NFS
11710963	America's Store Brand, infant formula, ready-to-feed
11710964	America's Store Brand, infant formula, prepared from liquid concentrate, made with tap water
11710965	America's Store Brand, infant formula, prepared from liquid concentrate, made with plain bottled water
11710966	America's Store Brand, infant formula, prepared from liquid concentrate, made with baby water
11710967	America's Store Brand, infant formula, prepared from powder, made with tap water
11710968	America's Store Brand, infant formula, prepared from powder, made with plain bottled water
11710969	America's Store Brand, infant formula, prepared from powder, made with baby water

Follow-On Formula

[2'-FL] = 0.24 g/100 g

11710480	Similac Go and Grow, infant formula, NS as to form
11710481	Similac Go and Grow, infant formula, prepared from powder, made with water, NFS
11710482	Similac Go and Grow, infant formula, prepared from powder, made with tap water
11710483	Similac Go and Grow, infant formula, prepared from powder, made with plain bottled water
11710484	Similac Go and Grow, infant formula, prepared from powder, made with baby water

Meal Replacement Products

[2'-FL] = 0.2 g/100 g

11710800	Pediasure, infant formula, NS as to form
11710801	Pediasure, infant formula, ready-to-feed
11710805	Pediasure Fiber, infant formula, NS as to form
11710806	Pediasure Fiber, infant formula, ready-to-feed

Baby Foods

Growing Up (Toddler) Milks

[2'-FL] = 0.2 g/100 g

11710680	Enfamil Enfagrow PREMIUM Next Step LIPIL, infant formula, NS as to form
11710681	Enfamil Enfagrow PREMIUM Next Step LIPIL, infant formula, ready-to-feed

11710683	Enfamil Enfagrow PREMIUM Next Step LIPIL, infant formula, prepared from powder, made with water, NFS
11710687	Enfamil Enfagrow PREMIUM Next Step LIPIL, infant formula, prepared from powder, made with tap water
11710688	Enfamil Enfagrow PREMIUM Next Step LIPIL, infant formula, prepared from powder, made with plain bottled water
11710689	Enfamil Enfagrow PREMIUM Next Step LIPIL, infant formula, prepared from powder, made with baby water
11710690	Enfamil Gentlease Next Step LIPIL, infant formula, NS as to form
11710693	Enfamil Gentlease Next Step LIPIL, infant formula, prepared from powder, made with water, NFS
11710697	Enfamil Gentlease Next Step LIPIL, infant formula, prepared from powder, made with tap water
11710698	Enfamil Gentlease Next Step LIPIL, infant formula, prepared from powder, made with plain bottled water
11710699	Enfamil Gentlease Next Step LIPIL, infant formula, prepared from powder, made with baby water
11710930	Gerber Good Start 2 Gentle Plus, infant formula, NS as to form
11710933	Gerber Good Start 2 Gentle Plus, infant formula, prepared from powder, made with water, NFS
11710937	Gerber Good Start 2 Gentle Plus, infant formula, prepared from powder, made with tap water
11710938	Gerber Good Start 2 Gentle Plus, infant formula, prepared from powder, made with plain bottled water
11710939	Gerber Good Start 2 Gentle Plus, infant formula, prepared from powder, made with baby water
11710940	Gerber Good Start 2 Protect Plus, infant formula, NS as to form
11710943	Gerber Good Start 2 Protect Plus, infant formula, prepared from powder, made with water, NFS
11710947	Gerber Good Start 2 Protect Plus, infant formula, prepared from powder, made with tap water
11710948	Gerber Good Start 2 Protect Plus, infant formula, prepared from powder, made with plain bottled water
11710949	Gerber Good Start 2 Protect Plus, infant formula, prepared from powder, made with baby water

Ready-to-Eat, Ready-to-Serve, Hot Cereals

[2'-FL] = 1.09 g/100 g

57820000	Cereal, baby food, jarred, NFS
57820100	Rice cereal, baby food, jarred, NFS
57822000	Mixed cereal with applesauce and bananas, baby food, jarred
57823000	Oatmeal with applesauce and bananas, baby food, jarred
57824000	Rice cereal with applesauce and bananas, baby food, jarred
57824500	Rice cereal with mixed fruit, baby food, jarred

Yogurt and Juice Beverages, Identified as "Baby" Drinks

[2'-FL] = 1.0 g/100 g

67202000	Apple juice, baby food
67202010	Apple juice, with added calcium, baby food
67203000	Apple-fruit juice blend, baby food
67203200	Apple-banana juice, baby food
67203400	Apple-cherry juice, baby food
67203500	Apple-grape juice, baby food
67203600	Apple-peach juice, baby food
67203700	Apple-prune juice, baby food
67203800	Grape juice, baby food
67204000	Mixed fruit juice, not citrus, baby food
67204100	Mixed fruit juice, not citrus, with added calcium, baby food
67205000	Orange juice, baby food
67211000	Orange-apple-banana juice, baby food
67212000	Pear juice, baby food
67230000	Apple-sweet potato juice, baby food
67230500	Orange-carrot juice, baby food

67250100 Banana juice with lowfat yogurt, baby food
 67250150 Mixed fruit juice with lowfat yogurt, baby food
 67260000 Fruit juice and water drink, with high vitamin C and added calcium, baby food

Desserts, "Junior Type"

[2'-FL] = 1.09 g/100 g

13310000 Custard pudding, flavor other than chocolate, baby food, NS as to strained or junior
 13311000 Custard pudding, baby food, flavor other than chocolate, strained
 13312000 Custard pudding, baby food, flavor other than chocolate, junior
 67100100 Fruit, baby food, NFS
 67100110 Fruit bar, with added vitamin C, baby food, toddler
 67100200 Tropical fruit medley, baby food, strained
 67100300 Apples, baby food, toddler
 67101000 Apple-raspberry, baby food, NS as to strained or junior
 67101020 Apple-raspberry, baby food, junior
 67102000 Applesauce, baby food, NS as to strained or junior
 67102020 Applesauce, baby food, junior
 67104000 Applesauce and apricots, baby food, NS as to strained or junior
 67104020 Applesauce and apricots, baby food, junior
 67104030 Applesauce with bananas, baby food, NS as to strained or junior
 67104060 Applesauce with bananas, baby food, junior
 67104080 Applesauce with cherries, baby food, junior
 67104090 Applesauce with cherries, baby food, NS as to strained or junior
 67108000 Peaches, baby food, NS as to strained or junior
 67108020 Peaches, baby food, junior
 67109000 Pears, baby food, NS as to strained or junior
 67109020 Pears, baby food, junior
 67113000 Apples and pears, baby food, NS as to strained or junior
 67113020 Apples and pears, baby food, junior
 67114000 Pears and pineapple, baby food, NS as to strained or junior
 67114020 Pears and pineapple, baby food, junior
 67304000 Plums, baby food, NS as to strained or junior
 67304020 Plums, baby food, junior
 67307000 Apricots, baby food, NS as to strained or junior
 67307020 Apricots, baby food, junior
 67308000 Bananas, baby food, NS as to strained or junior
 67308020 Bananas, baby food, junior
 67309000 Bananas and pineapple, baby food, NS as to strained or junior
 67309020 Bananas and pineapple, baby food, junior
 67309030 Bananas and strawberry, baby food, junior
 67404000 Fruit dessert, baby food, NS as to strained or junior
 67404020 Fruit dessert, baby food, junior
 67404050 Fruit Supreme dessert, baby food
 67404550 Cherry cobbler, baby food, junior
 67405000 Peach cobbler, baby food, NS as to strained or junior
 67405020 Peach cobbler, baby food, junior
 67412000 Dutch apple dessert, baby food, NS as to strained or junior
 67412020 Dutch apple dessert, baby food, junior
 67414100 Mango dessert, baby food
 67415000 Tutti-fruitti pudding, baby food, NS as to strained or junior
 67415020 Tutti-fruitti pudding, baby food, junior
 67430000 Fruit flavored snack, baby food
 67430500 Yogurt and fruit snack, baby food

Baby Crackers, Pretzels, Cookies, and Snack Items

[2'-FL] = 5.7 g/100 g

53801000	Cereal bar with fruit filling, baby food
53803050	Cookie, fruit, baby food
53803100	Cookie, baby food
53803250	Cookie, teething, baby
53803300	Cookie, rice, baby
54350000	Crackers, baby food
54350010	Gerber Finger Foods, Puffs, baby food
54350020	Finger Foods, Puffs, baby food
54360000	Crunchy snacks, corn based, baby food
54408100	Pretzel, baby food
57830100	Gerber Graduates Finger Snacks Cereal, baby food

Table 10. Proposed Conventional Food Categories and Intended Use

Proposed Food Category	Food Uses	Maximum 2'-FL Use Level (g/serving)	RACC ^a (g or mL)	Maximum 2'-FL Use Levels (g/100 g)
Beverages and Beverage Bases	Energy drinks	0.28	360	0.08
	Fitness water and thirst quenchers, sports and isotonic drinks	0.28	360	0.08
Breakfast Cereals	Ready-to-eat breakfast cereals for adults and children	1.2	15 (puffed) 40 (high-fiber) 60 (biscuit-types)	8.0 3.0 2.0
	Hot cereals for adults and children	1.2	40 (dry) ~250 prepared	0.48 (as consumed)
Dairy Product Analogs	Milk substitutes such as soy milk and imitation milks	0.28	240	0.12
Frozen Dairy Desserts and Mixes	Frozen desserts including ice creams* and frozen yogurts, frozen novelties	1.2	~70	1.7
Gelatins, Puddings, and Fillings	Dairy-based puddings, custards, and mousses	1.2	~70	1.7
	Fruit pie filling	1.2	85	1.41
	"Fruit prep" such as fruit filling in bars, cookies, yogurt, and cakes	1.2	~40	3.0
Grain Products and Pastas	Bars, including snack bars, meal-replacement bars, and breakfast bars	0.48	40	1.20
Jams and Jellies, Commercial	Jellies and jams, fruit preserves*, and fruit butters	1.2	~20	6.0
Milk, Whole and Skim	All <i>Acidophilus</i> or fortified milks, non-fat and low-fat milk fluids, including fluid milk and reconstituted milk powder*	0.28	240	0.12
Milk Products	Flavored milks, including chocolate milk, coffee drinks, cocoa, smoothies (dairy and fruit-based), other fruit and dairy combinations, yogurt drinks, and fermented milk drinks including kefir**	0.28	240	0.12

	Milk-based meal replacement beverages or diet beverages**	0.28	240	0.12
	Yogurt*. **	1.2	225	0.53
	Formula intended for pregnant women ("mum" formulas, -9 to 0 months)	1.2	200 ^b	0.6
Processed Fruits and Fruit Juiced	Fruit drinks, including vitamin and mineral-fortified products	0.28	240	0.12
	Fruit juices*	0.28	240	0.12
Sweet sauces, Toppings, and Syrups	Syrups used to flavor milk beverages	0.28	40	0.70
Other Categories				
Non-Exempt Infant and Follow-On Formula	Infant formula (0 to 6 months), including ready-to-drink formula or formula prepared from powder	0.24	100 ^b	0.24 (0.40 g/100 kcal) ^c
	Follow-on formula (6-12 months), including ready-to-drink formula or formula prepared from powder	0.24	100 ^b	0.24 (0.40 g/100 kcal) ^c
Baby Foods	Meal replacement products such as PediaSure®	0.24	120 ^b	0.2
	Growing-up (toddler) milks (12-36 months)	0.24	120 ^b	0.2
	Ready-to-eat, ready-to-serve, hot cereals	1.2	15 (dry) 110 (ready-to-serve)	1.09 (as consumed)
	Yogurt and juice beverages identified as "baby" drinks	1.2	120	1.0
	Desserts including fruit desserts, cobblers, yogurt/fruit combinations ("junior type" desserts)	1.2	110	1.09
	Baby crackers, pretzels, cookies, and snack items	0.4	7	5.7
Medical Foods	Oral nutritional supplements and enteral tube feeding (11 years and older)	4.0	200 ^b	2.0

^a Reference Amounts Customarily Consumed per Eating Occasion (RACC), based on values established in 21 CFR 101.12. Note: when a range of values is reported for a proposed food use, particular foods within that food use may differ with respect to their RACC.

^b No RACC value exists; therefore, approximate serving sizes are provided according to food manufacturer instructions.

^c The intended use level in infant formula and baby meal replacement products is 2.4 g per L (0.24 g per 100 mL), or 0.40 g per 100 kcal. For a 100 mL formula that contains 60 kcal, the conversion is as follows:

$$\frac{100 \text{ mL}}{60 \text{ kcal}} \times \frac{0.24 \text{ g}}{100 \text{ mL}} = 0.004 \frac{\text{g}}{\text{kcal}} \text{ or } 0.40 \frac{\text{g}}{100 \text{ kcal}}$$

* 2'-FL is intended for use in unstandardized products when standards of identity do not permit its addition.

** Includes ready-to-drink and powder forms.

From: [Richard Kraska](#)
To: [Morissette, Rachel](#)
Subject: RE: Response on GRN 737
Date: Monday, February 12, 2018 3:21:58 PM
Attachments: [image011.png](#)
[GRAS_2FL.PDF](#)

Hi Rachel

Sorry about the omission. The letter is attached.

Do you have an idea when you will be making a final response?

Thanks

Rich

Richard Kraska, Ph.D., DABT

Chief Scientific Officer and Executive Vice President

Co-Founder

GRAS Associates, LLC

27499 Riverview Center Parkway

Bonita Springs, FL 34134

T: 239-444-1724 | C: 216-470-7280 | F: 239-444-1723 | E: kraska@gras-associates.com



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From: Morissette, Rachel [mailto:Rachel.Morissette@fda.hhs.gov]

Sent: Monday, February 12, 2018 11:44 AM

To: Richard Kraska <kraska@gras-associates.com>

Subject: FW: Response on GRN 737

Dear Rich,

In your response letter to our questions you mention that Dr. Lönnerdal provided a letter discussing his concurrence with the Expert Panel's conclusion. However, I did not see this letter among the attachments that you sent. Can you please send a scanned copy of that letter containing his original signature?

Thank you.

Rachel

Rachel Morissette, Ph.D.

Consumer Safety Officer

Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov



From: Richard Kraska [<mailto:kraska@gras-associates.com>]
Sent: Friday, January 05, 2018 10:56 AM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>
Subject: Response on GRN 737

Hi Rachel

Attached please find our letter responding to your questions. Please confirm your receipt of this message.

In response to FDA comments, we have added Dr. Bo Lönnerdal to the expert panel. Dr. Lönnerdal is a recognized expert in pediatric nutrition.

Other attachments included are:

- CVs for all four members of the expert panel
- A short statement of qualification for the members of the expert panel
- A correction of Table 10 in the dossier
- A corrected, non-confidential report for the dietary intake estimate to be used to correct Appendix 8

Thank you for your help and we hope these responses are useful in the review.

Regards
Rich

Richard Kraska, Ph.D., DABT

Chief Scientific Officer and Executive Vice President

Co-Founder

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ONE SHIELDS AVENUE
DAVIS, CALIFORNIA 95616-8669

January 2, 2018

Richard Kraska, Ph.D., DABT
Chief Scientific Officer and Executive Vice President
GRAS Associates, LLC
27499 Riverview Center Parkway
Bonita Springs, FL 34134

Dear Dr. Kraska,

I have reviewed all the material in the GRAS notice on 2'-fucosyl lactose that you have submitted to FDA. I have considerable expertise in bioactive components in breast milk and have conducted many clinical studies on breast-fed infants and infants fed formula with various added bioactive ingredients of different origin.

I agree with the opinion of the Expert Panel that the Glycosyn and Friesland Campina product is safe and that the proposed uses of 2'-FL in infant formulas and conventional foods for toddlers, children and adults, and in medical foods are safe.

Sincerely,


Bo Lonnerdal, Ph.D.
Distinguished Professor Emeritus of Nutrition & Internal Medicine

From: [Richard Kraska](#)
To: [Morissette, Rachel](#); "Katrina Emmel"
Cc: lewis@gras-associates.com
Subject: RE: GRN 000735 medical food uses follow-up to our phone call
Date: Thursday, April 05, 2018 1:40:01 PM
Attachments: [image013.png](#)
[image037.png](#)

Rachel

That's great. We look forward to your final letter. Thanks again.

Rich

Richard Kraska, Ph.D., DABT

Chief Scientific Officer and Executive Vice President

Co-Founder

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From: Morissette, Rachel [mailto:Rachel.Morissette@fda.hhs.gov]
Sent: Thursday, April 5, 2018 1:37 PM
To: Richard Kraska <kraska@gras-associates.com>; 'Katrina Emmel' <emmel@gras-associates.com>
Cc: lewis@gras-associates.com
Subject: RE: GRN 000735 medical food uses follow-up to our phone call

Hi Richard,

The email below is sufficient for us to move ahead with your letter. The letter will reference the date we received your request to withdraw and will likely contain a footnote explaining that the intended uses were withdrawn. The filing letter included these uses so the response letter needs to address this discrepancy. However, there will not be any details in the letter beyond the fact that the company requested the uses to be withdrawn and the date that happened.

Best,

Rachel

Rachel Morissette, Ph.D.

Consumer Safety Officer

Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov



From: Richard Kraska [<mailto:kraska@gras-associates.com>]
Sent: Thursday, April 05, 2018 1:24 PM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>; 'Katrina Emmel' <emmel@gras-associates.com>
Cc: lewis@gras-associates.com
Subject: RE: GRN 000735 medical food uses follow-up to our phone call

Hi Rachel

Our client has authorized the withdrawal of the medical food use from the GRN. What documentation do you need to officially do this? If you require a formal letter can we forward that to you by email?

One other question: will your "no questions" letter discuss this withdrawal or will it be silent on medical foods?

Thanks for all your help on this notice.

Regards
Rich

Richard Kraska, Ph.D., DABT

Chief Scientific Officer and Executive Vice President

Co-Founder

GRAS Associates, LLC

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From: Morissette, Rachel [<mailto:Rachel.Morissette@fda.hhs.gov>]
Sent: Thursday, April 5, 2018 11:32 AM
To: Richard Kraska <kraska@gras-associates.com>; 'Katrina Emmel' <emmel@gras-associates.com>
Subject: GRN 000735 medical food uses follow-up to our phone call

Dear Richard,

Thank you for meeting with us today to discuss the inclusion of medical foods in the intended uses for GRN 000735. Just to briefly recap, we are requesting that Glycosyn and FrieslandCampina withdraw the intended uses in medical foods in GRN 000735 because these uses do not appear to meet the Orphan Drug Act's (21 U.S.C. 360ee(b)(3)) definition of a medical food as follows:

"A food which is formulated to be consumed or administered enterally under the supervision of a physician and which 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."

While the notice does mention that the administration would be under a physician's supervision for the dietary management of a disease or condition, the notice does not mention the need for distinctive nutritional requirements established by a medical evaluation. Currently, there are very few cases that meet this high standard and qualify as medical foods, with one example being the PKU diet that I mentioned. We acknowledge that FDA's interpretation of and policy regarding medical foods is evolving and we are referring companies to our 2016 Guidance About Medical Foods to show FDA's thinking on this topic.

You mentioned that you would like to take a few days to discuss this issue with your clients, which we agreed would be fine. I also mentioned that should the companies decide to withdraw those intended uses and come back later outside the review of this notice, we would suggest setting up a pre-submission meeting with our medical foods staff to discuss the next steps.

Please let me know if you have any questions.

Best regards,

Rachel

Rachel Morissette, Ph.D.

Consumer Safety Officer

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