

# Allergen Control for Food Processors



## Presentation Materials

California Department of Public Health  
Food and Drug Branch  
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# Resource 1



# Food Allergens and Controls Scorecard for Success



#	Allergen Identification	Fully	Partially	Not At All	N/A
1	Tree Nuts and/or tree nut derivatives are prohibited from product formulations and are excluded from the facility (almonds, Brazil nuts, cashews, coconuts, hazelnuts (filberts), macadamia nuts, pecans, pine nuts (pinyon, pinon), pistachios, walnuts, nut butters, oils, etc.).				
2	Peanuts and peanut derivatives are prohibited from product formulations and are excluded from the facility (peanut - pieces, protein, oil, butter, flour, mandelona nuts (an almond flavored peanut product), etc.).				
3	Milk and milk derivatives are prohibited from product formulations and are excluded from the facility (milk caseinate, whey, yogurt powder, cream cheese, etc.).				
4	Eggs and egg derivatives are prohibited from product formulations and are excluded from the facility (frozen yolk, egg white powder, egg protein, egg white, or yolk, etc.).				
5	Wheat and wheat derivatives are prohibited from product formulations and are excluded from the facility (flour, starches and brans, etc. Includes other wheat varieties such as spelt, durum, kamut, emmer, etc.).				
6	Soy and soy derivatives are prohibited from product formulations and are excluded from the facility (lecithin, oil, tofu and protein isolates, etc.).				
7	Fish and fish derivatives are prohibited from product formulations and are excluded from the facility (fish, fish protein, fish oil, extracts, etc.).				
8	Shellfish and shellfish derivatives are prohibited from product formulations and are excluded from the facility (crab, lobster, shrimp, etc.).				
	<b>Raw Materials</b>				
9	Written procedures are in place to assess incoming materials for food allergens.				
10	Suppliers are required to provide letters of guarantee, certificates of analysis, or similar documents for each shipment of ingredients.				
11	All raw materials are only purchased and received from pre-screened and approved suppliers.				
12	Lists of product specifications are provided to suppliers of raw materials and ingredients.				
13	Labels of incoming raw materials or ingredients are inspected upon receipt to check for food allergens and are properly identified.				

# Food Allergens and Controls Scorecard for Success



	Raw Materials (continued)	Fully	Partially	Not At All	N/A
14	Sub-ingredients and processing aids are reviewed for food allergens at regularly scheduled intervals and whenever new suppliers are used.				
15	Incoming ingredients and raw materials containing food allergens are clearly marked or tagged upon receipt (employing color coding, multiple languages, etc.).				
16	Damaged containers and spills identified are promptly segregated and removed.				
17	Dedicated pallets/bins are used to segregate allergenic ingredients.				
18	Allergenic ingredients are stored in specific, designated areas (lower shelves, different rooms, etc.) to avoid cross-contamination.				
19	Incoming raw materials and ingredients are inspected for evidence of contamination with the "Top 8 Food Allergens."				
20	Adequate, written records are maintained to track raw materials, ingredients, and products for product rotation, tracebacks, and traceforwards.				
	Facility Design				
21	The flow of products through the facility minimizes the potential for cross contact between non-allergenic foods and allergenic foods.				
22	Physical barriers are used to maintain separation between different food commodities and processing lines.				
23	Air handling and filtration systems are in place and are routinely maintained.				
24	Adequate space has been designated for each operation (staging, processing, packaging, storage, etc.) to allow for separation, inspection, cleaning, and sanitizing.				
	Manufacturing and Processing				
25	Labels of ingredients and raw materials are verified and rechecked before processing.				
26	Appropriate personnel conduct pre-operational inspections of all food processing lines/equipment for residues and potential sources for food allergen cross contact.				
27	Production runs are properly scheduled to minimize the potential for cross-contamination.				
28	Procedures to prevent cross-contamination from processing equipment are documented.				
29	Adequate time is allotted during changeovers for allergen control measures to be employed.				
30	Work-in-progress is protected from cross-contamination by other products on adjacent product lines.				

# Food Allergens and Controls Scorecard for Success



	<b>Manufacturing and Processing (continued)</b>	<b>Fully</b>	<b>Partially</b>	<b>Not At All</b>	<b>N/A</b>
31	Separate and dedicated equipment are used exclusively for the production of allergenic foods.				
32	Manufacturing/production records are maintained with sufficient information to facilitate a traceback/traceforward (lot codes, best if used by dates, etc.).				
33	A color coding, tagging or other system is in place to clearly identify equipment used for the production containing one of the "Top 8 Allergens."				
34	Formulations and recipes are periodically reviewed to determine if any of the "Top 8 Food Allergens" used can be replaced by non-allergenic ingredients.				
	<b>Cleaning and Sanitation</b>				
35	Specific, step-by-step instructions for cleaning all equipment are documented.				
36	Cleaning and sanitation procedures have been evaluated and have been determined to be effective through validation by an applicable analytical method (ELISA).				
37	Cleaned equipment and utensils are secured at the end of the workday/shift and properly stored to prevent accidental recontamination.				
38	Each cleaning and sanitation activity is documented on a checklist/log by the operator or sanitation employee.				
39	Cleaning logs document which pieces of equipment were cleaned, identity of employee who performed the activity, and the time it was performed.				
40	Cleaning logs are regularly reviewed for compliance with the allergen control program by a supervisor or manager.				
	<b>Rework</b>				
41	A rework plan is documented for all products.				
42	Food products containing allergens are identified and clearly marked when reworked.				
43	Rework is only processed during the same production run.				
44	Records are maintained for all rework that contain any of the "Top 8 Food Allergens."				
45	When rework is used in a different formulation, it is clearly marked and labeled with relevant information.				
	<b>Labeling and Packaging</b>				
46	Label and packaging specifications are documented and provided to suppliers.				
47	Label and packaging specifications are reviewed with suppliers at least annually, and whenever new suppliers are used.				

# Food Allergens and Controls Scorecard for Success



	Labeling and Packaging (continued)	Fully	Partially	Not At All	N/A
48	Old, unused, and outdated labels are discarded regularly.				
49	Labels and packaging materials used do not contain any food allergen ingredients.				
50	The labels for products containing one of the “Top 8 Food Allergens” properly list the common and usual name of the source of the ingredient in <b>parentheses</b> within the ingredient list in compliance with FALCPA. Select “N/A” if you are fully implementing the labeling control identified in item #51, below.				
51	The labels for products containing one of the “Top 8 Food Allergens” properly list the common and usual name of the source of the ingredient at the end of the ingredient statement, immediately following the word “ <b>Contains:</b> ” in compliance with FALCPA. Select “N/A” if you are fully implementing the labeling control identified in item #50, above.				
52	Lot coding, use by date, or other tracking system is in place and printed on each label.				
53	Labels and packaging materials are stored in a designated area, separated from food and chemical products.				
54	Finished, packaged, and labeled products are inspected prior to distribution to ensure compliance with labeling specifications for the “Top 8 Food Allergens.”				
55	Label and packaging inspection activities are documented on a log or checklist and verified for accuracy and completion by designated staff who is at the level of a supervisor or manager.				
	Employee Training				
56	A written, food allergen control plan is deployed and is accessible for review by all employees.				
57	The allergen control plan is reviewed at least annually by a team of staff from different operational areas (receiving, quality control, production, etc.).				
58	Employees are trained regarding food allergens before independently working with food, food packaging, and food contact surfaces.				
59	Training records are maintained documenting who attended the training, the name of the trainer, and the date the training occurred.				
60	The allergen training includes a definition of an allergen and a description of the “Top 8 Food Allergens.”				
61	The allergen training includes the importance of allergen control in a food facility as well as the potential serious public health impact of exposures due to cross contamination or misbranding.				

# Food Allergens and Controls Scorecard for Success



	<b>Employee Training (continued)</b>	<b>Fully</b>	<b>Partially</b>	<b>Not At All</b>	<b>N/A</b>
62	The allergen training describes the common areas where problems occur and lists specific control measures and appropriate corrective actions.				
63	Allergen training includes a review of frequently used aliases for the "Top 8 Food Allergens."				

	Sub Totals				
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# Food Allergens and Controls Scorecard for Success



This document provides an informal, numeric score to help you evaluate the effectiveness of your food allergen control plan. The scorecard is intended as a guide only and may not cover all situations.

How to finalize your results:

1. Transfer your subtotals from page four to their corresponding subtotal sections listed in the chart below.
2. Multiply your final tally from the “Fully” column by ten (10) and your score from the “Partially” column by five (5). Enter the results in each “Multiplication Subtotal” box.
3. Add your results from the “Multiplication Subtotal boxes together. Enter the result in the box labeled “Score.”
4. Subtract the number you entered in the “N/A” subtotal box from 63 (the total number of items from the chart). Multiply that number by 10 and enter it in the box labeled, “Total.”
5. Divide the number you calculated and entered in “Score” by the “Total” number, and multiply by 100. Enter that number in the box labeled “Your % Score.”

	Fully	Partially	Not At All	N/A
Subtotal				
Multiplication Subtotal				
Score				
Total				
Your % Score	%			

Use the chart below to evaluate your percentage score:

Score	Comments
>90%	You have implemented many allergen controls. Be sure to review your plan regularly to determine where adjustments can be made for improvement.
80% to 90%	You have implemented some allergen controls. You should evaluate your scorecard and promptly address any areas where you marked “Partially” or “Not At All.”
<79%	You have <b>NOT</b> implemented enough food allergen controls to protect against cross-contact or mislabeling. You should immediately re-evaluate your plan and make major modifications in order to reduce the risk of a severe adverse public health consequence.

# Food Allergens and Controls Scorecard for Success



## EXAMPLE

Yummy Yuckies Cereal Company, Inc. is evaluating their allergen control plan with the “Scorecard for Success.” After reviewing their plan and assessing their conformance with the 63 items, they realize a full evaluation of their allergen control plan must be done immediately. A table of their data is shown below.

	Fully	Partially	Not At All	N/A
Subtotal	35	20	5	3
Multiplication Subtotal	350	100		
Score	450			

Total	600
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Your % Score	75%
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# Resource 2



The Top 8 Food Allergens and Their Common Aliases

Egg		
albumin	emulsifier	ovamucin
apovitellin	globulin	ovamucoid
binder	lecithin	ovoglobulin
coagulant	livetin	ovotransferrin
dried egg solids	lysozyme	ovovitelia
egg white	mayonaise	ovovitellin
egg yellow	meringue	powedered egg
egg yolk	meringue powder	vitellin
eggnog	ovalbumin	whole egg

Milk		
ammonium caseinate	dried milk	milk solids
artificial butter flavor	dry milk solids	natural flavoring
butter	fully cream milk powder	potassium caseinate
butter fat	ghee	rennet casein
buttermilk solids	high protein flavor	sherbet
calcium caseinate	hydrolyzed casein	skim milk powder
caramel color	ice cream	sodium caseinate
caramel flavoring	ice milk	solids
casein	iron caseinate	sour cream (or solids)
caseinate	lactoglobulin	sour milk solids
cheese	lactalbumin	whey
cream curds	lactalbumin phosphate	whey powder
custards	lactose	whey protein concentrate
dairy product solids	magnesium caseinate	yogurt
de-lactosed whey	milk derivate	yogurt powder
demineralized whey	milk protein	zinc caseinate

Tree Nuts		
almond	filbert	nut butters
artificial nuts	gianduja	nutella
beechnut	ginkgo nut	pecan
brazil nut	hazelnut	pesto
bush nut	hickory nut	pili nut
butternut	lichee nut	pine nut
cashew	macadamia nut	pistachio
chestnut	marzipan/almond paste	praline
chinquapin nut	mashuga	shea nut
coconut	nangai nut	walnut



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Soy	
bulking agent	soy nuts
carob	soy panthenol
dofu	soy protein
edamame (soybeans in pods)	soy sauce
emulsifier	soy sprouts
guar gum	soya
gum arabic	soya flour
hydrolyzed soy protein	soybean
hydrolyzed vegetable protein (hvp)	soybean curd
kinnoko flour	soybean flour
kyodofu (freeze dried tofu)	soybean granules
lecithin	soybean oil
miso	soybean paste
msg (monosodium glutamate)	soybeans
natto	stabilizer
okara (soy pulp)	starch
protein	supro
protein extender	tamari
shoyu sauce	tempeh
soy albumin	teriyaki sauce
soy bran	textured soy flour (tsf)
soy concentrate	textured soy protein (tsp)
soy fiber	textured vegetable protein (tvp)
soy flour	thickener
soy formula	tofu
soy grits	vegetable broth
soy lecithin	vegetable gum
soy milk	vegetable starch
soy miso	yakidofu
soy nut butter	yuba (bean curd)

## The Top 8 Food Allergens and Their Common Aliases

Wheat	
all-purpose flour	kamut
bleached flour	malt
bran	malt extract
bread	matzo
bread crumbs	matzoh
bread flour	miller's bran
bromated flour	modified food starch
bulgur	modified starch
bulgur (cracked wheat)	msg (monosodium glutamate)
cake flour	protein
cereal extract	seitan
cornstarch	semolina
couscous	spelt
crackers, cracker meal	starch
durum flour	unbleached flour
durum wheat	vegetable gum
enriched flour	vegetable starch
farina	vital gluten
flour	wheat bran
gelatinized starch	wheat flour
germ	wheat germ
gluten	wheat gluten
graham flour	wheat starch
hard durum flour	white flour
high gluten flour	whole wheat
high protein flour	whole wheat flour
hydrolyzed vegetable protein	

Crustacean Shellfish	
barnacle	lobster
crab	Moreton Bay Bugs
crawfish	prawns
crayfish	scampi
ecrevisse	seafood flavoring
fish stock	shrimp
krill	tomalley
langostine	imitation shellfish
langouste	

Peanuts
arachic oil
arachis
arachis hypogaea
artificial nuts
beer nuts
boiled peanuts
cold pressed peanut oil
crushed nuts
crushed peanuts
dry roasted peanuts
earth nuts
emulsifier
expelled peanut oil
extruded peanut oil
goober peas
goobers
ground peanuts
ground nuts
hydrolyzed peanut protein
hypogaic acid
mandelonas
marzipan
mixed nuts
mole sauce
monkey nuts
nougat
nu nuts flavored nuts
nut pieces
nutmeat
oriental sauce
peanut
peanut butter
peanut flour
peanut paste
peanuts sauce, peanut syrup
Spanish peanuts
Virginia peanuts

Fish
anchovies
barbeque sauce
bass
bouillabaise
Caesar salad/dressing
caponata
catfish
cod
flounder
grouper
haddock
hake
halibut
herring
imitation fish
mahi mahi
meatloaf
perch
pike
polluck
salmon
scrod
snapper
sole
surimi
swordfish
tilapia
trout
tuna
Worcestershire sauce

\* This is not an exhaustive list. For specific medical advice regarding food allergens and substances in similar categories, consult a medical professional.

# Resource 3



# GLUTEN

## Guidelines for Implementing Gluten-Free Labeling of Foods 2013



As part of the Federal Food Allergen Labeling Consumer Protection Act of 2004 (FALCPA), the United States Food and Drug Administration (FDA) was instructed to develop a regulatory definition of “gluten free” and related terms. The Final Rule was published on August 5, 2013 in the Federal Register and became effective on September 4, 2013. Food processors must comply with the Final Rule by August 5, 2014.



### **Background**

Gluten is the naturally occurring storage protein of grains such as wheat, rye, barley and their crossbreeds. Most people can consume foods containing gluten without any adverse reactions; however, as many as 3 million people in the United States suffer from celiac disease. In those individuals, gluten causes their immune system to attack the lining of the small intestine. The resulting inflammation can hinder the body’s ability to properly absorb some nutrients and lead to conditions such as anemia, osteoporosis, diabetes, autoimmune thyroid disease, and intestinal cancers. There is no cure for celiac disease so individuals with the condition must carefully avoid the protein.

### **Major Provisions of the Final Rule**

Several provisions are outlined in the Final Rule, including:

- A. In order to be labeled as “gluten free,” a food must contain less than 20 parts per million (ppm) of gluten.
- B. Any food labeled as “gluten free,” “no gluten,” “free of gluten,” or “without gluten” must not contain 20 ppm or more of gluten. Foods exceeding that limit and labeled as such are considered misbranded.
- C. Use of the term “gluten free” is voluntary. A food which contains less than 20ppm of gluten is not required to be labeled as “gluten free.”
- D. Foods which do not naturally contain gluten (e.g. raw carrots, grapefruit juice, etc.) may use the “gluten free” claim.
- E. Food manufacturers must comply with the Final Rule by August 5, 2014.

### **Additional Information**

1. CDPH – Food and Drug Branch, Food Safety Program Information  
<http://www.cdph.ca.gov/programs/Pages/FDB%20Food%20Safety%20Program.aspx>
2. Final Rule from Federal Register  
<https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods#h-26>
3. FDA – Gluten-Free Labeling of Foods Guidance Document  
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362510.htm>



# Resource 4





# Handling Complaints

Complaints should be reviewed and investigated to determine the nature of the foodborne illness or injury. Complaints can come from many sources. It is important to know what questions to ask a complainant for follow-up investigation into the cause of the adulteration or misbranding.

“Do’s”	“Don’ts”
Take All Complaints Seriously - advise callers all complaints are treated with high priority.	Don’t be defensive or respond with unnecessary information, such as, “we’ve been in business for 10 years and have never received a complaint.”
Request Complainant Name and Contact Information – advise caller contact information is necessary for follow-up and investigation.	Don’t completely disregard calls from anonymous, unidentified persons.
Document the product name, date of purchase, lot code, and any other pertinent information from the product label.	Don’t tell caller “it’s not my problem” because the product was manufactured by another company. It’s too early to make that determination at this point in your investigation.
Describe any symptoms, date and time of complaint illness or injury. Listen carefully and document responses.	Don’t be dismissive or condescending. Calls to report illness or injury can lead to stressful situations.
Ask if the food was consumed by any other family or household member.	Don’t assume that only the caller consumed the food product.
Ask if complainant received medical treatment from a doctor and what was the diagnosis.	Don’t call health care providers without consultation with legal counsel. Health care providers may be restricted by privacy laws.



A food allergy can be life-threatening. For serious reactions, **call 911** or consult a doctor for urgent medical care.



# Resource 5



# PRODUCT COMPLAINT REPORT

Report No: \_\_\_\_\_

Illness [No Ill: \_\_\_\_\_]    Injury    Product Spoilage    Container Integrity    Foreign Object

Miscellaneous:    Odor    Taste    Color    Other \_\_\_\_\_

Product: \_\_\_\_\_

Complaint Taken By: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Complainant Name: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

City: \_\_\_\_\_ Zip: \_\_\_\_\_ County of Residence: \_\_\_\_\_

Product: \_\_\_\_\_ Brand: \_\_\_\_\_ Size: \_\_\_\_\_

Code/Expiration Date: \_\_\_\_\_ UPC: \_\_\_\_\_ Product sold:    Shelf-stable    Refrigerated    Frozen

Description of Problem (for illnesses see below): \_\_\_\_\_

Purchase Location: \_\_\_\_\_ Purchase Date and Time: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Phone \_\_\_\_\_

Product: Handling \_\_\_\_\_ Storage \_\_\_\_\_ Preparation: \_\_\_\_\_

Name	Age	Symptoms in order of appearance	Time	Medical Treatment Necessary	Diagnosis/Lab Confirmation

**D** = Diarrhea **V** = Vomiting **N** = Nausea **H** = Headache **D** = Dizziness **F** = Fever **B** = Burning **R** = Rash/Hives

Medical Provider Name: \_\_\_\_\_ Address: \_\_\_\_\_ Phone: \_\_\_\_\_

How much product consumed: \_\_\_\_\_ Product Remaining:  Yes    No    Unopened packages \_\_\_\_\_

Location of Remaining Product: \_\_\_\_\_

How is Product Stored: \_\_\_\_\_

Health Department Notification:    No    Yes Department \_\_\_\_\_

### Additional Illnesses

Name	Age	Symptoms in order of appearance	Time	Medical Treatment Necessary	Diagnosis/Lab Confirmation

Comments:

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Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

Disposition:

Internal Referral: \_\_\_\_\_

Date: \_\_\_\_\_

External Referral: \_\_\_\_\_

Date: \_\_\_\_\_

Regulatory Referral \_\_\_\_\_

Date: \_\_\_\_\_

Other \_\_\_\_\_

Date: \_\_\_\_\_

**Final Disposition/Closure:**

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_

# Resource 6





# Food Allergen Resources



## **Food Industry Assistance**

1. Allergen Control for Food Processors – Course Resources  
<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/AllergenControlResources.aspx>
2. California Department of Public Health, Food and Drug Branch Industry Education and Training  
<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/FoodIndustryTraining.aspx>
3. U.S. FDA Food Allergen Questions and Answers  
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm>
4. U.S. FDA Allergy Warning Letters  
<http://www.fda.gov/Food/ComplianceEnforcement/WarningLetters/default.htm>
5. U.S. Department of Agriculture (USDA) - Food Safety Inspection Service (FSIS)  
[http://www.fsis.usda.gov/wps/wcm/connect/1e98f24c-d616-443f-8490-f7372476d558/Allergies\\_and\\_Food\\_Safety.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/1e98f24c-d616-443f-8490-f7372476d558/Allergies_and_Food_Safety.pdf?MOD=AJPERES)

## **Consumer Resources**

6. Food Safety.gov  
<http://www.foodsafety.gov/poisoning/causes/allergens/>
7. FDA Food Allergies – Reducing the Risks  
<http://www.fda.gov/forconsumers/consumerupdates/ucm089307.htm>
8. Center for Disease Control and Prevention (CDC) Food Allergy Links  
<http://www.cdc.gov/healthyyouth/foodallergies/links.htm>
9. FDA Food Allergen Fact Sheet  
<http://www.fda.gov/food/resourcesforyou/consumers/ucm079311.htm>

## **General Information**

10. The Food Allergy Research and Education (FARE)  
[www.foodallergy.org](http://www.foodallergy.org)
11. The Food Allergy Research and Resource Program (FARRP)  
[www.farrp.org/](http://www.farrp.org/)
12. National Institute of Allergy and Infectious Diseases (NIAID) Food Allergy Overview  
<https://www.niaid.nih.gov/diseases-conditions/food-allergy>
13. American College of Allergy, Asthma, and Immunology  
<http://www.acaai.org/Pages/default.aspx>