

Annus Horribilis



Spices and Food Allergy Regulatory and Business Issues

**ASTA Annual Meeting
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Cumin?



Food Allergy Labeling and Consumer Protection Act of 2004 (FALCPA)

FALCPA was enacted by Congress in 2004 to respond to concerns about food allergens, especially concerns about children.

- Special concern was children with peanut allergy.

Until FALCPA was enacted there was no requirement to label foods specifically for the presence of allergens.

- Foods had to be labeled with a list of ingredients but this was not viewed as enough to protect sensitive individuals.

Food Allergy Labeling and Consumer Protection Act of 2004 (FALCPA)

FALCPA applies only to foods regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act.

- “Packaged foods” – domestic and imported

FALCPA does not apply to meat and poultry, and other products regulated by the U.S. Department of Agriculture (USDA).

- However, USDA may in its discretion to protect the public health require labeling of products for the presence of food allergens.

What are food allergens under FALCPA?

FALCPA specifically identifies the Big 8 as “major food allergens” subject to labeling.

1. Milk
2. Egg
3. Fish
4. Crustacean shellfish – not molluscan shellfish
5. Tree nuts
6. Wheat
7. Peanuts
8. Soybeans

What are food allergens under FALCPA?

FALCPA covers the Big 8 plus ingredients containing protein derived from them.

- Food additives and GRAS food ingredients derived from the Big 8 are subject to FALCPA.
- Carbohydrate carriers (derived from wheat or soy) are subject to FALCPA.

Labeling must be by common or usual name

- For tree nuts, fish and crustacean shellfish the individual species must be declared

What are NOT food allergens under FALCPA?

Raw agricultural commodities are not covered by FALCPA.

- Fresh fruits and vegetables and other RACs are not subject to the FALCPA requirements.

There are no spices among the Big 8

- Sesame and mustard are not covered by FALCPA but are on the ASTA Spice List
- Sesame and mustard are considered allergens in other countries including Canada.
- Sesame is the subject of a Citizens Petition submitted by CSPI to FDA to add it to the Big 8.

FALCPA is a public health statute

FALCPA, unlike many other FDA labeling requirements, is a public health statute meant to address a specific health and safety issue – food allergy.

Public health and safety is FDA's top priority explaining their focus on the spice industry on the issues of microbial contamination and allergen labeling.

- FDA generally doesn't focus the enforcement of non-safety related labeling issues or look for new non-safety labeling responsibilities such as non-GMO labeling.

Can foods containing allergens be sold?

Yes, but only if they are properly labeled.

The presence of an allergen in a food doesn't make the food illegal to sell but it is illegal if the allergen is not properly declared.

- A food containing an undeclared allergen is not necessarily adulterated under the FFDCA but it is misbranded.
- Undeclared allergens are a common source of recalls.

What is proper labeling under FALCPA?

The food label ingredient statement must contain the ***common or usual name*** of the major food allergen by either:

1. Having the common or usual name in the ingredient statement or the common or usual name in parentheses after the ingredient derived from it in the ingredient statement.
2. Use of “contains” labeling next to the ingredient statement with the common or usual name.

Single ingredient foods that are allergens may comply by stating the common or usual name of the food allergen or by using “Contains” labeling.

What about “advisory statements?”

Advisory statements are “May contain” statements.

- Includes statements describing the potential presence of unintentional ingredients.

FALCPA does not address advisory labeling but FDA has concerns about such labeling.

- “Should not be used as a substitute for adherence to current Good Manufacturing Practices.”
- Can reduce consumer options
- If they are used, they “must be truthful and not misleading.”

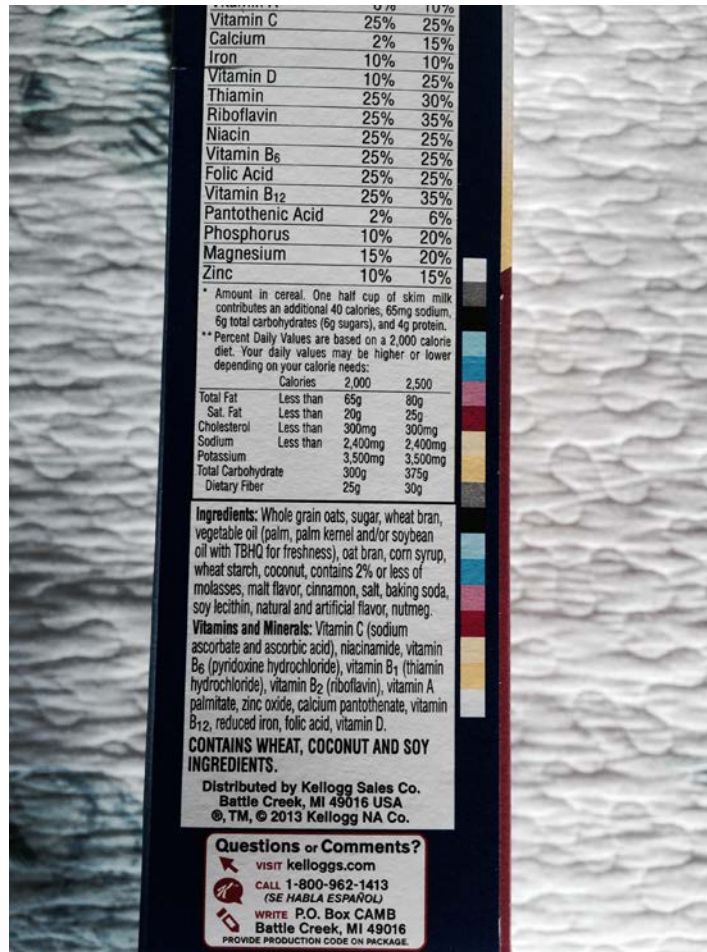
Does a food that is an allergen have
to have a separate declaration?



The ingredient statement is not enough – the common or usual name of this food is “pasta”



The ingredient statement is not enough – the common or usual name for this food is “cereal”



Nutrition Facts

	Amount in cereal	% Daily Value*
Vitamin C	25%	25%
Calcium	2%	15%
Iron	10%	10%
Vitamin D	10%	25%
Thiamin	25%	30%
Riboflavin	25%	35%
Niacin	25%	25%
Vitamin B ₆	25%	25%
Folic Acid	25%	25%
Vitamin B ₁₂	25%	35%
Pantothenic Acid	2%	6%
Phosphorus	10%	20%
Magnesium	15%	20%
Zinc	10%	15%

* Amount in cereal. One half cup of skim milk contributes an additional 40 calories, 65mg sodium, 6g total carbohydrates (6g sugars), and 4g protein.

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat. Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Ingredients: Whole grain oats, sugar, wheat bran, vegetable oil (palm, palm kernel and/or soybean oil with TBHQ for freshness), oat bran, corn syrup, wheat starch, coconut, contains 2% or less of molasses, malt flavor, cinnamon, salt, baking soda, soy lecithin, natural and artificial flavor, nutmeg.

Vitamins and Minerals: Vitamin C (sodium ascorbate and ascorbic acid), niacinamide, vitamin B₆ (pyridoxine hydrochloride), vitamin B₁ (thiamin hydrochloride), vitamin B₂ (riboflavin), vitamin A palmitate, zinc oxide, calcium pantothenate, vitamin B₁₂, reduced iron, folic acid, vitamin D.

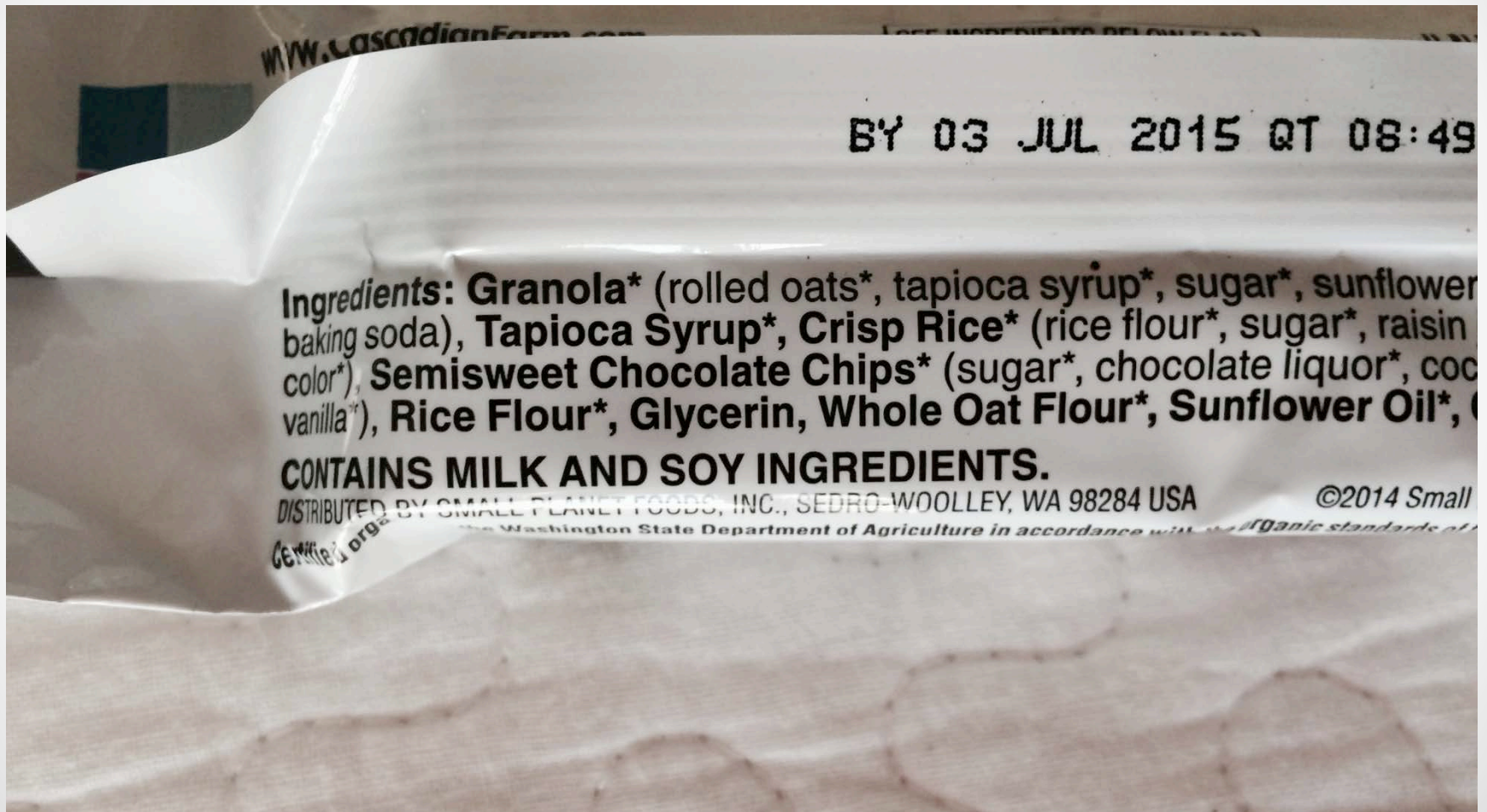
CONTAINS WHEAT, COCONUT AND SOY INGREDIENTS.

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The ingredient statement is not enough



Traces?

Nutrition Facts
 Serving Size 1 Bar (68g)
 Calories 240
 Calories from Fat 45

Total Fat 5g	8%	Sodium 150mg	6%	Insoluble Fiber
Sat. Fat 1.5g	8%	Potassium 230mg	7%	Sugars 23g
Trans Fat 0g		Total Carb. 44g	15%	Other Carb. 17g
Cholest. 0mg	0%	Dietary Fiber 4g	16%	Protein 10g

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

INGREDIENTS: Organic Brown Rice Syrup, ClifPro® (Soy Rice Crisps [Soy Protein Isolate, Rice Flour, Barley Malt Extract], Organic Roasted Soybeans, Organic Soy Flour), Organic Rolled Oats, Chocolate Chips (Dried Cane Syrup, Unsweetened Chocolate[†], Cocoa Butter[†], Soy Lecithin, Vanilla Extract), Organic Cane Syrup, ClifCrunch® (Organic Oat Fiber, Apple Fiber, Inulin [Chicory Extract], Organic Milled Flaxseed, Organic Psyllium), Organic Date Paste, Organic Soy Butter (Organic Roasted Soybeans, Organic Soybean Oil, Salt), Organic Sunflower Oil, Molasses Powder, Sea Salt, Natural Flavors, Cinnamon. **VITAMINS & MINERALS:** Dicalcium Phosphate, Ascorbic Acid (Vit. C), Magnesium Oxide, DL-Alpha Tocopheryl Acetate (Vit. E), Ferric Orthophosphate (Iron), Beta Carotene (Vit. A), Zinc Citrate, Biotin, Niacinamide (Vit. B3), D-Calcium Pantothenate (Vit. B5), Phytanadione (Vit. K1), Manganese Gluconate, Copper Gluconate, Riboflavin (Vit. B2), Folic Acid (Vit. B9), Sodium Selenite, Thiamin (Vit. B1), Pyridoxine Hydrochloride (Vit. B6), Ergocalciferol (Vit. D2), Cyanocobalamin (Vit. B12), Chromium Chloride, Potassium Iodide. **ALLERGEN STATEMENT: CONTAINS SOY. MAY CONTAIN TRACES OF MILK, PEANUTS, WHEAT, AND TREE NUTS. WE SOURCE INGREDIENTS THAT ARE NOT GENETICALLY ENGINEERED.**

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What about an allergen that is not intentionally added but is present through unintentional “cross contact?”

Analytical techniques now allow the detection of allergens at very low ppm and ppb levels.

- If you look for something you’re likely to find it!

FDA policy – FALCPA’s labeling requirements do not apply when allergens are unintentionally added to foods as the result of cross-contact. Cross-contact is when residues or trace amounts of an allergen are unintentionally incorporated into a food that is not intended to contain the allergen. **Cross-contact may result from customary methods of growing, harvesting, storing, transporting or producing food.**

What has FDA told us about how to address issues of allergens in spices?

There are no thresholds for allergens in spices or other foods.

- Can't dilute or test away a positive.

Risk assessments for individual foods are an option.

- This involves identifying the level of the allergen present, the probable exposure (consumption) to the allergen in the food, and a quantitation of potential risk.

Apply the principles of Good Manufacturing Practices and Good Agricultural Practices.

Good Agricultural Practices and Good Manufacturing Practices

Apply sound GAP and GMP principles meaning:

- Know and control your supply chain to the best of your abilities!
- This will become even more prominent with the implementation of FSMA regulations.

If the price for the spice is too good to be true then it probably is!

- You get what you pay for – don't buy yourself a problem!

What are your responsibilities as an responsible and ethical spice vendor?

Know and control your supply chain.

- GAPs and GMPs.
- Understand the operations and implications of the recall process.

Communicate thoroughly with your food manufacturing customers.

- Make sure your customers have all of the information that they need to label their foods properly.
- Your customers' foods must comply with FALCPA but they can't without accurate information from you.

What can we learn from the recent cumin travails?

FDA takes safety issues very seriously.

The root cause remains unclear but a prime suspect is economically-motivated intentional adulteration for the initial incidents with high levels ($>1,000$ ppm) of peanut protein resulting in the initial recalls.

- Economic adulteration usually isn't a high priority for FDA unless there is a safety issue.

Incidents with low levels of peanut protein resulting in recalls appear to be the result of unintentional cross-contact.

What can we learn from the recent cumin travails?

To summarize:

Know and control your supply chain.

- GAPs and GMPs

If high levels of an allergen are detected, communicate appropriately and thoroughly, and in compliance with FDA requirements on recalls and possible RFR responsibilities.

- Failure to communicate thoroughly with all stakeholders can damage your company and the entire spice industry.

What can we learn from the recent cumin travails?

For low levels of allergens detected in spices, focus on the possibility of unintentional cross-contact in the supply chain.

- Know and control your supply chain.

Focus on the use of quantitative risk assessment to address incidents of the presence of low levels of allergens.

Resources

ASTA website has much valuable information:

- FDA Consumer Advisory on Cumin
- FDA Guidance for industry on FALCPA
- Food Chemicals Codex draft guidance on food fraud mitigation
- ASTA GAP guide

Much information on FDA's website.

Food Allergy Research and Resource Program at the University of Nebraska.

Thank you!