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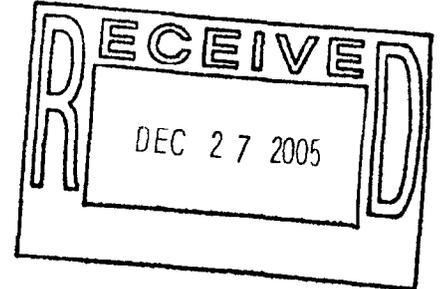
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December 23, 2005

PRIORITY MAIL

Ms. Felicia Billingslea
Director, Food Labeling and Standards
Food and Drug Administration
5100 Paint Branch Parkway (HFS-820)
College Park, MD 20740



Dear Ms. Billingslea:

**Subject: Notification Submitted Pursuant to Section 403(w)(7) of the
Food Allergen Labeling and Consumer Protection Act**

Pursuant to Section 403(w)(7)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FDCA), Purity Foods, Inc., submits the enclosed notification requesting exemption from the labeling requirements of Section 403(w)(1), established by the by the Food Allergen Labeling and Consumer Protection Act (FALCPA), for Purity Foods Vita Spelt®.

Purity Foods Vita Spelt® is derived from an ancestor of wheat, but is not "wheat" as that term is commonly used in or as the term is used in the FALCPA. Thus, Purity Foods Vita Spelt® is not a major food allergen. In addition, Purity Foods Vita Spelt® does not contain allergenic protein, as demonstrated by the evidence presented in this notification.

An original with three copies are enclosed for the FDA review. Should you have any questions related to this notification, please contact me at 517-775-4629 or nealfortin@fortinlaw.com.

Thank you for your attention.

Sincerely,

A handwritten signature in black ink that reads "Neal Fortin".

Neal D. Fortin
Attorney & Counselor at Law

Enclosures (4)
cc: Donald Stinchcomb

2006FL-0017

FLN 1

United States Department of Health and Human Services
Food and Drug Administration

**NOTIFICATION SUBMITTED PURSUANT TO SECTION 403(w)(7) OF THE
FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT**

Vita Spelt® produced by Purity Foods, Inc.

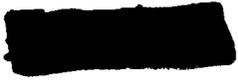
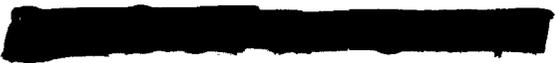
Submitted for

PURITY FOODS, INC.

December 23, 2005

by

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**NOTIFICATION SUBMITTED PURSUANT TO SECTION 403(w)(7) OF THE
FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT**

Vita Spelt® produced by Purity Foods, Inc.

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**NOTIFICATION SUBMITTED PURSUANT TO SECTION 403(w)(7) OF THE
FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT**

Vita Spelt® produced by Purity Foods, Inc.

I. INTRODUCTION

The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires all food manufacturers to identify the presence of any of the eight major food allergens in their foods.¹ The FALCPA was enacted to better inform consumers, allowing them to make informed choices and to protect public health. Under the act, the common or usual name of the ingredient must include the food source from which the major food allergen is derived.² This act was designed to make it easier for consumers to identify and avoid foods containing allergens to which they are allergic.

Purity Foods submits this notification pursuant to Section 403(w)(7)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for an exemption from the labeling requirements of subsection 403(w)(1) established by the FALCPA. This notification

¹ Food Allergen Labeling and Consumer Protection Act (hereinafter FALCPA) § 203(a).

² Federal Food, Drug, and Cosmetic Act (hereinafter FDCA) § 403(w)(1).

provides scientific evidence and other information establishing that Purity Foods Vita Spelt®—under the terms as used in the FALCPA—is not “wheat” and does not contain “allergenic protein.” Further, identifying Vita Spelt® as wheat will not serve the intent of the FALCPA, but rather will create consumer confusion and could indeed pose a risk to public health.

As will be discussed in detail below, the FALCPA establishes a notification process for obtaining an exemption from the definition of “major allergen” in those instances when there are data demonstrating that an ingredient derived from a major allergen does not contain “allergenic protein.” The data in this notification establish that Vita Spelt® does not contain “allergenic protein” as the term is used in the FALCPA.

This notification first explains our legal basis for concluding that it is appropriate for the FDA to review this request under the FALCPA notification provisions. Next, we provide a summary of the evidence supporting our position that Vita Spelt® is not “wheat,” as that term is used by the FALCPA. Finally, we provide evidence supporting our position that Vita Spelt® does not contain “allergenic protein,” as that term is used by the FALCPA.

II. LEGAL BASIS FOR FILING A FALCPA NOTIFICATION

A. Statutory Background

The FALCPA establishes labeling requirements for major allergens. The FALCPA amended the FDCA and deems a food misbranded “if it is, or it contains an ingredient that bears or contains, a major food allergen” unless the food is labeled in accordance with one of two labeling options.³ A “major food allergen” is defined in the

³ FDCA § 403(w)(1). The first option is placing the word “contains” followed by the name of the food source from which the major allergen is derived immediately after or adjacent to the ingredient statement. The second option is including the name of the food source from which

FALCPA as “Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.”⁴ A major food allergen also includes “a food ingredient that contains protein derived from a food specified in paragraph (l),” with the exception of highly refined oils and food ingredients that are exempt under the petition and notification procedures found in the statute.⁵

The FALCPA provides for exemptions from the allergen labeling provisions through a notification or petition to FDA.⁶ A notification is appropriate when there is “(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or (ii) a determination by [FDA] that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.”⁷ In instances when an ingredient does not qualify for the notification process, a petition can be filed requesting FDA to exempt a food ingredient from the labeling requirements by providing “scientific evidence . . . that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.”⁸

the major allergen is derived in a parenthetical note following the ingredient’s listing in the ingredient statement, except that such parenthetical listing is not necessary when the name of the food source appears as part of the listing of another major allergen in the food product.

⁴ FDCA § 201(qq).

⁵ FDCA § 201(qq)(2).

⁶ FDCA §§ 403(w)(6)-(7).

⁷ FDCA § 403(w)(7)(A) (emphasis added).

⁸ FDCA § 403(w)(6).

B. Vita Spelt® is not a Major Food Allergen

Spelt is not included in the FALCPA definition of major food allergens because spelt is not wheat.⁹ The term “wheat species” includes all plants in the *Triticum* genus.¹⁰ However, the term “wheat” alone means common wheat, not spelt. In addition, spelt is not derived from wheat; therefore, it does not comport with the FALCPA to label spelt as wheat.¹¹

We recognize that the FALCPA notification and petition procedures focus on food ingredients derived from major food allergens and not the reasons a food is excluded from the major food allergen category. Nonetheless, it is appropriate for the FDA to consider, as part of the notification and petition process, evidence that the spelt is not indicated by FALCPA’s use of term “wheat” and, thus, spelt is not a major food allergen. The FDA consideration is particularly relevant in this instance where there is also evidence that the food also does not cause an allergic response that poses a risk to human health and does not contain wheat allergenic protein.¹²

C. Vita Spelt® does not Contain Wheat Allergenic Protein

The notification process is appropriate when there is scientific evidence establishing that the food ingredient does not contain allergenic protein, as that term is used by the FALCPA.¹³ While the FALCPA does not define “allergenic protein,” the meaning reasonably should not include Vita Spelt®, which has been demonstrated to not cause an allergic response in some individuals with wheat allergy.

⁹ FDCA § 201(qq).

¹⁰ See Section III below.

¹¹ *Id.*

¹² See Section III below for the evidence and reasoning.

¹³ FDCA § 403(w)(7)(A).

In addition, the common and usual name “spelt” is already required to be listed in the ingredient statement on food labels. Because it is not derived from wheat, “spelt” is the appropriate information to provide to consumers to allow them to make informed choices and to protect the public health.

We recognize that our notification may lack some research on allergenicity that FDA would like to see, such as in vitro and in vivo allergen studies. Nonetheless, the most important issue is whether the ingredient, when eaten by the allergic consumer, would trigger an allergic reaction that would pose a serious risk to health. The data suggest that spelt may be easier for humans to digest than wheat, which can result in fewer reactions to the food. Most important, the data provide evidence that many wheat allergic consumers may eat Vita Spelt® without experiencing an allergic reaction. Therefore, for those who may be sensitive to spelt, the ingredient statement listing of “spelt” is the most appropriate information.

Moreover, the legislative history provides further support for our position that our evidence is appropriate for an FDA determination that Vita Spelt® does not contain wheat “allergenic protein” as that term is used by the FALCPA. The Senate Committee reporting the bill out of Committee to the full Senate stated that it “encourages FDA to adopt a reasonable standard for determining whether a food ingredient ‘does not contain an allergenic protein’ . . . for example, ingredients containing allergenic protein below [a future] established threshold would be eligible for the notification procedure.”¹⁴ The Senate Committee also directed FDA to create “a process . . . that minimizes the burden on the food manufacturer.”¹⁵ Given the statutory construction of the FALCPA, it is reasonable for the FDA to conclude that spelt does not contain wheat “allergenic protein,” as that term is used by the FALCPA.

¹⁴ S. Rep. No. 108-226 at p.7 (2004).

¹⁵ *Id.*

Identifying Vita Spelt® in the ingredient panel as being derived from wheat does not serve the intent of the FALCPA and will, indeed, cause consumer confusion, and will be a barrier to the dietary control of wheat allergy.¹⁶ Wheat-allergic consumers who have eaten spelt without incident will encounter spelt product labeled as containing wheat.¹⁷ This label may motivate the consumer to avoid the product because it is characterized as having the allergenic food they should avoid.¹⁸ Worse, this situation may cause these allergic consumers to conclude that they are no longer allergic to wheat, or to conclude that the FDA food allergy labeling scheme is meaningless.¹⁹ Those situations can present a risk to human health, which contradicts the intent of the FALCPA.²⁰

In summary, based on the FALCPA provision that allows for a labeling exemption, the fact that the products containing Vita Spelt® have been successfully used in the dietary management of wheat allergy, and the potential confusion and risk to human health caused by the identification of Vita Spelt® as being derived from wheat, we submit this notification for an exemption from the allergen labeling requirements for Vita Spelt®.

III. VITA SPELT® IS NOT A MAJOR FOOD ALLERGEN

Spelt is not “wheat” as that term is used by the FALCPA.²¹ Therefore, spelt is not a “major food allergen” as the term is defined by the FALCPA.²² This notification explains the reasons for these conclusions in the following sections:

¹⁶ See Section IV.C. below.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ FDCA § 201(qq)(1).

- The history of the use of spelt
- The scientific and vernacular use of the terms “wheat” and “spelt”

A. The History of the Use of Spelt

The majority of the evidence of the origin of spelt indicates that the origin of spelt must have occurred when either wild or cultivated emmer dispersed to regions where *T. tauschii* was an indigenous wild grass species.²³ “Spelt was widely distributed from the Near East origin during the Bronze Age (4,000-1,000 BC), throughout the Balkans, Europe, and transcaucasia. Some of the earliest recordings of spelt appear in the Bible (Exodus 9:30, Isaiah 28:25, and Ezekiel 4:9). Spelt was also well known to the ancient Roman Empire.²⁴

Spelt survived as a major crop until the start of the twentieth century, but at that time modern wheat supplanted its ancient ancestor.²⁵ United States production of spelt peaked in the early 1900’s, but declined steadily afterward.²⁶ Production of spelt today exists as a specialty grain for the gourmet, organic, health food, and other specialty markets.²⁷ Some consumers of spelt are wheat-sensitive individuals who can tolerate spelt.²⁸

²² FDCA § 201(qq).

²³ See Stallknecht, G.F., K.M. Gilbertson, & J.E. Ranney, *Alternative wheat cereals as food grains: Einkorn, emmer, spelt, kamut, and triticale*. p. 156-170, in J. JANICK (ED.), PROGRESS IN NEW CROPS (ASHS Press, Alexandria, VA 1996) available at <http://www.hort.purdue.edu/newcrop/proceedings1996/V3-156.html#SPELT> (last visited Dec. 12, 2005).

²⁴ DANIEL ZOHARY & MARIA HOFF, DOMESTICATION OF PLANTS OF THE OLD WORLD, 2nd ed. at 53 (1994).

²⁵ *Id.*

²⁶ *Supra* note 23.

²⁷ Small, E. *New crops for Canadian agriculture*. p. 15–52. In: J. JANICK (ED.), PERSPECTIVES ON NEW CROPS AND NEW USES (1999 ASHS Press, Alexandria, VA) available at <http://www.hort.purdue.edu/newcrop/proceedings1999/v4-015a.html#wheat> (last visited Dec. 12,

B. The Scientific and Vernacular Use of the Terms “Wheat” and “Spelt”

1. *Spelt refers to a grain that is a wheat relative, but distinct from wheat*

Initially, it is important to note that a dual meaning for a name is not uncommon in plant and animal nomenclature. For example, spruce trees are part of the pine family, but they are not pines. Lions and tigers are considered cats, but the unqualified term “cat” designates the common house cat. In taxonomic nomenclature, it is not uncommon for the name of a genus to refer both to all species within the genus, but also indicate one species in particular.²⁹

Similarly, there are two meanings of the term wheat—first, the generic name for all plants in the *Triticum* genus and, second, as a specific term for a more limited set of cereals. The “wheats” refers to the cereal grains from a variety of annual grasses of the genus *Triticum*.³⁰ In this sense, spelt falls in generic category as one of the wheats.³¹

2005). Spelt Wheat (*Triticum spelta* L.) (“It has become a top-selling organic and health food, grown as a specialist crop, often for people with allergies, and for pasta. Although minor, spelt is increasingly cultivated in Canada, with 825 ha reported in the 1996 Census of Agriculture, mostly in Ontario. Several thousand ha are cultivated in the US.”)

²⁸ *Id.* (Noting that spelt has become is grown as a specialist crop, “often for people with allergies”); Stallknecht, G.F., K.M. Gilbertson, & J.E. Ranney, *supra* note 23 (“The suggested attributes of spelt relative to wheat are ease of digestion, taste, and that individuals with certain allergies to common bread wheats can consume spelt.”) and NICOLETTE M. DUMKE, ALLERGY COOKING WITH EASE at 21 (1992).

²⁹ There are many examples in plant and animal nomenclature of the dual use of a name for both a general category and a specific type. For example, “lama” refers to a category of closely related South American animals in the camel family—the alpaca, guanaco, llama, and vicuña. Collectively, they are all known as lamas, but only the “llama” (*Lama glama*) is called by that specific name.

³⁰ *See, e.g.*, DANIEL ZOHARY & MARIA HOFF, DOMESTICATION OF PLANTS OF THE OLD WORLD, 2nd ed. at 18 (1994) (referring to “wheats” as *Triticum*); and MERRIAM-WEBSTER ONLINE DICTIONARY, “1 : a cereal grain that yields a fine white flour, is the chief breadstuff of temperate climates, is used also in pastas (as macaroni or spaghetti), and is important in animal feeds[;] 2 : any of various annual grasses (genus *Triticum* and especially *T. aestivum* and *T. turgidum*) of wide climatic adaptability that are cultivated in most temperate areas for the wheat they yield” <http://www.m-w.com/cgi-bin/dictionary> (last visited Dec. 13, 2005).

The second use of the term wheat is to describe common wheat, *Triticum aestivum* L. subsp. *aestivum*. In both the scientific and the vernacular usage, the unqualified term “wheat” refers to common wheat, *Triticum aestivum* L. subsp. *aestivum*, but not spelt.³² Some examples from literature that demonstrate the unqualified use of the term wheat as distinct from spelt follow. Note that these writings clearly distinguish wheat from spelt.

Dry matter production of ¹⁴C-assimilates of spelt . . . and wheat . . . as influenced by different temperatures before and during grain filling.³³

The effect of glumes on fungal infection of germinating seed of spelt . . . in comparison to wheat.³⁴

and

Loose smut occurs wherever wheat, spelt and barley are grown.³⁵

Likewise, the generic usage of the term wheat can be determined from the context. For example, in the title of a chapter of PROGRESS IN NEW CROPS is “*Alternative wheat cereals as food grains: Einkorn, emmer, spelt, kamut, and*

³¹ See, e.g., MERRIAM-WEBSTER ONLINE DICTIONARY: “Spelt . . . : a wheat (*Triticum aestivum spelta*) with lax spikes and spikelets containing two light red kernels” available at: <http://www.m-w.com/dictionary/spelt> (last visited Dec. 12, 2005).

³² Spelt is generally recognized as a distinct subspecies of wheat with the taxonomic classification of *Triticum aestivum* L. subsp. *spelta*, although some authors refer to it as a separate species, *Triticum spelta* L.

³³ Ruegger, A., H. Winzeler, and J. Nosberger, Dry matter production of ¹⁴C-assimilates of spelt (*Triticum spelta* L.) and wheat (*Triticum aestivum* L.) as influenced by different temperatures before and during grain filling, J. AGRON. CROP SCI. 165:110-120 (1990) (emphasis added).

³⁴ *Id.*

³⁵ Patrick E. Lipps, LOOSE SMUT OF WHEAT, SPELT AND BARLEY, Fact Sheet AC-12-96, The Ohio State University Extension, Plant Pathology, 2021 Coffey Road, Columbus, OH 43210-1087 (emphasis added).

triticale,”³⁶ there is no doubt that this author uses the word “wheat” as a generic term for Einkorn, emmer, spelt, kamut, and triticale.

In addition, the above example demonstrates the difference between the generic use and the specific use. It reveals that the generic use of the “wheat” does not mean that all wheat cereals can be called simply “wheat” without contextual explanation or other clarification. Although the author of the above example categorizes spelt and triticale generically as “wheat cereals,” the unqualified use of the word “wheat” would never refer to triticale because it is a hybrid of and rye and wheat.³⁷ Similarly, the unqualified use of the word “wheat” never refers to spelt.

This generic-specific distinction may seem nuanced when discussed in theory, but the distinction is not only the common language usage, but is easily understood by those commonly dealing with cereal grains, such as farmers, millers, and bakers. This distinction is also significant and even critical in the food trade. Any reader who believes otherwise should imagine writing a contract to supply “wheat” to a bakery, and substituting spelt; or vice versa.

In summary, spelt is a wheat-type cereal. However, the unqualified term “wheat” refers to common wheat, *Triticum aestivum* L. subsp. *aestivum*, not spelt.

2. Taxonomic Classification of Spelt

Taxonomically, the U.S. Department of Agriculture, Agricultural Research Program (ARS), considers spelt to be *Triticum aestivum* subsp. *spelta* L.³⁸ This relatively recent grouping is based on cytogenic affinity traits, rather than morphology

³⁶ Stallknecht, G.F., K.M. Gilbertson, & J.E. Ranney, *supra* note 23.

³⁷ Small, E. *supra* note 27.

³⁸ U.S. Department of Agriculture, Agricultural Research Program (ARS), Germplasm Resources Information Network (GRIN) <http://www.ars-grin.gov/cgi-bin/npgs/html/taxon.pl?406903>.

(spelt looks quite different from wheat).³⁹ A subspecies, by definition, is genetically distinct from the other populations within the same species.⁴⁰ The Farm Service Agency (FSA) of the U.S. Department of Agriculture notes that spelt is “closely related to but distinctly different than commercial wheat” specifically because it is a distinct subspecies of wheat, *Triticum aestivum* subsp. *spelta* L.⁴¹ Other sources also support this classification.⁴²

However, traditionally, spelt was considered a separate species (*Triticum spelta* L.) from common wheat (*Triticum aestivum*).⁴³ This classification of spelt as a distinct species was based in part on significant morphological differences between spelt and wheat. Spelt looks dramatically different from wheat. This distinction remains important because it distances spelt from wheat in our common language use of the term “wheat.” Spelt’s general properties also contrast with wheat (requiring

³⁹ See DANIEL ZOHARY & MARIA HOFF, DOMESTICATION OF PLANTS OF THE OLD WORLD, 2nd ed. at 24-27 (1994).

⁴⁰ See, e.g., MERRIAM-WEBSTER ONLINE DICTIONARY (“subdivision of a species: as a : a category in biological classification that ranks immediately below a species and designates a population of a particular geographical region genetically distinguishable from other such populations of the same species and capable of interbreeding successfully with them where its range overlaps theirs b : a named subdivision (as a race or variety) of a taxonomic species.”) <http://www.m-w.com/dictionary/subspecies>.

⁴¹ Letter from James F. Fitzpatrick, Washington State Executive Director for the Farm Service Agency State Office, U.S. Department of Agriculture, to Rene Featherstone (Aug. 6, 2003) (emphasis added).

⁴² See, e.g., Minnesota Department of Agriculture, *Spelt - Triticum aestivum* var. *spelt* (“Spelt (*Triticum aestivum* var. *spelta*) is a sub-species of common wheat.”) available at <http://www.mda.state.mn.us/mgo/crops/Spelt.htm> (last visited Dec. 12, 2005).

⁴³ See, e.g., Purdue University, New Crop Resource Online Program, *Triticum Species* (noting that Common Wheat is *Triticum aestivum* L. subsp. *aestivum*., Club Wheat, *T. aestivum* subspecies *compactum* (Host) MacKey, , and Spelt, *T. spelta* L. http://www.hort.purdue.edu/newcrop/nexus/Triticum_spp_nex.html (last visited Dec. 18, 2005); Magness, J.R., G.M. Markle, C.C. Compton. 1971. *Food and feed crops of the United States. Interregional Research Project IR-4*, IR Bul. 1 (Bul. 828 New Jersey Agr. Expt. Sta.); Small, E. *supra* note 27; and DANIEL ZOHARY & MARIA HOFF, DOMESTICATION OF PLANTS OF THE OLD WORLD, 2nd ed. at 24 (1994).

adjustments in handling and cooking, for example), and this also solidifies the common language distinction between spelt and wheat.

It also bears noting that the proper scientific name of spelt is only peripherally related to the FALCPA. Congress could have employed scientific names, but chose rather to use the common language. Generally, the words of a statute are interpreted according to their common meaning.⁴⁴ Simply put, Congress's use of the word "wheat" means wheat.

3. The Codex Standards for Wheat Flour and Wheat Grain

The Codex Alimentarius is a collection of international food standards adopted by the Codex Alimentarius Commission of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations.⁴⁵ The Codex Alimentarius is generally recognized as the most important international reference point for food standards.⁴⁶ In addition, the Codex standards are of immense significance in the facilitation of trade through harmonization of standards.

The Codex standard for wheat flour specifies that wheat flour may contain only flour from common wheat, *Triticum aestivum* L., or club wheat, *Triticum compactum* Host., or mixtures thereof.⁴⁷ Common wheat is clearly distinct from spelt, and under the Codex standard, spelt may not be put into a product called "wheat flour."

⁴⁴ See, e.g., *Bauer v. Dep't of Treasury*, 203 Mich. App. 97, 100; 512 N.W.2d 42 (1993), *lv. den.* 447 Mich. 979 (1994) ("The words of a statute are to be taken in the sense in which they will be understood by those who must abide it.")

⁴⁵ WORLD HEALTH ORGANIZATION AND FOOD AND AGRICULTURE ORGANIZATION, UNDERSTANDING THE CODEX ALIMENTARIUS (2005) available at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/008/y7867e/y7867e00.htm.

⁴⁶ E.g., many trade agreements reference the Codex standards.

⁴⁷ Codex Stan 152-1985 (Rev. 1, 1995) available at http://www.codexalimentarius.net/download/standards/50/CXS_152e.pdf.

Spelt is also not wheat under the Codex standard for wheat grain. The Codex standard for wheat grain states that it is the grains obtained from varieties of the species *Triticum aestivum* L.⁴⁸ “Wheat” grain does not include club wheat (*Triticum compactum* Host.), red durum wheat (*Triticum durum* Desf.), or durum wheat semolina. Although, as discussed above, some consider spelt as a subspecies of *Triticum aestivum*, but for the purposes of Codex, spelt is *Triticum spelta*.⁴⁹ In addition, spelt is even more distinct from common wheat than club wheat and durum wheat, which are expressly excluded from the definition of “wheat.”

The international Codex standards bear directly on United States products and standards. Should the FDA deny this notification, it would place United States food manufacturers in the awkward position of being held to a different standard than many of our international trading partners, including those that import into the United States. Most of our trading partners would not be bound to label spelt as wheat based on an FDA interpretation of the FALCPA. Many of our international trade agreements, such as the SPS and TBT Agreements, select the Codex standards as the benchmark against which national measures are evaluated. These trade agreements do not allow the United States to apply to standards to imported products different from the Codex standards unless there is sufficient scientific justification for doing so; and there is no scientific justification for labeling spelt as wheat.⁵⁰

If FDA should deny this notification, the decision would add considerable confusion to United States food labeling. U.S. produced spelt would be required to be identified as wheat, but imported spelt could be identified simply as spelt.

⁴⁸ Codex Stan 199-1995 (1995) available at http://www.codexalimentarius.net/web/standard_list.jsp.

⁴⁹ E-mail from F. Edward Scarbrough, U.S. Manager for Codex, USDA, forwarded to Senator Stabenow’s office (Sept. 6, 2005).

⁵⁰ See Section IV.C. below.

4. *The USDA Standards for Wheat*

The U.S. standards for wheat define wheat basically as common wheat (*Triticum aestivum* L. subsp. *aestivum*), club wheat (*T. compactum* Host.), and durum wheat (*T. durum* Desf.)⁵¹ Spelt is not only missing from the list of grains that may be included in wheat,⁵² but is expressly excluded from wheat as one of listed “other grains” without standards.⁵³

This exclusion of spelt from the United States Department of Agriculture definition and standards for wheat is reinforced by the application of this exclusionary definition by the Farm Service Agency (FSA). The FSA of the U.S. Department of Agriculture encompasses the Agricultural Stabilization and Conservation Service, and the farm credit portion of the Farmers Home Administration. The Farm Service Agency administers the farm commodity and conservation programs for farmers and makes and guarantees farm emergency, ownership, and operating loans.⁵⁴

The FSA notes that spelt is “closely related to but *distinctly different* than commercial wheat” because it is the subspecies of wheat, *Triticum aestivum* subsp.

⁵¹ The U.S. standard for wheat reads, “Grain that, before the removal of dockage, consists of 50 percent or more common wheat (*Triticum aestivum* L.), club wheat (*T. compactum* Host.), and durum wheat (*T. durum* Desf.) and not more than 10 percent of other grains for which standards have been established under the United States Grain Standards Act and that, after the removal of the dockage, contains 50 percent or more of whole kernels of one or more of these wheats.” 7 CFR § 810.2201. Grains for which standards are established do not include spelt. 7 CFR § 810.101.

⁵² 7 CFR § 810.101.

⁵³ “Other grains” (without standards) excluded from wheat are, “Barley, corn, cultivated buckwheat, einkorn, emmer, flaxseed, guar, hull-less barley, nongrain sorghum, oats, Polish wheat, popcorn, poulard wheat, rice, rye, safflower, sorghum, soybeans, spelt, sunflower seed, sweet corn, triticale, and wild oats.” 7 CFR § 810.2202(h) (emphasis added).

⁵⁴ Farm Service Agency, *The Farm Service Agency Online* <http://www.fsa.usda.gov/pas/aboutus.htm>.

spelta L.⁵⁵ Based on this fact and that the U.S. Standards for Wheat specifically exclude spelt from the definition of “wheat” by including spelt in the definition of “other grains.”⁵⁶

This classification of spelt as not wheat by the U.S. Department of Agriculture creates a situation where farmers growing spelt are excluded from many of the farm support programs in which farmers of wheat are entitled to participate. Therefore, should the FDA not accept this notification, it would not only put the FDA in conflict with the regulations of the U.S. Department of Agriculture, but would create a Kafkaesque scheme where spelt producers are barred from the traditional government support programs for wheat producers, but are also burdened with the expense and confusion of labeling their product with a misleading designation as wheat.

IV. VITA SPELT® DOES NOT CONTAIN WHEAT ALLERGIC PROTEIN

There are food allergens other than those directly addressed by the FALCPA. Congress did not intend the FALCPA to cover all food allergens, but rather choose to designate eight foods as “major food allergens.” Although there are other foods to which sensitive individuals may react, the labels of packaged foods containing these other allergens are not required to comply with the FALCPA labeling requirements.

We recognize that some individuals may become allergic to spelt. We also recognize that a very small number of exquisitely sensitive wheat-allergic individual may be unable to consume spelt.⁵⁷ This, however, does not preclude a finding that Vita

⁵⁵ Letter from James F. Fitzpatrick, Washington State Executive Director for the Farm Service Agency State Office, U.S. Department of Agriculture, to Rene Featherstone (Aug. 6, 2003) (emphasis added).

⁵⁶ *Id.*

⁵⁷ Note that the Codex standard and the European Union (EU) standard both require labeling of spelt as an ingredient due to its potential to cause an allergic reaction in some individuals, but spelt is identified as spelt, not as wheat. Codex General Standard for the

Spelt® does not contain wheat allergenic protein as that term is used in the FALCPA. The FALCPA does not require a finding that an ingredient is incapable of inducing an allergic response. The notification and petition provisions both recognize that FDA should exempt an ingredient from the definition of “major allergen” when there are data demonstrating that the food ingredient “does not cause an allergic response that poses a risk to human health.”⁵⁸

The FALCPA requires the notification to contain scientific evidence demonstrating that the food ingredient produced by the method described in the notification does not contain allergenic protein. This notification satisfies these requirements and contains the following sections: (1) a description of Vita Spelt®, (2) the method used to handle Vita Spelt® and to manufacture Vita Spelt® products, (3) the Purity Foods manufacturing process and the controls in place to ensure that it results in the production of a pure product, and (4) the data demonstrating that Vita Spelt® does not contain wheat allergenic protein.

A. Purity Foods’ Vita Spelt®

1. Description of Purity Foods’ Vita Spelt®

Purity Foods utilizes proprietary cultivars of spelt specifically for human food. Other cultivars of spelt do not necessarily have the same characteristics as Vita Spelt®.⁵⁹ In addition, other products may be incorrectly labeled as spelt. For example, sometimes emmer wheat is sometimes incorrectly called spelt.⁶⁰ Further, some incorrectly label

Labelling of Prepackaged Foods, Codex Stan 1-1985 (Rev. 1-1991) § 4.2.1.4.; and EU COUNCIL DIRECTIVE 2003/89/EC, amending the main EU labeling DIRECTIVE 2000/13/EC.

⁵⁸ FDCA §§ 403(w)(6)(C) and 403(w)(7)(A)(ii).

⁵⁹ See Stallknecht, G.F., K.M. Gilbertson, & J.E. Ranney, *supra* note 23 (“Studies on the nutritional aspects of spelt report wide variability in the chemical constituents of the grain.”)

⁶⁰ Minnesota Department of Agriculture, *Spelt - Triticum aestivum* var. *spelt*, available at <http://www.mda.state.mn.us/mgo/crops/Spelt.htm> (last visited Dec. 12, 2005).

“Champ,” a spelt-wheat hybrid, as spelt. For these reasons, this notification is narrowly limited to Purity Foods’ Vita Spelt® and excludes all other products identified as spelt.

2. Purity Foods Vita Spelt® Handling and Manufacturing

Purity Foods maintains cultivation and manufacturing process controls that serve to prevent cross contamination. In brief, Purity Foods only uses particular sources and varieties of seed, controls planting schedules, and inspects the fields. Purity Foods also controls the raw material handling and storage, which includes the use of dedicated spelt bulk grain storage to prevent cross-contamination of our spelt. Additionally, we probe every load of grain, inspect the trucks, and test every load of raw grain. We train personnel in an understanding of necessary measures of control and the reasons for them.

Purity Foods’ production and organization of raw ingredients exceed industry standards. We do this not only out of pride in the superiority of our products, but because the buyers of our product—gourmet, organic, health food, and other specialty markets—require such a product. Many specifics of our methods and procedures are confidential and proprietary information.

3. Purity Foods Use of Spelt

Purity Foods has successfully marketed spelt products since 1990. In sixteen years of sales, there have been few allergic reactions to the company’s spelt products. On the other hand, many customers have submitted testimonials that indicate they can eat Purity Foods’ Vita Spelt® products although they are sensitive or allergic to wheat.⁶¹

⁶¹ See Appendix C.

B. Description of the Digestibility of Spelt

Proteins are the source of nearly all allergic responses.⁶² Scientific data on the protein composition of spelt suggest that spelt may be easier for humans to digest than wheat.⁶³ The data also supports the conclusion that spelt protein composition is different than that of common wheat.⁶⁴ A number of reports indicate that some with wheat allergies can consume spelt without incidence.⁶⁵

However, we recognize that a small number of exquisitely sensitive wheat-allergic individual may be unable to consume spelt. This notification is not intended to avoid informing potential consumers of the allergen potential of spelt, but only that spelt is not wheat; and consumers should not be confused by the misleading identification of spelt as wheat. Therefore, we propose going further than the FALCPA requires and informing consumers of the relationship of spelt to wheat. We propose that spelt should be labeled on the ingredient statement of food in one of the following formats:

Ingredients: [Conventional ingredient listing]. **Contains:** Spelt, an ancestor of wheat. Some wheat-allergic individuals may react to spelt.

or

Ingredients: Spelt (an ancestor of wheat), [other ingredients].

⁶² INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION, UNDERSTANDING FOOD ALLERGY (2001).

⁶³ Stallknecht, G.F., K.M. Gilbertson, & J.E. Ranney, *supra* note 23.

⁶⁴ *Id.*

⁶⁵ Small, E. *supra* note 27 (Noting that spelt has become is grown as a specialist crop, “often for people with allergies.”); Stallknecht, G.F., K.M. Gilbertson, & J.E. Ranney, *supra* note 23 (“The suggested attributes of spelt relative to wheat are ease of digestion, taste, and that individuals with certain allergies to common bread wheats can consume spelt.”); NICOLETTE M. DUMKE, ALLERGY COOKING WITH EASE at 21 (1992) (“In spite of the close relationship [to wheat], spelt is tolerated by many wheat-sensitive individuals.”); *and* Appendix C testimonials

C. Consumer Confusion

In addition to limiting food choices, excessive labeling of foods is likely to result in consumer confusion.⁶⁶ Allergic consumers will wonder why a food they have eaten for years suddenly is labeled with an ingredient to which they know they are allergic.⁶⁷

Some consumers may incorrectly believe they have recovered from their allergies, while others may get in the habit of ignoring the excessive and unhelpful warnings.⁶⁸ Both situations result in health risk to consumers because they miss information that is truly helpful.⁶⁹ In the face of overly cautious warnings, other consumers may simply engage in risk taking behavior.⁷⁰ In addition, too much information crowded onto food labels conflicts with the need to make this information clear and simple to read.⁷¹

Under the FALCPA, the common or usual name of the ingredient must include the food source from which the major food allergen is derived.⁷² Spelt is not derived

⁶⁶ See, e.g., Tom Trautman, *Labeling Food Allergens*, 59 FOOD TECH. 92 (Feb. 2005); and Presentation of Stephen L. Taylor, "Food Allergens: From Chaos, Confusion and Concern to Commitment and Control," Ohio State University (Oct. 28, 2004).

⁶⁷ Martha Filipic, *Food Law Confusing the Allergic*, CINCINNATI POST C1 (Nov. 10, 2004) available at: 2004 WLNR 7345175 (quoting Steve Taylor, professor and chair of Food Science and Technology at the University of Nebraska "Consumers will say, 'I've been eating this for 20 years and never had a problem, and now it has this allergen on the label.'")

⁶⁸ See UNITED KINGDOM FOOD STANDARDS AGENCY, NUT ALLERGY LABELLING: REPORT OF RESEARCH INTO THE CONSUMER RESPONSE (2002) available at: <http://www.foodstandards.gov.uk/multimedia/pdfs/nutallergyresearch.pdf> (indicating that too many allergen warnings run the risk of devaluing the label); and Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) available at: <http://www.ifst.org/allergy.pdf>.

⁶⁹ Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) available at: <http://www.ifst.org/allergy.pdf>.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Federal Food, Drug, and Cosmetic Act (FDCA) § 403(w)(1).

from wheat, and calling it a derivative of wheat will confuse consumers. The FALCPA was intended to make it easier for consumers to identify and avoid foods containing allergens to which they are allergic. Identifying spelt as wheat will only make it more difficult for consumers to determine which foods they may eat safely.

In keeping with the FALCPA purpose of eliminating public confusion over allergens in their food, spelt should be identified as spelt. This identification is in keeping with the public health protections in place in the Codex Alimentarius and European Union (EU) law. The Codex through its General Standard for the Labelling of Prepackaged Foods recognizes that certain foods and ingredients that cause hypersensitivity⁷³ should always be declared.⁷⁴ Spelt is one of these foods.⁷⁵ Note, however, that this Codex standard recognizes spelt as a different ingredient than wheat and requires labeling of spelt as spelt, not as wheat.⁷⁶

Likewise, EU Council Directive requires manufacturers to declare any of a specified list of foods that are associated with hypersensitivity syndromes,⁷⁷ or any

⁷³ The Codex standard is concerned not only with food allergies but foods known to be associated with intolerances, such as the gluten intolerance of celiac disease.

⁷⁴ CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS CODEX STAN 1-1985 § 4.2.1.4. (Rev. 1-1991).

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ Like the Codex standards, the EU Directive is concerned not only with allergens, but also foods known to be associated with intolerances. The gluten proteins of grains that trigger celiac disease can also cause IgE-mediated allergies; however, the inclusion of gluten containing grains in the Codex and EU requirements to cover both allergenic properties and celiac toxic effects fails to note that the dose-response and management issues regarding these diseases are distinctly different.

product derived from such foods.⁷⁸ The EU law on allergens recognizes spelt as a distinct ingredient from wheat.⁷⁹ Spelt is labeled as spelt, not wheat.⁸⁰

V. CONCLUSION

Vita Spelt® as described in this notification, does not contain allergenic wheat protein as defined by the FALCPA and is, therefore, exempt from the allergen labeling requirement of section 203(w)(1) of the Federal Food, Drug and Cosmetic Act (as amended by the FALCPA). The exemption is anticipated in Section 403(w)(7)(A)(i) of the Federal Food, Drug and Cosmetic Act.

The FALCPA is intended to advance consumer awareness of sources of major food allergens. However, Vita Spelt® is not wheat and; therefore, Vita Spelt® is not a major food allergen. The FALCPA is also intended to advance consumer awareness of ingredients derived from major food allergens. However, Vita Spelt® is not derived from wheat. The FALCPA is also intended to clarify labeling for consumers by having the sources of major food allergens identified by their common or usual name. However, wheat is not the common or usual name for Vita Spelt®.

In addition, identifying Vita Spelt® as being a form of wheat does not serve the intent of the FALCPA because some individuals with wheat allergies may consume Vita Spelt® without incidence. The intent of the Food Allergen Labeling and Protection Act is to better inform consumers who are known to be allergic to one of the eight major food allergens that a specific food product contains the allergen so they may avoid the allergen. Identifying Vita Spelt® as being derived from wheat may incite some

⁷⁸ EU COUNCIL DIRECTIVE 2003/89/EC, amending the main EU labeling DIRECTIVE 2000/13/EC.

⁷⁹ Annex IIIa ingredients referred to in EU COUNCIL DIRECTIVE 2003/89/EC include cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains).

⁸⁰ *Id.*

consumers to risk taking behavior with the allergenic food they should avoid. It may cause the product to be perceived equivalent to common wheat. Such situations can present a risk to public health, which contradicts the intent of FALCPA. As recognized by both the Codex and EU requirements, identifying spelt as spelt advances the public health need to inform potentially sensitive consumers.

This notification complies with the requirements of Section 403(w)(7)(A)(i) of the Federal Food, Drug, and Cosmetic Act and with the intent of the Food Allergen Labeling and Consumer Protection Act — to protect public health. The FALCPA was enacted to better inform consumers, allowing them to make informed choices and to protect public health. Under the act, the common or usual name of the ingredient must include the food source from which the major food allergen is derived. This act was designed to make it easier for consumers to identify and avoid foods containing allergens to which they are allergic. While consumers who are allergic to a major allergen have to restrict their dietary choices, it is important that they are not unnecessarily alarmed by labels, nor further restricted in their dietary options when it is unnecessary.

VI. REFERENCE LIST

- DUMKE, NICOLETTE M., ALLERGY COOKING WITH EASE at 21 (1992).
- Lipps, Patrick E., *Loose Smut of Wheat, Spelt and Barley*, Fact Sheet AC-12-96, The Ohio State University Extension, Plant Pathology, 2021 Coffey Road, Columbus, OH 43210-1087.
- Magness, J.R., G.M. Markle, C.C. Compton, *Food and feed crops of the United States. Interregional Research Project IR-4*, IR Bul. 1 (Bul. 828 New Jersey Agr. Expt. Sta. 1971).
- Minnesota Department of Agriculture, *Spelt - Triticum aestivum var. spelt*, available at <http://www.mda.state.mn.us/mgo/crops/Spelt.htm> (last visited Dec. 12, 2005).
- Small, E. *New crops for Canadian agriculture*. p. 15-52. In: J. JANICK (ED.), PERSPECTIVES ON NEW CROPS AND NEW USES (1999 ASHS Press, Alexandria, VA) available at <http://www.hort.purdue.edu/newcrop/proceedings1999/v4-015a.html#wheat> (last visited Dec. 12, 2005).
- Stallknecht, G.F., K.M. Gilbertson, and J.E. Ranney, *Alternative wheat cereals as food grains: Einkorn, emmer, spelt, kamut, and triticale*. p. 156-170, in J. JANICK (ED.), PROGRESS IN NEW CROPS (ASHS Press, Alexandria, VA 1996) available at <http://www.hort.purdue.edu/newcrop/proceedings1996/V3-156.html#SPELT> (last visited Dec. 12, 2005).
- Zohary, Daniel & Hoff, Maria, *Domestication of Plants of the Old World*, 2nd ed. (1994).

VII. APPENDICES

- A. James F. Fitzpatrick, Washington State Executive Director for the Farm Service Agency State Office, U.S. Department of Agriculture, Letter to Rene Featherstone (Aug. 6, 2003)**
- B. Scarbrough, F. Edward, F. Edward, U.S. Manager for Codex, USDA, E-mail forwarded to Senator Stabenow's office (Sept. 6, 2005)**
- C. Testimonials of Consumers Regarding Lack of Wheat Allergenicity of Purity Foods spelt (representative samples)**

August 6, 2003

René Featherstone
Lentz Spelt Farms
PO Box 2
Marlin WA 98832

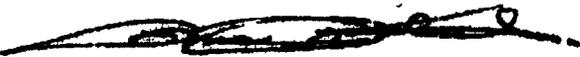
Dear Mr. Featherstone:

We are in receipt of your letter regarding the classification of spelt being grown in the Columbia Basin by Mr. Tony Lutz of Royal City. Your concern is that our Grant County FSA Office in Ephrata would not accept the wheat classification for proof of yield on his grain base. We have also reviewed the Laboratory Report of Analysis on the grain that was delivered to McKay Seed Company in Moses Lake.

We do agree that spelt is *Triticum aestivum* L., the taxonomical name for wheat. However, further review shows the taxonomical name of spelt to be *Triticum aestivum* subsp. *spelta* L. as determined by the USDA, ARS, National Genetic Resources Program, Germplasm Resources Information Network (GRIN) (<http://www.ars-grin.gov/npgs/hr/taxgenform.html>). This makes the grain closely related to but distinctly different than commercial wheat.

According to the U.S. Standards for Wheat (which can be found at <http://www.usda.gov/gipsa/reference-library/standards/standards.htm>), the reference lists common wheat as *Triticum aestivum* L., club wheat as *T. compactum* and durum wheat as *T. durum* Desf. These are the only wheat classifications that meet U.S. standards. The definition of wheat goes on to indicate that any sample of wheat cannot include more than 10 percent of "other grains". Specifically included with the "other grains" is spelt, which by virtue of it being considered an "other grain", is unfortunately not considered wheat for USDA or FSA purposes.

Please let me know if there are any further questions you have on this determination. In my absence, please feel free to contact our program specialist, Genie Caudill at 509.323.3017.



James F. Fitzgerald
State Executive Director

mec

cc: Ben Davis, Grant County FSA Office

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Appendix A

From: Scarbrough, Ed
Sent: Tuesday, September 06, 2005 11:03 AM
To: Kizzier, Kyle, Almeida, Paulo
Cc: Matten, Ellen
Subject: RE: codex question

The constituent may be referring to the Codex General Standard on Food Labelling:

*"4.2.1.4 The following foods and ingredients are known to cause hypersensitivity and shall always be declared:
Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
Crustacea and products of these;
Eggs and egg products;
Fish and fish products;
Peanuts, soybeans and products of these;
Milk and milk products (lactose included);
Tree nuts and nut products; and
Sulphite in concentrations of 10 mg/kg or more."*

In this standard, spelt is listed with wheat because they both contain gluten. Gluten intolerance is a serious medical condition and these cereals must always be labeled to alert the intolerant to their presence.

The list of allergens was adopted by Codex a few years ago - not at the recent Commission meeting. However, I think that the constituent has confused spelt's listing in the labeling section with the Codex standard for Wheat and Durum Wheat. Wheat is defined in the Codex standard as "(2.1) *Wheat is the grains obtained from varieties of the species Triticum aestivum L.*" Spelt is closely related, but comes from the species *Triticum spelta*, and is grown widely in Europe.

Ed Scarbrough

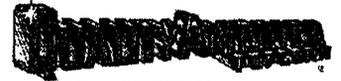
F. Edward Scarbrough, Ph.D.
U.S. Manager for Codex
Tel: (202) 720-2057
Fax: (202) 720-3157

PURITY FOODS INC.



Offices and Warehouse:
2871 W Jolly Road, Okemos, MI 48864 USA
Telephone: (517) 351-9231, FAX: (517) 351-9391

VITA-SPELT



ALLERGY QUESTIONNAIRE

How did you learn about Vita Spelt?

magazine - please specify _____
news ~~books~~ - please specify In a grocery store in our local park
local health food store - please specify the owner told your company
physician/health care provider on the table was a bit Spelt
other: _____

What grain allergies do you have? my children are allergic to wheat

Do you have a gluten intolerance? Probably

What grains can you eat? they can tolerate rice, barley, oats

In which form did you sample Vita Spelt?

pasta (spaghetti, elbows, egg noodles, shells, rotini, lasagne or angel hair)

flour Yes

flakes _____

kernels _____

bread mix _____

pancake/muffin mix _____

cookie mix _____

bread _____

other: _____

Did you have any adverse reactions? No

If yes, please describe the reaction: _____

What other Vita Spelt products would you like to purchase?

other pasta - please specify if you could produce a milk egg free pasta,

cold cereal a milk-egg-free cereal we would be very

snack foods - please specify happy to try them

May we use your comments/name for promotion or research purpose? _____

Signature: Karen Poole Date: May 4 1992

Additional Comments: I can tell you what a difference your Vita-Spelt flour has made in our daily lives. We can enjoy bakery products again that are soft, taste good, have a pleasant texture and are nutritious.

For a copy of the booklet, "SPELT - THE WONDERFOOD" by Dr. W. Strehlow, which depicts the many benefits of this nutritional grain and contains a collection of delicious recipes, please send \$3.00 to Purity Foods at the above address.

As a mother I am especially grateful that your
wheat flour is now available to us. It is very
difficult to provide a nutritious and balanced
diet when you are coping with ^{multiple} allergies.
I do find that companies who provide special
products tend to overlook the fact that many
people who are allergic to a food such as wheat
~~are~~ are also allergic to other foods as well. We must
avoid milk, eggs, corn and nuts as well. It is
practically impossible for me to purchase packaged
products the mixes as they nearly always contain ^{that}
milk products, eggs or corn in some form. These
are very common allergens and I am often wondering
if a company will someday come up with a product
line that eliminates these major allergens. It would
be suitable for a wide range of allergic people, unlike
them I continue to bake and cook from scratch.
Thanks to Vita-Spell my biscuits are light and
fluffy and my muffins look and taste like
muffins (you would be amazed what strange things
they take on when using other flours). I am very
grateful for companies like yours that take ^{an} ~~an~~
interest in us and make products available for
us to use. Thank you for your time and
trouble,

Mrs K G Poole

PURITY FOODS INC.



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2871 W. Jolly Road, Okemos, MI 48864 USA
Telephone: (517) 351-9231, FAX: (517) 351-9391

VITA-SPELT



ALLERGY QUESTIONNAIRE

How did you learn about Vita Spelt?

magazine - please specify _____
newsletter - please specify _____
local health food store - please specify OWNER OF GREATER BAKE FOODS
physician/health care provider CO-08
other: _____

What grain allergies do you have? WHEAT + SOY

Do you have a gluten intolerance? LOW

What grains can you eat? SPELT, RYE, CORN, RICE

In which form did you sample Vita Spelt?

pasta (spaghetti, elbows, egg noodles, shells, rotini, lasagne or angel hair)
~~_____~~ SHELLS
flour ✓ _____ flakes _____
kernels _____ bread mix _____
pancake/muffin mix _____ cookie mix _____
bread _____
other: _____

Did you have any adverse reactions? NO

If yes, please describe the reaction: _____

What other Vita Spelt products would you like to purchase?

other pasta - please specify ELBOWS, SPAGHETTI
cold cereal YES
snack foods - please specify _____

May we use your comments/name for promotion or research purpose? YES

Signature: [Signature] Date: 11-12-98

Address: 2290 BROAD ST. BAKER CITY, ORE. 97014

Additional Comments: MY HUSBAND + I HAVE
NUMEROUS ALLERGIES. SPELT IS AN
ANSWER TO MANY!

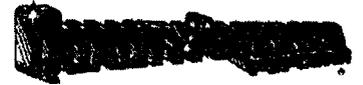
For a copy of the booklet, "SPELT - THE WONDERFOOD" by Dr. W. Strehlow, which depicts the many benefits of this nutritional grain and contains a collection of delicious recipes, please send \$3.00 to Purity Foods at the above address.

PURITY FOODS INC.



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Telephone: (517) 351-9231, FAX: (517) 351-9391

VITA-SPELT



ALLERGY QUESTIONNAIRE

How did you learn about Vita Spelt?

magazine - please specify _____
newsletter - please specify _____
local health food store - please specify WHOLE FOODS MARKET - AUSTIN, TX
physician/health care provider DR ROY MULLINS RECOMMENDED
other: SPELT FLOUR PRODUCTS

What grain allergies do you have? WHEAT & CORN & MALTED BARLEY
Do you have a gluten intolerance? NO
What grains can you eat? ALL OTHERS

In which form did you sample Vita Spelt?

pasta (spaghetti, elbows, egg noodles, shells, rotini, lasagne or angel hair)

flour ✓ _____ flakes _____
kernels _____ bread mix _____
pancake/touffia mix _____ cookie mix _____
bread _____
other: _____

Did you have any adverse reactions? NO
If yes, please describe the reaction. _____

What other Vita Spelt products would you like to purchase?

other pasta - please specify LASAGNE
cold cereal: SOMETHING LIKE OATIOS
snack foods - please specify _____

May we use your comments/name for promotion or research purpose? YES

Signature: Laura Dawson Date: 9/2/92
Address: 13313 Penthouse Quater Austin TX 78729

Additional Comments: I'VE BEEN LOOKING FOR LASAGNE NOODLES EVER SINCE I FOUND OUT I HAD THESE FOOD ALLERGIES THIS SPRING. PLEASE GET THEM TO THE AUSTIN WHOLE FOODS NORTH OR DAVENPORT

For a copy of the booklet, "SPELT - THE WONDERFOOD" by Dr. W. Stuchlow, which depicts the many benefits of this nutritional grain and contains a collection of delicious recipes, please send \$3.00 to Purity Foods at the above address.

OVER

*Send copy to Dawson
Att: Pam*



PURITY FOODS, INC.

Offices and Warehouse:

2871 W. Jolly Road

Okemos, MI 48864 USA

Telephone: (517) 351-9231 FAX: (517) 351-9391

Patricia King

1343 Ohltown Rd.

Youngstown, OH 44515

ALLERGY QUESTIONNAIRE

- How did you learn about Vita-Spelt?
 magazine - please specify _____
 newsletter - please specify _____
 local health food store - please specify friend from local store
 physician/health care provider _____
 other: _____
- What grain allergies do you have? wheat
- What grains can you eat? all except wheat
- In which form did you sample Vita-Spelt?
 pasta _____
 flour _____
 kernal _____
 other: _____
- Did you have any adverse reactions? none
 If yes, please describe the reaction. _____
- What other Vita-Spelt products would you like to purchase?
 other pasta - please specify _____
 flake cereal _____
 pancake mix _____
 muffin mix _____
 other: cookies?
- May we use your comments/name for promotion or research purpose? yes

8 Additional Comments:

I just made my first Spelt
cranberry muffins & they were great! I was
so excited that they tasted just like wheat
flour. Very good texture & flavor. I just
love the Spelt flour! Where have you been hiding?

For a copy of the booklet, "SPELT - THE WONDER FOOD" by Dr. W. Strehlow, which depicts the many benefits of this nutritional grain and contains a collection of delicious recipes, please send \$3.00 to Purity Foods at the above address.

Please send recipes on they
are available.

Appendix C

page 30

Pat King
1343 Ohltown Rd.
Yo., Oh. 44515

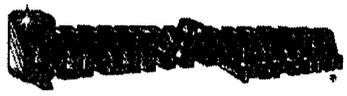
2/11/99

PURITY FOODS INC.



Offices and Warehouse:
2871 W. Jolly Road, Okemos, MI 48864 USA
Telephone: (517) 351-9231, FAX: (517) 351-9391

VITA-SPELT



ALLERGY QUESTIONNAIRE

How did you learn about Vita Spelt?
magazine - please specify _____
newsletter - please specify _____
local health food store - please specify Grocery Store, Co Op
physician/health care provider _____
other: _____

What grain allergies do you have? wheat, whole & white
Do you have a gluten intolerance? X
What grains can you eat? Rice, Buckwheat, Millet, Teff

In which form did you sample Vita Spelt?
pasta (spaghetti, elbows, egg noodles, shells, rotini, lasagne or angel hair)
flour X _____ flakes X _____
cereals X _____ bread mix _____
pancake/muffin mix _____ cookie mix _____
bread _____
other: Have used it in Europe 50 years ago. Could not find it in this country, still great taste.

Did you have any adverse reactions? NO
If yes, please describe the reaction: _____

What other Vita Spelt products would you like to purchase?
other pasta - please specify _____
cold cereal _____
snack foods - please specify Spelt Coffee

May we use your comments/name for promotion or research purpose? Yes
Signature: Rosemary Dany Date: 11-17-92
Address: 2331 S. Brainerd Ave - Okemos, MI, 48864

Additional Comments: Pancake & Muffin mix are very hard to find in Health Food Stores. Spelt does not bother my wheat & dairy allergies. Spelt is a wonderful full replacement for wheat. Thank you for giving me this info.
For a copy of the booklet, "SPELT - THE WONDERFOOD" by Dr. W. Strehlow, which depicts the many benefits of this nutritional grain and contains a collection of delicious recipes, please send \$3.00 to Purity Foods at the above address.



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Telephone: (517) 351-9231 FAX: (517) 351-9391

Don or Mary Ann Geck

392 Sole Rd.

Selah, WA 98942

ALLERGY QUESTIONNAIRE

1. How did you learn about Vita-Spelt?
 magazine - please specify _____
 newsletter - please specify _____
 local health food store - please specify _____
 physician/health care provider Dr. Murray Black: Yakima, WA.
 other: _____

2. What grain allergies do you have? Wheat - also am "gluten" intolerant

3. What grains can you eat? Rice, spelt, quinoa, amaranth
 (occasionally)

4. In which form did you sample Vita-Spelt?
 pasta X
 flour X
 kernal _____
 other: _____

5. Did you have any adverse reactions? NO! ☺
 If yes, please describe the reaction. _____

6. What other Vita-Spelt products would you like to purchase?
 other pasta - please specify _____
 flake cereal _____
 pancake mix NONE
 muffin mix _____
 other: _____

7. May we use your comments/name for promotion or research purpose? YES!

8. Additional Comments: Vita-Spelt Flour has been a life-saver for me!
I had thought that my wheat allergy & gluten intolerance meant the
end for baked goods, etc. But I've been able to use the flour with
100% success. Spelt makes me feel energetic - I love it! ☺

For a copy of the booklet, "SPELT - THE WONDER FOOD" by Dr. W. Strehlow, which depicts the many benefits of this nutritional grain and contains a collection of delicious recipes, please send \$3.00 to Purity Foods at the above address.

3.4.91

LAW OFFICE OF NEAL D. FORTIN

FAX: (517) 913-5927

FACSIMILE TRANSMITTAL SHEET

TO:	Ms. Catherine Copp	FROM:	Neal D. Fortin
COMPANY:	Food and Drug Administration	DATE:	1/11/2006
FAX NUMBER:	(301) 436-2637	TOTAL NO. OF PAGES INCLUDING COVER:	1
SUBJECT:	Notification Confidentiality	PHONE NUMBER:	(517) 775-4629

NOTES/COMMENTS:

The Notification I submitted on December 23, 2005, pursuant to § 403(w)(7) of the Food Allergen Labeling and Consumer Protection Act, was marked confidential and proprietary. Although so denominated, I understand and do not object to my document being placed in the public record.

Please contact me if you have any questions or need more information.