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Original Submission

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1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

REC'D MAR 23 2006

March 22, 2006

Writer's Direct Access
David R. Joy
(202) 434-4126
joy@khlaw.com

Via Overnight Delivery

Dr. Laura Tarantino
Director
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

**Re: GRAS Notification for Phosphatidylserine on Behalf of Degussa Food
Ingredients GmbH**

Dear Dr. Tarantino:

Pursuant to proposed 21 C.F.R. § 170.36(c), and on behalf of our client, Degussa Food Ingredients GmbH, we hereby notify the agency of Degussa's determination on the basis of scientific procedures that phosphatidylserine is generally recognized as safe (GRAS) when used as a nutrient supplement in various foods as described in the enclosed documents. As with all GRAS substances, this compound, when used in this application, is exempt from the premarket clearance requirement applicable to food additives under section 409 of the Food, Drug, and Cosmetic Act.

We trust you will find the enclosed notification acceptable. Should any questions arise during the review process, please do not hesitate to contact us, preferably by telephone, so that we may respond as quickly as possible.

Sincerely,

David R. Joy

Enclosure (GRAS Notification in triplicate)

cc: Dr. Dirk Cremer, Degussa Food Ingredients GmbH

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Before the
FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services
Washington, D.C.

GRAS NOTIFICATION

Name of Notifier: Degussa Food Ingredients GmbH

All Communications Should
be Sent to Counsel for Notifier: David R. Joy, Esq.
Keller and Heckman LLP
1001 G. Street NW
Washington, DC 20001

Name of Substance and Intended Use: Phosphatidylserine, for use as a nutrient
supplement in various foods.

Dated: March 22, 2006

Dr. Dirk Cremer
Manager Regulatory and Scientific
Affairs
Degussa Food Ingredients GmbH

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I. Claim of GRAS Status

A. Name and Address of Notifier:

Degussa Food Ingredients GmbH
Lise-Meitner-Str. 34
D-85354 Freising
Germany

B. Common or Usual Name of the Notified Substance:

The common or usual name of the substance that is the subject of this notification is phosphatidylserine.

C. Applicable Conditions of Use:

Phosphatidylserine is intended for use as a nutrient supplement in the following foods at a level of 20 mg per serving [serving sizes as determined by the 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) (USDA, 2000)]: yogurt (excluding fat-free yogurts), powdered milk, ready to drink soymilk, meal replacements, cereal bars, powdered beverage mixes, chewing gum, and breakfast cereals. Details are provided in Appendix I.

D. Basis for GRAS Determination:

The described use of phosphatidylserine has been shown to be generally recognized as safe (GRAS) on the basis of scientific procedures, in accordance with 21 C.F.R. § 170.30, as discussed more fully in the accompanying summary of the basis for the GRAS determination.

E. Statement of Availability of Data:

The data and information that are the basis for the GRAS determination will be sent to FDA upon request.

* * * * *

The foregoing and attached information considered, it is respectfully submitted that the use of phosphatidylserine for use as a nutrient supplement in the food types and within the indicated levels of use described above is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act because it is generally recognized as safe.

Respectfully Submitted,

Degussa Food Ingredients GmbH

By: _____

Dr. Dirk Cremer
Manager Regulatory and Scientific
Affairs

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F. Fatty Acid Profile

The following table shows the mean percentage of the fatty acids in Leci® PS 85 PN, as well as the range of observed variations, as indicated by minimum and maximum values observed over a two year period.

Fatty acid molecular mass in g/mol	Mean %* of total fatty acids in Leci® PS 85 PN
Palmitic acid (16:0) 255.2	14.6 (13.9-16.5)
Stearic acid (18:0) 283.2	4.2 (3.7-4.5)
Oleic acid (18:1; 9 Z) 281.2	9.2 (4.4-11.2)
Linoleic acid (18:2; 9 Z, 12 Z) 279.2	65.6 (62.2-70.1)
α -Linolenic acid (18: 3; 9 Z, 12 Z, 15 Z) 277.2	6.4 (5.9-7.2)
Sum	100

*: expressed as area % of normalized GC-FID chromatograms.

G. Molecular Weight

Based on the fatty acid profile given above, the average molecular weight of Leci® PS 85 PN is 778 g/mol.

H. Typical Composition and Specifications

The approximate bulk composition of Leci® PS 85 PN is listed below, based on the average of lots produced to date. Due solely to analytical imprecision, the sum is somewhat less than 100%. Specifications for Leci® PS 85 PN are provided in Appendix II.

Component	Percentage (by weight)	Assay
Phosphatidylserine	89.7	HPLC-ELSD (BA-AM-11)// 31P-NMR(Spectral Service SAA043)
Phosphatidic acid	3.2	HPLC-ELSD// 31P-NMR
Lyso-Phosphatidylserine	0.3	HPLC-ELSD// 31P-NMR
Lyso-Phosphatidic acid	0.3	HPLC-ELSD// 31P-NMR
Phosphatidylethanolamine	0.4	HPLC-ELSD// 31P-NMR

Triglycerides	0.1	HPLC-ELSD (BA-AM-11A)
Moisture	1	Karl Fischer Titration (BA-AM-5)
Sodium (Na ⁺)	3.1	ICP-AES
Calcium (Ca ⁺⁺)	0.2	ICP-AES
Chloride (Cl ⁻)	0.05	Ion-chromatography
free L-Serine	0.3	HPLC of OPA derivatives
Total Phytosterols	0.015	Gravimetrically after saponification (DGF F-III 1)
Tocopherol	0.02	HPLC
Sum	98.7	

I. Physical Properties

Leci® PS 85 PN occurs as a slightly amber powder, which melts at approximately 120 °C with decomposition. Its specific optical rotation is $[\alpha]_D = + 13^\circ$.

J. Manufacturing Process

Leci® PS 85 PN is prepared by a manufacturing process in which a high phosphatidylcholine (PC) enriched soy bean (Glycine max, L.) lecithin fraction is treated with L-serine. A transphosphatidyl reaction is enzymatically catalyzed by a purified, food grade enzyme. Except for the headgroup, the phosphatidylserine molecule present in Leci® PS 85 PN is identical with the phosphatidylcholine used to manufacture it, i.e, no change in the fatty acids attached to the molecule and no change in stereochemistry. Processing aids used such as sodium acetate (pH adjustment) and calcium chloride (enzyme co-factor) are of food grade quality as specified in current Food Chemicals Codex.

III. Level of Use and Intended Technical Effect

Leci® PS 85 PN is intended for addition to foods as a nutrient supplement, for those who wish to increase their daily intake of PS. While there is no Reference Daily Intake (RDI) for phosphatidylserine, the nutritive contribution of phosphatidylserine is widely recognized. Phosphatidylserine is a naturally occurring nutritive component in a wide variety of foods, but is present at high amounts only in certain fish, poultry, and meats, especially organ meats, many of which are not widely consumed. Therefore, vegetarians, vegans, and certain others who simply do not consume significant quantities of PS as a natural constituent of the diet may wish to supplement their intake with added PS.

IV. Summary of the Basis for a Conclusion that Phosphatidylserine is GRAS for its Intended Use

A. Nature and Occurrence

Phosphatidylserine (PS) is a phospholipid and a structural component of virtually all biological membranes of plants, animal and other life forms.^{1,2,3} Recent work has shown that phospholipids, including PS, also participate actively in cell signaling.^{4,5} The precise composition of the fatty acids in endogenous PS depends on its localization and function in the cell and of the cell, respectively. Typically a saturated fatty acid (C16-C18) is attached to sn-1 position of the glycerol and unsaturated acid or polyunsaturated acid (C16-C22) is attached to the sn-2 position. The structural differences in the unsaturated moiety are thought to be significant to the tertiary structure and functional activity of the specific PS molecule within its cellular environment.

The total human body pool of endogenous PS is estimated at 30 gm, about half of which is concentrated in the brain where it comprises approximately 17% (13 gm PS absolute) of the total brain phospholipids pool.^{6,7} Other PS-containing organs in humans include lung (7.4 %; 0.2 g PS abs.), kidney (5.7 %; 0.3 gm PS abs), liver (3.8 %; 2.4 gm PS abs.) and skeletal muscle (3.3 %; 12.4 gm abs.).⁸ The percent values provided here refer to the percentage of PS in the named tissue expressed on the basis of lipid phosphorus. A large amount of PS is also found within the inner leaflet of the plasma membrane of red blood cells. Each species, organ, cell and subcellular compartment has its unique phosphatidylserine-fatty acid pattern. The human body is able to produce PS endogenously via head-group exchange with phosphatidylcholine or

¹ Kuge, O. and Nishijima, M (2003) Biosynthetic regulation and intracellular transport of phosphatidylserine in mammalian cells. *Journal of Biochemistry* 133(4): 397-403.

² Vance, J (2003) Molecular and cell biology of phosphatidylserine and phosphatidylethanolamine metabolism. *Progress in Nucleic Acid Research and Molecular Biology*, 75: 69-111.

³ Vance, J and Vance D (2004) Phospholipid biosynthesis in mammalian cells. *Biochemistry and Cell Biology* 82: 113-128.

⁴ Mozzi R, Buratta S, and Goracci G (2003) Metabolism and functions of phosphatidylserine in mammalian brain. *Neurochemical Research* 28(2): 195-214.

⁵ Böse, J Gruber, A, Helming, L, *et al.* (2004) The phosphatidylserine receptor has essential functions during embryogenesis but not in apoptotic cell removal. *Journal of Biology* 3:Article 15.

⁶ Yorek, Mark A. Biological Distribution, p. 745 - 775; in Cevc, G. (Ed.) *Phospholipids Handbook* (1993), Marcel Dekker, Inc., New York.

⁷ Horrocks, L.A., van Rollins, M., Yates, A.J., in A.N. Davison and R.H.S. Thompson (Eds.), *The Molecular Basis of Neuropathology*, Edward Arnold Publishers, London, 1982, pp. 601-630.

⁸ *Id.*

phosphatidylethanolamine, catalyzed by phosphatidylserine synthase -1 or phosphatidylserine synthase -2 respectively.⁹

B. Background Dietary Intake of PS from Natural Sources

Dietary phosphatidylserine is found in small quantities in some animal food stuffs, principally organ meats such as brain, liver and kidney, but also in fish, muscle and some legumes.¹⁰ Dr. Hamm calculated an average PS intake of 130 mg/day, with light eaters of meat and fish consuming 100 mg and vegans less than 50 mg/p/day.¹¹ A more modest estimate of approximately 75 mg PS/day has been made by Bruni *et al.* (1989).¹²

The estimates above are expert estimates based on existing data, but are somewhat qualitative and do not include the possibility of high percentile consumers. To gain a better perspective on the actual U.S. consumption of PS, Degussa commissioned a survey from Exponent. Their Report is attached (Appendix III). Based on published data on the PS content of some foods, and consumption data from CSFII (USDA, 2000), Exponent estimated a lower-bound intake for the U.S. population of 96 mg/person/day (mean) and 184 mg/person/day (90th percentile). Because PS content data are not available for all foods, Exponent then estimated an upper bound intake by estimating the PS levels in foods for which PS content data were not available. This was done by applying the PS levels in known food to similar foods. The upper-bound intake results are 228 mg/person/day (mean) and 396 mg/person/day (90th percentile).

C. Bovine vs. Soy Derived PS

PS has traditionally been extracted from bovine brain and many of the clinical studies have been conducted on this form of PS. With concern over possible BSE contamination from bovine brain tissue, soy lecithin has become the most important commercial source of PS. The soy lecithin-derived PS is rich in linoleic acid-18:2 (66%), linolenic acid-18:3 (6.4%), oleic acid-18:1 (9.2 %) and palmitic acid-16:0 (14.6%). In contrast the bovine-derived PS is rich in oleic acid-18:1 (31.3%), and contains docosahexaenoic acid (DHA) -22:6 (9.9%), and mainly stearic acid-18:0 (40.3%). Thus, soy-based PS contains relatively more polyunsaturated acids and the bovine-based PS contains relatively more monounsaturated and saturated fatty acids. Expressed on the molecular level, soy lecithin-derived PS and bovine-derived PS differ in their molecular species profile. As discussed below (in D. and E.) in more detail, these differences in fatty acid composition (and PS species profile) are not expected to produce any significant toxicological

⁹ For a review see Vance, J (2003) Molecular and cell biology of phosphatidylserine and phosphatidylethanolamine metabolism. *Progress in Nucleic Acid Research and Molecular Biology*, 75: 69-111.

¹⁰ Kuksis A (1989) Animal sources of phospholipids, Chapter 4 in "Lecithins: Sources, Manufacture & Uses", 40-44 edited by Szuhaj BF.

¹¹ Hamm M (2004) Nutritional – scientific statement on the change of nutritive provision with phosphatidylserine (PS). Attached as Appendix IV.

¹² Bruni A, Mietto L, Bellini F *et al.* (1989) Pharmacological and autopharmacological action of phosphatidylserine. In *Phospholipids in the nervous system: Biochemical and Molecular Biology* NG Bazan, LA Horrocks, G. Toffano (eds) Fidia Research Series, Vol 17 Livana Press, Padova: 217-224.

differences. Ingestion of various PS molecular species and their remodeling is part of normal human physiology, first in the gastrointestinal tract where the PS molecular species profile of ingested PS of any origin from the daily food intake is remodeled in the mucosa to reflect the dietary intake of fatty acids, later on in any target tissue/organ where the PS species profile is tailor-modified to meet the specific needs of that particular tissue/organ. These facts strongly suggest that the original fatty acid composition of ingested PS and its molecular species distribution has little if any relevance concerning its safety.

D. Pharmacokinetics

Absorption - After ingestion, specific dietary PS molecules are first cleaved by pancreatic lipases.¹³ The resulting lysophospholipids are absorbed by the mucosal cells of the gastrointestinal tract. Within these cells they are rapidly reacylated with fatty acids of the body pool or further degraded. (Bruni *et al.* Ref cited.) and Johnston, 1977.¹⁴

Metabolism - As a consequence of the high PS decarboxylase activity within mucosal cells, most of the PS is converted into other phospholipids; mainly by a simple decarboxylation step to yield phosphatidylethanolamine (PE). Depending on the body's requirements, PE can subsequently be transformed to phosphatidylcholine (PC). Additionally there is evidence that PS can also be transformed into sphingolipids.¹⁵

Distribution - Pharmacokinetic studies with radiolabelled PS have been conducted in mice and rats with PS administered by intravenous injection, intraperitoneal injection or orally. These studies have demonstrated that after oral ingestion PS accumulates slowly in the blood with plateau levels between one and four hours.¹⁶ Phosphatidylserine administered parenterally is rapidly distributed, passes through the blood-brain barrier and reaches the cerebral tissues, where it appears to have an affinity for the hypothalamus. In vitro studies have shown that exogenous PS is rapidly integrated into cells.¹⁷ The reconstituted (re-modeled) PS molecules (*i.e.*, after reacylation) together with other phospholipids are distributed via the lymph and circulation. Within the circulation, further de- and re-acylation steps occur catalyzed by specific extracellular membrane-bound and lipoprotein-associated enzymes. After transfer to the target-organ and target-cell, respectively, the PS fatty acid pattern is again modified to fulfill its

¹³ Van der Bosch H, Aarsman AJ, van Deenen LL (1974) Isolation and properties of a phospholipase A1 from beef pancreas. *Biochem Biophys Acta* 348:197-209.

¹⁴ Johnston JM (1977) Gastrointestinal tissue. In *Lipid Metabolism in Mammals* (Snyder F, ed) pp151-187. New York and London: Plenum Press.

¹⁵ Meyer SGE and de Groot H (2003) [¹⁴C] serine from phosphatidylserine labels ceramide and sphingomyelin in L929 cells: evidence for a new metabolic relationship between glycerophospholipids and sphingolipids. *Archives of Biochem, and Biophys.* 410(1): 107-111.

¹⁶ Mazzari S, Zanotti A, Orlando P *et al.* (1982) Pharmacokinetics and pharmacodynamics of phosphatidylserine liposomes in mice. In Antolini *et al.* eds. *Transport in biomembranes: Model systems and reconstruction.* New York, Raven Press 257-63.

¹⁷ Vecchini A, Orlando P, Binaglia L *et al.* (1982) Interaction of cultured neuroblastoma cells with sonicated phosphatidylserine. In Horrocks *et al.* (eds). *Phospholipids in the Nervous System.* Vol 1. Raven Press, New York,

specific requirements. In the brain for example, the fatty acid pattern is selectively enriched in 18:0 stearic acid in sn-1-position and 22:6 docosahexaenoic acid in position sn-2.¹⁸

Elimination - In contrast to the metabolic fate of phosphatidylcholine, PS does not tend to accumulate.^{19,20} Regardless of the route of administration, the major fraction of PS, approximately 60%, is eliminated in feces. Approximately 10% of the dose is excreted via the urine. After oral administration, the main form eliminated in the feces (approximately 50%) is lyso-phosphatidylserine. Twenty four hours after oral administration of PS in rats, the total radioactivity extracted from the blood accounts for less than 0.3% of the dose applied. Metabolites recovered consisted of mainly lyso-PC, and to a lesser extent, lyso-PE.²¹

E. Animal Safety Data on PS

An extensive series of animal toxicity studies were conducted at Huntingdon Research Center. Most of the results (all the critical safety studies) have been published in Clinical Trials Journal (Heywood *et al.*, 1987).²² These studies were carried out using bovine cortex derived phosphatidylserine (BC-PS) rather than with PS obtained from soy lecithin. The only difference between these substances, aside from potential "impurities" from brain components present in BC-PS extracts, is the fatty acid composition in the side chains of the PS molecules as mentioned before already. While BC-PS molecules are mainly comprised of stearic, oleic and docosahexaenoic acid, soy-derived PS molecules consist mainly of linoleic, palmitic, oleic and linolenic acid. These different fatty acid side chains do not affect the overall oral toxicity for two reasons: First, as discussed above, the fatty acid portions of the molecules are largely cleaved prior to absorption by the mucosal cells. Second, all the fatty acids are safe and most in soy-derived PS even play vital roles in nutrition (see II F). There is no question about the safety of these fatty acids when administered orally at the suggested doses. In addition, several studies strongly suggest that PS of soy bean source is bioequivalent to bovine cortex derived PS.²³ There was therefore no reason to repeat such studies on soy-derived PS when adequate studies on BC-PS are available.

¹⁸ Mozzi R, Buratta S, Goracci G (2003) Metabolism and functions of phosphatidylserine in mammalian brain. *Neurochem Res* 28:195-214.

¹⁹ Fox, JM Betzing H and Lekim (1979) Pharmacokinetics of orally ingested phosphatidylcholine. *Nutrition and the brain* 5: 95-108.

²⁰ Toffano G Battistella A, and Orlando P. (1987) Pharmacokinetics of radiolabeled brain phosphatidylserine. *Clinical Trials J.* 24:18-24.

²¹ *Id.*

²² All toxicology studies reported in this section **Animal Safety Data** are reported in: Heywood R, Cozens DD, Richold M (1987) Toxicity of a phosphatidylserine preparation from bovine brain (BC-PS). *Clin Trials J.* 24:25-32. Complete study reports are available in Degussa's GRAS Notification Dossier.

²³ Sakai M Yamatoya H and Kudo S (1996) Pharmacological effects of phosphatidylserine enzymatically synthesized from soybean lecithin on brain functions in rodent *J Nutr. Sci. Vitaminol*, 42 :47-54.

1. Acute studies²⁴

The acute oral toxicity (LD₅₀) of BC-PS preparations in the rat was shown to be greater than 5,000 mg/kg bw. In a series of studies designed to determine the maximum dose of soy-derived PS tolerated in rats and mice it was found that single oral doses up to 2,000 mg/kg bw were well tolerated in both species. The i.v. LD₅₀ in rats for bovine PS was 236 mg/kg, which was consistent with the well tolerated i.v. dose of soy-derived PS of 125 mg/kg bw.

2. Repeat dose studies²⁵

26 weeks in Rats - Groups of Sprague Dawley rats (20 per sex and group) were administered PS daily by oral gavage for 26 weeks. Doses were 10, 100, and 1,000 mg/kg bw/day. The control group received a phosphate buffer solution. There was no significant difference in survival, weight gain and food consumption at the highest dose (1000 mg/kg bw) in comparison to control. Transient, post-dose salivation in some of the high-dose animals was observed. There were no treatment-related differences in mortality, food and water consumption, body weight gain or food utilization when compared to control. Minor adverse effects reported were (1) a slight elevation of alkaline phosphatase at the highest dose in males and females, (2) slightly lowered levels of albumin in males at the highest dose, (3) lowered pH values in urine in males and females at the highest dose, and (4) larger thyroid weights at autopsy for males only. There were no adverse macroscopic findings at necropsy or histological examination or other changes due to treatment. The adverse effects cited above were minor but were an indication that 1000 mg/kg bw dose (1%) slightly exceeded the no observed effect level (NOEL) for the substance in rats. These marginal adverse effects suggest that the true no-effect level would be much closer to 1000 mg/kg bw/day than to the 100 mg/kg bw/day dose.

26 weeks in Dogs - Four groups of pure-bred beagle dogs were administered PS once daily for 26 weeks. Doses administered were 10, 100 and 1,000 mg/kg bw/day. The control group received corn oil. There were no deaths recorded during the administration period. Organ weights were normal and there were no treatment related macroscopic findings. Water consumption was similar to controls. Animals receiving 1000 mg/kg bw/day gained significantly less weight than control animals. During the first 8 weeks of dosing dogs in the high dose group ate less than the controls. After moistened feed was offered in week 9 to stimulate consumption, food consumption matched the control values. Minor, but significantly reduced hematological and biochemical parameters, mainly reduced glucose and cholesterol levels were observed in dogs receiving 1000 mg/kg bw/day. As in the rat study, the observed effects at the highest doses were minimal, but could be indicative of some toxicity, and therefore the NOEL was slightly exceeded at 1000 mg/kg bw/day.

²⁴ Huntington Research Centre (1981a and b) Acute oral toxicity of BC-PS in the rat. Report N FDI/28/801108 dated March 18, 1981. Acute oral toxicity to rabbits of BC-PS Report N 81214D/FDI 31/AC dated June 2, 1981.

²⁵ Huntington Research Centre (1982a) Assessment of toxicity of BC-PS to rats when administered by daily oral gavage for 26 weeks. Report N FDI/42/82303 dated August 9, 1982. Huntington Research Centre (1983a) BC-PS oral toxicity study in Beagle dogs, repeated daily dosage for 26 weeks. Report N FDI/53-g82750 dated January 12, 1983.

3. Teratogenicity Studies²⁶

Teratogenicity in rats - The test compound was given by oral gavage to pregnant Sprague Dawley rats at dosages of 0, 10, 100, and 1,000 mg/kg bw/day from gestational days 6 to 15. On day 20 of pregnancy, the animals were sacrificed, litter values determined and fetuses subsequently examined for skeletal and visceral abnormalities. The only sign of toxicity in this rat study was a slight increase in post-dose salivation at 1,000 mg/kg/day. Litter values, assessed by litter size, post implantation loss, litter and mean fetal weights and embryonic development, were not affected by treatment up to 1000 mg/kg bw/day.

Teratogenicity in rabbits - PS was administered by oral gavage to groups of white New Zealand White pregnant rabbits. Doses of 0, 50, 150 and 450 mg/kg bw/day were administered from gestational days 6 – 15. At day 29 of pregnancy the animals were sacrificed and the litters were examined microscopically. Individual fetuses were examined externally and internally for evidence of visceral and skeletal abnormalities. At the highest dose of 450 mg/kg bw/day there was an early transient suppression of body-weight gain. Pregnancy and mortality were not affected nor were embryonic and fetal development with PS up to 450 mg/kg bw/day.

4. Genotoxicity studies²⁷

Several genetic toxicity studies showed PS to be without genotoxic or clastogenic activity. These included (1) a test for chromosomal damage in human lymphocytes, (2) a test for mutation in mouse lymphoma L5198Y cells, (3) an in vivo mouse micronucleus test, and a (4) test for DNA repair in cultured human epithelial (HELA S3) cells.

5. Clinical Studies in Humans

More than 30 clinical studies, employing >1500 subjects, have been conducted with PS. These studies included a geriatric population commonly encountered in clinical practice and affected by various diseases and under multiple drug therapies. While these studies were not designed as rigorous safety studies, careful clinical observations were made, and any adverse effects were recorded. The Table below lists the principal clinical trials. Doses of 300 mg/p/d were administered for period of up to 6 months and doses of 600 mg/p/d were administered up to 12 weeks without significant adverse effects. No drug interactions and no contraindications were reported. The Physicians Desk Reference (PDR) (2001) for Nutritional Supplements states that occasional gastrointestinal side effects, such as nausea and indigestion are reported; these are ascribed to the oily nature of the drug and vehicle and can be minimized by taking PS with meals.

²⁶ Huntington Research Centre (1983b) Effect of brain cortex phosphatidylserine on the pregnancy of the rat. Report N. FDI/47/82262 dated June 23, 1983. Huntington Research Centre (1982c). Effect of brain cortex phosphatidylserine on the pregnancy of the New Zealand white rabbit. Report N. FDA/48&49/82424 dated August 3, 1982.

²⁷ Huntington Research Centre (1989a) Mouse micronucleus test on BC-PS. Report N. FDI/213/881620 dated February 15, 1989.

Table 3.
Double-blind, placebo-controlled human efficacy trials: assessment of PS-related adverse effects. BC-PS: bovine cortex-derived PS, S-PS: soy-derived PS.

Author, Year of publication	Patients (number)	Dose (mg per day)	Duration	Adverse-effects
(Delwaide <i>et al.</i> , 1986)	35	300 (BC-PS)	6 weeks	"No significant side-effects observed"
(Cenacchi <i>et al.</i> , 1987)	130	300 (BC-PS)	60 days	"Treatment with phosphatidylserine does not modify the laboratory test results. The significant reductions in uric acid and SGPT, although favourable, are clinically negligible."
(Ransmayr <i>et al.</i> , 1987)	39	300 (BC-PS)	2 months	"Three patients in the drug group and two in the placebo group (oily vehicle) complained of moderate epigastric discomfort. At the end of the study, however, the side-effect disappeared spontaneously."
(Palmieri <i>et al.</i> , 1987)	87	300 (BC-PS)	60 days	"Blood biochemistry parameters showed no adverse effects"
(Villardita <i>et al.</i> , 1987)	170	300 (BC-PS)	90 days	No adverse-effects reported
(Amaducci, 1988)	142	200 (BC-PS)	3 months	"No adverse-effects reported, no influence on laboratory tests"
(Crook <i>et al.</i> , 1991)	149	300 (BC-PS)	12 weeks	"No adverse events attributable to drug treatment noted"
(Crook <i>et al.</i> , 1992)	51	300 (BC-PS)	12 weeks	"No adverse events attributable to drug treatment noted"
(Cenacchi <i>et al.</i> , 1993)	494	300 (BC-PS)	6 months	"No drug-attributable adverse-effects, ...no pharmacological interactions"
(Crook, 1998)	50	300 (S-PS)	12 weeks	No adverse-effects reported
(Gindin <i>et al.</i> , 1993)	57	300 (S-PS)	3 months	No adverse-effects reported
(Jorissen <i>et al.</i> , 2002)	120	300, 600 (S-PS)	12 weeks	"No influence on biochemical and haematological safety parameters nor on vital signs"

In the most recent clinical trial Jorissen *et al.* reported on the safety of daily doses of 300 and 600 mg Leci- PS in elderly people (120 subjects).²⁸ Standard biochemical and hematological safety parameters, blood pressure, heart rate and adverse events were assessed at baseline, 6 weeks and 12 weeks of PS treatment. No significant differences were found in any measured parameter between the treatment groups and the placebo group. Jorissen *et al.*

²⁸ Jorissen BL, Brouns F, Van Boxtel MP, Riedel WJ (2002) Safety of soy-derived phosphatidylserine in elderly people. *Nutr Neurosci* 5: 337-343.

concluded that: "soy-derived PS is a safe nutritional supplement for older persons if taken up to a dosage of 200 mg three times daily."

Additionally, we note that FDA has agreed to exercise enforcement discretion with respect to a qualified health claim regarding the relationship between PS and risk of dementia or cognitive dysfunction in the elderly.²⁹ Dietary supplements containing soy-derived PS are eligible to bear the claim. The petitioner for that health claim demonstrated that soy-derived PS is safe and lawful for such use at levels up to 500 mg/day in accordance with 21 C.F.R. § 101.14(b)(3)(ii).³⁰

F. ADI Determination for PS Added to the Diet

The acceptable daily intake (ADI) for a food additive or GRAS substance is typically determined by dividing the NOEL or NOAEL (no observed adverse effect level) from a lifetime study in animals by a safety factor of 100. For less-than-lifetime studies an additional safety factor of 10 (i.e., a total safety factor of 1000) is sometimes used. The repeat-dose animal safety data presented above consist of a 6 month study in rats and a 6 month study in dogs. Owing to additional supportive information in the present case, we believe that an adjustment for a less-than-lifetime study is unwarranted, and the traditional 100-fold safety has been used. Specifically, the 100-fold safety factor is justifiable for several reasons: (1) The wide (order of magnitude) dose spacing and the mild adverse effects observed in the animal studies at the highest dose indicates that a true no-effect level might well be closer to 1,000 mg/kg bw than to 100 mg/kg bw; (2) PS is an endogenous substance and there is rapid metabolism of PS into other endogenous body constituents, which are recognized as safe; (3) PS is present in the common diet from PS-containing fish, meat and legumes, etc., at levels that collectively are greater than added levels of PS for virtually all individuals (Appendix I and III).

Finally, there are dozens of clinical trials that testify to the safety of PS at doses as high as 300 mg/p/d; and in the Jorissen *et al.* study, at divided doses as high as 600 mg/p/d. Given that these human subjects include susceptible groups (the sick and elderly), there would seem to be ample justification to use this 600 mg/p/d level directly as the safe level. Safety factors for animal studies are precisely designed to bridge the lack of such human information.^{31,32} However, for purposes of this GRAS assessment, we shall assume a more conservative ADI value for added PS based on the animal studies. Applying the 100-fold safety factor, the ADI is

²⁹ "Letter Regarding Dietary Supplement Health Claim for Phosphatidylserine and Cognitive Dysfunction and Dementia" addressed to Jonathan Emord, dated February 24, 2003, available at <http://www.cfsan.fda.gov/~dms/ds-ltr33.html>.

³⁰ Petition for Health Claims: Phosphatidylserine and Cognitive Dysfunction, Phosphatidylserine and Dementia, Submitted to FDA April 18, 2002 by Dr. Kyl Smith, available at <http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091302/80027351.pdf>.

³¹ Renwick AG (1993) Data derived safety factors for the evaluation of food additives and environmental contaminants. Food Additive Contam 10: 275-305.

³² FAO/WHO Environmental Health Criteria 70 Principles for the Safety Assessment of Food Additives and Contaminants in Food. WHO, Geneva 1987.

1.0 mg/kg bw/day or approximately 60 mg/p/day for a 60 kg individual. In the animal and human clinical studies cited above, background PS from the diet was neither excluded nor quantified. We therefore deem it appropriate to apply this ADI only to PS added to the diet and not to PS that occurs naturally in foods.

G. EDI Determination for PS Added to the Diet

To obtain the estimated daily intake (EDI) of Leci PS that would result from Degussa's proposed uses of this substance, Degussa commissioned a study by Exponent. Dietary consumption of PS was estimated using consumption data from the 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) (USDA, 2000) and Exponent's Foods Analysis and Residue Evaluation Program (FARE™) software version 7.79. The CSFII is a nationally representative survey that collected 2-day food intake data for approximately 22,000 individuals. Only individuals with complete and reliable 2-day dietary records were included in the analysis (N=20,607). Households and individuals were surveyed in all four seasons and on all days of the week. In addition to information on food consumption, the survey collected physiological and demographic data such as sex, age, self-reported height and weight, ethnic group, pregnancy and lactation status, and household income. This information permits an assessment of food consumption by specific population groups of interest. The survey is designed to provide consumption estimates that are nationally representative of the US population. The intakes presented in this report are based on 2-day average daily intakes among subjects with 2 days of valid intake data.

The Exponent report, "Dietary Intake of Phosphatidylserine from Enriched Food Sources" (August 2, 2005), is attached as Appendix I. The estimated consumption of added PS is provided in Table 1 of the report and reproduced below.

	2-day Average Daily PS Intake (mg/day)		
	Per User	Per Capita	% ADI ³³
Total US Population			
Mean	26.4	6.72	44%
90th Percentile	52.2	20.2	87%
Children 7 to 12 years			
Mean	20.8	6.96	35%
90th Percentile	45.0	20.2	75%
Adults 50+ years			
Mean	28.0	5.98	47%
90th Percentile	52.4	16.5	87%

³³ % ADI was calculated by comparing the *Per User* 2-day average daily intake of PS (mg/day) to the ADI of 60 mg/day.

As seen in the table above, the EDI is lower than the ADI for the 90th percentile “user” of foods to which PS is proposed to be added for the total U.S. population and each of the specific age groups studied.

H. Incremental Increase in Serine and Phosphorous

Incremental increase in serine and phosphorous- The average molecular weight of typical Leci PS is approximately 778 g/mol with 4% phosphorous, 13% serine and 70% linoleic acid. The average individual in the United States consumes approximately 75 grams of protein each day, which contains approximately 3.5 grams of serine depending on the source of the protein.³⁴ Thus the serine component of added PS at the calculated ADI, $0.13 \times 60 \text{ mg} = 7.8 \text{ mg}$, is negligible compared to serine from protein, even for the occasional heavy eater of high PS foods. Phosphorus (P) represents 4% of PS and an added increment of 60 mg PS to the diet would increase the phosphorous load by $60 \text{ mg} \times 0.04 = 2.4 \text{ mg/d}$. The DRI (Dietary Reference Intake) for phosphorous for young adults is 1,250 mg/d and the tolerable upper limit for P is from 3-4 g/d.³⁵ Clearly, the added increment of P due to the intake of PS would be negligible. While the proposed (three 20 mg servings) intake of 60 mg/p/d PS is comparable to the average intake of PS from food, its contribution in terms of its added metabolic components (phosphorous, serine and fatty acids) is negligible.

V. Conclusion

Based on a review of the scientific literature Degussa Food Ingredients GmbH concludes that there is significant scientific agreement that soy-derived PS (Leci® PS 85 PN) is generally recognized as safe (GRAS). Specifically, there is general recognition that:

- Soy-derived PS is toxicologically equivalent to PS found in the natural diet and metabolizes to safe endogenous products. The amount proposed for addition to the diet (60 mg/day) is comparable to that normally consumed daily amount of PS from the diet (75 – 228 mg/day)
- In appropriate animal feeding studies, PS is without significant toxicity at dosage levels which represent over one hundred times the intended human use level for added PS.
- In hundreds of human clinical subjects, oral PS exhibits an excellent safety record showing the virtual absence of adverse effects at doses between 200 and 600 mg per day. No influence on standard biochemical and hematological safety parameters were reported.

³⁴ Results from USDA's 1994-96 Continuing survey of Food Intakes by Individuals and 1994-96 Diet and Health Knowledge survey, Table Set 1 Nutrient Intakes. Also Dietary Reference Intakes Part 2 Chapter 10 Protein and Amino Acids, Serine. Page 10-103.

³⁵ NAS (2000) Values from Food and Nutrition Board, Institute of Medicine, National Academy of Sciences: Recommended Intakes for Individuals.

In light of the data and discussion presented above, Degussa Food Ingredients GmbH respectfully concludes that use of Leci PS85 PN as a nutrient supplement, in the foods and at the levels of use specified above, is GRAS, as demonstrated through scientific procedures.

Appendix I

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Exponent[®]

Food & Chemicals

Technical Memorandum

**Dietary Intake of
Phosphatidylserine from
Enriched Food Sources**

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Technical Memorandum

Dietary Intake of Phosphatidylserine from Enriched Food Sources

Prepared for
Dr. Dirk Cremer
R&D Director Regulatory Affairs & Analytical
Methods
Degussa Food Ingredients
Lise Meitnerstr. 34
D-85354 Freising, Germany

Prepared by

Exponent, Inc.
1730 Rhode Island Ave NW
Suite, 1100
Washington, DC 20036

August 2, 2005

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Dietary Intake of Phosphatidylserine

Introduction

Degussa Food Ingredients (Degussa) is preparing a GRAS notice for phosphatidylserine (PS), a natural occurring phospholipid, and has requested Exponent, Inc.'s (Exponent) assistance in estimating dietary intake of PS from foods proposed for enrichment for the US population and the following population groups: children aged 7-12 years and adults aged 50+ years. Exponent previously estimated intakes of PS from naturally occurring sources for the same population groups and reported these intakes in a previous report (Exponent, 2005).

Dietary consumption of PS was estimated using consumption data from the 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) (USDA, 2000) and Exponent's Foods Analysis and Residue Evaluation Program (FARE™) software version 7.79. The CSFII is a nationally representative survey that collected 2-day food intake data for approximately 22,000 individuals. Only individuals with complete and reliable 2-day dietary records were included in the analysis (N=20,607). Households and individuals were surveyed in all four seasons and on all days of the week. In addition to information on food consumption, the survey collected physiological and demographic data such as sex, age, self-reported height and weight, ethnic group, pregnancy and lactation status, and household income. This information permits an assessment of food consumption by specific population groups of interest. The survey is designed to provide consumption estimates that are nationally representative of the US population. The intakes presented in this report are based on 2-day average daily intakes among subjects with 2 days of valid intake data.

PS Intake from Enriched Food Sources

Degussa identified the following 7 broad food categories to be included in the analysis:

1. Yogurt (excluding fat-free yogurts)
2. Milk (powdered milk and ready-to-drink soymilk)
3. Meal replacements
4. Cereal bars
5. Powdered beverages
6. Chewing gum
7. Breakfast cereals

For each broad food category, Exponent selected appropriate food codes from the USDA's CSFII food codes to include based on information provided by Degussa. All foods were assumed to be enriched at 20 mg PS per serving. Using the USDA average serving sizes included in the CSFII (USDA, 2000), Exponent calculated the PS content of each food code

included in the analysis. A complete list of food codes and PS use levels used in the analysis is presented in Appendix A.

Results

Summary intake estimates for the total US population, children 7-12 years, and adults 50 years and older are provided in Table 1. The mean per user dietary intake of PS from all enriched foods for the US population is 26.4 mg/day, while the 90th percentile PS intake is 52.2 mg/day. Among children 7-12 years, the mean per user PS intake from all enriched food sources was 20.8 mg/day and 45.0 mg/day at the 90th percentile. Among adults ages 50 years and older, the mean per user PS intake from all enriched food sources was 28.0 mg/day and 52.4 mg/day at the 90th percentile.

Per user and per capita PS intake estimates for the total US population and included subpopulations among average and high consumers (90th percentile) are all below the ADI of 60 mg/day, ranging from 35% to 87% of the ADI.

Summary intake estimates by food category are provided in Table 2. The mean per user dietary intake of PS in the US population ranges from 9.42 mg/day in the yogurt category to 34.2 mg/day in the powdered milk/soymilk category, while the 90th percentile PS intake in the US population ranges from 16.2 mg/day to 75.2 mg/day, respectively.

Discussion

Exponent previously estimated intakes of PS from naturally occurring sources for the same population groups and reported these intakes in a previous report (Exponent, 2005). The estimated intake of PS from naturally occurring sources among the US population was based on consumption of foods in the US diet that naturally contain various levels of PS. In addition to the intake of PS from the diet, an ADI has been established for the intake of PS through the consumption of foods that have been enriched with PS (Scheuplein, 2004). Based on two repeated dose studies in dogs and rats, adverse effects of PS were seen in the highest dose group (1000 mg/kg bw) and therefore, the NOEL was established to be the next lowest dose (100 mg/kg bw). After applying a 100-fold safety factor, the ADI is determined to be 1.0 mg/kg bw/day. This value, adjusted for a standard adults bodyweight of 60 kg, was determined to be 60 mg PS/day per person. It is important to note that these studies were conducted on animals that were not being fed a diet free of PS, therefore, this ADI is applicable to the intake of PS from foods that have been enriched with PS and does not take into account the intake of PS from naturally occurring sources.

Based on the results of the intake assessment presented in this report, estimated total intake of PS from enriched food sources in the Total US population and selected subpopulations does not exceed the ADI of 60 mg/day. Among the high consumers (90th percentile), estimated daily

total intake of PS ranged from 75% of the ADI among children 7-12 years to 87% of the ADI among the Total US population and adults 50 years and older.

References

Exponent, Inc. (Exponent) (2005). Technical Memorandum: Dietary intake of Phosphatidylserine. July 2005.

Scheuplein, B. (2004). Memorandum to John Eldred and John Moore: Safety of Degussa's phosphatidylserine. Keller and Heckman LLP. September 28, 2004.

U.S. Department of Agriculture (USDA) (2000). CSFII Data Set and Documentation: The 1994-96, 1998 Continuing Surveys of Food Intakes by Individuals. Food Surveys Research Group. Beltsville Human Nutrition Research Center. Agricultural Research Service. April 2000.

Table 1. Estimated Daily Intake of PS from Proposed Food Uses (mg/day) (20 mg/serving)

	2-day Average Daily PS Intake (mg/day)		
	Per User	Per Capita	% ADI ¹
Total US Population			
Mean	26.4	6.72	44%
90th Percentile	52.2	20.2	87%
Children 7 to 12 years			
Mean	20.8	6.96	35%
90th Percentile	45.0	20.2	75%
Adults 50+ years			
Mean	28.0	5.98	47%
90th Percentile	52.4	16.5	87%

Table 2. Average Daily Intake of PS Among "Users" From Proposed Uses by Category of Use (mg/day) (20 mg/serving)

Food Group	Total US		Children, 7-12 yr		Adults, 50+ yr	
	Mean	90th	Mean	90th	Mean	90th
Breakfast bars	13.9	23.4	12.2	20.0*	15.7	26.2*
Cereals	23.0	42.0	20.4	33.4*	22.4	42.0*
Chewing gum	26.4	50.2	26.6	50.2*	40.6*	ND
Meal Replacements	17.1	30.2*	11.3*	ND	13.5	20.6*
Powdered milk/soymilk	34.2	75.2	13.5*	ND	32.6	58.8
Powdered beverages	24.6	47.6	22.2	45.0	25.8	60.0
Yogurt	9.42	16.2	7.08	10.8*	9.98	20.0*

*Population size insufficient for a statistically reliable estimate.
 ND = Not Determined; unweighted N <15.

¹ % ADI was calculated by comparing the *Per User* 2-day average daily intake of PS (mg/day) to the ADI of 60 mg/day.

Appendix A: CSFII Food Codes Included in Analyses

Foodcode	Description	Serving size ¹ (grams)	Level of PS in food per serving ² (ppm)
Breakfast Bars			
53542100	GRANOLA BAR W/ OATS, SUGAR, RAISINS, COCONUT	43	465
53542200	GRANOLA BAR, OATS, FRUIT, NUTS, LOWFAT	24	833
53542210	GRANOLA BAR, NONFAT	43	465
53543100	GRANOLA BAR W/ PEANUTS, OATS, SUGAR, WHEAT GERM	43	465
53544100	GRANOLA BAR, W/ NOUGAT	34	588
53544200	GRANOLA BAR, CHOCOLATE-COATED	28	714
53544210	GRANOLA BAR, W/ COCONUT, CHOCOLATE-COATED	39	513
53544220	GRANOLA BAR W/ NUTS, CHOCOLATE-COATED	35	571
53544250	GRANOLA BAR, COATED W/ NONCHOCOLATE COATING	28	714
53544300	GRANOLA BAR, HIGH FIBER, YOGURT COATING, NOT CHOC	28	714
53544400	GRANOLA BARS, W/ RICE CEREAL	28	714
53544450	POWERBAR (FORTIFIED HIGH ENERGY BAR)	65	308
Cereal			
57000000	CEREAL, NFS	33	606
57100100	CEREAL, READY-TO-EAT, NFS	25	800
57227000	GRANOLA, NFS	55	364
57228000	GRANOLA, HOMEMADE	61	328
57229000	GRANOLA, LOWFAT, KELLOGG'S	32	625
57237100	HONEY BUNCHES OF OATS CEREAL	30	667
57237300	HONEY BUNCHES OF OATS W/ ALMONDS, POST	28	714
57308150	MUESLIX CEREAL, NFS	41	488
57308180	MUESLIX CRISPY BLEND	50	400
57308200	MUESLIX GOLDEN CRUNCH CEREAL	35	571
57308900	NATURAL MUESLI, JENNY'S CUISINE	35	571
57311000	NATURE VALLEY GRANOLA, TOASTED OAT MIXTURE	55	364
Chewing Gum			
91800100	CHEWING GUM, NFS	2.8	7143
91801000	CHEWING GUM, SUGARED	4	5000
91802000	CHEWING GUM, UNCOATED, SUGARLESS	2	10000
Meal Replacements			
11612000	INSTANT BREAKFAST, POWDER, MILK ADDED	279	72
11613000	INSTANT BFASST,PWDR,SWT W/ LO CAL SWT, MILK ADDED	279	72
11622000	DIET BEVERAGE POWDER, MILK ADDED	212	94
11622010	DIET BEVERAGE,PWDR,RECONST W/SKIM (INCL	264	76
11651010	MEAL REPLACEMENT, CAMBRIDGE, RECONST, ALL	286	70

¹ USDA average serving sizes included in the CSFII (USDA, 2000).

² All foods were assumed to be enriched at 20 mg PS per serving.

Foodcode	Description	Serving size ¹ (grams)	Level of PS in food per serving ² (ppm)
11830800	INSTANT BREAKFAST POWDER, NOT RECONSTITUTED	37	541
11830810	INSTANT BFAST,PWDR,SWT W/ LO CAL SWT,NOT	20	1000
11830850	HIGH CALORIE MILK BEVERAGE, POWDER, NOT RECONST	30	667
11830900	PROTEIN SUPPLEMENT, MILK BASED, DRY POWDER	43	465
11830940	MEAL REPLACEMENT,PROTEIN,MILK BASED,FRUIT JUICE	31	645
11830950	NUTRIENT SUPP,MILK-BASED,POWDERED,NOT	39	513
11830960	PROTEIN SUPP, MILK BASE, SODIUM CONTROLLED,	58	345
11830970	MEAL REPLACEMENT, PROTEIN TYPE, MILK-BASE, POWDER	58	345
11830980	PROTEIN SUPP, MILK-BASE, POWDER (INCL SUSTACAL)	57	351
11830990	NUTRIENT SUPP, MILK-BASE, POWDER (INCL SUSTAGEN)	31	645
11831500	NUTRIENT SUPPLEMENT,MILK-BASE,HIGH PROT,NOT	27	741
11832000	MEAL REPLACEMENT,MILK-&SOY-BASE,POWDER,NOT	44	455
11832500	MEAL REPLACEMENT,PROTEIN TYPE,MILK-	24	833
11835000	MEAL REPLACEMENT, CAMBRIDGE, POWDER, NOT	34	588
11835100	MEAL REPLACEMENT, POSITRIM DRINK MIX, DRY POWDER	43	465
11835150	DYNATRIM, MEAL REPLACEMENT, POWDER	34	588
11835200	LOSE-IT (NANCI), MEAL REPLACEMENT, POWDER	21	952
41435010	HIGH PROTEIN BAR, SOY BASE	71	282
41435110	HIGH PROTEIN BAR, CANDY-LIKE, SOY & MILK BASE	50	400
41435200	HIGH PROTEIN BAR, COOKIE TYPE,SOY & MILK BASE	34	588
Powdered Milk and Soy Milk			
11120000	MILK, DRY, RECONSTITUTED, NFS	245	82
11121100	MILK, DRY, RECONSTITUTED, WHOLE	244	82
11121210	MILK, DRY, RECONSTITUTED, LOWFAT	245	82
11122000	BUTTERMILK, DRY, RECONSTITUTED	245	82
11330000	MILK, SOY, DRY, RECONSTITUTED, NOT BABY	245	82
11810000	MILK, DRY, NOT RECONSTITUTED, NS AS TO FAT	23	870
11811000	MILK, DRY, WHOLE, NOT RECONSTITUTED	43	465
11812000	MILK, DRY, LOWFAT, NOT RECONSTITUTED	40	500
11820000	BUTTERMILK, DRY, NOT RECONSTITUTED	40	500
11830200	MILK, MALTED, DRY, UNFORTIFD, NOT RECONST, NOT CHOC	21	952
11830210	MILK, MALTED, DRY, FORTIFD, NOT RECONST, NOT CHOC	21	952
11830250	MILK, MALTED, DRY, UNFORTIFIED, NOT RECONST, CHOC	21	952
11830260	MILK, MALTED, DRY, FORTIFIED, NOT RECONST, CHOC	21	952
11830400	MILK BEV POWDER, DRY, NOT RECONST, NOT CHOC	22	909
11830450	MILK BEV MIX, W/ SUGAR,EGG WHITE, NOT	19	1053
11830500	MILK BEV POWDER W/ NFD MILK, LOW CAL, DRY, CHOC	21	952
11830550	MILK BEV POWDER W/ NFD MILK, LOW CAL, DRY, NOT CHOC	21	952
12200100	CREAM SUBSTITUTE, NS AS TO FROZEN,LIQUID OR	15	1333
12210400	CREAM SUBSTITUTE, POWDERED	3	6667
12210410	CREAM SUBST, LIGHT, POWDERED (INCL COFFEE MATE,	3	6667

Foodcode	Description	Serving size ¹ (grams)	Level of PS in food per serving ² (ppm)
Powdered Beverages			
11830100	COCOA W/DRY MILK & SUGAR, DRY MIX, NOT RECONST	28	714
11830110	COCOA POWDER W/ NFD MILK, LOW CAL SWEETENER, DRY	17	1176
11830120	COCOA W/ WHEY, LO CAL SWEETENER, FORTIFIED, DRY	11.6	1724
11830140	CHOCOLATE, INST, DRY MIX, FORTIFD, NOT RECONST,P.R.	28	714
11830150	COCOA POWDER, NOT RECONSTITUTED (NO DRY MILK)	11	1818
11830160	COCOA-FLAVORED BEVERAGE POWDER W/ SUGAR, DRY	22	909
11830170	COCOA, WHEY, LO CAL SWEETNER MIX, NOT RECONST	11	1818
11830180	COCOA-FLAV BEV MIX, LOW CALORIE, DRY, NOT RECONST	11	1818
92541010	FRUIT-FLAVORED DRINK, FROM SWEETENED	250	80
92541020	LEMONADE-FLAV DRINK, FROM POWDER, W/ SUGAR & VIT C	250	80
92541040	LEMONADE-FLAV DRINK, FROM POWDER, LO CAL, W/ VIT C	240	83
92541100	APPLE CIDER DRINK, FROM MIX, SUGAR & VIT C ADDED	250	80
92541120	APPLE CIDER DRINK, FROM MIX, LOW CAL, VIT C ADDED	240	83
92544000	FRUIT-FLAVOR DRINK, FROM UNSWEET PWDR,W/ VIT C,W/	240	83
92552000	FRUIT-FLAV DRINK, FROM MIX, HI VIT C ADDED, LOW CAL	240	83
92731000	FRUIT-FLAVORED DRINK, NON-CARB, FROM POWDER, W/	240	83
92741000	FRUIT-FLAVORED DRINK, NON-CARB, FROM LO CAL	240	83
92900110	FRUIT-FLAVORED CONCENTRATE, DRY, W/ SUGAR & VIT C	240	83
92900200	FRUIT-FLAV BEV, DRY CONC, LO CAL (INCL CRYSTAL LIGHT)	240	83
92900300	FRUIT-FLAV THIRST QUENCH BEV, DRY CONC (GATORADE)	240	83
Yogurt (excluding fat-free)			
11410000	YOGURT, NS AS TO TYPE OF MILK/FLAVOR	227	88
11411010	YOGURT, PLAIN, NS AS TO TYPE OF MILK	227	88
11411100	YOGURT, PLAIN, WHOLE MILK	227	88
11411200	YOGURT, PLAIN, LOWFAT MILK	227	88
11420000	YOGURT, VANILLA, LEMON, COFFEE, NS AS TO MILK TYPE	227	88
11421000	YOGURT, VANILLA, LEMON, COFFEE, WHOLE MILK	227	88
11422000	YOGURT, VANILLA, LEMON, COFFEE, LOWFAT MILK	227	88
11425000	YOGURT, CHOCOLATE, NS AS TO TYPE OF MILK	227	88
11426000	YOGURT, CHOCOLATE, WHOLE MILK	227	88
11430000	YOGURT, FRUIT VARIETY, NS AS TO MILK TYPE	227	88
11431000	YOGURT, FRUIT VARIETY, WHOLE MILK	227	88
11432000	YOGURT, FRUIT VARIETY, LOWFAT MILK	227	88
11444000	YOGURT, FRUIT & NUTS, NS AS TO TYPE OF MILK	227	88
11445000	YOGURT, FRUIT & NUTS, LOWFAT MILK	227	88
11553000	FRUIT SMOOTHIE DRINK, W/ FRUIT AND DAIRY PRODUCTS	152	132
11553100	FRUIT SMOOTHIE DRINK, NFS	152	132

Appendix II

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TECHNICAL DATA SHEET Leci® PS 85 PN

Product characteristics:	LECI®-PS 85 PN is a phosphatidylserine enriched, powdered soybean lecithin for use in nutritional supplements. It contains small quantities of a tocopherol (Vitamin E)/ascorbylpalmitate based antioxidant.			
Storage Conditions:	LECI®-PS 85 PN should be kept in the sealed bags, avoiding light and moisture, until ready for use. The optimum storage temperature is below 4°C. The shelf life of LECI®-PS 85 PN is min. 24 months from the date of manufacture, in the original unopened container under the storage conditions suggested above.			
Packaging:	1 kg net, Polyethylene/Alu/Polyester sealed bags			
Composition:¹	Phosphatidylserine and small amounts of other lipids, composed as follows:			
		min.	85	% ¹
	Phosphatidylserine (PS)	max.	9	%
	Total other Phospholipids	max.	1.5	%
	Triglycerides	max.	1.5	%
	Moisture	max.	0.1	%
	Antioxidant	max.	0.1	%
	Total fatty acids ²	approx.	70	% ¹
	Saturated fatty acids		9 - 15	%
	Mono unsaturated fatty acids		5 - 9	%
	Poly unsaturated fatty acids		38 - 63	%
	Of which			
	Linoleic acid		34 - 57	%
	Linolenic acid		3 - 6	%
Specification: (items reported on the CofA)	Ingredients:			typical value:
	Phosphatidylserine (PS)	min.	85 %	89.7 % ¹
	moisture	max.	1.5 %	< 1 %
	Peroxide value	max.	5	< 1
	Microbiology:			
	Total plate count	max.	1000/g	< 100
	Yeasts and moulds	max.	50/g	< 10
	Coliforms	negative	/g	complies
	E. coli	negative	/g	complies
	Salmonellae	negative	/25 g	complies

1: all percentage values absolute percentages by weight

2: Fatty acid present in the product are attached to the phospholipids glycerol backbone

Degussa Food Ingredients GmbH, Lise-Meitner-Str. 34, D-85354 Freising, Phone ++49-8161-548-0, Fax ++49-8161-548-580
Email: food.ingredients@degussa.com

All recommendations as well as formulations made herein are based on data to be believed reliable. Because of operating conditions in our customers plant are beyond our control we cannot assume responsibility for risks, formulas or liabilities that may result from the use of our products. No legal patent liability is assumed for any method or manner of use by the processor. Slight deviations of analytical data are within the tolerance limits of the methodology.

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TECHNICAL DATA SHEET Leci[®] PS 85 PN

Purity monitoring program

Contaminant	Typical level
Heavy metals As Hg Cd Pb	< 0.1 ppm ³ < 0.005 ppm ³ < 0.01 ppm ³ < 0.05 ppm ³
Pesticides Organo-phosphorus Organo-chloro Organo-nitro Pyrethroides	< (0.02 – 1) mg/kg ⁴ < (0.005 – 0.04) mg/kg ⁴ < 0.01 ⁴ < 0.05 ⁴
Mycotoxines Aflatoxine B1, B2, G1, G2 DON (Deoxynivalenol) ZEA (Zearalenon)	< 0.1 µg/kg ³ each < 10 µg/kg ³ < 10 µg/kg ³
PCB`s (TE12 WHO PCB)	< 0.1ng/kg
Dioxines and Furanes (TE WHO)	< 0.3 ng/kg
Volatile organic compounds Trichlormethane 1,1,1-Trichlorethane Trichlorethane Tetrachlorethane Benzene Toluene Ethylbenzene m-+p-Xylene o-Xylene Styrene	< 0.05 ppm ³ < 0.05 ppm ³ < 0.05 ppm ³ < 0.05 ppm ³ < 0.01 ppm ³ < 0.5 ppm ³ < 0.01 ppm ³ < 0.01 ppm ³ < 0.01 ppm ³ < 0.01 ppm ³

3 limit of quantification (LOQ)

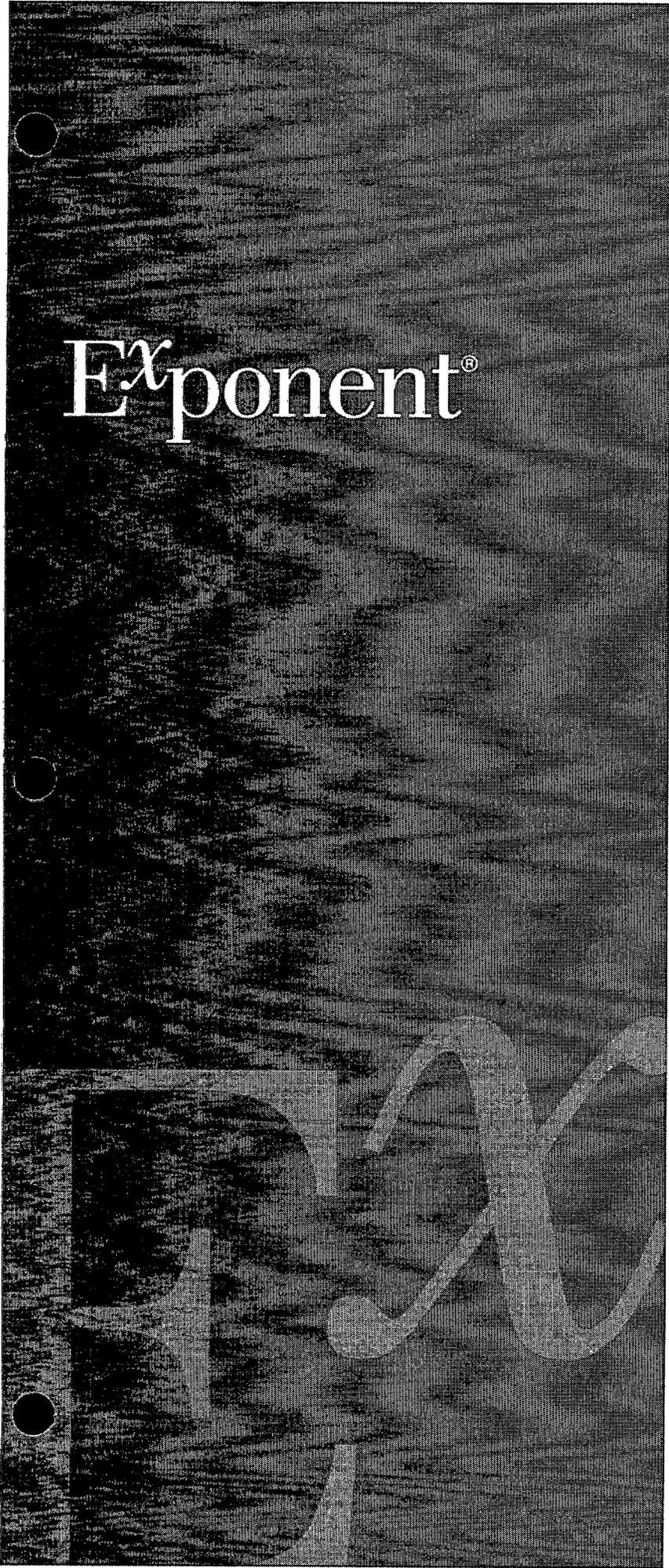
4: LOQ estimates

Degussa Food Ingredients GmbH, Lise-Meitner-Str. 34, D-85354 Freising, Phone ++49-8161-548-0, Fax ++49-8161-548-580
 Email: food.ingredients@degussa.com

All recommendations as well as formulations made herein are based on data to be believed reliable. Because of operating conditions in our customers plant are beyond our control we cannot assume responsibility for risks, formulas or liabilities that may result from the use of our products. No legal patent liability is assumed for any method or manner of use by the processor. Slight deviations of analytical data are within the tolerance limits of the methodology.

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Appendix III



Exponent[®]

Food & Chemicals

Technical Memorandum

**Dietary Intake of
Phosphatidylserine**

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Exponent®

Technical Memorandum

**Dietary Intake of
Phosphatidylserine**

Prepared for
Dr. Dirk Cremer
R&D Director Regulatory Affairs & Analytical
Methods
Degussa Food Ingredients
Lise Meitnerstr. 34
D-85354 Freising, Germany

Prepared by

Exponent, Inc.
1730 Rhode Island Ave NW
Suite, 1100
Washington, DC 20036

July 15, 2005

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Dietary Intake of Phosphatidylserine

Introduction

Degussa Food Ingredients (Degussa) is preparing a GRAS notice for phosphatidylserine (PS), a natural occurring phospholipid, and has requested E^xponent, Inc.'s, assistance in estimating dietary intake of PS in the US population. E^xponent derived dietary intake estimates of PS using E^xponent's DEEM-FCID™ proprietary software and consumption data from the 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) (USDA, 2000). The 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) records 2-day dietary intake data for 20,607 individuals of all ages. Households and individuals were surveyed in all four seasons and on all days of the week. In addition to information on food consumption, the survey collected physiological and demographic data such as sex, age, self-reported height and weight, ethnic group, pregnancy and lactation status, and household income. This information permits an assessment of food consumption by specific population groups of interest. The survey is designed to provide consumption estimates that are nationally representative of the US population.

The food consumption data in the 1994-96, 1998 CSFII database are reported on an "as consumed" basis (e.g., pizza, mixed salad, etc.), and are translated into raw agricultural commodities (RACs) (e.g., tomato puree, wheat flour, raw head lettuce, raw leaf lettuce, etc...) using an ingredient translation database developed by the US Environmental Protection Agency (EPA). DEEM – FCID is a proprietary software program that allows the user to assign "residue" values to RACs. Using the levels of the compound in each RAC, the total intake of the compound is estimated for each subject in the 1994-96, 1998 CSFII with valid dietary intake data. The intakes presented in this report are based on 2-day average daily intakes among subjects with 2 days of valid intake data.

PS Levels in Foods Included in the Assessment

Exponent conducted a thorough literature search to compile all available data on the amount of PS present in various foods. PS levels in the RACs included in this analysis were taken from food composition and nutrition tables (Bundesministerium et al, 2000). These data were the only publicly available data on the PS content of foods and are presented in Table 1.

The data presented in Table 1 is a summary of what is currently known about PS levels in foods and is not necessarily an accurate representation of all foods that contain PS. Therefore, in order to better estimate the true range of potential intake of PS from the diet, E^xponent used the currently available data and employed two surrogation strategies to assign PS levels to foods reported in the CSFII. The data in Table 1 was used as the basis for two intake estimates: 1.) a lower bound PS intake estimate (Surrogation Strategy A) in which the analysis was limited to

only those foods with known PS levels; and 2.) an upper bound PS intake estimate (Surrogation Strategy B) in which the analysis included those foods which most likely contain PS yet do not have a measured value available in the current literature. The methods behind these two strategies are described below.

Surrogation Strategy A

In order to calculate a lower bound estimate of PS intake in the US population, Exponent restricted the analysis to those foods with known levels of PS (i.e. only those foods listed in Table 1). The PS levels assigned to foods and the surrogation strategy employed by Exponent are presented in Appendix A and described below.

- Milk: The FCID recipes do not differentiate between cow, sheep, or buffalo's milk. To be conservative, all forms of milk (sugar, water, fat, etc) were assigned the PS level in cow's milk (10 ppm) since this food is the exact match for the CSFII consumption data. Consumption of sheep milk was not reported in the CSFII.
- Veal – muscles only: There does not exist an FCID code for veal, therefore this PS level was not used.
- Beef – muscles only: Applied to beef meat codes including dried beef and beef meat babyfood. Beef byproducts were excluded from the analysis.
- Ox Brain: Consumption of ox was not recorded in the food survey therefore this PS level was excluded from the analysis.
- Pork- muscles only: Applied to pork meat only, including babyfood. Pork byproducts were excluded from the analysis.
- Pig's spleen – The FCID recipes included a code for "pork meat byproducts". It is uncertain as to whether or not pig's spleen would be included in this category. If it were, we would have to know the approximate percentage of byproducts that is spleen. The PS value for spleen is one of the highest provided by Degussa, therefore, we did not include this value in the background assessment to ensure we did not artificially inflate the background consumption of PS from "pork meat byproducts".
- Chicken –The FCID recipes do not differentiate between parts of the chicken; therefore the average PS level in "breast with skin" and "leg with skin without bone" average of 1095 ppm was applied to chicken meat codes including baby food.

- Chicken heart –The FCID recipes do not include an ingredient code for chicken heart or chicken giblets, which commonly include the heart. This PS level was excluded from the background intake analysis.
- Turkey-The FCID recipes do not differentiate between parts of the turkey; therefore the average PS level in “breast without skin” and “leg without skin and bone” (475 ppm) was applied to the turkey meat codes including baby food.
- Saltwater fish – The FCID recipes do not differentiate between types of saltwater fish; therefore the PS levels in saltwater fish (i.e. herring, cod, mackerel, mullet, anchovy, sardine and hake) were averaged together resulting in a PS level of 1431 ppm.
- Freshwater fish- The FCID recipes do not differentiate between types of freshwater fish; therefore the PS levels in freshwater fish (i.e. eel and trout) were averaged together resulting in a PS level of 1745 ppm.
- Mollusks – The FCID recipes do not differentiate between types of mollusks; therefore the average PS level in soft clams and cuttle fish were averaged together resulting in a PS level of 590 ppm.
- Crustaceans: The FCID recipes do not differentiate between types of crustaceans; therefore the PS level in crayfish (400 ppm) was assigned to all crustaceans.
- Barley – The PS value in “Barley – without husk, whole grain” (200 ppm) was assigned to all FCID barley ingredients including barley flour, pearled barley, barley bran and the baby food varieties.
- Rice unpolished (i.e. brown rice) – was assigned the PS level of 30 ppm. White rice and wild rice were excluded from the analysis.
- Potato - Whole potato tubers only were assigned the PS level in potatoes (10 ppm). The processed forms (chips, dried flakes and flour) were excluded from the analysis.
- Carrots- Carrots and carrot baby food were assigned the PS level in carrots (20 ppm). The processed form of carrot ingredient (carrot juice) was excluded from the analysis.
- Bean seed, white dry – White beans include navy beans, northern beans, pea beans. Only these three seed varieties were included in the analysis and were assigned a PS level of 1070 ppm.

Surrogation Strategy B

In order to calculate an upper bound estimate of PS intake in the US population, Exponent broadly applied the levels of PS in known foods to other similar foods (i.e. RACs in similar crop groups). The PS levels assigned to additional foods and the surrogation strategy employed by Exponent are presented in Appendix B and described below.

- Milk: RACs relating to milk as reported in the USDA CSFII database do not differentiate between cow, sheep, or buffalo's milk. To be conservative, all forms of milk (sugar, water, fat, etc) were assigned the PS level in sheep's milk because it had the highest measured PS level in all of the milk products listed in Table 1.
- Meats (excluding poultry): PS levels in muscle were available for pork, beef, and veal. However, the only data we had on PS levels in organ meats (kidney, liver) was for pigs. We used the ratio of PS levels in pork meat to PS levels in pig kidney and liver to calculate estimated PS levels in sheep, goat, and beef organs. For example:

$$\frac{\text{PS level in pig kidney}}{\text{PS level in pork - muscles only}} = \frac{218 \text{ mg/100g edible}}{57 \text{ mg/100 g edible}} = 3.82$$

IF:

$$\frac{\text{PS level in pig kidney}}{\text{PS level in pork - muscles only}} = \frac{\text{PS level in beef, kidney}}{\text{PS level in beef - muscles only}}$$

THEN:

PS level in beef, kidney = PS level in beef - muscles only (69 mg/100g edible) x 3.82 = 264 mg/100g edible

Based on this approach, the following PS levels were used for organ meats:

Food	Ratio PS level in pig organ:pig meat	mg PS per 100g edible portion <u>in muscle</u>	mg PS per 100g edible portion	mg PS/kg food
Beef, kidney	3.82	69	264	2640
Beef, liver	0.88	69	61	610
Sheep, kidney	3.82	72	275	2750
Sheep, liver	0.88	72	63	630
Goat, kidney	3.82	72	275	2750
Kidney, liver	0.88	72	63	630

The PS levels in “veal – muscles only” were used to derive levels in sheep and goat meat and organs. Meat fats and “meat, byproducts” were assigned the same PS level that was assigned to “meat”.

- Poultry:
 - “Chicken, meat” was assigned the PS level in “chicken – leg with skin, without bone”, the higher of the two chicken meat levels.
 - “Chicken, skin” was assigned the PS level in “chicken – leg with skin, without bone”, the higher of the “chicken with skin” levels.
 - “Turkey, meat” was assigned the PS level in “turkey – leg without skin and bone”, the higher of the two turkey meat levels.
 - “Turkey, skin” was assigned the PS level in “in “chicken – leg with skin, without bone”, the higher of the chicken with skin levels, since there was not a level reported for turkey skin.
 - “Turkey, liver” was assigned the PS level in “Chicken, liver”.
 - “Poultry, other” foods were assigned the max of the turkey or chicken value as appropriate.
- Saltwater fish: All saltwater fish were assigned the PS level in mackerel, the highest of the saltwater fish PS levels.
- Freshwater fish: All freshwater fish (excluding tuna because tuna has its own food code) were assigned the PS level in eel, the higher of the two freshwater fish PS levels for eel and trout.
- Crustaceans: All crustaceans were assigned the PS level in crayfish – the only crustacean with a measured PS level.
- Mollusks: All mollusks were assigned the PS level in soft clams, the highest of the mollusk PS levels.
- Grains: All grains were assigned the PS level in barley, with the exception of rice, which was assigned the rice value. The PS level in barley was higher than the level in rice and therefore the approach is conservative. Corn syrup, corn oil, and soybean oil are not included in the analysis. Corn syrup is highly processed and hydrolyzed and there would be no PS in the final product. Corn oil and soybean oil do not contain phospholipids (Degussa, personal communication).
- Potato: All tubers in the same group as potatoes were assigned the PS level in potatoes.
- Carrot: All root vegetables in the same group as carrots were assigned the PS level in carrots.

- Beans: all beans were assigned a PS level based on the white bean seed value. The software used to calculate intakes separates the beans into succulent (with moisture) and seed (without moisture). Succulent beans were assigned a PS value equal to what would be expected in cooked dry beans since dry beans are not eaten dry and water is typically added during cooking. In other words, the PS level in the dry bean was adjusted based on the moisture content in a cooked bean and that adjusted value was assigned to succulent beans. Using data from the USDA National Nutrient Database for Standard Reference (Release 17) (USDA, 2004), cooked white beans were determined to be 63% water. The dry white beans referenced in Table 1 contain 10.3% water. Using the calculation described below, we estimated the PS level in a cooked bean to be 441 mg PS/kg succulent bean.

dry beans (seeds):

10.3% water (Bundesministerium et al, 2000)

1070 mg PS per kg dry seed (Bundesministerium et al, 2000)

1193 mg PS per kg dry matter in the seed

succulent beans:

63% water (USDA, 2004)

1193 mg PS per kg dry matter in the seed

441 mg PS per kg succulent bean

- All remaining fruits and vegetables: All the remaining fruits and vegetables (i.e., those fruits and vegetables that do not fit into a crop group that contains a food with a known PS level) were assigned a PS level of 157 mg/kg. This is the average PS level of the known vegetable and bean PS levels (carrots, potatoes, and beans - succulent).
- Eggs: Eggs are known to contain lecithin, which is also chemically known as "phosphatidylcholine" (PC). Since PS and PC are typically found in the same foods, it was thought that eggs might contain PS. However, even though eggs are rich in lecithin, it was recently reported that there are no measured levels of PS in eggs (Jujena,1997). Therefore, eggs were assigned a value of 0 mg PS/kg.

Results

Surrogation Strategy A

Summary intake estimates for the total US population, children 7-12 years, and adults 50 years and older are provided in Table 2. Per User and Per capita intakes were estimated, however the percent consumers of foods containing PS for the total US population, children 7-12 years, and adults 50 years and older is 99.76%, 100%, and 100%, respectively, and therefore per user and per capita estimates are identical.

Per user estimates of PS intake from natural sources for the total US population and included subpopulations among average consumers range from 72 mg/day among children 7-12 years to 98.3 mg/day among adults 50+ years. Per user estimates of PS intake from natural sources for the total US population and included subpopulations among high consumers (90th percentile) range from 135 mg/day among children 7-12 years to 184 mg/day among the total US population.

Surrogation Strategy B

Summary intake estimates for the total US population, children 7-12 years, and adults 50 years and older are provided in Table 3. Per User and Per capita intakes were estimated, however the percent consumers of foods containing PS for the total US population, children 7-12 years, and adults 50 years and older is 99.9%, 100%, and 100%, respectively, and therefore per user and per capita estimates are identical.

Per user estimates of PS intake from natural sources for the total US population and included subpopulations among average consumers range from 184 mg/day among children 7-12 years to 243 mg/day among adults 50+ years. Per user estimates of PS intake from natural sources for the total US population and included subpopulations among high consumers (90th percentile) range from 296 mg/day among children 7-12 years to 415 mg/day among adults 50+ years.

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Table 1. Measured PS levels in Dairy, Meat, Fish, Vegetables, Grain, and Beans (Bundesministerium et al, 2000)

Food	mg PS per 100g edible portion	mg PS/kg food
Buffalo milk	1	10
Cow's milk - whole milk	1	10
Cow's milk - min 3.5% fat content	1	10
Sheep milk	2	20
Veal - muscles only	72	720
Beef - muscles only	69	690
Ox brain	713	7130
Pork - muscles only	57	570
Pig's liver	50	500
Pig's spleen	239	2390
Pig's kidney	218	2180
Chicken - breast with skin	85	850
Chicken - leg with skin, without bone	134	1340
Chicken heart	414	4140
Chicken liver	123	1230
Turkey - breast without skin	45	450
Turkey - leg without skin and bone	50	500
Herring - Atlantic	360	3600
Cod	28	280
Mackerel	480	4800
Mullet	76	760
Anchovy	25	250
Sardine	16	160
Hake	17	170
Tuna	194	1940
Eel	335	3350
Trout	14	140
Crayfish	40	400
Soft clam	87	870
Cuttle fish	31	310
Barley - without husk, whole grain	20	200
Rice - unpolished	3	30
Potato	1	10
Carrot	2	20
Bean seed - white, dry	107	1070

Table 2. Surrogation Strategy A: Estimated Daily PS Intake Among Users (mg/day)

		2-day Average Daily PS Intake (mg/ day)
Total US Population		
	Mean	96.0
	90th Percentile	184
Children 7 to 12 years		
	Mean	72.0
	90th Percentile	135
Adults 50+ years		
	Mean	98.3
	90th Percentile	181

Table 3. Surrogation Strategy B: Estimated Daily PS Intake Among Users (mg/day)

		2-day Average Daily PS Intake (mg/day)
Total US Population		
	Mean	228
	90th Percentile	396
Children 7 to 12 years		
	Mean	184
	90th Percentile	296
Adults 50+ years		
	Mean	243
	90th Percentile	415

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Appendix A: PS Levels in Foods Included in Intake Assessment Using Surrogation Strategy A

Food Code	FCID Food Description	PS level (mg/kg food)
01010500	Beet, garden, roots	Not surrogated
01010501	Beet, garden, roots-babyfood	Not surrogated
01010520	Beet, sugar	Not surrogated
01010521	Beet, sugar-babyfood	Not surrogated
01010530	Beet, sugar, molasses	Not surrogated
01010531	Beet, sugar, molasses-babyfood	Not surrogated
01010670	Burdock	Not surrogated
01010780	Carrot	20
01010781	Carrot-babyfood	20
01010790	Carrot, juice	Not surrogated
01010840	Celeriac	Not surrogated
01011000	Chicory, roots	Not surrogated
01011680	Ginseng, dried	Not surrogated
01011900	Horseradish	Not surrogated
01012500	Parsley, turnip rooted	Not surrogated
01012510	Parsnip	Not surrogated
01012511	Parsnip-babyfood	Not surrogated
01013140	Radish, roots	Not surrogated
01013160	Radish, Oriental, roots	Not surrogated
01013270	Rutabaga	Not surrogated
01013310	Salsify, roots	Not surrogated
01013880	Turnip, roots	Not surrogated
01030150	Arrowroot, flour	Not surrogated
01030151	Arrowroot, flour-babyfood	Not surrogated
01030170	Artichoke, Jerusalem	Not surrogated
01030820	Cassava	Not surrogated
01030821	Cassava-babyfood	Not surrogated
01031390	Dasheen, corm	Not surrogated
01031660	Ginger	Not surrogated
01031661	Ginger-babyfood	Not surrogated
01031670	Ginger, dried	Not surrogated
01032960	Potato, chips	Not surrogated
01032970	Potato, dry (granules/ flakes)	Not surrogated
01032971	Potato, dry (granules/ flakes)-babyfood	Not surrogated
01032980	Potato, flour	Not surrogated
01032981	Potato, flour-babyfood	Not surrogated
01032990	Potato, tuber, w/peel	10
01032991	Potato, tuber, w/peel-babyfood	10
01033000	Potato, tuber, w/o peel	10

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Food Code	FCID Food Description	PS level (mg/kg food)
01033001	Potato, tuber, w/o peel-babyfood	10
01033660	Sweet potato	Not surrogated
01033661	Sweet potato-babyfood	Not surrogated
01033710	Tanier, corm	Not surrogated
01033870	Turmeric	Not surrogated
01034060	Yam, true	Not surrogated
01034070	Yam bean	Not surrogated
02000510	Beet, garden, tops	Not surrogated
02001010	Chicory, tops	Not surrogated
02001400	Dasheen, leaves	Not surrogated
02003150	Radish, tops	Not surrogated
02003170	Radish, Oriental, tops	Not surrogated
02003320	Salsify, tops	Not surrogated
03001640	Garlic	Not surrogated
03001650	Garlic, dried	Not surrogated
03001651	Garlic, dried-babyfood	Not surrogated
03001980	Leek	Not surrogated
03002370	Onion, dry bulb	Not surrogated
03002371	Onion, dry bulb-babyfood	Not surrogated
03002380	Onion, dry bulb, dried	Not surrogated
03002381	Onion, dry bulb, dried-babyfood	Not surrogated
03002390	Onion, green	Not surrogated
03003380	Shallot	Not surrogated
04010050	Amaranth, leafy	Not surrogated
04010180	Arugula	Not surrogated
04011040	Chrysanthemum, garland	Not surrogated
04011330	Cress, garden	Not surrogated
04011340	Cress, upland	Not surrogated
04011380	Dandelion, leaves	Not surrogated
04011500	Endive	Not surrogated
04012040	Lettuce, head	Not surrogated
04012050	Lettuce, leaf	Not surrogated
04012480	Parsley, leaves	Not surrogated
04013130	Radicchio	Not surrogated
04013550	Spinach	Not surrogated
04013551	Spinach-babyfood	Not surrogated
04020760	Cardoon	Not surrogated
04020850	Celery	Not surrogated
04020851	Celery-babyfood	Not surrogated
04020860	Celery, juice	Not surrogated
04020870	Celtuce	Not surrogated
04021520	Fennel, Florence	Not surrogated
04023220	Rhubarb	Not surrogated
04023670	Swiss chard	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
05010610	Broccoli	Not surrogated
05010611	Broccoli-babyfood	Not surrogated
05010620	Broccoli, Chinese	Not surrogated
05010640	Brussels sprouts	Not surrogated
05010690	Cabbage	Not surrogated
05010710	Cabbage, Chinese, napa	Not surrogated
05010720	Cabbage, Chinese, mustard	Not surrogated
05010830	Cauliflower	Not surrogated
05011960	Kohlrabi	Not surrogated
05020630	Broccoli raab	Not surrogated
05020700	Cabbage, Chinese, bok choy	Not surrogated
05021170	Collards	Not surrogated
05021940	Kale	Not surrogated
05022290	Mustard greens	Not surrogated
05023180	Rape greens	Not surrogated
05023890	Turnip, greens	Not surrogated
06003470	Soybean, seed	Not surrogated
06003480	Soybean, flour	Not surrogated
06003481	Soybean, flour-babyfood	Not surrogated
06003490	Soybean, soy milk	Not surrogated
06003491	Soybean, soy milk-babyfood or infant formula	Not surrogated
06003500	Soybean, oil	Not surrogated
06003501	Soybean, oil-babyfood	Not surrogated
06010430	Bean, snap, succulent	Not surrogated
06010431	Bean, snap, succulent-babyfood	Not surrogated
06012570	Pea, edible podded, succulent	Not surrogated
06020310	Bean, broad, succulent	Not surrogated
06020330	Bean, cowpea, succulent	Not surrogated
06020370	Bean, lima, succulent	Not surrogated
06022550	Pea, succulent	Not surrogated
06022551	Pea, succulent-babyfood	Not surrogated
06022590	Pea, pigeon, succulent	Not surrogated
06030300	Bean, black, seed	Not surrogated
06030320	Bean, broad, seed	Not surrogated
06030340	Bean, cowpea, seed	1070
06030350	Bean, great northern, seed	1070
06030360	Bean, kidney, seed	Not surrogated
06030380	Bean, lima, seed	Not surrogated
06030390	Bean, mung, seed	Not surrogated
06030400	Bean, navy, seed	1070
06030410	Bean, pink, seed	Not surrogated
06030420	Bean, pinto, seed	Not surrogated
06030980	Chickpea, seed	Not surrogated
06030981	Chickpea, seed-babyfood	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
06030990	Chickpea, flour	Not surrogated
06031820	Guar, seed	Not surrogated
06031821	Guar, seed-babyfood	Not surrogated
06032030	Lentil, seed	Not surrogated
06032560	Pea, dry	Not surrogated
06032561	Pea, dry-babyfood	Not surrogated
06032580	Pea, pigeon, seed	Not surrogated
08001480	Eggplant	Not surrogated
08002340	Okra	Not surrogated
08002700	Pepper, bell	Not surrogated
08002701	Pepper, bell-babyfood	Not surrogated
08002710	Pepper, bell, dried	Not surrogated
08002711	Pepper, bell, dried-babyfood	Not surrogated
08002720	Pepper, nonbell	Not surrogated
08002721	Pepper, nonbell-babyfood	Not surrogated
08002730	Pepper, nonbell, dried	Not surrogated
08003740	Tomatillo	Not surrogated
08003750	Tomato	Not surrogated
08003751	Tomato-babyfood	Not surrogated
08003760	Tomato, paste	Not surrogated
08003761	Tomato, paste-babyfood	Not surrogated
08003770	Tomato, puree	Not surrogated
08003771	Tomato, puree-babyfood	Not surrogated
08003780	Tomato, dried	Not surrogated
08003781	Tomato, dried-babyfood	Not surrogated
08003790	Tomato, juice	Not surrogated
09010750	Cantaloupe	Not surrogated
09010800	Casaba	Not surrogated
09011870	Honeydew melon	Not surrogated
09013990	Watermelon	Not surrogated
09014000	Watermelon, juice	Not surrogated
09020210	Balsam pear	Not surrogated
09020880	Chayote, fruit	Not surrogated
09021020	Chinese waxgourd	Not surrogated
09021350	Cucumber	Not surrogated
09023080	Pumpkin	Not surrogated
09023090	Pumpkin, seed	Not surrogated
09023560	Squash, summer	Not surrogated
09023561	Squash, summer-babyfood	Not surrogated
09023570	Squash, winter	Not surrogated
09023571	Squash, winter-babyfood	Not surrogated
10001060	Citrus citron	Not surrogated
10001070	Citrus hybrids	Not surrogated
10001080	Citrus, oil	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
10001800	Grapefruit	Not surrogated
10001810	Grapefruit, juice	Not surrogated
10001970	Kumquat	Not surrogated
10001990	Lemon	Not surrogated
10002000	Lemon, juice	Not surrogated
10002001	Lemon, juice-babyfood	Not surrogated
10002010	Lemon, peel	Not surrogated
10002060	Lime	Not surrogated
10002070	Lime, juice	Not surrogated
10002071	Lime, juice-babyfood	Not surrogated
10002400	Orange	Not surrogated
10002410	Orange, juice	Not surrogated
10002411	Orange, juice-babyfood	Not surrogated
10002420	Orange, peel	Not surrogated
10003070	Pummelo	Not surrogated
10003690	Tangerine	Not surrogated
10003700	Tangerine, juice	Not surrogated
11000070	Apple, fruit with peel	Not surrogated
11000080	Apple, peeled fruit	Not surrogated
11000081	Apple, peeled fruit-babyfood	Not surrogated
11000090	Apple, dried	Not surrogated
11000091	Apple, dried-babyfood	Not surrogated
11000100	Apple, juice	Not surrogated
11000101	Apple, juice-babyfood	Not surrogated
11000110	Apple, sauce	Not surrogated
11000111	Apple, sauce-babyfood	Not surrogated
11001290	Crabapple	Not surrogated
11002100	Loquat	Not surrogated
11002660	Pear	Not surrogated
11002661	Pear-babyfood	Not surrogated
11002670	Pear, dried	Not surrogated
11002680	Pear, juice	Not surrogated
11002681	Pear, juice-babyfood	Not surrogated
11003100	Quince	Not surrogated
12000120	Apricot	Not surrogated
12000121	Apricot-babyfood	Not surrogated
12000130	Apricot, dried	Not surrogated
12000140	Apricot, juice	Not surrogated
12000141	Apricot, juice-babyfood	Not surrogated
12000900	Cherry	Not surrogated
12000901	Cherry-babyfood	Not surrogated
12000910	Cherry, juice	Not surrogated
12000911	Cherry, juice-babyfood	Not surrogated
12002300	Nectarine	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
12002600	Peach	Not surrogated
12002601	Peach-babyfood	Not surrogated
12002610	Peach, dried	Not surrogated
12002611	Peach, dried-babyfood	Not surrogated
12002620	Peach, juice	Not surrogated
12002621	Peach, juice-babyfood	Not surrogated
12002850	Plum	Not surrogated
12002851	Plum-babyfood	Not surrogated
12002860	Plum, prune, fresh	Not surrogated
12002861	Plum, prune, fresh-babyfood	Not surrogated
12002870	Plum, prune, dried	Not surrogated
12002871	Plum, prune, dried-babyfood	Not surrogated
12002880	Plum, prune, juice	Not surrogated
12002881	Plum, prune, juice-babyfood	Not surrogated
13010550	Blackberry	Not surrogated
13010560	Blackberry, juice	Not surrogated
13010561	Blackberry, juice-babyfood	Not surrogated
13010580	Boysenberry	Not surrogated
13011420	Dewberry	Not surrogated
13012080	Loganberry	Not surrogated
13013200	Raspberry	Not surrogated
13013201	Raspberry-babyfood	Not surrogated
13013210	Raspberry, juice	Not surrogated
13013211	Raspberry, juice-babyfood	Not surrogated
13020570	Blueberry	Not surrogated
13020571	Blueberry-babyfood	Not surrogated
13021360	Currant	Not surrogated
13021370	Currant, dried	Not surrogated
13021490	Elderberry	Not surrogated
13021740	Gooseberry	Not surrogated
13021910	Huckleberry	Not surrogated
14000030	Almond	Not surrogated
14000031	Almond-babyfood	Not surrogated
14000040	Almond, oil	Not surrogated
14000041	Almond, oil-babyfood	Not surrogated
14000590	Brazil nut	Not surrogated
14000680	Butternut	Not surrogated
14000810	Cashew	Not surrogated
14000920	Chestnut	Not surrogated
14001550	Filbert	Not surrogated
14001560	Filbert, oil	Not surrogated
14001850	Hickory nut	Not surrogated
14002130	Macadamia nut	Not surrogated
14002690	Pecan	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
14002820	Pistachio	Not surrogated
14003910	Walnut	Not surrogated
15000250	Barley, pearled barley	200
15000251	Barley, pearled barley-babyfood	200
15000260	Barley, flour	200
15000261	Barley, flour-babyfood	200
15000270	Barley, bran	200
15000650	Buckwheat	Not surrogated
15000660	Buckwheat, flour	Not surrogated
15001200	Corn, field, flour	Not surrogated
15001201	Corn, field, flour-babyfood	Not surrogated
15001210	Corn, field, meal	Not surrogated
15001211	Corn, field, meal-babyfood	Not surrogated
15001220	Corn, field, bran	Not surrogated
15001230	Corn, field, starch	Not surrogated
15001231	Corn, field, starch-babyfood	Not surrogated
15001240	Corn, field, syrup	Not surrogated
15001241	Corn, field, syrup-babyfood	Not surrogated
15001250	Corn, field, oil	Not surrogated
15001251	Corn, field, oil-babyfood	Not surrogated
15001260	Corn, pop	Not surrogated
15001270	Corn, sweet	Not surrogated
15001271	Corn, sweet-babyfood	Not surrogated
15002260	Millet, grain	Not surrogated
15002310	Oat, bran	Not surrogated
15002320	Oat, flour	Not surrogated
15002321	Oat, flour-babyfood	Not surrogated
15002330	Oat, groats/rolled oats	Not surrogated
15002331	Oat, groats/rolled oats-babyfood	Not surrogated
15003230	Rice, white	Not surrogated
15003231	Rice, white-babyfood	Not surrogated
15003240	Rice, brown	30
15003241	Rice, brown-babyfood	30
15003250	Rice, flour	Not surrogated
15003251	Rice, flour-babyfood	Not surrogated
15003260	Rice, bran	Not surrogated
15003261	Rice, bran-babyfood	Not surrogated
15003280	Rye, grain	Not surrogated
15003290	Rye, flour	Not surrogated
15003440	Sorghum, grain	Not surrogated
15003450	Sorghum, syrup	Not surrogated
15003810	Triticale, flour	Not surrogated
15003811	Triticale, flour-babyfood	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
15004010	Wheat, grain	Not surrogated
15004011	Wheat, grain-babyfood	Not surrogated
15004020	Wheat, flour	Not surrogated
15004021	Wheat, flour-babyfood	Not surrogated
15004030	Wheat, germ	Not surrogated
15004040	Wheat, bran	Not surrogated
15004050	Wild rice	Not surrogated
18000020	Alfalfa, seed	Not surrogated
19010280	Basil, fresh leaves	Not surrogated
19010281	Basil, fresh leaves-babyfood	Not surrogated
19010290	Basil, dried leaves	Not surrogated
19010291	Basil, dried leaves-babyfood	Not surrogated
19011030	Chive	Not surrogated
19011180	Coriander, leaves	Not surrogated
19011181	Coriander, leaves-babyfood	Not surrogated
19011440	Dillweed	Not surrogated
19011840	Herbs, other	Not surrogated
19011841	Herbs, other-babyfood	Not surrogated
19012020	Lemongrass	Not surrogated
19012200	Marjoram	Not surrogated
19012201	Marjoram-babyfood	Not surrogated
19012490	Parsley, dried leaves	Not surrogated
19012491	Parsley, dried leaves-babyfood	Not surrogated
19013340	Savory	Not surrogated
19021050	Cinnamon	Not surrogated
19021051	Cinnamon-babyfood	Not surrogated
19021190	Coriander, seed	Not surrogated
19021191	Coriander, seed-babyfood	Not surrogated
19021430	Dill, seed	Not surrogated
19022740	Pepper, black and white	Not surrogated
19022741	Pepper, black and white-babyfood	Not surrogated
19023540	Spices, other	Not surrogated
19023541	Spices, other-babyfood	Not surrogated
20001630	Flaxseed, oil	Not surrogated
20003190	Rapeseed, oil	Not surrogated
20003191	Rapeseed, oil-babyfood	Not surrogated
20003300	Safflower, oil	Not surrogated
20003301	Safflower, oil-babyfood	Not surrogated
20003640	Sunflower, seed	Not surrogated
20003650	Sunflower, oil	Not surrogated
20003651	Sunflower, oil-babyfood	Not surrogated
21000440	Beef, meat	690
21000441	Beef, meat-babyfood	690
21000450	Beef, meat, dried	690

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Food Code	FCID Food Description	PS level (mg/kg food)
21000460	Beef, meat byproducts	Not surrogated
21000461	Beef, meat byproducts-babyfood	Not surrogated
21000470	Beef, fat	Not surrogated
21000471	Beef, fat-babyfood	Not surrogated
21000480	Beef, kidney	Not surrogated
21000490	Beef, liver	Not surrogated
21000491	Beef, liver-babyfood	Not surrogated
23001690	Goat, meat	Not surrogated
23001700	Goat, meat byproducts	Not surrogated
23001710	Goat, fat	Not surrogated
23001720	Goat, kidney	Not surrogated
23001730	Goat, liver	Not surrogated
24001890	Horse, meat	Not surrogated
25002900	Pork, meat	570
25002901	Pork, meat-babyfood	570
25002910	Pork, skin	Not surrogated
25002920	Pork, meat byproducts	Not surrogated
25002921	Pork, meat byproducts-babyfood	Not surrogated
25002930	Pork, fat	Not surrogated
25002931	Pork, fat-babyfood	Not surrogated
25002940	Pork, kidney	2180
25002950	Pork, liver	500
26003390	Sheep, meat	Not surrogated
26003391	Sheep, meat-babyfood	Not surrogated
26003400	Sheep, meat byproducts	Not surrogated
26003410	Sheep, fat	Not surrogated
26003411	Sheep, fat-babyfood	Not surrogated
26003420	Sheep, kidney	Not surrogated
26003430	Sheep, liver	Not surrogated
27002220	Milk, fat	10
27002221	Milk, fat - baby food/infant formula	10
27012230	Milk, nonfat solids	10
27012231	Milk, nonfat solids-baby food/infant formula	10
27022240	Milk, water	10
27022241	Milk, water-babyfood/infant formula	10
27032251	Milk, sugar (lactose)-baby food/infant formula	10
28002210	Meat, game	Not surrogated
29003120	Rabbit, meat	Not surrogated
40000930	Chicken, meat	1095
40000931	Chicken, meat-babyfood	1095
40000940	Chicken, liver	1230
40000950	Chicken, meat byproducts	Not surrogated
40000951	Chicken, meat byproducts-babyfood	Not surrogated
40000960	Chicken, fat	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
40000961	Chicken, fat-babyfood	Not surrogated
40000970	Chicken, skin	Not surrogated
40000971	Chicken, skin-babyfood	Not surrogated
50003820	Turkey, meat	475
50003821	Turkey, meat-babyfood	475
50003830	Turkey, liver	Not surrogated
50003831	Turkey, liver-babyfood	Not surrogated
50003840	Turkey, meat byproducts	Not surrogated
50003841	Turkey, meat byproducts-babyfood	Not surrogated
50003850	Turkey, fat	Not surrogated
50003851	Turkey, fat-babyfood	Not surrogated
50003860	Turkey, skin	Not surrogated
50003861	Turkey, skin-babyfood	Not surrogated
60003010	Poultry, other, meat	Not surrogated
60003020	Poultry, other, liver	Not surrogated
60003030	Poultry, other, meat byproducts	Not surrogated
60003040	Poultry, other, fat	Not surrogated
60003050	Poultry, other, skin	Not surrogated
70001450	Egg, whole	Not surrogated
70001451	Egg, whole-babyfood	Not surrogated
70001460	Egg, white	Not surrogated
70001461	Egg, white (solids)-babyfood	Not surrogated
70001470	Egg, yolk	Not surrogated
70001471	Egg, yolk-babyfood	Not surrogated
80001570	Fish-freshwater finfish	1745
80001580	Fish-freshwater finfish, farm raised	1745
80001590	Fish-saltwater finfish, tuna	1940
80001600	Fish-saltwater finfish, other	1431
80001610	Fish-shellfish, crustacean	400
80001620	Fish-shellfish, mollusc	590
86010000	Water, direct, all sources	Not surrogated
86011000	Water, direct, tap	Not surrogated
86012000	Water, direct, bottled	Not surrogated
86013000	Water, direct, other	Not surrogated
86014000	Water, direct, source-NS	Not surrogated
86020000	Water, indirect, all sources	Not surrogated
86021000	Water, indirect, tap	Not surrogated
86022000	Water, indirect, bottled	Not surrogated
86023000	Water, indirect, other	Not surrogated
86024000	Water, indirect, source-NS	Not surrogated
95000010	Acerola	Not surrogated
95000060	Amaranth, grain	Not surrogated
95000160	Artichoke, globe	Not surrogated
95000190	Asparagus	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
95000200	Avocado	Not surrogated
95000220	Bamboo, shoots	Not surrogated
95000230	Banana	Not surrogated
95000231	Banana-babyfood	Not surrogated
95000240	Banana, dried	Not surrogated
95000241	Banana, dried-babyfood	Not surrogated
95000540	Belgium endive	Not surrogated
95000600	Breadfruit	Not surrogated
95000730	Cactus	Not surrogated
95000740	Canistel	Not surrogated
95000770	Carob	Not surrogated
95000890	Cherimoya	Not surrogated
95001090	Cocoa bean, chocolate	Not surrogated
95001100	Cocoa bean, powder	Not surrogated
95001110	Coconut, meat	Not surrogated
95001111	Coconut- meat-babyfood	Not surrogated
95001120	Coconut, dried	Not surrogated
95001130	Coconut, milk	Not surrogated
95001140	Coconut, oil	Not surrogated
95001141	Coconut, oil-babyfood	Not surrogated
95001150	Coffee, roasted bean	Not surrogated
95001160	Coffee, instant	Not surrogated
95001280	Cottonseed, oil	Not surrogated
95001281	Cottonseed, oil-babyfood	Not surrogated
95001300	Cranberry	Not surrogated
95001301	Cranberry-babyfood	Not surrogated
95001310	Cranberry, dried	Not surrogated
95001320	Cranberry, juice	Not surrogated
95001321	Cranberry, juice-babyfood	Not surrogated
95001410	Date	Not surrogated
95001510	Feijoa	Not surrogated
95001530	Fig	Not surrogated
95001540	Fig, dried	Not surrogated
95001750	Grape	Not surrogated
95001760	Grape, juice	Not surrogated
95001761	Grape, juice-babyfood	Not surrogated
95001770	Grape, leaves	Not surrogated
95001780	Grape, raisin	Not surrogated
95001790	Grape, wine and sherry	Not surrogated
95001830	Guava	Not surrogated
95001831	Guava-babyfood	Not surrogated
95001860	Honey	Not surrogated
95001861	Honey-babyfood	Not surrogated
95001880	Hop	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
95001920	Jaboticaba	Not surrogated
95001930	Jackfruit	Not surrogated
95001950	Kiwifruit	Not surrogated
95002090	Longan	Not surrogated
95002110	Lychee	Not surrogated
95002120	Lychee, dried	Not surrogated
95002140	Mamey apple	Not surrogated
95002150	Mango	Not surrogated
95002151	Mango-babyfood	Not surrogated
95002160	Mango, dried	Not surrogated
95002170	Mango, juice	Not surrogated
95002171	Mango, juice-babyfood	Not surrogated
95002180	Maple, sugar	Not surrogated
95002190	Maple syrup	Not surrogated
95002270	Mulberry	Not surrogated
95002280	Mushroom	Not surrogated
95002350	Olive	Not surrogated
95002360	Olive, oil	Not surrogated
95002430	Palm heart, leaves	Not surrogated
95002440	Palm, oil	Not surrogated
95002441	Palm, oil-babyfood	Not surrogated
95002450	Papaya	Not surrogated
95002451	Papaya-babyfood	Not surrogated
95002460	Papaya, dried	Not surrogated
95002470	Papaya, juice	Not surrogated
95002520	Passionfruit	Not surrogated
95002521	Passionfruit-babyfood	Not surrogated
95002530	Passionfruit, juice	Not surrogated
95002531	Passionfruit, juice-babyfood	Not surrogated
95002540	Pawpaw	Not surrogated
95002630	Peanut	Not surrogated
95002640	Peanut, butter	Not surrogated
95002650	Peanut, oil	Not surrogated
95002750	Peppermint	Not surrogated
95002760	Peppermint, oil	Not surrogated
95002770	Persimmon	Not surrogated
95002780	Pine nut	Not surrogated
95002790	Pineapple	Not surrogated
95002791	Pineapple-babyfood	Not surrogated
95002800	Pineapple, dried	Not surrogated
95002810	Pineapple, juice	Not surrogated
95002811	Pineapple, juice-babyfood	Not surrogated
95002830	Plantain	Not surrogated
95002840	Plantain, dried	Not surrogated

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Food Code	FCID Food Description	PS level (mg/kg food)
95002890	Pomegranate	Not surrogated
95003060	Psyllium, seed	Not surrogated
95003110	Quinoa, grain	Not surrogated
95003330	Sapote, Mamey	Not surrogated
95003350	Seaweed	Not surrogated
95003351	Seaweed-babyfood	Not surrogated
95003360	Sesame, seed	Not surrogated
95003361	Sesame, seed-babyfood	Not surrogated
95003370	Sesame, oil	Not surrogated
95003371	Sesame, oil-babyfood	Not surrogated
95003460	Soursop	Not surrogated
95003510	Spanish lime	Not surrogated
95003520	Spearmint	Not surrogated
95003530	Spearmint, oil	Not surrogated
95003580	Starfruit	Not surrogated
95003590	Strawberry	Not surrogated
95003591	Strawberry-babyfood	Not surrogated
95003600	Strawberry, juice	Not surrogated
95003601	Strawberry, juice-babyfood	Not surrogated
95003610	Sugar apple	Not surrogated
95003620	Sugarcane, sugar	Not surrogated
95003621	Sugarcane, sugar-babyfood	Not surrogated
95003630	Sugarcane, molasses	Not surrogated
95003631	Sugarcane, molasses-babyfood	Not surrogated
95003680	Tamarind	Not surrogated
95003720	Tea, dried	Not surrogated
95003730	Tea, instant	Not surrogated
95003800	Tomato, Tree	Not surrogated
95003900	Vinegar	Not surrogated
95003970	Water chestnut	Not surrogated
95003980	Watercress	Not surrogated

Appendix B: PS Levels in Foods Included in Intake Assessment Using Surrogation Strategy B

Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
01010500	Beet, garden, roots	20	Carrot
01010501	Beet, garden, roots-babyfood	20	Carrot
01010520	Beet, sugar	20	Carrot
01010521	Beet, sugar-babyfood	20	Carrot
01010530	Beet, sugar, molasses	20	Carrot
01010531	Beet, sugar, molasses-babyfood	20	Carrot
01010670	Burdock	20	Carrot
01010780	Carrot	20	Carrot
01010781	Carrot-babyfood	20	Carrot
01010790	Carrot, juice	20	Carrot
01010840	Celeriac	20	Carrot
01011000	Chicory, roots	20	Carrot
01011680	Ginseng, dried	20	Carrot
01011900	Horseradish	20	Carrot
01012500	Parsley, turnip rooted	20	Carrot
01012510	Parsnip	20	Carrot
01012511	Parsnip-babyfood	20	Carrot
01013140	Radish, roots	20	Carrot
01013160	Radish, Oriental, roots	20	Carrot
01013270	Rutabaga	20	Carrot
01013310	Salsify, roots	20	Carrot
01013880	Turnip, roots	20	Carrot
01030150	Arrowroot, flour	10	Potato
01030151	Arrowroot, flour-babyfood	10	Potato
01030170	Artichoke, Jerusalem	10	Potato
01030820	Cassava	10	Potato
01030821	Cassava-babyfood	10	Potato
01031390	Dasheen, corm	10	Potato

WD000921.000 D0T0 0705 0001

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
01031660	Ginger	10	Potato
01031661	Ginger-babyfood	10	Potato
01031670	Ginger, dried	10	Potato
01032960	Potato, chips	10	Potato
01032970	Potato, dry (granules/ flakes)	10	Potato
01032971	Potato, dry (granules/ flakes)-babyfood	10	Potato
01032980	Potato, flour	10	Potato
01032981	Potato, flour-babyfood	10	Potato
01032990	Potato, tuber, w/peel	10	Potato
01032991	Potato, tuber, w/peel-babyfood	10	Potato
01033000	Potato, tuber, w/o peel	10	Potato
01033001	Potato, tuber, w/o peel-babyfood	10	Potato
01033660	Sweet potato	10	Potato
01033661	Sweet potato-babyfood	10	Potato
01033710	Tanier, corm	10	Potato
01033870	Turmeric	10	Potato
01034060	Yam, true	10	Potato
01034070	Yam bean	10	Potato
02000510	Beet, garden, tops	157	Average of plant values
02001010	Chicory, tops	157	Average of plant values
02001400	Dasheen, leaves	157	Average of plant values
02003150	Radish, tops	157	Average of plant values
02003170	Radish, Oriental, tops	157	Average of plant values
02003320	Salsify, tops	157	Average of plant values
03001640	Garlic	157	Average of plant values
03001650	Garlic, dried	157	Average of plant values
03001651	Garlic, dried-babyfood	157	Average of plant values
03001980	Leek	157	Average of plant values
03002370	Onion, dry bulb	157	Average of plant values
03002371	Onion, dry bulb-babyfood	157	Average of plant values
03002380	Onion, dry bulb, dried	157	Average of plant values

WD000921.000 DOTD 0705 0001

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
03002381	Onion, dry bulb, dried-babyfood	157	Average of plant values
03002390	Onion, green	157	Average of plant values
03003380	Shallot	157	Average of plant values
04010050	Amaranth, leafy	157	Average of plant values
04010180	Arugula	157	Average of plant values
04011040	Chrysanthemum, garland	157	Average of plant values
04011330	Cress, garden	157	Average of plant values
04011340	Cress, upland	157	Average of plant values
04011380	Dandelion, leaves	157	Average of plant values
04011500	Endive	157	Average of plant values
04012040	Lettuce, head	157	Average of plant values
04012050	Lettuce, leaf	157	Average of plant values
04012480	Parsley, leaves	157	Average of plant values
04013130	Radicchio	157	Average of plant values
04013550	Spinach	157	Average of plant values
04013551	Spinach-babyfood	157	Average of plant values
04020760	Cardoon	157	Average of plant values
04020850	Celery	157	Average of plant values
04020851	Celery-babyfood	157	Average of plant values
04020860	Celery, juice	157	Average of plant values
04020870	Celtuce	157	Average of plant values
04021520	Fennel, Florence	157	Average of plant values
04023220	Rhubarb	157	Average of plant values
04023670	Swiss chard	157	Average of plant values
05010610	Broccoli	157	Average of plant values
05010611	Broccoli-babyfood	157	Average of plant values
05010620	Broccoli, Chinese	157	Average of plant values
05010640	Brussels sprouts	157	Average of plant values
05010690	Cabbage	157	Average of plant values
05010710	Cabbage, Chinese, napa	157	Average of plant values
05010720	Cabbage, Chinese, mustard	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
05010830	Cauliflower	157	Average of plant values
05011960	Kohlrabi	157	Average of plant values
05020630	Broccoli raab	157	Average of plant values
05020700	Cabbage, Chinese, bok choy	157	Average of plant values
05021170	Collards	157	Average of plant values
05021940	Kale	157	Average of plant values
05022290	Mustard greens	157	Average of plant values
05023180	Rape greens	157	Average of plant values
05023890	Turnip, greens	157	Average of plant values
06003470	Soybean, seed	1070	Bean seed - white, dry
06003480	Soybean, flour	1070	Bean seed - white, dry
06003481	Soybean, flour-babyfood	1070	Bean seed - white, dry
06003490	Soybean, soy milk	1070	Bean seed - white, dry
06003491	Soybean, soy milk-babyfood or infant formula	1070	Bean seed - white, dry
06003500	Soybean, oil	Not surrogated	
06003501	Soybean, oil-babyfood	Not surrogated	
06010430	Bean, snap, succulent	441	Bean seed - white, dry adjusted for moisture content
06010431	Bean, snap, succulent-babyfood	441	Bean seed - white, dry adjusted for moisture content
06012570	Pea, edible podded, succulent	441	Bean seed - white, dry adjusted for moisture content
06020310	Bean, broad, succulent	441	Bean seed - white, dry adjusted for moisture content
06020330	Bean, cowpea, succulent	441	Bean seed - white, dry adjusted for moisture content
06020370	Bean, lima, succulent	441	Bean seed - white, dry adjusted for moisture content
06022550	Pea, succulent	441	Bean seed - white, dry adjusted for moisture content
06022551	Pea, succulent-babyfood	441	Bean seed - white, dry adjusted for moisture content
06022590	Pea, pigeon, succulent	441	Bean seed - white, dry adjusted for moisture content
06030300	Bean, black, seed	1070	Bean seed - white, dry
06030320	Bean, broad, seed	1070	Bean seed - white, dry
06030340	Bean, cowpea, seed	1070	Bean seed - white, dry
06030350	Bean, great northern, seed	1070	Bean seed - white, dry
06030360	Bean, kidney, seed	1070	Bean seed - white, dry
06030380	Bean, lima, seed	1070	Bean seed - white, dry

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
06030390	Bean, mung, seed	1070	Bean seed - white, dry
06030400	Bean, navy, seed	1070	Bean seed - white, dry
06030410	Bean, pink, seed	1070	Bean seed - white, dry
06030420	Bean, pinto, seed	1070	Bean seed - white, dry
06030980	Chickpea, seed	1070	Bean seed - white, dry
06030981	Chickpea, seed-babyfood	1070	Bean seed - white, dry
06030990	Chickpea, flour	1070	Bean seed - white, dry
06031820	Guar, seed	1070	Bean seed - white, dry
06031821	Guar, seed-babyfood	1070	Bean seed - white, dry
06032030	Lentil, seed	1070	Bean seed - white, dry
06032560	Pea, dry	1070	Bean seed - white, dry
06032561	Pea, dry-babyfood	1070	Bean seed - white, dry
06032580	Pea, pigeon, seed	1070	Bean seed - white, dry
08001480	Eggplant	157	Average of plant values
08002340	Okra	157	Average of plant values
08002700	Pepper, bell	157	Average of plant values
08002701	Pepper, bell-babyfood	157	Average of plant values
08002710	Pepper, bell, dried	157	Average of plant values
08002711	Pepper, bell, dried-babyfood	157	Average of plant values
08002720	Pepper, nonbell	157	Average of plant values
08002721	Pepper, nonbell-babyfood	157	Average of plant values
08002730	Pepper, nonbell, dried	157	Average of plant values
08003740	Tomatillo	157	Average of plant values
08003750	Tomato	157	Average of plant values
08003751	Tomato-babyfood	157	Average of plant values
08003760	Tomato, paste	157	Average of plant values
08003761	Tomato, paste-babyfood	157	Average of plant values
08003770	Tomato, puree	157	Average of plant values
08003771	Tomato, puree-babyfood	157	Average of plant values
08003780	Tomato, dried	157	Average of plant values
08003781	Tomato, dried-babyfood	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
08003790	Tomato, juice	157	Average of plant values
09010750	Cantaloupe	157	Average of plant values
09010800	Casaba	157	Average of plant values
09011870	Honeydew melon	157	Average of plant values
09013990	Watermelon	157	Average of plant values
09014000	Watermelon, juice	157	Average of plant values
09020210	Balsam pear	157	Average of plant values
09020880	Chayote, fruit	157	Average of plant values
09021020	Chinese waxgourd	157	Average of plant values
09021350	Cucumber	157	Average of plant values
09023080	Pumpkin	157	Average of plant values
09023090	Pumpkin, seed	157	Average of plant values
09023560	Squash, summer	157	Average of plant values
09023561	Squash, summer-babyfood	157	Average of plant values
09023570	Squash, winter	157	Average of plant values
09023571	Squash, winter-babyfood	157	Average of plant values
10001060	Citrus citron	157	Average of plant values
10001070	Citrus hybrids	157	Average of plant values
10001080	Citrus, oil	Not surrogated	
10001800	Grapefruit	157	Average of plant values
10001810	Grapefruit, juice	157	Average of plant values
10001970	Kumquat	157	Average of plant values
10001990	Lemon	157	Average of plant values
10002000	Lemon, juice	157	Average of plant values
10002001	Lemon, juice-babyfood	157	Average of plant values
10002010	Lemon, peel	157	Average of plant values
10002060	Lime	157	Average of plant values
10002070	Lime, juice	157	Average of plant values
10002071	Lime, juice-babyfood	157	Average of plant values
10002400	Orange	157	Average of plant values
10002410	Orange, juice	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
10002411	Orange, juice-babyfood	157	Average of plant values
10002420	Orange, peel	157	Average of plant values
10003070	Pummelo	157	Average of plant values
10003690	Tangerine	157	Average of plant values
10003700	Tangerine, juice	157	Average of plant values
11000070	Apple, fruit with peel	157	Average of plant values
11000080	Apple, peeled fruit	157	Average of plant values
11000081	Apple, peeled fruit-babyfood	157	Average of plant values
11000090	Apple, dried	157	Average of plant values
11000091	Apple, dried-babyfood	157	Average of plant values
11000100	Apple, juice	157	Average of plant values
11000101	Apple, juice-babyfood	157	Average of plant values
11000110	Apple, sauce	157	Average of plant values
11000111	Apple, sauce-babyfood	157	Average of plant values
11001290	Crabapple	157	Average of plant values
11002100	Loquat	157	Average of plant values
11002660	Pear	157	Average of plant values
11002661	Pear-babyfood	157	Average of plant values
11002670	Pear, dried	157	Average of plant values
11002680	Pear, juice	157	Average of plant values
11002681	Pear, juice-babyfood	157	Average of plant values
11003100	Quince	157	Average of plant values
12000120	Apricot	157	Average of plant values
12000121	Apricot-babyfood	157	Average of plant values
12000130	Apricot, dried	157	Average of plant values
12000140	Apricot, juice	157	Average of plant values
12000141	Apricot, juice-babyfood	157	Average of plant values
12000900	Cherry	157	Average of plant values
12000901	Cherry-babyfood	157	Average of plant values
12000910	Cherry, juice	157	Average of plant values
12000911	Cherry, juice-babyfood	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
12002300	Nectarine	157	Average of plant values
12002600	Peach	157	Average of plant values
12002601	Peach-babyfood	157	Average of plant values
12002610	Peach, dried	157	Average of plant values
12002611	Peach, dried-babyfood	157	Average of plant values
12002620	Peach, juice	157	Average of plant values
12002621	Peach, juice-babyfood	157	Average of plant values
12002850	Plum	157	Average of plant values
12002851	Plum-babyfood	157	Average of plant values
12002860	Plum, prune, fresh	157	Average of plant values
12002861	Plum, prune, fresh-babyfood	157	Average of plant values
12002870	Plum, prune, dried	157	Average of plant values
12002871	Plum, prune, dried-babyfood	157	Average of plant values
12002880	Plum, prune, juice	157	Average of plant values
12002881	Plum, prune, juice-babyfood	157	Average of plant values
13010550	Blackberry	157	Average of plant values
13010560	Blackberry, juice	157	Average of plant values
13010561	Blackberry, juice-babyfood	157	Average of plant values
13010580	Boysenberry	157	Average of plant values
13011420	Dewberry	157	Average of plant values
13012080	Loganberry	157	Average of plant values
13013200	Raspberry	157	Average of plant values
13013201	Raspberry-babyfood	157	Average of plant values
13013210	Raspberry, juice	157	Average of plant values
13013211	Raspberry, juice-babyfood	157	Average of plant values
13020570	Blueberry	157	Average of plant values
13020571	Blueberry-babyfood	157	Average of plant values
13021360	Currant	157	Average of plant values
13021370	Currant, dried	157	Average of plant values
13021490	Elderberry	157	Average of plant values
13021740	Gooseberry	157	Average of plant values

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Ex

Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
13021910	Huckleberry	157	Average of plant values
14000030	Almond	Not surrogated	
14000031	Almond-babyfood	Not surrogated	
14000040	Almond, oil	Not surrogated	
14000041	Almond, oil-babyfood	Not surrogated	
14000590	Brazil nut	Not surrogated	
14000680	Butternut	Not surrogated	
14000810	Cashew	Not surrogated	
14000920	Chestnut	Not surrogated	
14001550	Filbert	Not surrogated	
14001560	Filbert, oil	Not surrogated	
14001850	Hickory nut	Not surrogated	
14002130	Macadamia nut	Not surrogated	
14002690	Pecan	Not surrogated	
14002820	Pistachio	Not surrogated	
14003910	Walnut	Not surrogated	
15000250	Barley, pearled barley	200	Barley - without husk, whole grain
15000251	Barley, pearled barley-babyfood	200	Barley - without husk, whole grain
15000260	Barley, flour	200	Barley - without husk, whole grain
15000261	Barley, flour-babyfood	200	Barley - without husk, whole grain
15000270	Barley, bran	200	Barley - without husk, whole grain
15000650	Buckwheat	200	Barley - without husk, whole grain
15000660	Buckwheat, flour	200	Barley - without husk, whole grain
15001200	Corn, field, flour	200	Barley - without husk, whole grain
15001201	Corn, field, flour-babyfood	200	Barley - without husk, whole grain
15001210	Corn, field, meal	200	Barley - without husk, whole grain
15001211	Corn, field, meal-babyfood	200	Barley - without husk, whole grain
15001220	Corn, field, bran	200	Barley - without husk, whole grain
15001230	Corn, field, starch	200	Barley - without husk, whole grain
15001231	Corn, field, starch-babyfood	200	Barley - without husk, whole grain
15001240	Corn, field, syrup	Not surrogated	

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
15001241	Corn, field, syrup-babyfood	Not surrogated	
15001250	Corn, field, oil	Not surrogated	
15001251	Corn, field, oil-babyfood	Not surrogated	
15001260	Corn, pop	200	Barley - without husk, whole grain
15001270	Corn, sweet	200	Barley - without husk, whole grain
15001271	Corn, sweet-babyfood	200	Barley - without husk, whole grain
15002260	Millet, grain	200	Barley - without husk, whole grain
15002310	Oat, bran	200	Barley - without husk, whole grain
15002320	Oat, flour	200	Barley - without husk, whole grain
15002321	Oat, flour-babyfood	200	Barley - without husk, whole grain
15002330	Oat, groats/rolled oats	200	Barley - without husk, whole grain
15002331	Oat, groats/rolled oats-babyfood	200	Barley - without husk, whole grain
15003230	Rice, white	30	Rice - unpolished
15003231	Rice, white-babyfood	30	Rice - unpolished
15003240	Rice, brown	30	Rice - unpolished
15003241	Rice, brown-babyfood	30	Rice - unpolished
15003250	Rice, flour	30	Rice - unpolished
15003251	Rice, flour-babyfood	30	Rice - unpolished
15003260	Rice, bran	30	Rice - unpolished
15003261	Rice, bran-babyfood	30	Rice - unpolished
15003280	Rye, grain	200	Barley - without husk, whole grain
15003290	Rye, flour	200	Barley - without husk, whole grain
15003440	Sorghum, grain	200	Barley - without husk, whole grain
15003450	Sorghum, syrup	200	Barley - without husk, whole grain
15003810	Triticale, flour	200	Barley - without husk, whole grain
15003811	Triticale, flour-babyfood	200	Barley - without husk, whole grain
15004010	Wheat, grain	200	Barley - without husk, whole grain
15004011	Wheat, grain-babyfood	200	Barley - without husk, whole grain
15004020	Wheat, flour	200	Barley - without husk, whole grain
15004021	Wheat, flour-babyfood	200	Barley - without husk, whole grain
15004030	Wheat, germ	200	Barley - without husk, whole grain

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
15004040	Wheat, bran	200	Barley - without husk, whole grain
15004050	Wild rice	30	Rice - unpolished
18000020	Alfalfa, seed	Not surrogated	
19010280	Basil, fresh leaves	Not surrogated	
19010281	Basil, fresh leaves-babyfood	Not surrogated	
19010290	Basil, dried leaves	Not surrogated	
19010291	Basil, dried leaves-babyfood	Not surrogated	
19011030	Chive	Not surrogated	
19011180	Coriander, leaves	Not surrogated	
19011181	Coriander, leaves-babyfood	Not surrogated	
19011440	Dillweed	Not surrogated	
19011840	Herbs, other	Not surrogated	
19011841	Herbs, other-babyfood	Not surrogated	
19012020	Lemongrass	Not surrogated	
19012200	Marjoram	Not surrogated	
19012201	Marjoram-babyfood	Not surrogated	
19012490	Parsley, dried leaves	Not surrogated	
19012491	Parsley, dried leaves-babyfood	Not surrogated	
19013340	Savory	Not surrogated	
19021050	Cinnamon	Not surrogated	
19021051	Cinnamon-babyfood	Not surrogated	
19021190	Coriander, seed	Not surrogated	
19021191	Coriander, seed-babyfood	Not surrogated	
19021430	Dill, seed	Not surrogated	
19022740	Pepper, black and white	Not surrogated	
19022741	Pepper, black and white-babyfood	Not surrogated	
19023540	Spices, other	Not surrogated	
19023541	Spices, other-babyfood	Not surrogated	
20001630	Flaxseed, oil	Not surrogated	
20003190	Rapeseed, oil	Not surrogated	
20003191	Rapeseed, oil-babyfood	Not surrogated	

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
20003300	Safflower, oil	Not surrogated	
20003301	Safflower, oil-babyfood	Not surrogated	
20003640	Sunflower, seed	Not surrogated	
20003650	Sunflower, oil	Not surrogated	
20003651	Sunflower, oil-babyfood	Not surrogated	
21000440	Beef, meat	690	Beef, muscles only
21000441	Beef, meat-babyfood	690	Beef, muscles only
21000450	Beef, meat, dried	690	Beef, muscles only
21000460	Beef, meat byproducts	690	Beef, muscles only
21000461	Beef, meat byproducts-babyfood	690	Beef, muscles only
21000470	Beef, fat	690	Beef, muscles only
21000471	Beef, fat-babyfood	690	Beef, muscles only
21000480	Beef, kidney	2640	Used ratio of PS levels in pig kidney to pig muscles (690*3.82)
21000490	Beef, liver	610	Used ratio of PS levels in pig liver to pig muscles (690*0.88)
21000491	Beef, liver-babyfood	610	Used ratio of PS levels in pig liver to pig muscles (690*0.88)
23001690	Goat, meat	720	Veal - muscles only
23001700	Goat, meat byproducts	720	Veal - muscles only
23001710	Goat, fat	720	Veal - muscles only
23001720	Goat, kidney	2750	Used ratio of PS levels in pig kidney to pig muscles (720*3.82)
23001730	Goat, liver	630	Used ratio of PS levels in pig kidney to pig muscles (720*0.88)
24001890	Horse, meat	Not surrogated	
25002900	Pork, meat	570	Pork - muscles only
25002901	Pork, meat-babyfood	570	Pork - muscles only
25002910	Pork, skin	570	Pork - muscles only
25002920	Pork, meat byproducts	570	Pork - muscles only
25002921	Pork, meat byproducts-babyfood	570	Pork - muscles only
25002930	Pork, fat	570	Pork - muscles only
25002931	Pork, fat-babyfood	570	Pork - muscles only
25002940	Pork, kidney	2180	Pig's kidney
25002950	Pork, liver	500	Pig's liver
26003390	Sheep, meat	720	Veal - muscles only

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
26003391	Sheep, meat-babyfood	720	Veal - muscles only
26003400	Sheep, meat byproducts	720	Veal - muscles only
26003410	Sheep, fat	720	Veal - muscles only
26003411	Sheep, fat-babyfood	720	Veal - muscles only
26003420	Sheep, kidney	2750	Used ratio of PS levels in pig kidney to pig muscles (720*3.82)
26003430	Sheep, liver	630	Used ratio of PS levels in pig kidney to pig muscles (720*0.88)
27002220	Milk, fat	20	Sheep milk (max of milk values)
27002221	Milk, fat - baby food/infant formula	20	Sheep milk (max of milk values)
27012230	Milk, nonfat solids	20	Sheep milk (max of milk values)
27012231	Milk, nonfat solids-baby food/infant formula	20	Sheep milk (max of milk values)
27022240	Milk, water	20	Sheep milk (max of milk values)
27022241	Milk, water-babyfood/infant formula	20	Sheep milk (max of milk values)
27032251	Milk, sugar (lactose)-baby food/infant formula	20	Sheep milk (max of milk values)
28002210	Meat, game	Not surrogated	
29003120	Rabbit, meat	Not surrogated	
40000930	Chicken, meat	1340	Chicken - leg with skin, without bone
40000931	Chicken, meat-babyfood	1340	Chicken - leg with skin, without bone
40000940	Chicken, liver	1230	Chicken liver
40000950	Chicken, meat byproducts	1340	Chicken - leg with skin, without bone
40000951	Chicken, meat byproducts-babyfood	1340	Chicken - leg with skin, without bone
40000960	Chicken, fat	1340	Chicken - leg with skin, without bone
40000961	Chicken, fat-babyfood	1340	Chicken - leg with skin, without bone
40000970	Chicken, skin	1340	Chicken - leg with skin, without bone
40000971	Chicken, skin-babyfood	1340	Chicken - leg with skin, without bone
50003820	Turkey, meat	500	Turkey - leg without skin and bone
50003821	Turkey, meat-babyfood	500	Turkey - leg without skin and bone
50003830	Turkey, liver	1230	chicken liver
50003831	Turkey, liver-babyfood	1230	chicken liver
50003840	Turkey, meat byproducts	500	Turkey - leg without skin and bone
50003841	Turkey, meat byproducts-babyfood	500	Turkey - leg without skin and bone
50003850	Turkey, fat	500	Turkey - leg without skin and bone

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
50003851	Turkey, fat-babyfood	500	Turkey - leg without skin and bone
50003860	Turkey, skin	1340	Chicken - leg with skin, without bone
50003861	Turkey, skin-babyfood	1340	Chicken - leg with skin, without bone
60003010	Poultry, other, meat	1340	Chicken - leg with skin, without bone (Max of chicken and turkey values)
60003020	Poultry, other, liver	1230	Chicken liver
60003030	Poultry, other, meat byproducts	1340	Chicken - leg with skin, without bone (Max of chicken and turkey values)
60003040	Poultry, other, fat	1340	Chicken - leg with skin, without bone (Max of chicken and turkey values)
60003050	Poultry, other, skin	1340	Chicken - leg with skin, without bone (Max of chicken skin values)
70001450	Egg, whole	Not surrogated	
70001451	Egg, whole-babyfood	Not surrogated	
70001460	Egg, white	Not surrogated	
70001461	Egg, white (solids)-babyfood	Not surrogated	
70001470	Egg, yolk	Not surrogated	
70001471	Egg, yolk-babyfood	Not surrogated	
80001570	Fish-freshwater finfish	3350	Eel (Max of freshwater fish values)
80001580	Fish-freshwater finfish, farm raised	3350	Eel (Max of freshwater fish values)
80001590	Fish-saltwater finfish, tuna	1940	Tuna
80001600	Fish-saltwater finfish, other	4800	Mackerel (Max of saltwater fish)
80001610	Fish-shellfish, crustacean	400	Crayfish
80001620	Fish-shellfish, mollusc	870	Soft clam (Max of molluscs)
86010000	Water, direct, all sources	Not surrogated	
86011000	Water, direct, tap	Not surrogated	
86012000	Water, direct, bottled	Not surrogated	
86013000	Water, direct, other	Not surrogated	
86014000	Water, direct, source-NS	Not surrogated	
86020000	Water, indirect, all sources	Not surrogated	
86021000	Water, indirect, tap	Not surrogated	
86022000	Water, indirect, bottled	Not surrogated	
86023000	Water, indirect, other	Not surrogated	
86024000	Water, indirect, source-NS	Not surrogated	
95000010	Acerola	157	Average of plant values
95000060	Amaranth, grain	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
95000160	Artichoke, globe	157	Average of plant values
95000190	Asparagus	157	Average of plant values
95000200	Avocado	157	Average of plant values
95000220	Bamboo, shoots	157	Average of plant values
95000230	Banana	157	Average of plant values
95000231	Banana-babyfood	157	Average of plant values
95000240	Banana, dried	157	Average of plant values
95000241	Banana, dried-babyfood	157	Average of plant values
95000540	Belgium endive	157	Average of plant values
95000600	Breadfruit	157	Average of plant values
95000730	Cactus	157	Average of plant values
95000740	Canistel	157	Average of plant values
95000770	Carob	157	Average of plant values
95000890	Cherimoya	157	Average of plant values
95001090	Cocoa bean, chocolate	Not surrogated	
95001100	Cocoa bean, powder	Not surrogated	
95001110	Coconut, meat	Not surrogated	
95001111	Coconut- meat-babyfood	Not surrogated	
95001120	Coconut, dried	Not surrogated	
95001130	Coconut, milk	Not surrogated	
95001140	Coconut, oil	Not surrogated	
95001141	Coconut, oil-babyfood	Not surrogated	
95001150	Coffee, roasted bean	Not surrogated	
95001160	Coffee, instant	Not surrogated	
95001280	Cottonseed, oil	Not surrogated	
95001281	Cottonseed, oil-babyfood	Not surrogated	
95001300	Cranberry	157	Average of plant values
95001301	Cranberry-babyfood	157	Average of plant values
95001310	Cranberry, dried	157	Average of plant values
95001320	Cranberry, juice	157	Average of plant values
95001321	Cranberry, juice-babyfood	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
95001410	Date	157	Average of plant values
95001510	Feijoa	157	Average of plant values
95001530	Fig	157	Average of plant values
95001540	Fig, dried	157	Average of plant values
95001750	Grape	157	Average of plant values
95001760	Grape, juice	157	Average of plant values
95001761	Grape, juice-babyfood	157	Average of plant values
95001770	Grape, leaves	157	Average of plant values
95001780	Grape, raisin	157	Average of plant values
95001790	Grape, wine and sherry	157	Average of plant values
95001830	Guava	157	Average of plant values
95001831	Guava-babyfood	157	Average of plant values
95001860	Honey	Not surrogated	
95001861	Honey-babyfood	Not surrogated	
95001880	Hop	157	Average of plant values
95001920	Jaboticaba	157	Average of plant values
95001930	Jackfruit	157	Average of plant values
95001950	Kiwifruit	157	Average of plant values
95002090	Longan	157	Average of plant values
95002110	Lychee	157	Average of plant values
95002120	Lychee, dried	157	Average of plant values
95002140	Mamey apple	157	Average of plant values
95002150	Mango	157	Average of plant values
95002151	Mango-babyfood	157	Average of plant values
95002160	Mango, dried	157	Average of plant values
95002170	Mango, juice	157	Average of plant values
95002171	Mango, juice-babyfood	157	Average of plant values
95002180	Maple, sugar	Not surrogated	
95002190	Maple syrup	Not surrogated	
95002270	Mulberry	157	Average of plant values
95002280	Mushroom	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
95002350	Olive	157	Average of plant values
95002360	Olive, oil	Not surrogated	
95002430	Palm heart, leaves	157	Average of plant values
95002440	Palm, oil	Not surrogated	
95002441	Palm, oil-babyfood	Not surrogated	
95002450	Papaya	157	Average of plant values
95002451	Papaya-babyfood	157	Average of plant values
95002460	Papaya, dried	157	Average of plant values
95002470	Papaya, juice	157	Average of plant values
95002520	Passionfruit	157	Average of plant values
95002521	Passionfruit-babyfood	157	Average of plant values
95002530	Passionfruit, juice	157	Average of plant values
95002531	Passionfruit, juice-babyfood	157	Average of plant values
95002540	Pawpaw	157	Average of plant values
95002630	Peanut	Not surrogated	
95002640	Peanut, butter	Not surrogated	
95002650	Peanut, oil	Not surrogated	
95002750	Peppermint	Not surrogated	
95002760	Peppermint, oil	Not surrogated	
95002770	Persimmon	157	Average of plant values
95002780	Pine nut	Not surrogated	
95002790	Pineapple	157	Average of plant values
95002791	Pineapple-babyfood	157	Average of plant values
95002800	Pineapple, dried	157	Average of plant values
95002810	Pineapple, juice	157	Average of plant values
95002811	Pineapple, juice-babyfood	157	Average of plant values
95002830	Plantain	157	Average of plant values
95002840	Plantain, dried	157	Average of plant values
95002890	Pomegranate	157	Average of plant values
95003060	Psyllium, seed	157	Average of plant values
95003110	Quinoa, grain	157	Average of plant values

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Food Code	FCID Food Description	PS level (mg/kg food)	Surrogation Explanation
95003330	Sapote, Mamey	157	Average of plant values
95003350	Seaweed	Not surrogated	
95003351	Seaweed-babyfood	Not surrogated	
95003360	Sesame, seed	Not surrogated	
95003361	Sesame, seed-babyfood	Not surrogated	
95003370	Sesame, oil	Not surrogated	
95003371	Sesame, oil-babyfood	Not surrogated	
95003460	Soursop	157	Average of plant values
95003510	Spanish lime	157	Average of plant values
95003520	Spearmint	Not surrogated	
95003530	Spearmint, oil	Not surrogated	
95003580	Starfruit	157	Average of plant values
95003590	Strawberry	157	Average of plant values
95003591	Strawberry-babyfood	157	Average of plant values
95003600	Strawberry, juice	157	Average of plant values
95003601	Strawberry, juice-babyfood	157	Average of plant values
95003610	Sugar apple	157	Average of plant values
95003620	Sugarcane, sugar	Not surrogated	
95003621	Sugarcane, sugar-babyfood	Not surrogated	
95003630	Sugarcane, molasses	Not surrogated	
95003631	Sugarcane, molasses-babyfood	Not surrogated	
95003680	Tamarind	157	Average of plant values
95003720	Tea, dried	Not surrogated	
95003730	Tea, instant	Not surrogated	
95003800	Tomato, Tree	157	Average of plant values
95003900	Vinegar	Not surrogated	
95003970	Water chestnut	157	Average of plant values
95003980	Watercress	157	Average of plant values

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Appendix IV

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**Nutritional-scientific statement
on the change of nutritive provision
with phosphatidylserine (PS)**

formulated by

Prof.Dr. troph. Michael Hamm

**Nutritional Scientist and Member of the Scientific Committee
of the ISME, private research insitute for sports, medicine and
nutrition**

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I. Introduction

It generally applies that the larger is the content of an organ in phospholipids, the more vital it is. Phospholipids are of tremendous importance for the whole cell metabolism. The membranes of nerve cells exhibit the highest content with the prime function of participation in the transmission of signals.

Phospholipids are taken in with food consumption. They are contained in animal and vegetable foodstuffs. The phospholipid phosphatidylserine is found, however, practically only in animal foodstuffs – particularly in the innards and meat. The PS-intake also proceeds mainly via these foodstuffs. In contrast, eggs and vegetable foodstuffs, with the exception of legumes, can be largely disregarded for the calculation of the PS provision. As a consequence, vegetarians – especially vegans – are the population group with lowest PS-intake.

On the one hand, the phospholipids contained in food are of great value for preserving health and maintaining performance; on the other hand, due to the possibility that they can become synthesized in the body itself, they are not an essential nutrient in the traditional and narrow sense. However, self-synthesis diminishes with increasing age.

The question is asked about what is a reasonable nutritional intake, or respectively an intake recommendation for phospholipids. The WHO (1974) worked on the basis of a daily lecithin intake of 3 g to 5 g lecithin.

Already in 1997, Feldheim discussed the estimated different daily lecithin intake in the diet in various countries, e.g. 3 g in the USA, 1.9 g in France and Ireland, and about 1.4 g in Germany.

The signs are increasing that through a sufficient phospholipid intake via food consumption a lot of metabolic processes can be

optimized. As example, various studies record an increase in the cognitive performance when PS in the range of 100 to 300 mg is substituted daily. A decline in the phospholipid intake with food could have contrastly a disadvantageous effect.

II. Changes in consumption and nutritive minimum provision of PS

Different points of view come together and have to be included in the discussion. Changes in consumer attitude (e.g. acceptance of innards) increased nutritional awareness (e.g. fat- and cholesterol-conscious eating) and not least food crises such as BSE and foot and mouth disease have resulted entirely in the fact that the consumption of food containing PS is declining. The following figures shall make this clear. Technological processing of fats and oils (refining, fat hardening) reduce the phospholipid content almost completely and contribute likewise to a declining PS-intake.

On account of that, especially for meat, there are only from 1986 differentiated consumption figures available – figures after subtracting bones, animal foodstuff and losses - a comparison can then be made as an example between the consumption data of 1986 (in former times) and 2000 (today). Thus the consumption of innards diminished from 2 kg per head and per annum in 1986 to 1 kg in 2000. Especially innards containing PS like brain have been practically removed fully from the meal plan. The total consumption of meat fell in the comparative time period from 63.3 kg per head in 1986 to 61.4 kg in 2000. Moreover, additional changes in preferences for individual types of meat have arisen (e.g. increase in poultry, decrease in beef).

Tab. 1 Consumption of individual foods in former times and today

Foodstuff	1986 per head and per year	2000 per head and per year
innards	2 kg	1 kg
beef	15.7 kg	9.7 kg
pork	43.1 kg	39.6 kg
poultry	6 kg	9.3 kg

Source: ZMP Balance – livestock and meat 2001

In the case of the foods also containing PS like milk and milk products as well as fish with a slightly increasing tendency, the following average daily consumption data are available, according to the Food Report 2000 of the German Society for Nutrition:

- milk and milk products: women about 200 g and men about 225 g
- cheese and curd cheese: women and men about 35 g
- fish and fish products are consumed on average at under 20 g per head and per day.

In the case of milk and milk products, those with a low fat content are recommended, and partially also favored (drinking milk with 1.5% fat instead of 3.5% fat), whereby the phospholipid intake should be lowered by around 50% in this food group.

The consumption of eggs, however, remained almost constant between 1992 and the end of 2001 with on average 224 units per head and year. Since eggs likewise as vegetable foodstuffs contain practically no PS (Juneja, 1997), this food was not included in the calculation of the PS-intake in the former times/today comparison.

III. Estimation of the daily PS-intake and nutritive minimal provision in the former times/today comparison

The following data enable an approximate calculation:

Table 2: PS-intake of individual foodstuffs

Foodstuffs	PS-intake in mg/100 g
liver (pig)	50
kidney (pig)	218
spleen (pig)	239
brain (cattle)	713
innards (average value)	305
beef	69
pork	57
poultry (leg)	134
poultry (breast)	85
poultry (average value)	109.5
herring	360
mackerel	480
milk (3.5% fat)	1
milk (1.5% fat)	approx. 0.5
white beans	107

Source: Souci, Fachmann, Kraut 2000

Which PS amounts can be achieved under consideration of a balanced mixed diet?

Taking as basis in respect of the group of animal protein carriers are:

- 3-4 meat portions à 100-120 g weekly
- 1-2 fish portions à 150-120 g
- ¼ liter of milk or sour milk daily
- 1-2 slices of cheese daily
- 3-4 times sausage weekly
- 2-3 eggs weekly

An approximate daily PS-intake of about 130 mg can be deduced from this, if these consumption recommendations are actually followed closely. However, it is known that people eat differently, e.g. more meat and sausage, and clearly less fish, whereby particularly the rich-in-fat sea fish comes into consideration as a source of PS (see Appendix 1, Digression on Omega-3 fatty acids and PS-content in the brain).

Finally the PS-intake is compared in the former times/today comparison and with different eating habits, in order to estimate from this the extent of a possible nutritive minimum provision.

Table 3: Daily PS-intake in comparison

PS-intake 1980s (former times)	PS-intake 2000 (today) relatively much meat and fish	light-eater (low-fat milk products, lean fish)	vegetarians
250 g	180 mg	100 mg	< 50 mg

Included in the calculation were the consumption data of 1986 and 2000 together with the known PS-contents of animal foods, except for eggs under the average-value formation in different fat contents within a food group.

IV. Conclusion

This rough calculation shows a nutritive minimum provision between former times and today in a magnitude range of 70 mg to 150 mg PS per day, depending on the currently usual mixed diet or whether an especially (fat-) calorie-conscious diet is practised; for a vegetarian diet even from 200 mg to 250 mg PS.

A supplementary PS-intake in the diet can therefore be recommended for the following people in order to prevent a nutritive minimum provision or possibly a deficiency in provision:

- vegetarians
- persons losing weight
- people who consciously eat low-in-fat and -cholestral food and therefore eat less meat as well as
- older people with a declining bodily phosphatidylserine synthesis.

A daily supplementary intake of at least 100 mg to max 300 mg appears plausible and also explains the improvement in the mental performance which can be attained with a dietary supplementary intake in the range of 100 mg to 300 mg PS in various studies.

Hamburg, July 2002

Prof. Dr. troph. Michael Hamm
Nutritional Scientist and
Member of the Scientific Committee of the ISME

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APPENDIX 1

DIGRESSION: fish consumption, provision with Omega-3 fatty acids (docosahexaenoic acid) and their influence on the PS-content in the brain

The fish consumption in Germany lies presently at just short of 20 grams daily per head of population (see Nutrition Report 2000). This corresponds to a daily intake amount, assumed also for the US population, of a maximum of 100 mg long-chained Omega-3 fatty acids (eicosapentanoic acid and docosahexaenoic acid) from fish fat. In a consensus statement of the work group Omega 3 that was published in the *Ernährungs-Umschau* (Nutrition Review) 2002, at least 300 mg of these fatty acids contrastly were recommended from the fat-containing cold-water fish.

For a variety of reasons, the provision situation with Omega-3 fatty acids in the history of human nutrition – particularly after the use of industrial food production – has dramatically changed. It is assumed that prehistoric man consumed a sufficient and, relative to Omega-6 fatty acids, balanced amount of Omega-3 fatty acids (ratio 2:1 to 1:1) (so-called Stone Age Diet). Only through humans becoming sedentary and because of the changed feeding basis of economically useful farm animals as well as the totally changed nutritional spectrum of humans, has a lower intake of Omega-3 fatty acids resulted, and particularly in the last centuries a clear overproportion in Omega-6 fatty acids. At present, the relation is >20:1, whereas the German Society for Nutrition recommends an Omega-6 to Omega-3 ratio of 5:1.

On the whole, the present intake of fats can be described as follows:

- too high a proportion of energy provision from fats
- too high an intake of saturated fatty acids
- too high an intake of multiple non-saturated Omega-6 fatty acids
- too low an intake of Omega-3 fatty acids both of vegetable and maritime origin.

This results in a recommendation of at least two fish meals weekly and the preferred usage of vegetable oils containing alpha-linolenic acid (rape oil or linseed oil). The Omega-3 fatty acids, alpha-linolenic acid, is in the human metabolism output substance for the biologically activating Omega-3 fatty acids, eicosapentanoic acid and docosahexaenoic acid. The conversion is, however, strongly restricted and amounts to a maximum of 10%, so that the consumption of fat-containing seafish represents the most efficient and surest form of provision of long-chained Omega-3 fatty acids.

The Omega-3 fatty acid, docosahexaenoic acid, which is of maritime origin, has a special significance in the development of the brain- and sight performance. It is known that multiple non-saturated fatty acids are essential functional parts of cell membranes. About 60 percent of the total fatty acids of the retina and 40 percent of multiple non-saturated brains lipids consist of docosahexaenoic acid. What is more, there is a narrow connection between docosahexaenoic acid content in the membrane phospholipids and the biosynthesis and enrichment of phosphatidylserine in the brain.

Docosahexaenoic acid is the dominant multiple non-saturated fatty acid in the phosphatidylserine molecule and influences so decisively its synthesis. A lack of Omega-3 fatty acids results in a selective and significant reduction of PS in the brain (see Garcia et al. 1998 and Hamilton et al. 2000).

These physiological requirements of a sufficient provision of Omega-3 fatty acids in the diet with respect to one's own bodily PS-synthesis provides a further argument for a PS-intake to supplement the diet, given the background of the unfavorable food consumption situation relating to this.

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Submission End

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