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February 21, 2020

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Subject: GRAS Notification – Dried Yeast Fermentate

Dear Sir:

On behalf of Cargill, Inc., ToxStrategies, Inc. (its agent) is submitting, for FDA review, a copy of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, dried yeast fermentate, described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, for addition to food.

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

GRAS Determination of a Dried Fermentate from the Yeast *Saccharomyces cerevisiae*

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GRAS Determination of a Dried Fermentate from the Yeast *Saccharomyces cerevisiae*

SUBMITTED BY:

Cargill, Inc.
15407 McGinty Road West
Wayzata, MN 55391

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

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February 11, 2020

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Acronyms

ATCC	American Type Culture Collection
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
cGMP	current Good Manufacturing Practice
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
JECFA	Joint FAO/WHA Expert Committee on Food Additives
NHANES	National Health and Nutrition Examination Survey
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
ppm	parts per million
QPS	qualified presumption of safety
U.S.C.	United States Code
WHO	World Health Organization

§ 170.225 Part 1, GRAS Notice: Signed Statements and Certification

(1) GRAS Notice Submission

Cargill, Inc. (Cargill), through its agent, ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for the use of a dried fermentate from the yeast *Saccharomyces cerevisiae* in select foods for human consumption, in accordance with Subpart E of 21 CFR § 170.

(2) Nam eand Addrss

Cargill, Inc.
15407 McGinty Road West
Wayzata, MN 55391

(3) Nam eof Notifie d Subs tance

The name of the substance that is the subject of this Generally Recognized as Safe (GRAS) notification is dried *Saccharomyces cerevisiae* yeast fermentate.

(4) Intended Use in Food

The dried yeast fermentate is intended for use as a nutritional ingredient in select foods in the categories listed at 500 mg/serving.

(5) Statutory Basis for GRAS Determination

Cargill, through its agent ToxStrategies, Inc., confirms that its dried yeast fermentate ingredient, meeting the specifications described herein, has been determined to be GRAS through scientific procedures in accordance with 21 CFR § 170.30(a) and (b).

(6) Premarket Approval Statement

Cargill further asserts that the use of the dried yeast fermentate in foods, as described below, is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, based on a conclusion that the notified substance is GRAS under the conditions of its intended use.

(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well as any information that has become available since the GRAS determination, will be sent to the U.S. Food and Drug Administration (FDA) on request, or are available for the FDA's

review and copying during customary business hours from ToxStrategies, Inc., Naperville, Illinois.

(8) Data and Information Confidentiality Statement

None of the data and information items in the GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

(9) GRAS Notice Certification

To the best of our knowledge, this GRAS determination is a complete, representative, and balanced document. Cargill is not aware of any information that would be inconsistent with a finding that the proposed uses and use levels for the dried yeast fermentate in food, meeting the appropriate specifications described herein, and used according to current Good Manufacturing Practices (cGMP), is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier

[redacted]

02/21/2020
Date

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Cargill, Inc.

(11) FSIS Statement

The dried yeast fermentate will not be used in products under the jurisdiction of the U.S. Department of Agriculture (USDA).

§ 170.230 Part 2, Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Identity

The subject of this GRAS determination is a dried fermentate made using the yeast *Saccharomyces cerevisiae*. A fermentate is the product of a fermentation process. Epicor® is the trade name for the dried fermentate powder produced using a proprietary, non-genetically modified *Saccharomyces cerevisiae* strain that was derived from American Type Culture Collection (ATCC) 7752. ATCC 7522 is a non-pathogenic, non-toxigenic, food-grade yeast. Briefly, Epicor is produced by this *S. cerevisiae* strain through anaerobic fermentation in a defined medium. Following fermentation, the entire wet fermentate is dehydrated (i.e., dried fermentate) and further processed through milling or flaking processes to generate a powder, granules, or flakes. The heating step in the dehydration process kills the yeast cells, which results in a dried product that contains inactive yeast cells, fermentation medium, and the associated natural fermentative by-products. Epicor is intended for use as a nutritional ingredient in both conventional foods and dietary supplements.

Common or Chemical Names

Epicor® is a dried fermentate from *Saccharomyces cerevisiae* composed of proteins, lipids, carbohydrates, cellulose and minerals and is made using ATCC 7522 *Saccharomyces cerevisiae* in a manufacturing process that uses aerobic propagation, anaerobic fermentation, and dehydration. It has been described by various names, including: "EpiCor®", "DIAM-H-04-2," "DIAMH-04-02." "DIAM," "yeast fermentate," "yeast culture," "dried fermentate," "dried yeast fermentate," "modified yeast supplement," "yeast fermentate (*S. cerevisiae*)," "dried yeast fermentate (derived using *Saccharomyces cerevisiase*)," "complex dried fermentate," and "dried fermentate complex."

Typical Properties

The dried yeast fermentate is brownish, crystalline-appearing particles and a free-flowing powder. It has a characteristic toasted, savory odor. It is hygroscopic and only partially soluble in water.

Manufacturing Process

Epicor® brand dried yeast fermentate is manufactured following three general steps—aerobic propagation, anaerobic fermentation, and dehydration. No constituent of Epicor® is concentrated or isolated during the manufacturing process. All phases of manufacturing, packaging, and labeling are conducted in accordance with applicable laws and regulations, including FDA current Good Manufacturing Practices (cGMPs) for food.

In addition, throughout all phases, electronic control systems are used in conjunction with in-process testing to monitor and adjust the manufacturing process.

The raw materials used are appropriate raw materials for yeast growth such as various salts, yeast extract and a glucose source. The raw materials are of a purity and quality suitable for the use of the dried yeast fermentate as a food ingredient.

Aerobic Propagation

Saccharomyces cerevisiase yeast cells are propagated in aerobic conditions with the appropriate nutrient blend. The process starts by following standard microbiological procedures to seed the initial yeast culture into a bio-reactor, with starting medium. The starting medium is composed entirely of food-grade materials, including an appropriate fermentable sugar source, vitamins, minerals, a nitrogen source, and potable water. Once the inoculum is added, sterilized air is bubbled into the bio-reactor, and a continuous stream of medium is added into the bio-reactor. Once the cell mass reaches the desired amount, the contents are transferred into the next bio-reactor for the subsequent anaerobic fermentation step.

Anaerobic Fermentation

The yeast produced in the aerobic propagation phase is subjected to fermentation under anaerobic conditions. In addition to the yeast biomass, a solution containing food-grade fermentable sugars, corn steep water, and potable water is added to the bioreactor. The commercially available corn steep water is a by-product of food-grade wet corn milling and is generated in the production of starches and sweeteners. It is rich in soluble protein, peptides, sugars, minerals, and lactic acid. Following fermentation, the resulting wort is removed from the bio-reactor for the final dehydration step.

Dehydration

The liquid wort from the fermentation is dehydrated and then further milled or flaked to the desired particle size range before packaging. The dehydration step utilizes a low-temperature/short-residence-time (200°F for 5 minutes) continuous drying process designed to retain the final product color, flavor, aroma, and nutritional content. During the drying process 8 eight samples of product are collected at different time points in the drying process and then incubated in the complete medium. This process is followed for all production lots and confirms that none of the samples are able to grow and the yeast is dead. The final composition is a brown, crystalline powder with a moisture content below 8% (wt/wt).

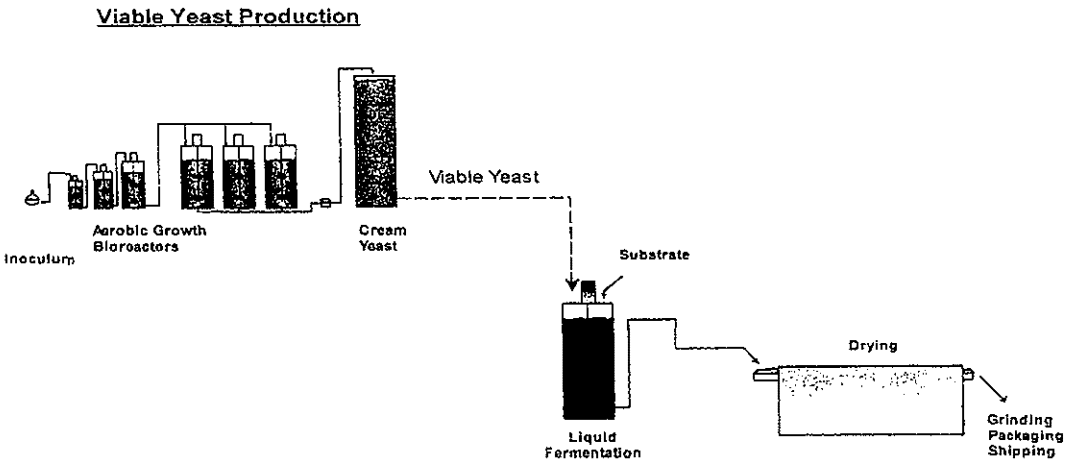

Figure 1. Manufacturing process flow diagram: DIAM H-04-2 process

Product Specifications

The proposed food-grade specifications for Cargill's dried yeast fermentate and analytical data from three non-consecutive lots of Epicor® are presented in Table 1. Table 2 presents the typical nutritional profile of the Epicor® dried yeast fermentate.

Table 1. Specifications and lot analyses for yeast fermentate (Epicor®)

Parameter	Specification	Method	Batch Number		
			0105-070319	0107-090519	0110-130819
Appearance	Brownish, crystalline-appearing particles, free-flowing powder		Free-flowing brownish powder	Free-flowing brownish powder	Free-flowing brownish powder
Odor	Characteristic toasted, savory		Characteristic toasted, savory	Characteristic toasted, savory	Characteristic toasted, savory
Protein	≥ 25% (w/w)	AOAC 990.03	27.19	25.75	27.63
Total Dietary Fiber	≥ 10% (w/w)	AOAC 991.43	14.0	13.5	14.6
Total Polyphenols	≥ 3% (w/w)	Folin-Ciocalteu	6.32	6.32	5.79
Moisture	≤ 8% (w/w)	AOCS Ca 2e-84	3.90	3.94	3.37
Water Activity	< 0.5 (w/w)	AOAC 978.18	0.205	0.269	0.212
Microbiology					
Aerobic Plate Count	< 5,000 cfu/g	FDA BAM III	110	ND	50

Yeast and Mold	< 100 cfu/g	FDA BAM XVIII	ND	ND	ND
Total Coliforms	<10 cfu/g	AOAC 991.14	ND	ND	ND
E. coli	ND/10 g	USP 62	ND	ND	ND
Enterobacteriaceae	< 100 cfu/g	AOAC 2003.01	ND	ND	ND
Staphylococcus aureus	< 10 cfu/g	FDA BAM XII	ND	ND	ND
Salmonella	ND/25 g	AOAC 2013.01	ND	ND	ND
Heavy Metals					
Lead (Pb)	< 0.5 ppm	AOAC 2013.06	0.14	0.12	0.11
Cadmium (Cd)	< 0.5 ppm	AOAC 2013.06	0.02	0.02	0.02
Arsenic (As)	< 1 ppm	AOAC 2013.06	0.29	0.24	0.27
Mercury (Hg)	< 0.3 ppm	AOAC 2013.06	< 0.010	< 0.010	< 0.010

cfu/g — colony-forming units per gram; ND — non detected; ppm — parts per million; w/w — weight to weight

Table 2. Typical nutritional profile (per 100g) for yeast fermentate (Epicor®)

Parameter	Value
Calories	310
Total fat (g)	5
Saturated fats (g)	<1
Trans fat (mg)	0
Cholesterol (mg)	0
Carbohydrates (g)	41
Dietary fiber (g)	10
Sugars (g)	1
Protein (g)	30
Ash (g)	20
Vitamin A (IU)	80
Thiamin (mg)	2.1
Riboflavin (mg)	3
Niacin (mg)	17
Vitamin B6 (ug)	2.5
Folic acid (ug)	300
Vitamin B12 (ug)	7.7
Biotin (ug)	100
Calcium (g)	1.1
Iron (mg)	17
Phosphorus (mg)	130
Magnesium (mg)	810
Zinc (mg)	11.8
Copper (mg)	1.3
Manganese (mg)	3.4
Sodium (mg)	204
Potassium (g)	7
Sulfur (mg)	140

In addition, the yeast fermentate has been characterized further and contains the following substances:

- *S. cerevisiae*
- Carbohydrates ~40%
  - Dietary fiber ~12%
- Total fats ~5%
  - Saturated fats <1%
  - Trans fat 0%
- Minerals ~20%
- Polyphenols ~5%
- Other substances present at low levels:
  - Vitamins (including vitamin A, vitamin B1, vitamin B2, vitamin B3, vitamin B5, vitamin B6, vitamin B12, folic acid, and biotin)

Dead whole yeast cells make up approximately 30% of the yeast fermentate. DNA from yeast used in the manufacturing process has been analyzed and shows a 100% genetic match to *Saccharomyces cerevisiae*. According to the National Center for Biotechnology Information Taxonomy Database, 2009, *Saccharomyces cerevisiae* is of the lineage: *Eukaryota; Fungi; Dikarya; Ascomycota; Saccharomycotina; Saccharomycetes; Saccharomycetales; Saccharomycetaceae; Saccharomyces; Saccharomyces cerevisiae.*

In summary, the analytical results demonstrate that the yeast fermentate is consistently manufactured to meet the established specifications and does not contain unacceptable levels of contaminants. The analytical results also confirm the absence of impurities and contaminants (e.g., heavy metals and microbiological contaminants).

Stability Data

A shelf-life stability assessment was performed on Epicor®. For the study, the product was removed from its original packaging after 67 weeks of room-temperature storage and moved into bags composed of multi-layer film that has been heat-sealed (intended to increase moisture, oxygen, and odor barrier characteristics). It was then placed inside the same wax-coated fiber drum used with the former packaging system for an accelerated storage study. The batch was tested under accelerated conditions of 40° C (104° F) and 75% relative humidity for six months (24 weeks). Interim results were recorded at 1, 2, 4, 8, 12, and 18 weeks.

Testing for accelerated and ambient conditions began (week 0) after the previous storage of 67 weeks under normal conditions. The product was analyzed for properties relevant to identity, quality, strength, purity, and composition of the dried fermentate.

Fourier transform near infra-red (FT-NIR) spectroscopy was performed during the accelerated part of the study and revealed no significant changes over time. During the accelerated storage, there were some physical changes in the product, including product darkening and clumping. However, these changes were a result of the accelerated conditions and did not affect the quality of the product and were not evident when the samples were stored at normal recommended conditions (cool and dry).

Protein content remained constant at 24 weeks; moisture remained under 8% (except one measurement that was 8.05% at 24 weeks), all microbiological and heavy-metal tests remained within specification.

§ 170.235 Part 3, Dietary Exposure

Cargill proposes to use the yeast fermentate (Epicor®) at 500 mg/serving in various food categories as summarized in Table 3 below. To estimate the intake of Epicor®, Exponent examined the daily intake of both total yeast in the US diet as well as the yeast fermentate in the food categories proposed for use in this dossier. (Exponent 2009, see Appendix B)

The analysis captured yeast intake from all foods with reported consumption in the NHANES 2003-04 survey. The NHANES 2003-2004 (NCHS, 2007) is a complex multistage probability sample designed to be representative of the civilian U.S. population. The survey collects two days of food intake data, in addition to nutrition, demographic, and health information. The NHANES survey over-samples minorities, low-income groups, adolescents (12-19 years), and adults 60 years of age and older and statistical weights are provided by the National Center for Health Statistics (NCHS) to adjust for the differential probabilities of selection. Participants included 10,122 subjects in 2003-2004. Only individuals with complete and reliable 2-day dietary records were included in the analysis (N=8,354).

EpiCor® is proposed to be added to only those foods in the categories listed in Table 3 at 500 mg/serving. Exponent first calculated the Epicor® content of each food in ppm using the serving size reference amounts customarily consumed per eating occasion provided by the US Food and Drug Administration (FDA) provided in the Code of Federal Regulations Title 21 (21CFR101.12). The intakes of EpiCor® from foods were calculated by multiplying each NHANES respondent's 2-day average food intake with the proposed use levels. Food consumption estimates were expressed in units of g_{food}/day on both the per capita and per user basis at the mean and 90_{th} percentile. The per capita mean daily intake for all targeted foods was 588.7 g_{food}/day (1,179 g_{food}/day at the 90_{th} percentile) and the per user mean daily intake was 601 g_{food}/day (1,183 g_{food}/day, 90_{th} percentile).

Exponent (2009) estimated the total daily per capita and 90th percentile intake of Epicor® yeast fermentate from its proposed uses in foods for the overall general population. The total estimated intake was calculated by summing the calculated daily intake from each of the targeted food categories. On both a *per-capita* and a *per-user* basis, the estimated daily intake (EDI) for the yeast fermentate from the proposed uses for the US population was **1.9 g/day at the mean and 3.5 g/day at the 90th percentile**.

Table 3. U.S. population food intake (g_{food}/day), NHANES 2003-2004

Target Food Categories Description	CFR Category	N	Per Capita		Per User	
			Mean	90th Percentile	Mean	90th Percentile
Milk	30	5,303	183.8	511.0	296.4	629.0
Flavored Milks and Milk Drinks	31	1,446	35.2	126.4	223.4	452.4
Milk - Snack Dips, Spreads	31	502	1.7	0.0	23.7	60.0
Milk, Other	31	1,207	11.6	30.4	67.5	152.5
Frozen Yogurt	20	124*	1.5	--	89.3	--
100% Fruit Juices	35	3,818	90.5	288.0	233.8	473.8
Processed Juice Drinks	35	1,500	31.0	107.8	218.4	447.2
Ready-To-Drink Tea Beverages	7	892	43.8	153.7	339.5	697.1
Sport/Fitness Water Beverages	3	17*	1.9	--	511.4	--
Fruit Flavored Drinks	3	2,579	89.0	300.9	362.5	780.2
Breads	1	6,545	49.4	108.5	59.5	116.4
Ready-To-Eat Bars	1	376	1.8	0.0	26.2	43.1
Ready-To-Eat Dry Cereals	4	3,429	14.4	47.6	37.2	70.5
Hard Candy	25	801	0.9	0.0	10.3	22.7
Mints	38	3*	--	--	17.1	--
Tofu	33	109*	0.8	--	43.7	--
Soups/Broth	40	1,377	31.5	130.0	201.0	369.6
TOTAL		8,005	588.7	1,179.0	601.0	1,183.0

N, total unweighted no. of users
* A sample size of at least 200 is necessary to reliably estimate the 90th percentile from a population distribution

For comparison purposes, Exponent also estimated daily intake of total yeast in the U.S. diet using NHANES 2003-2004 survey data. Based on this assessment, for the U.S. population, the *per-capita* average daily intake for yeast from all foods was 1.3 g/day (2.9 g/day, 90th percentile), and the *per-user* average daily intake was 1.5 g/day (3 g/day, 90th percentile).

By comparison, the Canadian Food Inspection Agency (CFIA, 2018), in its *Guide to Food Labeling and Advertising*, Section 6.3.1. Reasonable Daily Intake for Various Foods (Schedule K), also provided a reasonable daily intake of 14 g/day for yeast. The reasonable daily intake was used to evaluate, for regulatory purposes, the nutritional contribution of specific foods to the diet. The reasonable daily intake was used by the CFIA to determine the amount of vitamin and mineral nutrients that may be present in the food when they are added. The reasonable daily intake for most foods was considered to be one average serving of the food.

A comparison of Epicor® intake with total yeast intake in the U.S. diet can also be made. The yeast fermentate product contains approximately 30-33% inactive whole yeast cells, which is a higher percentage of yeast cells than found in other yeast-containing products such as bread, beer, or wine. Thus, the 90th percentile per user EDI yeast –equivalent from the proposed Epicor® uses in food is approximately 1 gm/day (.33 x 3 g/day) which is below the estimated current U.S. meant daily intake of yeast of 1.5 g/day , per user, and well below the U.S.90th percentile daily intake of 3 g/day , per user. The 90th percentile per use EDI for Epicor® is also well below the reasonable intake for yeast established by CFIA, assuming the yeasts identified in the Canadian estimate were similar to that used in Epicor®.

§ 170.240 Part 4, Self-Limiting Levels of Use

The use of the proposed yeast fermentate in foods is considered to be self-limiting for technological reasons, such as product texture and/or flavor profile, which could affect consumer acceptance.

§ 170.245 Part 5, Experience Based on Common Use in Food

While there exists an extensive history of the safe consumption of *S. cerevisiae* yeast and yeast products by both humans and animals, and *S. cerevisiae* products have FDA GRAS status, the statutory basis for our conclusion of its GRAS status in the notice is based on scientific procedures and not common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval of *Saccharomyces cerevisiae* Yeast and Yeast Products in Foods

The dried yeast fermentate (Epicor®) is a yeast product akin to many other yeast products made using *S. cerevisiae* that have a long history of safe consumption by humans and animals. Humans world-wide have consumed *S. cerevisiae* (also known as "bakers" or "brewers" yeast) through the consumption of its fermentative products, which include bread, beer, and wine.

Yeasts have been used at least since the beginning of recorded history for food and beverage production. One review indicates that yeast use in foods and beverages can be traced to 6000 BC (Verstrepen et al., 2006). Widespread use and unintentional presence of unmodified *S. cerevisiae* in food, prior to passage of the modern Food and Drug Act in the US, has led some to conclude that it can be classified as GRAS via the "prior sanction" mechanism (Verstrepen et al., 2006). FDA lists a number of ingredients manufactured using *S. cerevisiae* that are permitted in food, at least some of which contain the intact organism or parts of the organism (FDA, 2001). The European Union has also recognized the long history of safe use of *S. cerevisiae* in humans by adding it to the Qualified Presumption of Safety (QPS) list that allows a very abbreviated safety review for products made by or containing the organism (EFSA, 2010).

S. cerevisiae is found throughout the environment and occurs naturally in a number of foods. As noted above, *S. cerevisiae* can be found in live and/or dead forms in bread, beer, wine, capers, cucumbers (pickles), olives, and other fermented vegetables (Arroyo-Lopez et al., 2008). Prepared Spanish olives contain up to a million *S. cerevisiae* per milliliter. It is likely that most humans are exposed daily to foods containing millions of live *S. cerevisiae* through consumption of wine, beer, fruits, salads, and cheese and other dairy foods, as well as other traditional and ethnic fermented foods. FDA allows dried *S. cerevisiae* in foods, along with a number of yeast components, including protein, glycan, and enzymes (US FDA, 2001).

S. cerevisiae's complete genome sequence was reported in 1996 (Goffeau et al., 1996). This led to the development of many new genetically modified strains of *S. cerevisiae*, several of which have a notification of their GRAS status on FDA's website (GRN 120, 2003; GRN 175, 2005; GRN 350, 2010). Hata et al. (1991) have reported on the specific insertion of a glucoamylase gene from *A. oryzae* into *S. cerevisiae*. It is obvious from the above-mentioned published reviews involving *S. cerevisiae* that many modified strains are considered GRAS, but their status has not been notified to FDA (as is permitted by the regulation). Further, *S. cerevisiae* has an extensive history of use in the food-processing arena and is generally recognized as a food-grade microorganism (Liu et al., 2014).

In its safety evaluation of carbohydrase from *Saccharomyces cerevisiae*, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered that

Saccharomyces cerevisiae belongs to the group of micro-organisms traditionally accepted as constituents of foods or normally used in the preparation of foods (Joint FAO/WHO Expert Committee on Food Additives 1971).

Despite considerable use of the organism in research and the presence of *S. cerevisiae* in food, there are limited reports in the literature of its pathogenicity to humans or animals, and only in those cases where the human had a debilitating condition. Tests for the factors associated with the virulence of yeasts (i.e., phospholipases) indicate that this organism is nonpathogenic. The organism has not been shown to produce toxins to humans." (Environmental Protection Agency,1997) *Saccharomyces cerevisiae* was therefore included as a recipient microorganism at 40 CFR § 725.420 (EPA 1997) for the tiered exemption.

According to scientific experts, a nontoxigenic organism is defined as "one which does not produce injurious substances at levels that are detectable or demonstrably harmful under ordinary conditions of use or exposure" and a nonpathogenic organism is defined as "one that is very unlikely to produce disease under ordinary circumstances." (Pariza, Foster 1983).

The European Food Safety Agency (EFSA) concluded that Baker's yeast (*Saccharomyces cerevisiae*) fits this definition of nontoxigenicity and nonpathogenicity and that it is also not a major food allergen. EFSA therefore gave Baker's yeast a Qualified Presumption of Safety (QPS) status (EFSA Opinion of the Scientific Committee, 2007). This means that in Europe, Baker's yeast can be safely used in food and feed production and is exempt from the need for further safety assessment.

The FDA considers *Saccharomyces cerevisiae* and several derived products safe for consumption. Indeed, FDA has approved dried yeast as an ingredient for food (21 C.F.R. §172.896), and Baker's yeast extract has been affirmed by the FDA as a GRAS flavoring agent and adjuvant (21 C.F.R. §184.1983). The FDA has also approved various yeast-derived products for their use in food. These include Baker's yeast protein (21 C.F.R. §172.325), Yeast-malt sprout extract (21 C.F.R. §172.590) and Baker's yeast glycan (21 C.F.R. §172.898).

Saccharomyces cerevisiae is also considered Generally Recognized as Safe through its use in the brewing, baking and winemaking industry and has been the subject of several GRAS Notices, 120, 175, 239, 260, 284, 350, 353.

Safety

Introduction

For the present GRAS determination for the yeast fermentate (Epicor®), comprehensive literature searches were performed pertinent to its safety and intended use and use level. Literature searches have been performed to identify available safety data through August 2019. This included searching sources of information such as publicly available

assessments; databases; or reviews from organizations that include EFSA, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), FDA, and the World Health Organization (WHO); as well as general internet searching and searching databases such as Embase, Medline, Toxline, and PubMed.

Fermentative and Oxidative Byproducts

Yeasts are considered facultative aerobes, which means that they can grow in both the presence (aerobic) and absence (anaerobic) of oxygen and can instantly change their biochemistry to survive in one or the other condition (Reed and Nagodawithana 1991).

The metabolism of carbohydrates by yeast generally leads to the formation of ethanol and carbon dioxide, or water and carbon dioxide, depending on the amount of oxygen and glucose present. These reactions lead to the production of energy, which is required for yeast survival. Yeast grown anaerobically is considered fermentative, because it ferments sugars into ethanol and carbon dioxide (Abeles et al., 1992). Minimal multiplication of yeast cells occurs under anaerobic conditions. On the other hand, yeast grown under highly aerobic conditions is considered oxidative; sugar is oxidized into carbon dioxide and water. However, unless grown using very low sugar levels, aerobic conditions generally lead to both oxidative and fermentation processes (Reed and Nagodawithana, 1991).

Numerous other organic compounds are produced during yeast metabolism. In the case of beer, bread, or other products that involve yeast growth, these metabolite compounds are ingested with consumption of the final product. The compounds that are formed depend on the specific starting ingredients and circumstances under which the yeast has been grown. Some of these fermentation compounds include organic acids, esters, carbonyl compounds, aldehydes, and ketones (Reed and Nagodawithana, 1991). Unchanged raw materials that were not fermented, as well as yeast particles often end up in the finished fermented product.

Safety Data

A battery of toxicology studies has been conducted with the yeast fermentate, and the results have been published in the peer-reviewed literature (Schauss et al., 2012). The studies include acute, subchronic, and chronic studies, as well as mutagenicity/genotoxicity studies. These studies are summarized below.

Animal Studies

Acute Oral Toxicity

The acute oral toxicity of Epicor® yeast fermentate was examined in Crl:CD BR Sprague-Dawley rats. The study was conducted in accordance with the OECD Acute Oral Toxicity Test Guideline No. 423, Limit Test (Schauss et al., 2012). Groups of 10 male and 10 female rats were administered a single dose of 2,000 mg of Epicor® yeast fermentate/kg bw by oral gavage, which represents the limit test for acute oral toxicity testing. The rats were observed daily for a period of 14 days, at which time they were necropsied. Gross lesions were preserved and subjected to microscopic examination. All animals survived

the observation period, with no clinical signs of toxicity detected at any time. Body weights and weight gains were within normal parameters. Autopsies revealed no toxic gross pathological changes. There was no observable toxicity in either male or female rats at a dose of 2,000 mg/kg body weight, the limit dose. Therefore, the acute oral LD_{50} of the yeast fermentate was considered greater than 2,000 mg/kg bw.

Repeat-Dose Oral Toxicity

The subchronic toxicity of Epicor® yeast fermentate was evaluated in male and female Crl:CD Sprague-Dawley rats. The study was conducted in accordance with the OECD Repeated Dose 90-day Oral Toxicity Study in Rodents, Guideline No. 408 for subchronic oral toxicity studies (Schauss et al., 2012). Groups of 20 male and 20 female rats were administered the test material by gavage daily for 90 consecutive days at doses of 0, 30, 200, and 1500 mg yeast fermentate/kg bw/day. Similar groups of rats served as controls and received only the vehicle control solution. No deaths occurred in either the treated or control groups, and there were no treatment-related clinical signs of toxicity. There were no differences between the treated groups and controls in body-weight gain, food or water consumption, tests for sensory reactivity, grip strength, and motor activity. No abnormal ophthalmological changes were observed. There were no treatment-related effects on hematology, chemistry blood coagulation, and urinalysis parameters. Slight statistically significant changes in one or several groups in lymphocyte count, cholesterol, serum protein, sodium, potassium, chloride, calcium, and creatine were attributed to low within-group differences and were not considered biologically significant. Gross pathology examinations did not reveal any specific treatment-related changes. No treatment-related differences were found in organ weights or organ weight ratios. Administration of the yeast fermentate for 90 days at doses up to 1500 mg/kg bw/day in male and female rats did not result in observable toxicity. Therefore, the no-observed-adverse-effect level (NOAEL) was considered to be 1,500 mg/kg bw/day, the highest dose tested.

Evans et al. (2012) conducted two short-term studies in Sprague-Dawley rats. The first study examined the ability of a dried fermentate from *S. cerevisiae* (Epicor®) to prevent or reduce inflammation when given orally for 14 days to rats (7 mg/kg bw/day) prior to receiving 1% carrageenan (localized inflammation model). The dried fermentate significantly ($P < 0.05$) reduced swelling at all time points (1, 2, 3, 6, 12, and 24 hours) versus the control. Edema severity and PGE2 levels were reduced by approximately 50% and 25% ($P < 0.05$), respectively. Study 2 examined the ability of Epicor® (7 mg/kg bw/day) to treat established inflammation induced by type-2 collagen in mice over 4 weeks (autoimmune arthritis model). Significantly reduced arthritis scores, antibody response to type-2 collagen, and interferon-gamma levels were observed compared to controls (all parameters $P < 0.05$). No treatment-related adverse effects were noted. The authors concluded that Epicor® favorably impacted multiple acute and potentially chronic immunologic inflammatory control mechanisms.

Chronic Toxicity

The oral toxicity of Epicor® yeast fermentate was evaluated for one year in male and female Crl:CD Sprague-Dawley rats (Schauss et al., 2012). The study was conducted in accordance with the OECD Guideline for the testing of chemicals No. 452, Chronic Toxicity Study, adopted September 2, 1998.

The study design included 80 female and 80 male rats. Yeast fermentate was administered by oral gavage at doses of 0, 20, 200, and 800 mg/kg bw/day for 364 days. Animals were observed twice daily, as well as at least once on weekends, throughout the year. Control rats received a 1% methylcellulose solution (vehicle)

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No spontaneous deaths occurred in any of the 160 Sprague-Dawley rats during the one-year study. One male and one female rat, both from the high-dose 800 mg/kg dose group, were found in tumor-provoked moribund states (the male had a mass on the skin of the left foreleg, and the female had three nodules in the inguinal region) and were subsequently sacrificed. The increased incidence of these tumors was not statistically significant, and their formation was not considered related to treatment with Epicor® yeast fermentate. One female rat was accidentally over-anesthetized during scheduled blood sampling at week 33.

The development of the animals during the experimental period corresponded appropriately to their species and age; body-weight gains in treated and control groups of both genders were similar throughout the study. Food consumption was similar between all treatment groups and control groups.

Statistically significant decreased water consumption occurred in the male and female 800 mg/kg bw/day groups. The male 800 mg/kg bw/day group displayed a statistically significant decrease in water consumption on 24 nonconsecutive individual weeks out of the 52-week treatment. The female 800 mg/kg bw/day group displayed statistically significant decreased water consumption only during the first 10 weeks of the study. The water consumption of the mid-dose 200 mg/kg bw/day male group was increased compared to controls over a period of 20 weeks, although the increase was not statistically significant. Hence, no dose-dependent correlation could be established between decreased water consumption and treatment with yeast fermentate. The results also did not correlate with any clinical signs or symptoms, gross or histopathological findings, specific gravity changes in the urine, or clinical chemistry and hematology changes. Therefore, the results were considered of no clinical significance.

No ophthalmologic changes were observed following treatment (week 51) in any of the control and treatment groups. No test-article-related differences in visual (finger approach) or auditory (startle) reactivity, pain perception (tail pinch), grip strength, or motor activity were noted. Several sporadic, statistically significant alterations in hematology, as well as some non-dose-related alterations in clinical blood chemistry, were seen during a few of the weeks during the year. However, no changes in

hematology, blood coagulation, or blood chemistry effects were considered related to the consumption of the test article due to their sporadic or non-dose-dependent nature.

The urinalysis performed during weeks 13, 32, and 51 revealed no Epicor® yeast fermentate-related differences between control and treatment groups. No treatment-related differences in organ weights or differences in the ratios of body weight to organ weight were found. Internal macroscopic examinations found no treatment-related pathological changes in subcutaneous tissues, regional lymph nodes, fatty tissues, skeletal muscles, joints, or bones in any animal. Tumor-like tissue changes in mammary glands occurred in 15%–20% of the 200- and 800 mg/kg bw/day female treatment groups. These increased benign mammary tumors were identified histopathologically as adenomas and fibro-adenomas and were not statistically significant. The incidence of these benign tumors fell within the historical control range of 6.3%–32% for mammary-gland adenomas and 67.4% for fibroadenomas reported by Dinse et al. (2010). These benign neoplastic changes are well recognized to occur spontaneously in Sprague-Dawley rats (Giknis and Clifford, 2004). Due to the lack of statistical significance and incidences falling within the historical control group ranges, the benign tumors in the treatment group were considered unrelated to treatment with the test vehicle. Microscopic examination revealed no significant test-article-related histopathological changes.

In summary, the yeast fermentate was well tolerated in daily oral doses up to 800 mg/kg bw/day without spontaneous mortality, toxic clinical symptoms, or significant changes in chemistry or urinalysis. While water consumption showed a statistically significant decrease throughout the study in the high-dose 800 mg/kg bw/day male group, it was not established as being dose dependent, and was not associated with any other clinical signs or symptoms. Therefore, the NOAEL was considered by the authors to be 800 mg Epicor® yeast fermentate/kg bw/day for both males and females, the highest dose tested.

Mutagenicity/Genotoxicity

Epicor® yeast fermentate was evaluated for mutagenic activity in the bacterial reverse mutation test using *Salmonella typhimurium* strains TA97a, TA98, TA100, TA1535, and *Escherichia coli* strain WP2 uvrA, in the presence and absence of an exogenous metabolic activation system (Aroclor-induced rat liver S9) (Schauss et al., 2012). No evidence of mutagenic activity was detected for the test substance in *Salmonella typhimurium* tester strains TA97a, TA98, TA100, and TA1535 or *Escherichia coli* strain WP2 wvrA, with or without exogenous metabolic activation systems. It was concluded that the test article was non-mutagenic in the bacterial reverse mutation assay.

Epicor® yeast fermentate was tested for mutagenic activity using the mouse lymphoma L5178Y cell line (Schauss et al., 2012). The positive controls in the study showed the expected significant increase in the mutant frequency as compared to the negative control. The results of the study were negative, indicating that the yeast fermentate was not mutagenic under the conditions of the assay.

Mitogenic activity of EpiCor® was assessed in the lymphocyte proliferation assay

using human lymphocytes (Jensen et al., 2007). Lymphocytes treated with the positive control (phytohemagglutinin) showed substantial proliferation reflected in a significant loss of membrane fluorescence. No differences in cell division levels between untreated cells and cells treated with serial dilutions of EpiCor® were observed. EpiCor® was not considered mitogenic under the conditions of the assay.

Schauss et al. (2012) also reported the results of an assay of the mitogenic activity of Epicor® yeast fermentate in the lymphocyte proliferation assay using human lymphocytes. Lymphocytes treated with the positive control (the known mitogen, phytohemagglutinin), showed substantial proliferation, reflected in a significant loss of membrane fluorescence. No differences in cell division levels between untreated cells and cells treated with serial dilutions of Epicor® yeast fermentate were observed. Therefore, the yeast fermentate was not considered mitogenic under the conditions of the assay.

Schauss et al. (2012) also reported the results of an *in vitro* evaluation of CYP1A2 and CYP3A4 induction in Fa2N-4 cells. Because induction of CYP enzymes is a major mechanism for some drug-to-drug and supplement-to-drug interactions, this study was conducted to evaluate whether the Epicor® yeast fermentate could induce human CYP enzymes *in vitro*—specifically, cytochrome P450 1A2 (CYP1A2) and cytochrome P450 3A4 (CYP3A4). The cells employed for the tests were immortalized human hepatocytes (Fa2N-4 cells). The CYP mRNA levels were determined with a branched DNA (bDNA) assay (Czerwinski et al., 2002). Initially, the potential cytotoxicity of the yeast fermentate on Fa2N-4 cells was evaluated, based on cellular release of lactate dehydrogenase (LDH) and light microscopic observations of the cultures. No toxicity was observed. In addition to treatment of the Fa2N-4 cells, Fa2N-4 cells were also tested with DMSO, the diluent solubilizing agent (negative control), and with two positive controls, omeprazole (as an inducer of CYP1A2) and rifampin (as an inducer of CYP3A4). CYP-specific reactions were also used to measure the enzymatic activity of CYP1A2 (phenacetin O-dealkylation) and CYP3A4 (midazolam 1'-hydroxylation).

There was no induction of mRNA expression or enzymatic activity by the negative control. The expected positive induction of CYP1A2 and CYP3A4 was found with omeprazole and rifampin, respectively, confirming that the test performed as expected. The yeast fermentate did not induce the CYPlA2 or CYP3A4 mRNA expression or enzymatic activity. A test performed with yeast fermentate treatment concurrently with the positive controls showed that it did not interfere with the induction of CYP1A2 and CYP3A4 by the positive controls. Based on the study data, it was concluded that the yeast fermentate ingredient was unlikely to contribute to supplement-to-drug interactions that involve CYP enzymes.

Human Studies

Epicor® yeast fermentate was compared to a placebo in a published human study to determine its effects on colds and flu-like symptoms in healthy subjects (Moyad et al., 2008). Healthy subjects (N=116) aged 18 to 76 years (mean age = 44; 57% females) were randomized to consume 500 mg of the yeast fermentate or placebo over 12 weeks.

Clinical examinations and comprehensive serologic evaluations were performed at baseline, six weeks, and twelve weeks. The subjects also reported symptoms throughout the study in a diary. The subjects who took the yeast fermentate supplement reported significantly reduced incidence and duration of colds and flu compared to the control group. The treated subjects also experienced fewer overall adverse events ($p=0.23$) than the controls; however, the result was not statistically significant. The rate of adverse events was 30.8% in the yeast fermentate-treated group, and 39.1% in the placebo group. No serious adverse events were reported in the yeast fermentate group; however, two serious events occurred in the placebo group (one hospitalization for bowel obstruction, which was recurring for this subject, and one hospitalization for pneumonia). There were no abnormalities in any of the laboratory serologic parameters (i.e., complete blood count, complete metabolic profile, and other general health serologic parameters) in the Epicor® yeast fermentate-treated group.

Moyad et al. (2009) conducted a 12-week, randomized, double-blind, placebo-controlled clinical trial of 96 healthy subjects with a recent clinically documented history of seasonal allergies and allergic rhinitis. Participants received once-daily supplementation with 500 mg of EpiCor® or placebo during the 12-week period of the highest recorded concentrations of total pollen counts for the specific Midwest geographic area. Clinical outcome measurements included in-clinic examinations, validated questionnaire and standard diary, and serologic analysis at baseline, 6- and 12-weeks. During the highest pollen count period (weeks 1-6), EpiCor® significantly reduced the mean severity of specific allergic rhinitis symptoms, including a significant reduction in nasal congestion ($P=0.04$), rhinorrhea ($P=0.005$), and a nonsignificant reduction in ocular discharge symptoms. A significantly ($P=0.04$) reduced total number of days with nasal congestion (12.5 fewer days) favored EpiCor® compared with placebo, as did the nasal congestion section of the quality of life questionnaire ($P=0.04$). Subjects receiving the intervention also experienced significantly ($P=0.03$) higher salivary IgA levels. Adverse events reported were similar to placebo. The authors concluded that the yeast-derived product appeared to be safe and efficacious.

Jensen et al. (2008) conducted a double-blind, randomized, placebo-controlled pilot study designed to evaluate the effects of consumption of EpiCor®. Twenty-five healthy participants consumed 0.5 grams EpiCor® or placebo daily for five weeks. Hematocrit levels increased significantly in the EpiCor® group ($p<0.04$). A mild increase in saliva sIgA upon EpiCor® consumption ($p=0.16$) prompted a subsequent 8-week open-label study involving 22 people showing a significant increase in sIgA ($p<0.05$). EpiCor® consumption led to a mild increase in serum IL-10 ($p<0.2$); no other differences in Th1/Th2 cytokines were observed. Minor health complaints decreased in the EpiCor® group compared to the placebo group ($p<0.02$). Seasonal allergies increased in the placebo group but were not observed in the EpiCor® group as reflected by increased serum IgE in the placebo group compared to the EpiCor® group ($p<0.13$).

In addition, Epicor® yeast fermentate has been marketed as a dietary supplement for more than a decade. Epicor® is currently sold for use in multi-ingredient dietary supplements and also as a sole ingredient. Since 2007, approximately 25 million EpiCor® dietary

supplements have been sold per year in the U.S. with no documented adverse events reported to be a result of Epicor® consumption.

Safety Summary

The yeast fermentate product Epicor® is currently marketed for use as a dietary supplement. This GRAS determination supports additional uses in food for human consumption. Regulatory authorities have reviewed the extensive safety database on *S. cervisiae* and found no issues of concern with respect to its use in human food or human food production. Numerous studies have been conducted, and published data are available that support the safety of the intended uses of the yeast fermentate product, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults.

Basis for the GRAS Determination

Introduction

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

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

These criteria are applied in the analysis below to determine whether the use of the *S. cerevisiae* yeast fermentate ingredient in human food that is the subject of this GRAS determination is GRAS based on scientific procedures. All data relied upon in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the Federal Food, Drug, and Cosmetics Act.

Safety Determination

The Cargill yeast fermentate ingredient (from *S. cervisiae*) that is the subject of the current GRAS determination is proposed for use as a nutritional ingredient at a maximum use level of 500 mg/serving in specified foods identified in this dossier for human consumption. The dried yeast fermentate (Epicor®) is a yeast product akin to many other yeast products made using *S. cerevisiae* that have a long history of safe consumption by humans and animals. Humans world-wide have consumed *S. cerevisiae* (also known as "bakers" or "brewers" yeast) through the consumption of its fermentative products, which include bread, beer, and wine.

Yeasts have been used at least since the beginning of recorded history for food and beverage production. Widespread use and unintentional presence of unmodified *S. cerevisiae* in food, prior to passage of the modern Food and Drug Act in the US, has led some to conclude that it can be classified as GRAS via the "prior sanction" mechanism (Verstrepen et al., 2006). FDA lists a number of ingredients manufactured using *S. cerevisiae* that are permitted in food, at least some of which contain the intact organism or parts of the organism (US FDA, 2001).

S. cerevisiae is found throughout the environment and occurs naturally in a number of foods. *S. cerevisiae* can be found in live and/or dead forms in bread, beer, wine, capers, cucumbers (pickles), olives, and other fermented vegetables (Arroyo-Lopez et al., 2008). It is likely that most humans are exposed daily to foods containing millions of live *S. cerevisiae* through consumption of wine, beer, fruits, salads, and cheese and other dairy foods, as well as other traditional and ethnic fermented foods. FDA permits the use of dried *S. cerevisiae* as an ingredient in foods, along with a number of yeast components, including protein, glycan, and enzymes (FDA, 2001).

S. cerevisiae's complete genome sequence was reported in 1996 (Goffeau et al., 1996). This led to the development of many new genetically modified strains of *S. cerevisiae*, several of which have a notification of their GRAS status on FDA's website (GRN 120, 2003; GRN 175, 2005; GRN 350, 2010).

S. cerevisiae has a long history of being considered non-pathogenic. It is used in many food manufacturing processes, including bread making, beer brewing, and grape fermentation for wine. Regulatory authorities have evaluated the safety of *S. cerevisiae* and consider the organism safe for use in food manufacturing. Several GRAS notifications for modified strains of *S. cerevisiae* used in winemaking have been sent to FDA, and that agency has responded that they had no further questions on the GRAS determinations. In summary, regulatory authorities have reviewed the extensive safety database on *S. cervisiae* and found no issues of concern with respect to its use in human food or human food production.

Numerous toxicology studies employing the proposed yeast fermentate ingredient have been conducted and published that provide support for the safety of the intended uses of the ingredient. These studies include *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as

clinical studies in adults. NOAELs of 800 and 1500 mg/kg/day have been reported in 1-year and chronic and 90-day subchonic studies in rats.

General Recognition of the Safety of a Dried Yeast Fermentate from *Saccharomyces cerevisiae*

The intended use of the dried yeast fermentate has been determined to be safe through scientific procedures, as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, and this determination is based on the following:

- The Cargill yeast fermentate ingredient that is the subject of the current GRAS determination is derived from *S. cerevisiae*, also (also known as "bakers" or "brewers" yeast).
- Epicor® is the trade name for the dried fermentate powder produced using a proprietary non-genetically modified *S. cerevisiae* strain that was derived from ATCC 7752. ATCC 7522 is a non-pathogenic, non-toxigenic, food-grade yeast. The yeast fermentate is produced by this *S. cerevisiae* strain through anaerobic fermentation in a defined medium. Following fermentation, the entire wet fermentate is dehydrated (i.e., dried fermentate) and further modified through milling or flaking processes to generate a powder, granules, or flakes. The heating step in the dehydration process kills the yeast cells, which results in a dried product containing dead yeast cells, fermentation medium, and the associated natural fermentative by-products.
- The yeast fermentate ingredient is intended for use as a nutritional supplement in selected foods for human consumption.
- Epicor® yeast fermentate has been marketed as a dietary supplement for more than a decade. Epicor® is currently sold for use in multi-ingredient dietary supplements, and also as a sole ingredient.
- The yeast fermentate product is proposed for use in a wide range of foods, including cookies, meal replacement and probiotic beverages, nutritional bars, soy milk, yogurt and yogurt beverages, soy protein bars, fruit beverages, chocolate confections, and soups.
- The *per user* estimated daily intake of the yeast fermentate from consumption of the listed foods is estimated to be approximately 1.9 g/day at the mean and 3.5 g/day at the 90th percentile, or 32 and 58 mg/kg bw/day (for a 60-kg individual), respectively.
- The current US daily intake of yeast in the diet for the US population 2 years and older is as follows: the *per-capita* average daily intake for yeast from all foods was 1.3 g/day (2.9 g/day, 90th percentile), and the *per-user* average daily intake was 1.5 g/day (3 g/day, 90th percentile).
- The Canadian Food Inspection Agency provided an estimate of a reasonable daily

intake of 14 g/day for yeast (CFIA, 2018). The reasonable daily intake was used to evaluate, for regulatory purposes, the nutritional contribution of specific foods to the diet.

- *S. cerevisiae* has a long history of being considered non-pathogenic. It is used in many food manufacturing processes, including bread making, beer brewing, and grape fermentation for wine. The FDA, EPA (1997), and EFSA have evaluated the safety of *S. cerevisiae* and consider the organism safe for use in food manufacturing. Several GRAS notifications for modified strains of *S. cerevisiae* used in winemaking have been sent to FDA, and that agency has responded that they had no further questions on the GRAS determinations.
- Numerous toxicology studies employing the proposed yeast fermentate ingredients have been conducted and published that support the safety of the intended uses of the ingredient. These studies include *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults. NOAELs of 800 and 1500 mg/kg/day have been reported in 1-year and chronic and 90-day subchronic studies in rats, well above the estimated 90th percentile per-user daily intake of 58 mg/kg bw/day.
- The body of publicly available scientific literature on the consumption and safety of *S. cerevisiae* and the yeast fermentate product is sufficient to support the safety and GRAS determination of the proposed yeast fermentate ingredient.

Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of the yeast fermentate ingredient that is the subject of this evaluation has been made through the deliberations of an Expert Panel convened by Cargill and comprised Michael Carakostas, DVM, Ph.D., Stanley M. Tarka, Jr., Ph.D., F.A.T.S., and Thomas Vollmuth, Ph.D. The Panel's GRAS opinion is included as Exhibit 1 to this document. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that the yeast fermentate ingredient, produced in a manner consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use.

The Panel further unanimously concluded that use of the yeast fermentate ingredient in the specified human foods described herein is GRAS based on scientific procedures, and that other experts qualified to assess the safety of food and food ingredients for human consumption would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Cargill's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Cargill has concluded that the yeast fermentate ingredient is GRAS under the intended conditions

of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Cargill is not aware of any information that would be inconsistent with a finding that the proposed use of the yeast fermentate ingredient in food for human consumption, meeting appropriate specifications, and used according to cGMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendix A (analytical Certificates of Analysis for yeast fermentate, and additional analytical data), Appendix B (the Exponent 2009 intake assessment), and Exhibit 1, (the signed Expert Panel report) are not generally available but are attached for reference.

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APPENDIX A

Certificates of Analysis and Analytical Results

Certificate of Analysis

EpiCor®
Product Code: E3000

Date of Issue:	2019/03/28 (yyyy/mm/dd)
Lot Number:	0105-070319
Manufactured Date:	2019/03/07 (yyyy/mm/dd)
Stability:	Product warranted to be within test limit until 2022/03/07 (yyyy/mm/dd) when stored in unopened, original factory-sealed container.
Description:	EpiCor is a natural dried fermentate made using *Saccharomyces cerevisiae* manufactured by Embria Health Sciences, L.L.C. in the United States using specialized fermentation and drying processes.
General Appearance:	Free-flowing brownish powder. Differences in color are customary and not indicative of product quality.
Odor:	Characteristic toasted savory.

TEST	LIMIT	RESULT	METHOD
Identity	Pass	Pass	FT-NIR-QC206
Protein	≥ 25%	27.19	AOAC 990.03
Total Dietary Fiber	≥ 10%	14.0	AOAC 991.43
Total Polyphenols	≥ 3%	6.32	Folin-Ciocalteu
Moisture	≤ 8%	3.90	AOCS Ca 2e-84
Water Activity	< 0.5	0.205	AOAC 978.18
Microbiology			
Aerobic Plate Count	< 5,000 cfu/g	110	FDA BAM III
Yeast & Mold	< 100 cfu/g	ND	FDA BAM XVIII
Total Coliforms	< 10 cfu/g	ND	AOAC 991.14
E. coli	ND / 10 g	ND	USP 62
Enterobacteriaceae	< 100 cfu/g	ND	AOAC 2003.01
Staphylococcus aureus	< 10 cfu/g	ND	FDA BAM XII
Salmonella	ND / 25 g	ND	AOAC 2013.01
Heavy Metals			
Lead (Pb)	< 1 ppm	0.14	AOAC 2013.06
Cadmium (Cd)	< 1 ppm	0.02	AOAC 2013.06
Arsenic (As)	< 1 ppm	0.29	AOAC 2013.06
Mercury (Hg)	< 0.3 ppm	<0.010	AOAC 2013.06

Note: ND = none detected.

Packaging (25kg): Heat-sealed poly bag in a fiber drum.
Storage: Dry conditions; in the tightly closed original container.

Certificate of Analysis

EPICOR®

EpiCor®

Product Code: E3000

Date of Issue:	2019/06/04 (yyyy/mm/dd)
Lot Number:	0107-090519
Manufactured Date:	2019/05/09 (yyyy/mm/dd)
Stability:	Product warranted to be within test limit until 2022/05/09 (yyyy/mm/dd) when stored in unopened, original factory-sealed container.
Description:	EpiCor is a natural dried fermentate made using *Saccharomyces cerevisiae* manufactured by Embria Health Sciences, L.L.C. in the United States using specialized fermentation and drying processes.
General Appearance:	Free-flowing brownish powder. Differences in color are customary and not indicative of product quality.
Odor:	Characteristic toasted savory.

TEST	LIMIT	RESULT	METHOD
Identity	Pass	Pass	FT-NIR-QC206
Protein	≥ 25%	25.75	AOAC 990.03
Total Dietary Fiber	≥ 10%	13.5	AOAC 991.43
Total Polyphenols	≥ 3%	6.32	Folin-Ciocalteu
Moisture	≤ 8%	3.94	AOCS Ca 2e-84
Water Activity	< 0.5	0.269	AOAC 978.18
Microbiology			
Aerobic Plate Count	< 5,000 cfu/g	ND	FDA BAM III
Yeast & Mold	< 100 cfu/g	ND	FDA BAM XVIII
Total Coliforms	< 10 cfu/g	ND	AOAC 991.14
E. coli	ND / 10 g	ND	USP 62
Enterobacteriaceae	< 100 cfu/g	ND	AOAC 2003.01
Staphylococcus aureus	< 10 cfu/g	ND	FDA BAM XII
Salmonella	ND / 25 g	ND	AOAC 2013.01
Heavy Metals			
Lead (Pb)	< 1 ppm	0.12	AOAC 2013.06
Cadmium (Cd)	< 1 ppm	0.02	AOAC 2013.06
Arsenic (As)	< 1 ppm	0.24	AOAC 2013.06
Mercury (Hg)	< 0.3 ppm	<0.010	AOAC 2013.06

Note: ND = none detected.

Packaging (25kg): Heat-sealed poly bag in a fiber drum.
Storage: Dry conditions; in the tightly closed original container.

[redacted] 6/4/2019

Certificate of Analysis

EpiCor®

Product Code: E3000

Date of Issue:	2019/08/27 (yyyy/mm/dd)
Lot Number:	0110-130819
Manufactured Date:	2019/08/13 (yyyy/mm/dd)
Stability:	Product warranted to be within test limit until 2022/08/13 (yyyy/mm/dd) when stored in unopened, original factory-sealed container.
Description:	EpiCor is a natural dried fermentate made using *Saccharomyces cerevisiae* manufactured by Embria Health Sciences, L.L.C. in the United States using specialized fermentation and drying processes.
General Appearance:	Free-flowing brownish powder. Differences in color are customary and not indicative of product quality.
Odor:	Characteristic toasted savory.

TEST	LIMIT	RESULT	METHOD
Identity	Pass	Pass	FT-NIR-QC206
Protein	≥ 25%	27.63	AOAC 990.03
Total Dietary Fiber	≥ 10%	14.6	AOAC 991.43
Total Polyphenols	≥ 3%	5.79	Folin-Ciocalteu
Moisture	≤ 8%	3.37	AOCS Ca 2e-84
Water Activity	< 0.5	0.212	AOAC 978.18
Microbiology			
Aerobic Plate Count	< 5,000 cfu/g	50	FDA BAM III
Yeast & Mold	< 100 cfu/g	ND	FDA BAM XVIII
Total Coliforms	< 10 cfu/g	ND	AOAC 991.14
E. coli	ND / 10 g	ND	USP 62
Enterobacteriaceae	< 100 cfu/g	ND	AOAC 2003.01
Staphylococcus aureus	< 10 cfu/g	ND	FDA BAM XII
Salmonella	ND / 25 g	ND	AOAC 2013.01
Heavy Metals			
Lead (Pb)	< 1 ppm	0.11	AOAC 2013.06
Cadmium (Cd)	< 1 ppm	0.02	AOAC 2013.06
Arsenic (As)	< 1 ppm	0.27	AOAC 2013.06
Mercury (Hg)	< 0.3 ppm	<0.01	AOAC 2013.06

Note: ND = none detected.

Packaging (25kg): Heat-sealed poly bag in a fiber drum.
Storage: Dry conditions; in the tightly closed original container.

[redacted] 8/27/2019
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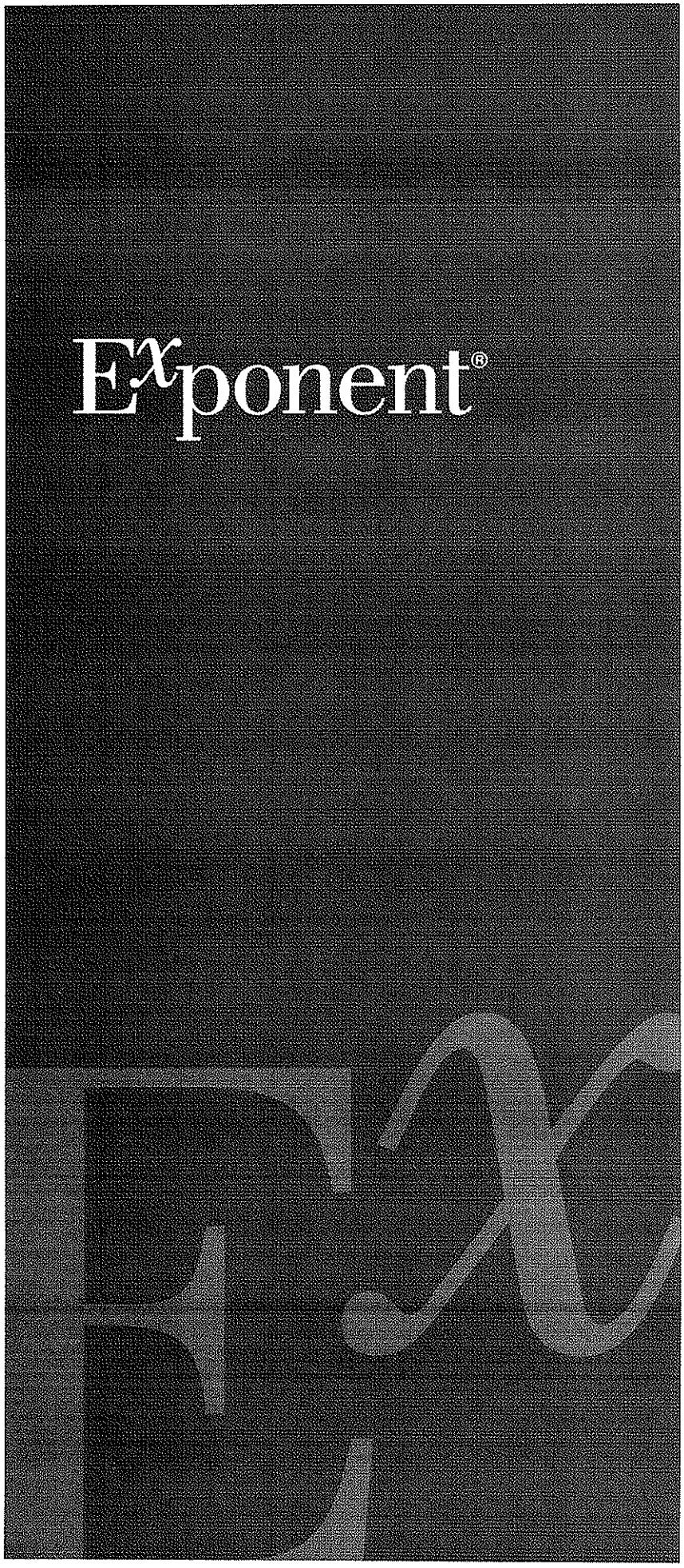
APPENDIX B

Exponent Intake Assessment (2009)



Center for Chemical Regulation and Food Safety

ESTIMATED DIETARY INTAKE OF EPICOR® BY THE US POPULATION

ESTIMATED DIETARY INTAKE OF EPICOR® BY THE US POPULATION

Prepared for

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Prepared by

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March 30, 2009

Contents

List of Tables

Acronyms and Abbreviations

ADI	Average Daily Intake
CFR	Code of Federal Regulations
CSFII	Continuing Survey of Food Intakes by Individuals
EDI	Estimated Daily Intake
FDA	Food and Drug Administration
FARE	Foods Analysis and Residue Evaluation Program
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
USDA	United States Department of Agriculture

Introduction

At the request of Embria® Health Sciences, Exponent estimated the total daily intake of EpiCor® from its uses in foods for the overall U.S. population. EpiCor® is proposed to be added to foods in categories listed in table 1 at 500 mg/serving. The complete list of food codes under each food category is provided in Appendix A of this report. EpiCor® is a dried fermentate that results from the anaerobic fermentation of *Saccharomyces cerevisiae* and nutrients.

The data and method used to develop the estimated daily intake (EDI) of EpiCor® from the proposed use and results are provided in this report. For comparison purposes, the current yeast consumption for the overall U.S population and reasonable daily intake of yeast from the Canadian Food Inspection Agency are also summarized in this report.

Data and Methods

Dietary intake of EpiCor® was estimated using Exponent's Foods and Residue Evaluation Program (FARE™ 8.13) software, and data from National Health and Nutrition Examination Survey (NHANES, 2003-2004). The NHANES 2003-2004 (NCHS, 2007) is a complex multistage probability sample designed to be representative of the civilian U.S. population. The survey collects two days of food intake data, in addition to nutrition, demographic, and health information. The NHANES survey over-samples minorities, low-income groups, adolescents (12-19 years), and adults 60 years of age and older and statistical weights are provided by the National Center for Health Statistics (NCHS) to adjust for the differential probabilities of selection. Participants included 10,122 subjects in 2003-2004. Only individuals with complete and reliable 2-day dietary records were included in the analysis (N=8,354).

Exponent estimated the daily intake on a "per user" basis. In this analysis, a "user" is anyone who reported consuming a food on either of the survey days (USDA's "user" definition). We identify each individual who reported consuming a food on either of the survey days, and we use that individual's responses for both survey days. Zero consumption days are included in calculating that individual's average daily intake. Provided that acute toxicity is not of concern, it is appropriate to average exposures over a longer period than one day. Therefore, Exponent® used each respondent's food consumption averaged over the two days of the NHANES 2003-2004 survey. For example, if someone reported consuming 100 grams of bread on day 1 and 150 grams of bread on day 2, his/her 2-day average bread consumption would be 125 grams ([100+150]/2).

Exponent uses the statistically weighted values from the survey in its analyses. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population and the selected age-gender subgroups.

A 2-day average typically overestimates long-term (chronic) daily intake; however, only two nonconsecutive days' worth of food consumption data are available in the most recent NHANES 2003-2004 survey database. Although the 1989-91 CSFII included food consumption diaries on

three nonconsecutive days, Exponent believes that rapidly evolving trends in diet and the pace of introduction of new foods call into question the representativeness of the older data for today's consumers. Therefore, Exponent used the best publicly available dietary intake data for this analysis.

Proposed Uses of EpiCor® in Foods

EpiCor® is proposed to be added to foods in the categories listed in table 1 at 500 mg/serving. The complete list of food codes under each food category is provided in Appendix A of this report.

Exponent calculated the Epicor® content of each food in ppm using the serving size reference amounts customarily consumed per eating occasion provided by the US Food and Drug Administration (FDA) provided in the Code of Food Regulation (21CFR101.12). The intakes of Epicor from foods were calculated by multiplying each NHANES respondent's 2-day average food intake with the proposed use levels. For mixed dishes containing a portion of the proposed food, Exponent used FARE recipes to determine the portion of interest. Results are presented in mg/day on both the *per capita* and *per user* basis. Analyses were conducted using Exponent's proprietary software program FARE™ version 8.13.

Estimated Daily Intake (EDI)

Target Foods and EDI for EpiCor®

US food consumption estimates for the food categories being targeted for EpiCor® uses are summarized in Table 1. Food consumption estimates are expressed in units of g_{food}/day on both the *per capita* and *per user* bases at the mean and 90th percentile. The *per capita* mean daily intake for all targeted foods is 588.7g_{food}/day (1,179 g_{food}/day at the 90th percentile) and the *per user* mean daily intake is 601 g_{food}/day (1,183 g_{food}/day, 90th percentile). The food category with the highest consumption is the milk category, with a mean *per user* of 296.4g/day (629g/day, 90th percentile).

Table 2 presents the EDI for EpiCor® for the overall U.S. population. Data are expressed in units of g/day for *per capita* and *per user* at the mean, and 90th percentiles. On both a *per capita* and *per user* bases, the EDI for Epicor® from the proposed uses for the US population is 1.9 g/day at the mean and 3.5 g/day at the 90th percentile.

Current Yeast Consumption

For comparison purposes, Exponent also estimated daily intake of yeast in the current US diet. The analysis captured yeast intake from all foods with reported consumption in the NHANES 2003-04 survey. For the US population, the *per capita* average daily intake for yeast from all foods is 1.3g/day (2.9 g/day, 90th percentile) and the *per user* average daily intake is 1.5 g/day (3g/day, 90th percentile).

The Canadian Food Inspection Agency in its 2003 Guide to Food Labeling and Advertising, Section 6.3.1. Reasonable Daily Intake for Various Foods (Schedule K) also provided a reasonably daily intake of 14 g/day for yeast. The reasonable daily intake was used to evaluate, for regulatory purposes, the nutritional contribution of specific foods to the diet. The reasonable daily intake were used by the Canadian Food Inspection Agency to determine the amount of vitamin and

mineral nutrients that may be present in the food when they are added. The reasonable daily intake for most foods was considered to be one average serving of the food. [1]

Comparison of EpiCor® Intake with Yeast Intake in Current Diet

Based on information from Embria[2] the maximum yeast-equivalent from EpiCor is approximately 33% by weight. Thus, the 90th percentile *per user* EDI yeast-equivalent from the proposed EpiCor® uses in foods is approximately 1g/day, which is below the current US mean daily intake of yeast (1.5g/day, *per user*) and well below the US 90th percentile daily intake (3 g/day, *per user*)

The 90th percentile *per user* EDI for EpiCor® (3.5 g/day) is also well below the reasonable daily intake for yeast that has been established by the Canadian Food Inspection Agency. However, for this comparison to hold, Embria will need to confirm that the identity of the yeast for which the Canadian Food Inspection Agency has established a reasonable daily intake of 14 g/day is similar to EpiCor®.[3]

[1] http://www.inspection.gc.ca/english/fssa/labeti/guide/ch6c.shtml (accessed 10/20/2008)
[2] Information provided by Kevin Boot 10/31/08
[3] To be confirmed by Embria, per discussion with Kevin Boot on 10/31/08

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Table 1. US Population Food Intake (g_{food}/day), NHANES 2003-04

Target Food Categories Description	CFR Category	N	Per Capita		Per User	
			Mean	90th Percentile	Mean	90th Percentile
Milk	30	5,303	183.8	511.0	296.4	629.0
Flavored Milks and Milk Drinks	31	1,446	35.2	126.4	223.4	452.4
Milk - Snack Dips, Spreads	31	502	1.7	0.0	23.7	60.0
Milk, Other	31	1,207	11.6	30.4	67.5	152.5
Frozen Yogurt	20	124*	1.5	--	89.3	--
100% Fruit Juices	35	3,818	90.5	288.0	233.8	473.8
Processed Juice Drinks	35	1,500	31.0	107.8	218.4	447.2
Ready-To-Drink Tea Beverages	7	892	43.8	153.7	339.5	697.1
Sport/Fitness Water Beverages	3	17*	1.9	--	511.4	--
Fruit Flavored Drinks	3	2,579	89.0	300.9	362.5	780.2
Breads	1	6,545	49.4	108.5	59.5	116.4
Ready-To-Eat Bars	1	376	1.8	0.0	26.2	43.1
Ready-To-Eat Dry Cereals	4	3,429	14.4	47.6	37.2	70.5
Hard Candy	25	801	0.9	0.0	10.3	22.7
Mints	38	3*	--	--	17.1	--
Tofu	33	109*	0.8	--	43.7	--
Soups/Broth	40	1,377	31.5	130.0	201.0	369.6
TOTAL		8,005	588.7	1,179.0	601.0	1,183.0

N, total unweighted no. of users

* A sample size of at least 200 is necessary to reliably estimate the 90th percentile from a population distribution

Table 2. Estimated Daily Intake of EpiCor® (g/day) from All Proposed Food Uses, US Population, NHANES 2003-2004

US Population	N	Per Capita		Per User	
		Mean	90th Percentile	Mean	90th Percentile
All Food Use Categories*	8,005	1.9	3.5	1.9	3.5

*Proposed use level: 500mg/serving
N, total unweighted no. of users

APPENDIX A: Food Codes Included in Analysis

Milk (CFR Category 30: Milk fluid, whole, skim)

Food Code	NH0304 Description
11100000	MILK, NFS
11111000	MILK, COW'S, FLUID, WHOLE
11111100	MILK, COW'S, FLUID, WHOLE, LOW SODIUM
11111150	MILK, CALCIUM FORTIFIED, WHOLE, COW'S, FLUID
11111170	MILK, CALCIUM FORTIFIED, SKIM/NONFAT, COW, FLUID
11112000	MILK, COW'S, FLUID, NOT WHOLE, NS AS TO % FAT
11112110	MILK, COW'S, FLUID, 2% FAT
11112120	MILK, COW'S, FLUID, ACIDOPHILUS, 1% FAT
11112130	MILK, COW'S, FLUID, ACIDOPHILUS, 2% FAT
11112210	MILK, COW'S, FLUID, 1% FAT
11113000	MILK, COW'S, FLUID, SKIM OR NONFAT
11114300	MILK, LOW LACTOSE, 1% FAT
11114320	MILK, LOW LACTOSE, NONFAT
11114330	MILK, COW'S FL LACTOSE REDUCED 2% FAT (LACTAID)
11114350	MILK, COW'S, FLUID, LACTOSE REDUCED, WHOLE
11116000	MILK, GOAT'S, FLUID, WHOLE

Flavored Milks and Milk Drinks (CFR Category 31: Milk Products, drinks, dry, milk origin)

Food Codes	NH0304 Food Description
11511000	MILK, CHOCOLATE, NFS
11511100	MILK, CHOCOLATE, WHOLE MILK BASED
11511200	MILK, CHOCOLATE, RED FAT, 2%
11511300	MILK, CHOCOLATE, SKIM MILK BASED
11511400	MILK, CHOCOLATE, LOWFAT MILK-BASED
11512000	COCOA,HOT CHOCOLATE,NOT FROM DRY MIX, W/WHOLE MILK
11512500	SPANISH-STYLE HOT CHOCOLATE DRINK, PUERTO RICAN STYLE, MADE
11513000	COCOA & SUGAR MIXTURE, MILK ADDED, NS TYPE MILK
11513100	COCOA & SUGAR MIXTURE, WHOLE MILK ADDED
11513150	COCOA & SUGAR MIX, RED FAT MILK ADDED
11513200	COCOA & SUGAR MIXTURE, LOWFAT MILK ADDED
11513300	COCOA & SUGAR MIXTURE, SKIM MILK ADDED
11513400	CHOCOLATE SYRUP MILK ADDED, NS AS TO TYPE OF MILK
11513500	CHOCOLATE SYRUP, WHOLE MILK ADDED
11513550	CHOCOLATE SYRUP, RED FAT MILK ADDED
11513600	CHOCOLATE SYRUP, LOWFAT MILK ADDED
11513700	CHOCOLATE SYRUP, SKIM MILK ADDED
11514100	COCOA, SUGAR, & DRY MILK MIXTURE, WATER ADDED
11514300	COCOA W/ NF DRY MILK, LO CAL SWEETENER, WATER ADDED

11514500	COCOA W/ WHEY, LO CAL SWEETNR, FORTIFD, WATER ADDED
11516000	COCOA, WHEY, LO CAL SWEETNER MIX, LOWFAT MILK ADDED
11519000	MILK BEVERAGE, NOT CHOCOLATE, W/ WHOLE MILK
11519050	MILK, NOT CHOCOLATE, WHOLE MILK BASED
11520000	MILK, MALTED, UNFORTIFIED, FLAVOR NS
11521000	MILK, MALTED, UNFORTIFIED, CHOCOLATE FLAVOR
11522000	MILK, MALTED, UNFORTIFIED, NATURAL FLAVOR
11526000	MILK, MALTED, FORTIFIED, CHOCOLATE (INCL OVALTINE)
11527000	MILK, MALTED, FORTIFIED, (INCL OVALTINE)
11531000	EGGNOG, MADE W/ WHOLE MILK (INCLUDE EGG NOG, NFS)
11531500	EGGNOG, MADE W/ 2% REDUCED FAT MILK
11541000	MILK SHAKE, NS AS TO FLAVOR OR TYPE
11541100	MILK SHAKE,HOMEMADE/ FOUNTAIN-TYPE, NS AS TO FLAVOR
11541110	MILK SHAKE, HOMEMADE OR FOUNTAIN-TYPE, CHOCOLATE
11541120	MILK SHAKE, HOMEMADE/FOUNTAIN-TYPE, NOT CHOCOLATE
11541400	MILK SHAKE WITH MALT (INCL MALTED MILK W/ICE CREAM)
11541500	MILK SHAKE, MADE W/ SKIM MILK, CHOCOLATE
11541510	MILK SHAKE,MADE W/ SKIM MILK, NOT CHOCOLATE
11542100	CARRY-OUT MILK SHAKE, CHOCOLATE
11542200	CARRY-OUT MILK SHAKE, NOT CHOCOLATE
11551050	MILK FRUIT DRINK (INCL LICUADO)
11552200	ORANGE JULIUS
11553000	FRUIT SMOOTHIE DRINK, W/ FRUIT AND DAIRY PRODUCTS
11553100	FRUIT SMOOTHIE DRINK, NFS
11560000	CHOC-FLAVORED DRINK, WHEY-&MILK-BASED(INCL YOO-HOO)
11560020	MILK DRINK, WHEY&MILK-BASE, NOT CHOC (INCL YOO-HOO)
11561010	CAFE CON LECHE PREPARED W/ SUGAR
11611000	INSTANT BREAKFAST, FLUID, CANNED
11612000	INSTANT BREAKFAST, POWDER, MILK ADDED
11613000	INSTANT BFAST,PWDR,SWT W/ LO CAL SWT, MILK ADDED
11623000	MEAL SUPPLEMENT / REPLACEMENT,PREPARED,RTD
11631000	HIGH CALORIE BEV, CANNED OR POWDERED, RECONSTITUTED
11641000	MEAL REPLACEMENT, MILK BASED, HIGH PROTEIN, LIQUID
11830100	COCOA W/DRY MILK & SUGAR, DRY MIX, NOT RECONST
11830110	COCOA POWDER W/ NFD MILK, LOW CAL SWEETENER, DRY
11830120	COCOA W/ WHEY, LO CAL SWEETENER, FORTIFIED, DRY MIX
11830150	COCOA POWDER, NOT RECONSTITUTED (NO DRY MILK)
11830160	COCOA-FLAVORED BEVERAGE POWDER W/ SUGAR, DRY MIX
11830170	COCOA, WHEY, LO CAL SWEETNER MIX, NOT RECONST
11830200	MILK, MALTED, DRY, UNFORTIFD, NOT RECONST, NOT CHOC
11830210	MILK, MALTED, DRY, FORTIFD, NOT RECONST, NOT CHOC
11830260	MILK, MALTED, DRY, FORTIFIED, NOT RECONST, CHOC
11830400	MILK BEV POWDER, DRY, NOT RECONST, NOT CHOC
11830450	MILK BEV MIX, W/ SUGAR,EGG WHITE, NOT RECONSTITUTED
11830500	MILK BEV POWDER W/ NFD MILK, LOW CAL, DRY, CHOC
11830800	INSTANT BREAKFAST POWDER, NOT RECONSTITUTED
11830810	INSTANT BFAST,PWDR,SWT W/ LO CAL SWT,NOT RECONSTUT
11830850	HIGH CALORIE MILK BEVERAGE, POWDER, NOT RECONST

11830900	PROTEIN SUPPLEMENT, MILK BASED, DRY POWDER
11830940	MEAL REPLACEMENT,PROTEIN,MILK BASED,FRUIT JUICE MIX
11830970	MEAL REPLACEMENT, PROTEIN TYPE, MILK-BASE, POWDER
11831500	NUTRIENT SUPPLEMENT,MILK-BASE,HIGH PROT,NOT RECONST
11832000	MEAL REPLACEMENT,MILK-&SOY-BASE,POWDER,NOT RECONST
11835100	MEAL REPLACEMENT, POSITRIM DRINK MIX, DRY POWDER

Milk – Snack Dips and Spreads (CFR Category 31: Milk Products, drinks, dry, milk origin)

Food Codes	NH0304 Food Description
12310100	SOUR CREAM (INCL W/ CHIVES)
12310300	SOUR CREAM, REDUCED FAT
12310350	SOUR CREAM, LIGHT
12310370	SOUR CREAM, FAT FREE
12350000	DIP, SOUR CREAM BASE (INCLUDE BUTTERMILK-TYPE DIP)
12350020	DIP, SOUR CREAM BASE, REDUCED CALORIE
12350100	SPINACH DIP, SOUR CREAM BASE

Milk, Other (CFR Category 31: Milk Products, drinks, dry, milk origin)

Food Codes	NH0304 Food Description
11115000	BUTTERMILK, FLUID (INCLUDE KEFIR MILK)
11115100	BUTTERMILK, FLUID, 1% FAT
11115200	BUTTERMILK, FLUID, 2% FAT
11120000	MILK, DRY, RECONSTITUTED, NFS
11121100	MILK, DRY, RECONSTITUTED, WHOLE
11121210	MILK, DRY, RECONSTITUTED, LOWFAT
11121300	MILK, DRY, RECONSTITUTED, NONFAT
11210000	MILK, EVAPORATED, NS AS TO FAT CONTENT & DILUTION
11210050	MILK, EVAPORATED, NS FAT & DILUTION, IN COFFEE/TEA
11210100	MILK, EVAPORATED, NS AS TO FAT, UNDILUTED
11211000	MILK, EVAPORATED, WHOLE, NS AS TO DILUTION
11211050	MILK, EVAPORATED, WHOLE, IN COFFEE/TEA
11211100	MILK, EVAPORATED, WHOLE, UNDILUTED
11211200	MILK, EVAPORATED, WHOLE, DILUTED
11211400	MILK, EVAPORATED, 2% FAT, NS AS TO DILUTION
11212000	MILK, EVAPORATED, SKIM, NS AS TO DILUTION
11212050	MILK, EVAPORATED, SKIM, IN COFFEE/TEA
11212100	MILK, EVAPORATED, SKIM, UNDILUTED
11220000	MILK, CONDENSED, SWEETENED, NS AS TO DILUTION
11220100	MILK, CONDENSED, SWEETENED, UNDILUTED
11220200	MILK, CONDENSED, SWEETENED, DILUTED
11410000	YOGURT, NS AS TO TYPE OF MILK/FLAVOR
11411010	YOGURT, PLAIN, NS AS TO TYPE OF MILK
11411100	YOGURT, PLAIN, WHOLE MILK
11411200	YOGURT, PLAIN, LOWFAT MILK

11411300	YOGURT, PLAIN, NONFAT MILK
11420000	YOGURT, VANILLA, LEMON, COFFEE, NS AS TO MILK TYPE
11421000	YOGURT, VANILLA, LEMON, COFFEE, WHOLE MILK
11422000	YOGURT, VANILLA, LEMON, COFFEE, LOWFAT MILK
11423000	YOGURT, VANILLA, LEMON, COFFEE, NONFAT MILK
11424000	YOGURT, VANILLA, LEMON, COFFEE, NONFAT MILK, LOW CAL SWEET
11425000	YOGURT, CHOCOLATE, NS AS TO TYPE OF MILK
11427000	YOGURT, CHOCOLATE, NONFAT MILK
11430000	YOGURT, FRUIT VARIETY, NS AS TO MILK TYPE
11431000	YOGURT, FRUIT VARIETY, WHOLE MILK
11432000	YOGURT, FRUIT VARIETY, LOWFAT MILK
11432500	YOGURT, FRUIT VARIETY, LOWFAT MILK, SWEETENED WITH LOW-CALOR
11433000	YOGURT, FRUIT VARIETY, NONFAT MILK
11433500	YOGURT, FRUITED, NONFAT MILK, LOW CAL SWEETENER
11445000	YOGURT, FRUIT & NUTS, LOWFAT MILK
11810000	MILK, DRY, NOT RECONSTITUTED, NS AS TO FAT
11811000	MILK, DRY, WHOLE, NOT RECONSTITUTED
11812000	MILK, DRY, LOWFAT, NOT RECONSTITUTED
11813000	MILK, DRY, NONFAT, NOT RECONSTITUTED
11825000	WHEY, SWEET, DRY
12100100	CREAM, FLUID, NS AS TO LIGHT, HEAVY OR HALF & HALF
12110100	CREAM, LIGHT, FLUID (INCL COFFEE CRM, TABLE CREAM)
12110300	CREAM, LIGHT, WHIPPED, UNSWEETENED
12120100	CREAM, HALF & HALF
12120110	CREAM, HALF & HALF, FAT FREE
12130100	CREAM, HEAVY, FLUID
12130200	CREAM, HEAVY, WHIPPED, UNSWEETENED
12140000	CREAM, HEAVY, WHIPPED, SWEETENED
12140100	CREAM, WHIPPED, PRESSURIZED CONTAINER

Frozen Yogurt (CFR Category 20: Frozen dairy desserts and mixes; CFR Category 1: Baked goods and baking mixes)

Food Codes	NH0304 Food Description
11459990	YOGURT, FROZEN, NS AS TO FLAVOR, NS TO TYPE OF MILK
11460000	YOGURT, FROZEN, NOT CHOCOLATE, TYPE OF MILK NS
11460100	YOGURT, FROZEN, CHOCOLATE, TYPE OF MILK NS
11460150	YOGURT, FROZEN, NS AS TO FLAVOR, LOWFAT MILK
11460160	YOGURT, FROZEN, CHOCOLATE, LOWFAT MILK
11460170	YOGURT, FROZEN, NOT CHOCOLATE, LOWFAT MILK
11460190	YOGURT, FROZEN, NS AS TO FLAVOR, NONFAT MILK
11460200	YOGURT, FROZEN, CHOCOLATE, NONFAT MILK
11460250	YOGURT,FROZEN,NOT CHOCOLATE,W/ SORBET/SORBET-COATED
11460300	YOGURT, FROZEN, NOT CHOCOLATE, NONFAT MILK
11460400	YOGURT,FRZ,CHOCOLATE,NONFAT MILK,W/ LOW-CAL SWEET
11460410	YOGURT,FRZ,NOT CHOC,NONFAT MILK,W/ LOW-CAL SWEET
11460440	YOGURT, FROZEN, NOT CHOCOLATE, WHOLE MILK

11461250	YOGURT, FROZEN, CONE, CHOCOLATE
11461260	YOGURT, FROZEN, CONE, NOT CHOCOLATE
11461270	YOGURT, FROZEN, CONE, NOT CHOCOLATE, LOWFAT MILK
11461280	YOGURT, FROZ, CONE, CHOCOLATE, LOWFAT MILK
53366000	PIE, YOGURT, FROZEN

100% Fruit Juices (CFR Category 35: Processed fruits and fruit juices)

Food Codes	NH0304 Food Description
42404010	COCONUT WATER, CANNED OR BOTTLED
61201020	GRAPEFRUIT JUICE, NS AS TO FORM
61201220	GRAPEFRUIT JUICE, CANNED, BOTTLED OR IN A CARTON
61201620	GRAPEFRUIT JUICE, FROZEN (RECONSTITUTED WITH WATER)
61204000	LEMON JUICE, NS AS TO FORM
61204200	LEMON JUICE, CANNED OR BOTTLED
61204600	LEMON JUICE, FROZEN
61207000	LIME JUICE, NS AS TO FORM
61207200	LIME JUICE, CANNED OR BOTTLED
61207600	LIME JUICE, FROZEN
61210000	ORANGE JUICE, NFS
61210220	ORANGE JUICE, CANNED, BOTTLED OR IN A CARTON
61210250	ORANGE JUICE, W/ CALCIUM, CAN/BOTTLED/CARTON
61210620	ORANGE JUICE, FROZEN (RECONSTITUTED WITH WATER)
61210720	ORANGE JUICE, FROZEN, NOT RECONSTITUTED
61210820	ORANGE JUICE,FROZ, W/,CALCIUM ADDED,RECON W/WATER
61213000	TANGERINE JUICE, NFS
61213220	TANGERINE JUICE, CANNED
61214000	GRAPE-TANGERINE-LEMON JUICE
61216000	GRAPEFRUIT & ORANGE JUICE, NFS
61216220	GRAPEFRUIT & ORANGE JUICE, CANNED
61219000	ORANGE & BANANA JUICE
61219100	PINEAPPLE-ORANGE-BANANA JUIICE
61219150	ORANGE-WHITE GRAPE-PEACH JUICE
61222000	PINEAPPLE-GRAPEFRUIT JUICE, NFS
61225000	PINEAPPLE-ORANGE JUICE, NFS
61225200	PINEAPPLE-ORANGE JUICE, CANNED, NS AS TO SWEETENER
61225220	PINEAPPLE-ORANGE JUICE, CANNED
61225600	PINEAPPLE-ORANGE JUICE, FROZEN, RECONST W/ WATER
61226000	STRAWBERRY-BANANA-ORANGE JUICE
64100100	FRUIT JUICE, NFS (INCLUDE MIXED FRUIT JUICES)
64100110	FRUIT JUICE BLEND, 100% JUICE, W/ VITAMIN C
64104010	APPLE JUICE
64104150	APPLE-CHERRY JUICE
64104200	APPLE-PEAR JUICE
64104450	APPLE-RASPBERRY JUICE
64104500	APPLE-GRAPE JUICE
64104550	APPLE-GRAPE-RASPBERRY JUICE
64104600	BLACKBERRY JUICE (INCL BOYSENBERRY JUICE)

64105400	CRANBERRY JUICE, UNSWEETENED
64105500	CRANBERRY-WHITE GRAPE JUICE MIXTURE, UNSWEETENED
64116020	GRAPE JUICE
64120010	PAPAYA JUICE
64121000	PASSION FRUIT JUICE
64124020	PINEAPPLE JUICE
64124200	PINEAPPLE-APPLE-GUAVA JUICE, W/ ADDED VITAMIN C
64125000	PINEAPPLE JUICE-NON-CITRUS JUICE BLEND, UNSWEETENED
64132010	PRUNE JUICE
64132020	PRUNE JUICE, UNSWEETENED
64132500	STRAWBERRY JUICE
64133100	WATERMELON JUICE
64200100	FRUIT NECTAR, NFS
64201010	APRICOT NECTAR
64201500	BANANA NECTAR
64202010	CANTALOUPE NECTAR
64203020	GUAVA NECTAR
64204010	MANGO NECTAR
64205010	PEACH NECTAR
64210010	PAPAYA NECTAR
64213010	PASSION FRUIT NECTAR
64215010	PEAR NECTAR
64221010	SOURSOP (GUANABANA) NECTAR

Processed Juice Drinks (CFR Category 35: Processed fruits and fruit juices)

Food Codes	NH0304 Food Description
64101010	APPLE CIDER (INCLUDE CIDER, NFS)
64122030	PEACH JUICE, W/ SUGAR
64134000	FRUIT SMOOTHIE DRINK, W/ FRUIT ONLY
92510150	APPLE JUICE DRINK
92510170	APPLE-CRANBERRY-GRAPE JUICE DRINK
92510200	APPLE-ORANGE-PINEAPPLE JUICE DRINK
92510610	FRUIT DRINK (INCLUDE FRUIT PUNCH & FRUIT ADE)
92510630	FRUIT JUICE DRINK, NFS
92510650	TAMARIND DRINK, P.R. (REFRESCO DE TAMARINDO)
92510720	FRUIT PUNCH, MADE W/ FRUIT JUICE & SODA
92510730	FRUIT PUNCH, MADE W/ SODA, FRUIT JUICE & SHERBET
92510820	GRAPE JUICE DRINK
92510910	GRAPEFRUIT JUICE DRINK
92510950	GUAVA JUICE DRINK
92511200	ORANGE-MANGO JUICE DRINK
92511220	ORANGE DRINK (INCLUDE ORANGE ADE, YABA DABA DEW)
92511250	CITRUS FRUIT JUICE DRINK (INCL 5-ALIVE)
92511260	ORANGE-CRANBERRY JUICE DRINK
92511270	ORANGE-PEACH JUICE DRINK
92511280	ORANGE-GRAPE-BANANA JUICE DRINK
92511290	PAPAYA JUICE DRINK

92511310	PINEAPPLE-GRAPEFRUIT JUICE DRINK
92511340	PINEAPPLE-ORANGE JUICE DRINK
92511350	ORANGE-RASPBERRY JUICE DRINK
92530510	CRANBERRY JUICE DRINK W/VIT C ADDED(INCL COCKTAIL)
92530520	CRANBERRY-APPLE JUICE DRINK W/ VITAMIN C ADDED
92530810	GRAPEFRUIT JUICE DRINK W/ VITAMIN C ADDED
92530840	GUAVA JUICE DRINK W/ VIT C ADDED
92530950	VEGETABLE & FRUIT JUICE DRINK, W/ VIT C
92531120	PINEAPPLE-ORANGE JUICE DRINK W/ VITAMIN C ADDED

Ready-To-Drink Tea Beverages (CFR Category 7: Coffee and tea, regular, instant)

Food Codes	NH0304 Food Description
92205000	RICE BEVERAGE (INCL RICE TEA)
92301000	TEA, NS AS TO TYPE, UNSWEETENED
92301060	TEA, NS AS TO TYPE, PRESWEETENED W/ SUGAR
92301080	TEA, PRESWEETENED W/ LOW CALORIE SWEETENER
92301100	TEA, NS AS TO TYPE, DECAFFEINATED, UNSWEETENED
92301130	TEA, NS AS TO TYPE, PRESWEETENED, NS AS TO SWEETNER
92301160	TEA, DECAFFEINATED, W/ SUGAR, NFS
92301180	TEA, DECAFFEINATED, LOW CALORIE SWEETENER, NFS
92301190	TEA, PRESWEETENED, NS SWEETENER, DECAFFEINATED
92302500	TEA, DECAFFEINATED, UNSWEETENED
92306000	TEA, HERBAL (INCLUDE SASSAFRAS,LICORICE)
92306020	TEA, HERB, PRESWEET W/ SUG
92306030	TEA, HERB, PRESWEET W/ LOW CAL SWEET
92306040	TEA, HERB, PRESWEET, NS AS TO SWEET
92306100	CORN BEVERAGE(INCLUDE CORN TEA)
92306700	TEA, CHAMOMILE

Sport/Fitness Water Beverages (CFR Category 3: Beverages and beverage bases, nonalcoholic)

Food Codes	NH0304 Food Description
92900300	FRUIT-FLAV THIRST QUENCH BEV, DRY CONC (GATORADE)
94210100	PROPEL FITNESS WATER

Fruit Flavored Drinks (CFR Category 3: Beverages and beverage bases, nonalcoholic)

Food Codes	NH0304 Food Description
92510120	APPLE-CHERRY DRINK
92510310	BANANA-ORANGE DRINK
92510410	BLACK CHERRY DRINK
92510810	GRAPEADE & GRAPE DRINK

92511000	LEMONADE, FROZEN CONCENTRATE, NOT RECONSTITUTED
92511010	LEMONADE
92511020	LEMON-LIMEADE
92511110	LIMEADE
92511240	ORANGE-LEMON DRINK
92511400	RASPBERRY-FLAVORED DRINK
92511510	STRAWBERRY-FLAVORED DRINK
92520410	FRUIT DRINK, LOW CALORIE
92520810	GRAPE DRINK, LOW CALORIE
92520910	LEMONADE, LOW CALORIE
92530310	CHERRY DRINK W/ VITAMIN C ADDED
92530410	CITRUS DRINK W/ VITAMIN C ADDED
92530610	FRUIT PUNCH/DRINK/ADE W/ VIT C ADDED (INCL HI-C)
92530710	GRAPE DRINK W/ VITAMIN C ADDED
92530910	LEMONADE W/ VITAMIN C ADDED
92531010	ORANGE DRINK & ORANGEADE W/ VITAMIN C ADDED
92531020	ORANGE BREAKFAST DRINK, FROM FROZEN CONCENTRATE
92531030	ORANGE BREAKFAST DRINK
92531210	SRAWBERRY-FLAVORED DRINK W/ VITAMIN C ADDED
92541010	FRUIT-FLAVORED DRINK, FROM SWEETENED PWDR,FORTIFIED W/ VIT C
92541020	LEMONADE-FLAVORED DRINK, MADE FROM POWDERED MIX, WITH SUGAR
92541040	LEMONADE-FLAVORED DRINK, MADE FROM POWDERED MIX, LOW CALORIE
92541100	APPLE CIDER DRINK, FROM MIX, SUGAR & VIT C ADDED
92542000	FRUIT-FLAVORED DRINK, FROM POWDER, W/HI VIT C(TANG)
92544000	FRUIT-FLAVOR DRINK, FROM UNSWEET PWDR,W/ VIT C,W/ SUGAR
92550050	APPLE-WHITE GRAPE JUICE DRINK,LOW CAL,W/VIT C ADDED
92550110	CRANBERRY JUICE COCKTAIL, LO CAL, W/ VIT C ADDED
92550210	CRANBERRY-APPLE JUICE DRINK, LO CAL, VIT C ADDED
92550300	GRAPEFRUIT JUICE DRINK,LOW CALORIE,W/ VITAMIN C
92550610	FRUIT-FLAVORED DRINK, LOW CAL, W/ VITAMIN C ADDED
92551700	JUICE DRINK, LOW CALORIE
92552000	FRUIT-FLAV DRINK, FROM MIX, HI VIT C ADDED, LOW CAL
92552100	ORANGE-CRANBERRY JUICE DRINK,LOW CAL,W/ VIT C ADDED
92553000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE, LOW CAL
92560000	FRUIT-FLAVORED THIRST QUENCHER BEVERAGE
92582100	CITRUS JUICE DRINK, CALCUIM FORTIFIED
92582110	ORANGE BREAKFAST DRINK, CALCIUM FORTIFIED
92731000	FRUIT-FLAVORED DRINK,NON-CARB,FROM POWDER, W/ SUGAR
92741000	FRUIT-FLAVORED DRINK, NON-CARB, FROM LO CAL POWDER
92900100	TANG, DRY CONCENTRATE
92900110	FRUIT-FLAVORED CONCENTRATE, DRY, W/ SUGAR & VIT C
92900200	FRUIT-FLAV BEV, DRY CONC,LO CAL(INCL CRYSTAL LIGHT)

Breads (CFR Category 1: Baked goods and baking mixes)

Food Codes	NH0304 Food Description
51000100	BREAD, NS AS TO MAJOR FLOUR
51000110	BREAD, NS AS TO MAJOR FLOUR, TOASTED
51000180	BREAD, HOMEMADE/PURCH AT A BAKERY, NS AS TO FLOUR
51000190	BREAD, HOMEMADE/PURCH AT A BAKERY, TOASTD,NS FLOUR
51000200	ROLL, NS AS TO MAJOR FLOUR
51000230	ROLL, NS AS TO MAJOR FLOUR, TOASTED
51000250	ROLL, HOMEMADE/PURCH AT A BAKERY, NS AS TO FLOUR
51000300	ROLL, HARD, NS AS TO MAJOR FLOUR
51101000	BREAD, WHITE
51101010	BREAD, WHITE, TOASTED
51101050	BREAD, WHITE, HOMEMADE OR PURCHASED AT A BAKERY
51101060	BREAD, WHITE, HOMEMADE OR PURCH AT A BAKERY TOASTED
51102010	BREAD, WHITE W/ WHOLE WHEAT SWIRL
51102020	BREAD, WHITE W/ WHOLE WHEAT SWIRL, TOASTED
51105010	BREAD, CUBAN (INCLUDE SPANISH, PORTUGUESE)
51105040	BREAD, CUBAN, TOASTED (INCLUDE SPANISH, PORTUGUESE)
51106200	BREAD, LARD, P.R. (PAN DE MANTECA)
51107010	BREAD, FRENCH OR VIENNA
51107040	BREAD, FRENCH OR VIENNA, TOASTED
51108010	FOCACCIA, ITALIAN FLATBREAD, PLAIN
51108100	NAAN, INDIAN FLATBREAD
51109010	BREAD, ITALIAN, GRECIAN, ARMENIAN
51109040	BREAD, ITALIAN, GRECIAN, ARMENIAN, TOASTED
51109100	BREAD, PITA
51109110	BREAD, PITA, TOASTED
51110010	BREAD, BATTER
51111010	BREAD, CHEESE (INCLUDE ONION CHEESE)
51111040	BREAD, CHEESE, TOASTED (INCLUDE ONION CHEESE)
51113010	BREAD, CINNAMON
51113100	BREAD, CINNAMON, TOASTED
51119010	BREAD, EGG, CHALLAH
51119040	BREAD, EGG, CHALLAH, TOASTED
51119100	BREAD, LOWFAT, 98% FAT FREE
51119110	BREAD, LOWFAT, 98% FAT FREE, TOASTED
51121010	BREAD, GARLIC
51121040	BREAD, GARLIC, TOASTED (INCLUDE TEXAS TOAST)
51121110	BREAD, ONION
51122000	BREAD, REDUCED CALORIE/HIGH FIBER
51122010	BREAD, REDUCED CALORIE/HIGH FIBER, TOASTED
51122050	BREAD, REDUCED CALORIE/HIGH FIBER, ITALIAN
51122060	BREAD, REDUCED CALORIE/HIGH FIBER, ITALIAN,TOASTED
51122100	BREAD, REDUCED CALORIE/ HIGH FIBER, W/ FRUIT/NUTS
51122110	BREAD, REDUCED CALORIE/HI FIBER, W/FRUIT/NUTS,TOAST
51122300	BREAD, WHITE, SPECIAL FORMULA, ADDED FIBER
51123010	BREAD, HIGH PROTEIN

51123020	BREAD, HIGH PROTEIN, TOASTED
51126010	BREAD, MILK & HONEY (INCLUDE ARNOLD'S)
51126020	BREAD, MILK & HONEY, TOASTED (INCLUDE ARNOLD'S)
51127010	BREAD, POTATO
51127020	BREAD, POTATO, TOASTED
51129010	BREAD, RAISIN
51129020	BREAD, RAISIN, TOASTED
51130520	BREAD, WHITE, LOW SODIUM/NO SALT, TOASTED
51133010	BREAD, SOUR DOUGH
51133020	BREAD, SOUR DOUGH, TOASTED
51135000	BREAD, VEGETABLE
51140100	BREAD DOUGH, FRIED
51150000	ROLL, WHITE, SOFT
51150100	ROLL, WHITE, SOFT, TOASTED
51151060	ROLL, WHITE, SOFT, HOMEMADE/PURCH AT A BAKERY
51152000	ROLL, WHITE, SOFT, REDUCED CALORIE/ HIGH FIBER
51153000	ROLL, WHITE, HARD
51153010	ROLL, WHITE, HARD, TOASTED
51154550	ROLL, EGG BREAD
51154600	ROLL, CHEESE
51155000	ROLL, FRENCH OR VIENNA
51155010	ROLL, FRENCH OR VIENNA, TOASTED
51156500	ROLL, GARLIC
51157000	ROLL, HOAGIE, SUBMARINE,
51157010	ROLL, HOAGIE, SUBMARINE, TOASTED
51158100	ROLL, MEXICAN, BOLILLO
51159000	ROLL, SOUR DOUGH
51160000	ROLL, SWEET
51160010	ROLL, SWEET, TOASTED
51160100	ROLL, SWEET, CINNAMON BUN, NO FROSTING
51160110	ROLL, SWEET, CINNAMON BUN, FROSTED
51161000	ROLL, SWEET, W/ FRUIT, NO FROSTING
51161020	ROLL, SWEET, W/ FRUIT, FROSTED
51161030	ROLL, SWEET, W/ FRUIT, FROSTED, DIET
51161050	ROLL, SWEET, W/ NUTS, FROSTED
51161070	ROLL, SWEET, W/ FRUIT, FROSTED, FAT FREE
51161100	ROLL, SWEET, W/ FRUIT & NUTS, NO FROSTING
51161150	ROLL, SWEET, W/ FRUIT & NUTS, FROSTED
51161200	ROLL, SWEET, W/ NUTS, NO FROSTING
51161250	ROLL, SWEET, NO TOPPING, MEXICAN (PAN DULCE)
51161260	ROLL SWEET, CRUMB TOPPING, MEXICAN (PAN DULCE)
51161270	ROLL, SWEET, SUGAR TOPPING, MEXICAN (PAN DULCE)
51161280	ROLL,SWEET,W/ RAISINS & ICING,MEXICAN (PAN DULCE)
51180010	BAGEL
51180020	BAGEL, TOASTED
51180030	BAGEL, W/ RAISINS
51180040	BAGEL, W/ RAISINS, TOASTED
51180080	BAGEL W/ FRUIT OTHER THAN RAISINS

51180090	BAGEL W/ FRUIT OTHER THAN RAISINS, TOASTED
51182010	BREAD, STUFFING (INCLUDE HOMEMADE; STUFFING, NFS)
51182020	BREAD STUFFING W/ EGG
51184000	BREAD STICK, HARD
51184010	BREAD STICK, SOFT
51184020	BREAD STICK, NS AS TO HARD OR SOFT
51184030	BREAD STICK, SOFT, PREP W/ GARLIC & PARMESAN CHEESE
51184100	BREAD STICK, HARD, LOW SODIUM
51185000	CROUTONS
51186010	MUFFIN, ENGLISH (INCLUDE SOUR DOUGH)
51186020	MUFFIN, ENGLISH, TOASTED
51186100	MUFFIN, ENGLISH, W/ RAISINS
51186120	MUFFIN, ENGLISH, W/ RAISINS, TOASTED
51186180	MUFFIN, ENGLISH, W/ FRUIT OTHER THAN RAISINS, TSTD
51188100	PANNETONE (ITALIAN-STYLE SWEET BREAD)
51201010	BREAD, 100% WHOLE WHEAT
51201020	BREAD, 100% WHOLE WHEAT, TOASTED
51201060	BREAD, 100% WHOLE WHEAT, HOME-MADE
51201070	BREAD, 100% WHOLE WHEAT, HOME-MADE, TOASTED
51201150	BREAD, PITA, 100% WHOLE WHEAT
51204010	BREAD, WHEAT GERM
51207010	BREAD, SPROUTED WHEAT
51207020	BREAD, SPROUTED WHEAT, TOASTED
51208010	BAGEL, 100% WHOLE WHEAT, TOASTED
51208100	BAGEL, 100% WHOLE WHEAT, W/ RAISINS
51208110	BAGEL, 100% WHOLE WHEAT, W/ RAISINS, TOASTED
51220000	ROLL, 100% WHOLE WHEAT
51220030	ROLL, 100% WHOLE WHEAT, HOME RECIPE/BAKERY
51300110	BREAD, WHOLE WHEAT, NS AS TO 100%
51300120	BREAD, WHOLE WHEAT, NS AS TO 100%, TOASTED
51300140	BREAD, WHOLE WHEAT, NS AS TO 100%, MADE FROM HOME RECIPE OR
51300150	BREAD, WHOLE WHEAT, NS 100%, HOME RECIPE/BAKERY, TOASTED
51300180	BREAD, PURI OR POORI (INDIAN PUFF BREAD), WW, NS 100%, FRIED
51300210	BREAD, WHOLE WHEAT, NS AS TO 100%, W/ RAISINS
51300220	BREAD, WHOLE WHEAT,NS AS TO 100%,W/ RAISINS,TOASTED
51301010	BREAD, WHEAT OR CRACKED WHEAT
51301020	BREAD, WHEAT OR CRACKED WHEAT, TOASTED
51301040	BREAD, CRACKED WHEAT, HOME RECIPE/BAKERY
51301050	BREAD, CRACKED WHEAT, HOME RECIPE/BAKERY, TOASTED
51301120	BREAD, WHEAT OR CRACKED WHEAT, W/ RAISINS
51301510	BREAD, CRACKED WHEAT, REDUCED CALORIE/ HIGH FIBER
51301520	BREAD, CRACKED WHEAT, RED CALORIE/ HI FIBER, TOAST
51301540	BREAD, FRENCH, WHOLE WHEAT, NS 100%, HOMEMADE/BAKERY
51301550	BREAD, FRENCH, WHOLE WHEAT, NS 100%, HOMEMADE, TOASTED
51301600	BREAD, PITA, WHOLE WHEAT, NS AS TO 100%
51301610	BREAD, PITA, WHOLE WHEAT, NS AS TO 100%, TOASTED
51301620	BREAD, PITA, CRACKED WHEAT
51301700	BAGEL, WHEAT

51301710	BAGEL, WHEAT, TOASTED
51301750	BAGEL, WHOLE WHEAT, NS AS TO 100%
51301760	BAGEL, WHOLE WHEAT, NS AS TO 100%, TOASTED
51301800	BAGEL, WHEAT, W/ RAISINS
51301810	BAGEL, WHEAT, W/ RAISINS, TOASTED
51301820	BAGEL, WHEAT, W/ FRUITS & NUTS
51301830	BAGEL, WHEAT, W/ FRUITS & NUTS, TOASTED
51301900	BAGEL, WHEAT BRAN
51302010	BREAD, WHEAT BRAN
51302020	BREAD, WHEAT BRAN, TOASTED
51302500	MUFFIN, ENGLISH, WHEAT BRAN
51303010	MUFFIN, ENGLISH, WHEAT OR CRACKED WHEAT
51303020	MUFFIN, ENGLISH, WHEAT OR CRACKED WHEAT, TOASTED
51303030	MUFFIN, ENGLISH, WHOLE WHEAT, NS AS TO 100%
51303040	MUFFIN, ENGLISH, WHOLE WHEAT, NS AS TO 100%, TOASTED
51303050	MUFFIN, ENGLISH, WHEAT OR CRACKED WHEAT W/ RAISINS
51303070	MUFFIN, ENGLISH, WHOLE WHEAT, NS AS TO 100%, WITH RAISINS
51303080	MUFFIN, ENGLISH, WHOLE WHEAT, NS 100%, W/RAISINS, TOASTED
51320010	ROLL, WHEAT OR CRACKED WHEAT
51320040	ROLL, CRACKED WHEAT, HOME RECIPE/BAKERY
51320500	ROLL, WHOLE WHEAT, NS AS TO 100%
51320510	ROLL, WHOLE WHEAT, NS AS TO 100%, TOASTED
51320530	ROLL, WHOLE WHEAT, NS 100%, MADE FROM HOMEMADE/BAKERY
51320540	ROLL, WHOLE WHEAT, NS AS TO 100%, HOMEMADE/BAKERY, TOASTED
51401010	BREAD, RYE
51401020	BREAD, RYE, TOASTED
51401030	BREAD, MARBLE RYE & PUMPERNICKEL
51401040	BREAD, MARBLE RYE & PUMPERNICKEL, TOASTED
51401060	BREAD, RYE, REDUCED CALORIE/ HIGH FIBER (INCL LESS)
51401070	BREAD, RYE, REDUCED CALORIE/ HIGH FIBER, TOASTED
51404010	BREAD, PUMPERNICKEL
51404020	BREAD, PUMPERNICKEL, TOASTED
51404500	BAGEL, PUMPERNICKEL
51407010	BREAD, BLACK
51420000	ROLL, RYE
51421000	ROLL, PUMPERNICKEL
51501010	BREAD, OATMEAL
51501020	BREAD, OATMEAL, TOASTED
51501040	BREAD, OAT BRAN
51501050	BREAD, OAT BRAN, TOASTED
51501060	BREAD, OAT BRAN, REDUCED CALORIE/ HIGH FIBER
51501070	BREAD, OAT BRAN REDUCED CALORIE/HI FIBER, TOASTED
51501080	BAGEL, OAT BRAN
51501090	BAGEL, OAT BRAN, TOASTED
51502010	ROLL, OATMEAL
51502100	ROLL, OAT BRAN
51503000	MUFFIN, ENGLISH, OAT BRAN
51503010	MUFFIN, ENGLISH, OAT BRAN, TOASTED

51601010	BREAD, MULTIGRAIN, TOASTED
51601020	BREAD, MULTIGRAIN
51601220	BREAD, MULTIGRAIN, W/ RAISINS, TOASTED
51602010	BREAD, MULTIGRAIN, REDUCED CALORIE/ HIGH FIBER
51602020	BREAD, MULTIGRAIN, REDUCED CALORIE/ HI FIBER, TOAST
51620000	ROLL, MULTIGRAIN
51630000	BAGEL, MULTIGRAIN
51630010	BAGEL, MULTIGRAIN, TOASTED
51630100	BAGEL, MULTIGRAIN, W/ RAISINS
51630110	BAGEL, MULTIGRAIN, W/ RAISINS, TOASTED
51630200	MUFFIN, ENGLISH, MULTIGRAIN
51801010	BREAD, BARLEY
51804020	BREAD, SOY, TOASTED
51805010	BREAD, SUNFLOWER MEAL
51805020	BREAD, SUNFLOWER MEAL, TOASTED
51806010	BREAD, RICE
51807000	INJERA (AMERICAN-STYLE ETHIOPIAN BREAD)
51808000	BREAD, LOW GLUTEN
52403000	BREAD, NUT
52404060	BREAD, PUMPKIN (INCLUDE W/ RAISINS)
52405010	BREAD, FRUIT, W/O NUTS
52405100	BREAD, FRUIT & NUT
52406010	BREAD, WHOLE WHEAT, W/ NUTS
52407000	BREAD, ZUCCHINI (INCL SQUASH BREAD; W/ NUTS)
52408000	BREAD, IRISH SODA

Ready-To-Eat Bars (CFR Category 1: Baked goods and baking mixes; CFR Category 33: Plant protein, meat substitutes)

Food Codes	NH0304 Food Description
53540000	BREAKFAST BAR, NFS
53540200	BREAKFAST BAR, CEREAL CRUST W/ FRUIT FILLING, LOWFAT
53540250	BREAKFAST BAR, CEREAL CRUST W/ FRUIT FILLING, FAT FREE
53540500	BREAKFAST BAR, DATE, W/ YOGURT COATING
53540600	MILK 'N CEREAL BAR
53541200	MEAL REPLACEMENT BAR (INCL SLIM FAST BAR)
53542100	GRANOLA BAR W/ OATS, SUGAR, RAISINS, COCONUT
53542200	GRANOLA BAR, OATS, FRUIT, NUTS, LOWFAT
53542210	GRANOLA BAR, NONFAT
53544200	GRANOLA BAR, CHOCOLATE-COATED
53544210	GRANOLA BAR, W/ COCONUT, CHOCOLATE-COATED
53544220	GRANOLA BAR W/ NUTS, CHOCOLATE-COATED
53544250	GRANOLA BAR, COATED W/ NONCHOCOLATE COATING
53544300	GRANOLA BAR, HIGH FIBER, YOGURT COATING, NOT CHOC
53544400	GRANOLA BARS, W/ RICE CEREAL
53544450	POWERBAR (FORTIFIED HIGH ENERGY BAR)

Ready-To-Eat Dry Cereals (CFR Category 4: Breakfast cereals, RTE, instant, hot)

Food Codes	NH0304 Food Description
56210000	NESTUM, CEREAL
57000000	CEREAL, NFS
57000050	KASHI CEREAL, NS AS TO READY-TO-EAT OR COOKED
57000100	OAT CEREAL, NFS
57100100	CEREAL, READY-TO-EAT, NFS
57100400	CHARACTER CEREALS, TV OR MOVIE, GENERAL MILLS
57100500	CHARACTER CEREALS, TV OR MOVIE, KELLOGGS
57101000	ALL-BRAN CEREAL
57101020	ALL BRAN CEREAL W/ EXTRA FIBER
57103000	ALPHA-BITS CEREAL
57103020	ALPHA-BITS W/ MARSHMALLOWS CEREAL
57103050	AMARANTH FLAKES CEREAL
57103100	APPLE CINNAMON CHEERIOS
57103500	APPLE CINNAMON SQUARES MINI-WHEATS CEREAL, KELLOGG'S
57104000	APPLE JACKS CEREAL
57106050	BANANA NUT CRUNCH CEREAL (POST)
57106100	BASIC 4 (RTE CEREAL)
57106250	BERRY BERRY KIX
57106260	BERRY BURST CHEERIOS
57106530	BLUEBERRY MORNING, POST
57107000	BOOBERRY CEREAL
57110000	ALL-BRAN BRAN BUDS CEREAL, KELLOGG'S (FORMERLY BRAN BUDS)
57111000	BRAN CHEX CEREAL
57117000	CAP'N CRUNCH CEREAL
57119000	CAP'N CRUNCH'S CRUNCH BERRIES CEREAL
57120000	CAP'N CRUNCH'S PEANUT BUTTER CRUNCH CEREAL
57123000	CHEERIOS
57124000	CHEX CEREAL, NFS
57124200	CHOCOLATE FLAVORED FROSTED PUFFED CORN CEREAL
57124500	CINNAMON GRAHAMS CEREAL, GENERALMILLS
57125000	CINNAMON TOAST CRUNCH CEREAL
57125900	HONEY NUT CLUSTERS CEREAL
57126000	COCOA KRISPIES CEREAL
57127000	COCOA PEBBLES CEREAL
57128000	COCOA PUFFS CEREAL
57128880	COMPLETE OAT BRAN FLAKES, KELLOGG'S
57130000	COOKIE-CRISP CEREAL (INCLUDE ALL FLAVORS)
57131000	CRUNCHY CORN BRAN CEREAL, QUAKER
57132000	CORN CHEX CEREAL
57134000	CORN FLAKES, NFS (INCLUDE STORE BRANDS)
57135000	CORN FLAKES, KELLOGG
57137000	CORN PUFFS CEREAL
57138000	TOTAL CORN FLAKES
57139000	COUNT CHOCULA CEREAL

57143000	CRACKLIN' OAT BRAN CEREAL
57144000	CRISP CRUNCH CEREAL
57148000	CRISPIX CEREAL
57148600	HARMONY CEREAL, GEN MILLS
57151000	CRISPY RICE CEREAL
57152000	CRISPY WHEATS'N RAISINS CEREAL
57201800	DISNEY CEREALS, KELLOGG'S
57206000	FAMILIA CEREAL
57206700	FIBER ONE CEREAL
57207000	BRAN FLAKES CEREAL, NFS (FORMERLY 40% BRAN FLAKES, NFS)
57208000	COMPLETE WHEAT BRAN FLAKES, KELLOGG'S (FORM.40% BRAN FLAKES)
57209000	NATURAL BRAN FLAKES CEREAL, POST
57211000	FRANKENBERRY CEREAL
57212100	FRENCH TOAST CRUNCH CEREAL, GENERAL MILLS
57213000	FROOT LOOPS CEREAL
57213850	FROSTED CHEERIOS CEREAL
57214000	FROSTED MINI-WHEATS CEREAL (INCL ALL FLAVORS)
57214100	FROSTED WHEAT BITES
57215000	FROSTY O'S CEREAL
57218000	FROSTED RICE KRISPIES CEREAL
57219000	FRUIT & FIBRE CEREAL, NFS
57221000	FRUIT & FIBRE CEREAL, W/ DATES, RAISINS, & WALNUTS
57221650	FRUIT HARVEST CEREAL, KELLOGG'S
57221700	FRUIT RINGS, NFS (INCLUDE STORE BRANDS)
57221800	FRUIT WHIRLS CEREAL
57223000	FRUITY PEBBLES CEREAL
57224000	GOLDEN GRAHAMS CEREAL
57227000	GRANOLA, NFS
57228000	GRANOLA, HOMEMADE
57229000	GRANOLA, LOWFAT, KELLOGG'S
57229500	GRANOLA W/ RAISINS, LOWFAT, KELLOGG'S
57230000	GRAPE-NUTS CEREAL
57231000	GRAPE-NUT FLAKES
57231200	GREAT GRAINS, RAISIN, DATE, & PECAN,WHOLE GRAIN CEREAL, POST
57231250	GREAT GRAINS DOUBLE PECAN WHOLE GRAIN CEREAL, POST
57232100	HEALTHY CHOICE ALMOND CRUNCH CEREAL W/ RAISINS
57237100	HONEY BUNCHES OF OATS CEREAL
57237300	HONEY BUNCHES OF OATS W/ ALMONDS, POST
57238000	HONEYCOMB CEREAL, PLAIN
57239000	HONEYCOMB CEREAL, STRAWBERRY
57239100	HONEY CRUNCH CORN FLAKES CEREAL, KELLOGG'S
57240100	HONEY NUT CHEX CEREAL
57241000	HONEY NUT CHEERIOS
57241200	HONEY NUT SHREDDED WHEAT CEREAL, POST
57243000	Smacks, Kellogg's (formerly Honey Smacks)
57244000	JUST RIGHT CEREAL
57245000	JUST RIGHT FRUIT & NUT CEREAL (W/ RAISINS, DATES, NUTS)
57301100	KABOOM CEREAL

57301500	KASHI, PUFFED
57302100	KING VITAMAN CEREAL
57303100	KIX CEREAL
57304100	LIFE CEREAL (PLAIN & CINNAMON)
57305100	LUCKY CHARMS CEREAL
57305150	FROSTED OAT CEREAL W/ MARSHMALLOWS
57305170	MALT-O-MEAL COCO-ROOS CEREAL
57305180	MALT-O-MEAL CORN BURSTS CEREAL
57305210	MALT-O-MEAL FROSTED FLAKES
57305500	MALT-O-MEAL HONEY & NUT TOASTY O'S CEREAL
57305600	MALT-O-MEAL MARSHMALLOW MATEYS CEREAL
57306120	MALTO-O-MEAL PUFFED WHEAT CEREAL
57306500	MALT-O-MEAL GOLDEN PUFFS CEREAL (FORMERLY SUGAR PUFFS)
57306700	MALT-O-MEAL TOASTED OAT CEREAL
57306800	MALT-O-MEAL TOOTIE FRUITIES (RTE CEREAL)
57307150	MARSHMALLOW SAFARI CEREAL, QUAKER
57307500	MILLET, PUFFED (CEREAL)
57308150	MUESLIX CEREAL, NFS
57308190	MUESLI WITH RAISINS, DATES, AND ALMONDS
57308300	MULTI BRAN CHEX
57308400	MULTI GRAIN CHEERIOS
57309100	NATURE VALLEY GRANOLA, W/ FRUIT & NUTS
57316200	NUTTY NUGGETS (RALSTON)
57316300	OAT BRAN FLAKES, HEALTH VALLEY
57316410	APPLE CINNAMON OATMEAL CRISP CEREAL (OATMEAL CRISP W/ APPLES
57316450	OATMEAL CRISP W/ ALMONDS CEREAL
57316500	OATMEAL RAISIN CRISP CEREAL
57316710	OH'S, HONEY GRAHAM CEREAL
57316750	OH'S, FRUITANGY CEREAL
57318000	100% BRAN CEREAL
57319000	100% NATURAL CEREAL, PLAIN, QUAKER
57319500	SUN COUNTRY 100% NATURAL GRANOLA, WITH ALMONDS
57320500	100 % NATURAL CEREAL, W/ OATS,HONEY & RAISINS,QUAKER
57321700	OPTIMUM, NATURE'S PATH
57322500	OREO O'S CEREAL, POST
57323000	SWEET CRUNCH CEREAL, QUAKER (FORMERLY POPEYE)
57323050	SWEET PUFFS CEREAL, QUAKER
57325000	PRODUCT 19 CEREAL
57327450	QUAKER OAT BRAN CEREAL
57327500	QUAKER OATMEAL SQUARES CEREAL (FORMERLY QUAKER OAT SQUARES)
57329000	RAISIN BRAN CEREAL, NFS
57330000	RAISIN BRAN CEREAL, KELLOGG
57331000	RAISIN BRAN CEREAL, POST
57332050	RAISIN BRAN, TOTAL
57332100	RAISIN NUT BRAN CEREAL
57335550	REESE'S PEANUT BUTTER PUFFS CEREAL
57336000	RICE CHEX CEREAL
57339000	RICE KRISPIES CEREAL

57339500	RICE KRISPIES TREATS CEREAL (KELLOGG'S)
57340000	PUFFED RICE CEREAL
57340700	SCOOBY DOO CINN MARSHMLLW CRL, KELLOGG'S
57341000	SHREDDED WHEAT 'N BRAN CEREAL
57341200	SMART START, KELLOGG'S
57344000	SPECIAL K CEREAL
57346500	OATMEAL HONEY NUT HEAVEN, QUAKER
57347000	CORN POPS CEREAL
57347500	STRAWBERRY SQUARES MINI-WHEATS CEREAL(STRAWBERRY SQUARES)
57348000	FROSTED CORN FLAKES, NFS
57349000	FROSTED FLAKES, KELLOGG
57355000	GOLDEN CRISP CEREAL
57401100	TOASTED OAT CEREAL
57403100	TOASTIES, POST
57404100	MALT-O-MEAL TOASTY O'S CEREAL
57404200	MALT-O-MEAL APPLE & CINNAMON TOASTY O'S
57406100	TOTAL CEREAL
57407100	TRIX CEREAL
57408100	UNCLE SAM'S HI FIBER CEREAL
57409100	WAFFLE CRISP CEREAL, POST
57410000	WEETABIX WHOLE WHEAT CEREAL
57411000	WHEAT CHEX CEREAL
57412000	WHEAT GERM CEREAL, PLAIN
57416000	PUFFED WHEAT CEREAL, PLAIN
57416010	WHEAT, PUFFED, PRESWEETENED W/ SUGAR
57417000	SHREDDED WHEAT, 100%
57418000	WHEATIES CEREAL
57601100	WHEAT BRAN, UNPROCESSED

Hard Candy (CFR Category 25: Hard candy; CFR Category 38: Soft candy, including bars, chocolates, mints, nougat)

Food Codes	NH0304 Food Description
91700010	CANDY, NFS
91745020	HARD CANDY
91745040	BUTTERSCOTCH HARD CANDY
91770020	DIETETIC OR LOW CALORIE HARD CANDY

Mints (CFR Category: Soft candy, including bars, chocolates, mints, nougat)

Food Codes	NH0304 Food Description
91770000	DIETETIC OR LOW CALORIE CANDY, NFS
91770050	MINTS, DIETETIC OR LOW CALORIE

Tofu (CFR Category 33: Plant protein products, meat substitutes; CFR Category 1: Baked goods and baking mixes)

Food Codes	NH0304 Food Description
41420010	SOYBEAN CURD
41420050	SOYBEAN CURD CHEESE
41421010	SOYBEAN CURD, DEEP-FRIED
41435110	HIGH PROTEIN BAR, CANDY-LIKE, SOY & MILK BASE
41480000	TOFU FROZEN DESSERT, NOT CHOCOLATE (INCL TOFUTTI)
41480010	TOFU FROZEN DESSERT, CHOCOLATE (INCLUDE TOFUTTI)
41811900	SOYBURGER, MEATLESS, NO BUN
53390100	PIE, TOFU W/ FRUIT

Soups/Broth (CFR Category 40: Soups and soup mixes, commercially prepared)

Food Codes	NH0304 Food Description
14710100	CHEDDAR CHEESE SOUP
14710110	CHEDDAR CHEESE SOUP, CANNED, UNDILUTED
14710200	BEER SOUP, MADE W/ MILK
28310110	BEEF BROTH, BOUILLON OR CONSOMME (INCL BROTH, NFS)
28310150	OXTAIL SOUP
28310210	CHILI BEEF SOUP
28311010	PEPPERPOT (TRIPE) SOUP (INCL MENUDO/MONDONGO SOUP)
28315100	BEEF VEG SOUP W/POTATO, STEW TYPE (INCL CHUNKY STY)
28315120	BEEF VEG SOUP W/ NOODLES, STEW TYPE, CHUNKY STYLE
28315130	BEEF VEG SOUP W/ RICE, STEW TYPE, CHUNKY STYLE
28315160	ITALIAN WEDDING SOUP
28316020	BEEF & MUSHROOM SOUP, CANNED, LOW SODIUM (INCL BEEF
28317010	BEEF STROGANOFF SOUP, CHUNKY STYLE
28320110	PORK & RICE SOUP, STEW TYPE, CHUNKY STYLE
28320120	PORK VEG SOUP W/ NOODLES, STEW TYPE, CHUNKY STYLE
28340110	CHICKEN BROTH/BOUILLON/CONSOMME (INCL FROM POWDER)
28340140	CHICKEN BROTH/BOULLION, DRY, NOT RECONSTITUTED
28340310	CHICKEN GUMBO SOUP
28340510	CHICKEN NOODLE SOUP, CHUNKY
28340520	CHICKEN SOUP, CANNED, UNDILUTED
28340530	CHICKEN SOUP
28340550	SWEET & SOUR SOUP
28340610	CHICKEN VEGETABLE SOUP, STEW TYPE (INCL CHUNKY)
28340630	CHICKEN VEG SOUP W/ RICE, STEW TYPE, CHUNKY STYLE
28340640	CHICKEN VEG SOUP W/ NOODLES, STEW TYPE, CHUNKY STYL
28340700	BIRD'S NEST SOUP (CHICKEN, HAM, NOODLES)
28340750	HOT & SOUR SOUP (INCLUDE HOT & SPICY CHINESE SOUP)
28345030	CHICKEN/TURKEY SOUP, CM OF, CAN, RED SOD, W/ WATER
28345040	CHICKEN/TURKEY SOUP, CM OF, CAN, RED SOD, UNDILUTED
28345110	CHICKEN SOUP, CREAM OF, NS AS TO MILK OR WATER

28345120	CHICKEN/TURKEY SOUP,CREAM OF, W/ MILK
28345130	CHICKEN SOUP, CREAM OF, PREPARED W/ WATER
28345140	CHICKEN SOUP, CREAM OF, CANNED, UNDILUTED
28345160	CHICKEN & MUSHROOM SOUP, CREAM OF, W/ MILK
28350110	CRAB SOUP, NS AS TO TOMATO-BASE OR CREAM
28350210	CLAM CHOWDER, NS AS TO MANHATTAN OR NEW ENGLAND
28350220	CLAM CHOWDER, MANHATTAN (INCLUDE CHUNKY)
28355110	CLAM CHOWDER, NEW ENG, NS AS TO MILK OR WATER ADDED
28355120	CLAM CHOWDER, NEW ENGLAND, W/ MILK
28355130	CLAM CHOWDER, NEW ENGLAND, W/ WATER
28355140	CLAM CHOWDER, CANNED, NEW ENGLAND, RED SODIUM, RTS
28355350	SALMON SOUP, CREAM STYLE
28355410	SHRIMP SOUP, CREAM OF, NS AS TO MILK/WATER ADDED
28355420	SHRIMP SOUP, CREAM OF, W/ MILK
28355430	SHRIMP SOUP, CREAM OF, W/ WATER
41601010	BEAN SOUP, NFS
41601020	BEAN W/ BACON OR PORK SOUP
41601030	BLACK BEAN SOUP
41601070	SOYBEAN SOUP, MISO BROTH
41601090	BEAN SOUP W/ MACARONI (INCL PASTA E FAGIOLI)
41601110	BEAN & HAM SOUP, CHUNKY STYLE (INCL CAMPBELL'S OLD
41601120	BEAN SOUP W/ VEG, RICE, & PORK (INCL CAMPBELL'S CHU
41601180	BEAN & HAM SOUP, HOME RECIPE
41602010	CHUNKY PEA & HAM SOUP
41602030	SPLIT PEA & HAM SOUP
41602050	SPLIT PEA SOUP
41602070	SPLIT PEA SOUP, CAN, REDUCED SODIUM, W/ WATER/RTS
58400000	SOUP, NFS
58400100	NOODLE SOUP, NFS
58400200	RICE SOUP, NFS
58401010	BARLEY SOUP (INCLUDE BEEF/CHICKEN/MUSHROOM BARLEY)
58402010	BEEF NOODLE SOUP
58402020	BEEF DUMPLING SOUP
58402030	BEEF RICE SOUP
58403010	CHICKEN NOODLE SOUP (INCLUDE CHICKEN & STARS SOUP)
58403020	CHICKEN NOODLE SOUP, CANNED, UNDILUTED
58403030	CHICKEN NOODLE SOUP, CANNED, LOW SODIUM
58403050	CHICKEN NOODLE SOUP, CREAM OF
58403060	CHICKEN NOODLE SOUP,CAN,RED SODIUM,READY-TO-SERVE
58404010	CHICKEN RICE SOUP (INCL TURKEY RICE SOUP)
58404040	CHICKEN RICE SOUP, CAN, RED SODIUM, PREP W/ WATER/RTS
58404510	CHICKEN SOUP W/ DUMPLINGS, POTATOES
58404520	CHICKEN SOUP W/ DUMPLINGS
58406010	TURKEY NOODLE SOUP
58407000	INSTANT SOUP, NFS
58407010	INSTANT SOUP, NOODLE (INCLUDE MEAT & VEG FLAVORS)
58407030	SOUP, MOSTLY NOODLES(INCL SPAGHETTI SOUP,TOP RAMEN)
58407040	INSTANT SOUP, RICE (INCLUDE MEAT/CHICKEN FLAVOR)

58407050	INSTANT SOUP, NOODLE W/ EGG, SHRIMP OR CHICKEN
58421000	SOPA SECA (DRY SOUP), Mexican style, NFS
58450300	NOODLE SOUP, MADE W/ MILK
71801000	POTATO SOUP, NS AS TO MADE W/MILK OR WATER
71801010	POTATO SOUP, CREAM OF, W/ MILK
71801020	POTATO SOUP, PREPARED W/ WATER
71801040	POTATO SOUP, INSTANT, MADE FROM DRY MIX
72302000	BROCCOLI SOUP (INCLUDE CREAM OF BROCCOLI SOUP)
72302100	BROCCOLI CHEESE SOUP, PREP W/ MILK
73501000	CARROT SOUP, CREAM OF, W/ MILK
74601000	TOMATO SOUP, NFS
74601010	TOMATO SOUP, CREAM OF,PREP W/ MILK
74602010	TOMATO SOUP, PREPARED W/ WATER
74602030	TOMATO SOUP, CANNED, UNDILUTED
74602050	TOMATO SOUP, INSTANT TYPE, PREPARED W/ WATER
74602100	TOMATO SOUP, CANNED, LOW SODIUM, READY-TO-SERVE
74602200	TOMATO SOUP, CAN, RED. SODIUM, PREP. W/ WATER
74602300	TOMATO SOUP, CAN, RED. SODIUM, PREP W/ MILK
74603010	TOMATO BEEF SOUP, PREPARED W/ WATER
74604010	TOMATO BEEF NOODLE SOUP, PREPARED W/ WATER
74604100	TOMATO BEEF RICE SOUP, PREPARED W/ WATER
74604500	TOMATO NOODLE SOUP, PREPARED W/ WATER
74604600	TOMATO NOODLE SOUP, CREAM OF
74605010	TOMATO RICE SOUP, PREPARED W/ WATER
74606010	TOMATO VEGETABLE SOUP, PREP W/ WATER
74606020	TOMATO VEGETABLE SOUP W/NOODLES, PREPARED W/ WATER
75600150	SOUP, CREAM OF, NFS
75601000	ASPARAGUS SOUP, CREAM OF, NS AS TO W/ MILK OR WATER
75601010	ASPARAGUS SOUP, CREAM OF,W/ MILK
75601100	BEET SOUP (BORSCHT)
75603000	CELERY SOUP, CREAM OF, NS AS TO MILK OR WATER ADDED
75603010	CELERY SOUP, CREAM OF, W/ MILK
75603020	CELERY SOUP, CREAM OF, PREPARED W/ WATER
75603030	CELERY SOUP, CREAM OF, CANNED, UNDILUTED
75605010	LEEK SOUP, CREAM OF, PREP W/ MILK
75607000	MUSHROOM SOUP, NFS
75607010	MUSHROOM SOUP, CREAM OF, PREP W/ MILK
75607020	MUSHROOM SOUP, CREAM OF, PREPARED W/ WATER
75607030	MUSHROOM SOUP, CANNED, UNDILUTED (INCL CREAM OF)
75607040	MUSHROOM SOUP, W/ MEAT BROTH, PREPARED W/ WATER
75607050	MUSHROOM SOUP, CM OF, LOW SOD, PREP W/ WATER
75607060	MUSHROOM SOUP, CREAM OF, NS AS TO W/ MILK OR WATER
75607130	MUSHROOM SOUP, MADE FROM DRY MIX
75607140	MUSHROOM SOUP, CM OF, CAN, RED SOD, PREP W/ WATER
75607150	MUSHROOM SOUP, CM OF, CAN, RED SOD, UNDILUTED
75608010	ONION SOUP, CREAM OF, PREP W/ MILK
75608030	ONION SOUP, CREAM OF, CANNED, UNDILUTED
75608100	ONION SOUP, FRENCH

75608200	ONION SOUP, MADE FROM DRY MIX
75608300	ONION SOUP, DRY MIX, NOT RECONSTITUTED
75609000	PEA SOUP, NFS
75609010	PEA SOUP, PREP W/ MILK
75609020	PEA SOUP, PREPARED W/ WATER
75609050	PEA SOUP, CAN, LOW SOD, PREP W/ WATER
75611010	VEGETABLE SOUP, CREAM OF, PREP W/ MILK
75612010	ZUCCHINI SOUP, CREAM OF, PREP W/ MILK
75646010	SHAV SOUP
75647000	SEAWEED SOUP
75649010	VEGETABLE SOUP, PREP W/ WATER OR READY-TO-SERVE
75649030	VEGETABLE SOUP, CANNED, LOW SODIUM
75649050	VEGETABLE SOUP, MADE FROM DRY MIX
75650990	MINESTRONE SOUP, CANNED, REDUCED SODIUM, RTS
75651010	VEGETABLE BEAN SOUP, PREPARED W/ WATER
75651020	VEGETABLE BEEF SOUP, PREPARED W/ WATER
75651030	VEGETABLE BEEF NOODLE SOUP, PREPARED W/ WATER
75651040	VEGETABLE NOODLE SOUP, PREPARED W/ WATER
75651050	VEGETABLE CHICKEN SOUP, W/ WATER OR READY-TO-SERVE
75651070	VEGETABLE RICE SOUP, PREPARED W/ WATER
75651080	VEG BEEF SOUP W/RICE, PREP W/ WATER, READY-TO-SERVE
75651090	VEGETABLE CHICKEN SOUP, CAN, LOW SOD, PREP W/ WATER
75651110	VEG CHICKEN RICE SOUP, PREPARED W/ WATER / READY TO
75651120	VEG CHICKEN NOODLE SOUP,PREP W/WATER,READY-TO-SERVE
75651140	VEG SOUP W/ CHICKEN BROTH, MEXICAN STYLE (SOPA RANCHERA)
75651150	VEGETABLE NOODLE SOUP, CAN, RED SODIUM, PREP W/ WATER/RTS
75654010	VEGETARIAN VEGETABLE SOUP, PREPARED W/ WATER
75654020	VEGETARIAN VEGETABLE SOUP, UNDILUTED
75656020	VEGETABLE SOUP, CHUNKY STYLE
75656060	VEG BEEF SOUP, CHUNKY STYLE (INCL VEG W/ MEAT SOUPS
75657000	VEGETABLE BROTH, BOUILLON (INCL POT LIQUOR)

EXHIBIT 1

Report of the Expert Panel

OPINION OF A GRAS PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF A DRIED YEAST FERMENTATE FOR USE AS AN INGREDIENT IN HUMAN FOOD

Introduction

An independent panel of experts (GRAS Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Cargill, Inc. (Cargill) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of a dried yeast fermentate from *Saccharomyces cerevisiae* for use in food for human consumption. The dried yeast fermentate is intended for use as a nutritional ingredient in select foods. The yeast fermentate ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature on the safety of the dried yeast fermentate from *Saccharomyces cerevisiae* was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The GRAS Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on December 18, 2019 via teleconference. Based on their independent, critical evaluation of all of the available information, the GRAS Panel unanimously concluded that the intended uses and use levels described herein for Cargill's dried yeast fermentate ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Dried Fermentate from the Yeast *Saccharomyces cerevisiae***) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

The dried yeast fermentate product that is the subject of this GRAS determination is the product of a fermentation process. Epicor® is the trade name for the dried fermentate powder produced using a proprietary, non-genetically modified *Saccharomyces cerevisiae* strain that was derived from American Type Culture Collection (ATCC) 7752. ATCC 7522 is a non-pathogenic, non-toxigenic, food-grade yeast.

Manufacturing Process

Epicor® is produced by the proprietary, non-genetically modified *S. cerevisiae* strain through anaerobic fermentation in a defined medium. Following fermentation, the entire wet fermentate is dehydrated (i.e., dried fermentate) and further processed through milling or flaking processes to generate a powder, granules, or flakes. The heating step in the dehydration process kills the yeast cells, which results in a dried product that contains

inactive yeast cells, fermentation medium, and the associated natural fermentative by-products.

History of Use

The dried yeast fermentate (Epicor®) is a yeast product akin to many other yeast products made using *S. cerevisiae* that have a long history of safe consumption by humans and animals. Humans world-wide have consumed *S. cerevisiae* (also known as "bakers" or "brewers" yeast) through the consumption of its fermentative products, which include bread, beer, and wine.

Yeasts have been used at least since the beginning of recorded history for food and beverage production. One review indicates that yeast use in foods and beverages can be traced to 6000 BC (Verstrepen et al., 2006). Widespread use and unintentional presence of unmodified *S. cerevisiae* in food, prior to passage of the modern Food and Drug Act in the US, has led some to conclude that it can be classified as GRAS via the "prior sanction" mechanism (Verstrepen et al., 2006). FDA lists a number of ingredients manufactured using *S. cerevisiae* that are permitted in food, at least some of which contain the intact organism or parts of the organism (FDA, 2001). The European Union has also recognized the long history of safe use of *S. cerevisiae* in humans by adding it to the Qualified Presumption of Safety (QPS) list that allows a very abbreviated safety review for products made by or containing the organism (EFSA, 2010).

S. cerevisiae is found throughout the environment and occurs naturally in a number of foods. As noted above, *S. cerevisiae* can be found in live and/or dead forms in bread, beer, wine, capers, cucumbers (pickles), olives, and other fermented vegetables (Arroyo-Lopez et al., 2008). Prepared Spanish olives contain up to a million *S. cerevisiae* per milliliter. It is likely that most humans are exposed daily to foods containing millions of live *S. cerevisiae* through consumption of wine, beer, fruits, salads, and cheese and other dairy foods, as well as other traditional and ethnic fermented foods. FDA allows dried *S. cerevisiae* in foods, along with a number of yeast components, including protein, glycan, and enzymes (US FDA, 2001).

S. cerevisiae's complete genome sequence was reported in 1996 (Goffeau et al., 1996). This led to the development of many new genetically modified strains of *S. cerevisiae*, several of which have a notification of their GRAS status on FDA's website (GRN 120, 2003; GRN 175, 2005; GRN 350, 2010). *S. cerevisiae* has an extensive history of use in the food-processing arena and is generally recognized as a food-grade microorganism (Liu et al., 2014).

Intended Use and Intake Assessment

The dried yeast fermentate is intended for use as a nutritional ingredient in select foods and food categories at 500 mg/serving. These include milk flavored-milks and milk drinks, milk – snack dips and spreads, frozen yogurt, 100%fruit juices, processed juice drinks, ready-to-drink tea beverages, sport/fitness water drinks, fruit-flavored drinks,

breads, ready-to-eat bars, ready-to-eat dry cereals, hard candy, mints, tofu, and soups/broth.

The daily intake of yeast in the current US diet was estimated and the analysis captured yeast intakes from all foods with reported consumption in the NHANES 2003-04 survey. Participants included 10,122 subjects in 2003-2004. Only individuals with complete and reliable 2-day dietary records were included in the analysis (N=8,354).

EpiCor® is proposed to be added to foods in the categories listed in Table 3 at 500 mg/serving. The Epicor® content of each food in ppm was calculated using the serving size and reference amounts customarily consumed per eating occasion provided by the US Food and Drug Administration (FDA) provided in the Code of Federal Regulations, Title 21 (21CFR101.12). The intakes of EpiCor® from foods were calculated by multiplying each NHANES respondent's 2-day average food intake with the proposed use levels. Food consumption estimates are expressed in units of g food/day on both the per capita and per user basis at the mean and 90th percentile. The per capita mean daily intake for all targeted foods is 588.7 g food/day (1,179 g food/day at the 90th percentile) and the per user mean daily intake is 601 g food/day (1,183 g food/day, 90th percentile). The food category with the highest consumption is the milk category, with a mean per user of 296.4 g/day (629 g/day, @ the 90th percentile).

The Epicor content of each food and daily intake were calculated using the serving size and reference amounts customarily consumed per eating occasion for each food category in Table 3. (Serving sizes and reference amounts customarily consumed taken from the US Food and Drug Administration as provided in the Code of Federal Regulations, Title 21 (21CFR101.12.) The total estimated intake was calculated by summing the calculated daily intake from each of the targeted food categories. On both a *per-capita* and a *per-user* basis, the estimated daily intakes (EDI) for the yeast fermentate from the proposed uses for the US population were **1.9 g/day at the mean and 3.5 g/day at the 90th percentile, respectively**.

Safety Data

The yeast fermentate product Epicor® is currently marketed for use as a dietary supplement. This GRAS determination supports additional uses in food for human consumption. Regulatory authorities have reviewed the extensive safety database on *S. cervisiae* and found no issues of concern with respect to its use in human food or human food production. Numerous studies have been conducted, and published data (Schauss et al., 2012) are available that support the safety of the intended uses of the yeast fermentate product, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults.

General Recognition of the Safety of Dried Yeast Fermentate from *Saccharomyces cerevisiae*

The intended use of the dried yeast fermentate has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, and this conclusion is based on the following:

- The Cargill yeast fermentate ingredient that is the subject of the current GRAS determination is derived from *S. cerevisiae*, also (also known as "bakers" or "brewers" yeast).
- Epicor® is the trade name for the dried fermentate powder produced using a proprietary non-genetically modified *S. cerevisiae* strain that was derived from ATCC 7752. ATCC 7522 is a non-pathogenic, non-toxigenic, food-grade yeast. The yeast fermentate is produced by this *S. cerevisiae* strain through anaerobic fermentation in a defined medium. Following fermentation, the entire wet fermentate is dehydrated (i.e., dried fermentate) and further modified through milling or flaking processes to generate a powder, granules, or flakes. The heating step in the dehydration process kills the yeast cells, which results in a dried product containing dead yeast cells, fermentation medium, and the associated natural fermentative by-products.
- The yeast fermentate ingredient is intended for use as a nutritional supplement in selected foods for human consumption.
- Epicor® yeast fermentate has been marketed as a dietary supplement for more than a decade. Epicor® is currently sold for use in multi-ingredient dietary supplements, and also as a sole ingredient.
- The yeast fermentate product is proposed for use in a wide range of foods, including cookies, meal replacement and probiotic beverages, nutritional bars, soy milk, yogurt and yogurt beverages, soy protein bars, fruit beverages, chocolate confections, and soups.
- The *per user* estimated daily intake of the yeast fermentate from consumption of the specified foods is estimated to be approximately 1.9 g/day at the mean and 3.5 g/day at the 90th percentile, or 32 and 58 mg/kg bw/day (for a 60-kg individual), respectively.
- The current US daily intake of yeast in the diet for the US population 2 years and older is as follows: the *per-capita* average daily intake for yeast from all foods was 1.3 g/day (2.9 g/day, 90th percentile), and the *per-user* average daily intake was 1.5 g/day (3 g/day, 90th percentile).
- The Canadian Food Inspection Agency provided an estimate of a reasonable daily intake of 14 g/day for yeast (CFIA, 2018). The reasonable daily intake was used to evaluate, for regulatory purposes, the nutritional contribution of specific foods to the diet.
- *S. cerevisiae* has a long history of use and for being recognized as non-

pathogenic. It is used in many food manufacturing processes, including bread making, beer brewing, and grape fermentation for wine. The FDA, EPA (1997), and EFSA have evaluated the safety of *S. cerevisiae* and consider the organism safe for use in food manufacturing. Several GRAS notifications for modified strains of *S. cerevisiae* used in winemaking have been submitted to the FDA, and that agency has responded that they had no further questions on these GRAS determinations.

- Numerous toxicology studies employing the proposed yeast fermentate ingredients have been conducted and published that support the safety of the intended uses of the ingredient. These studies include *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults. NOAELs of 800 and 1500 mg/kg/day have been reported in 1-year and in chronic and 90-day subchronic studies in rats, well above the estimated 90th percentile per-user daily intake of 58 mg/kg bw/day.
- The body of publicly available scientific literature on the consumption and safety of *S. cerevisiae* and the yeast fermentate product is sufficient to support the safety and GRAS determination of the proposed yeast fermentate ingredient that is the subject of this assessment.

Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Cargill's dried yeast fermentate as an ingredient in conventional foods. We unanimously conclude that the intended use of Cargill's dried yeast fermentate, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of Dried Fermentate from the Yeast *Saccharomyces cerevisiae*", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of Cargill's dried yeast fermentate in foods for human consumption, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in conventional foods specified herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

_____ _____

Michael Carakostas, DVM, Ph.D. Date
Consultant
MC Scientific Consulting LLC

_____ _____

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

_____ _____

Thomas Vollmuth, Ph.D. Date
Consultant
Vollmuth and Associates, LLC

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It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

[redacted]

Michael Carakostas, DVM, Ph.D.
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20-February 2020
Date

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Michael Carakostas, DVM, Ph.D. — Date
Consultant
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[redacted]

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — 20 February 2020
The Tarka Group, Inc. — Date
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Vollmuth and Associates, LLC

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Michael Carakostas, DVM, Ph.D.
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2/21/2020
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