FAQs for the American Spice Trade Association (ASTA) on the Potential Risks Related to Allergens in Spices

January 2021

Introduction:

Food allergies are the result of an immune response that occurs in certain individuals to a food or a component within the food (typically a naturally occurring protein) that is normally well-tolerated by most consumers. There are multiple types of adverse reactions to foods, including food intolerances (such as lactose intolerance), immediate or Immunoglobulin E (IgE)-mediated hypersensitivity reactions (such as a peanut allergy), and delayed or cell-mediated hypersensitivity reactions (such as celiac disease).

The majority of regulatory and food safety interventions related to food allergens address IgE-mediated food allergies because the immediate onset of symptoms following exposure to small doses of food can be quite severe, and possibly life-threatening. Symptoms may include skin problems (*e.g.*, hives, itching), respiratory problems (*e.g.*, asthma, difficulty breathing, swelling of the throat), or gastrointestinal problems (*e.g.*, nausea, vomiting, diarrhea). The most severe effect is anaphylactic shock, which can involve cutaneous, respiratory, gastrointestinal, and cardiovascular systems, and can result in death.

In the U.S., it is estimated that 3.5 to 4.0% of the overall population suffers from food allergies. Avoidance is the only current strategy for individuals with food allergies. As such, food allergic consumers must rely on accurate labeling to manage their health.

Purpose:

It is the mission of American Spice Trade Association (ASTA) to ensure the supply of clean safe spice in the United States. To this end, ASTA develops education and resources to assist its members with understanding of common industry practices and regulatory compliance, including the need to ensure that allergens are appropriately managed in the supply chain and any subsequent labeling complies with U.S. law. The purposes of these Frequently Asked Questions (FAQs) are to help ASTA members understand the regulatory requirements and common industry practices related to risk assessment, handling, and testing of allergens in spices.[1]

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[1] The information contained herein is not intended to constitute medical or legal advice or recommendations. ASTA does not warrant or guarantee the accurateness, completeness, adequacy, or currency of this information. Every company should make its own independent decisions about what allergen practices to follow.

Section 1: Regulatory Requirements Related to Allergen Labeling and Handling

How are allergens regulated in the U.S.?

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires allergens in food products in the United States to be labeled to identify the eight major food allergens. FALCPA was created as an amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA) requiring the labeling of any food (including components of flavorings, colorings, and incidental additives) that contains major food allergens. The 8 major food allergens (*i.e.*, the "big 8") identified by FALCPA are milk, eggs, fish (*e.g.*, bass, flounder, cod), crustacean shellfish (*e.g.*, crab lobster, shrimp), tree nuts (*e.g.*, almonds, walnuts, pecans), peanuts, wheat, and soybeans.

FALCPA is enforced by the U.S. Food and Drug Administration (FDA). The FDA has also published guidance for the food industry on how to comply with these labeling requirements, which is available online at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4.

Where can I find resources on allergens in different global regions?

The Food Allergen Research and Resource Program at the University of Nebraska has a list of allergen regulations around the world on its website: https://farrp.unl.edu/IRChart. This database includes allergen information for more food products and ingredients than the "big 8."

What does FALCPA require?

Under FALCPA, foods do not have to be free of the 8 major food allergens listed above; however, any food product containing these allergens (if they are intentionally added to the product)[2] must be clearly labeled. The food label ingredient statement must list the food allergen by a name easily understandable by consumers in one of two ways:

(1) List the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients (*e.g.*, Ingredients: whey (milk), lecithin (soy)); or
(2) Use "Contains" followed by the common or usual name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients (*e.g.*, Contains wheat, milk, and soy).

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[2] FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact. In the context of food allergens, "cross-contact" occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.

What are the major 8 allergens in the U.S.?

The major 8 allergens defined by FALCPA in the United States are:

- Wheat
- Milk
- Eggs
- Soy
- Fish
- Crustacean shellfish
- Peanut
- Tree nut

It is noteworthy that some of these allergens are actually categories of foods, rather than one food item. For example, fish (salmon, tuna, bass, etc.), crustacean shellfish (crab, shrimp, lobster, etc.),[3] and tree nuts (e.g. almonds, walnuts, etc.) refer to a broad category of products. These foods should be labeled by their specific type of nut or species on the label, as in "almonds" versus "treenuts," and "bass" versus "fish." It is also noteworthy that coconut is considered to be a treenut.

What are the requirements related to the disclosure of sulfites?

Scientific reports have documented that there are individuals who have adverse reactions related to the consumption of food containing sulfites. As such, FDA regulations require that sulfites that are added to foods need to be declared on the label. There is an exemption for incidental additives when there is no function for the sulfite in the finished product and the concentration is less than 10ppm. Products containing undeclared sulfites at concentrations of more than 10ppm are subject to product recalls.

Some spice and seasoning products, such as garlic, are known to contain naturally occurring sulfites. Naturally occurring sulfites are not required to be disclosed under the regulations A food with more than 10 ppm sulfites from naturally occurring sulfites would not be considered misbranded based on the lack of a disclosure of sulfites. However, in the event a food contained naturally occurring sulfites exceeding 10 ppm, and at a level that could cause an adverse reaction in a sulfite sensitive individual, a company might want to disclose their presence for product liability reasons. Note that "contains sulfites" would seem to be the preferable disclose in this situation, compared to "may contain sulfites," which could be viewed as inconsistent with the rule and might invite scrutiny of the labeling.

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[3] Under FALCPA, crustacean shellfish (such as crab, lobster, or shrimp), and ingredients that contain protein derived from crustacean shellfish, are major food allergens, but molluscan shellfish (such as oysters, clams, mussels, or scallops) are not.

The FDA regulations and guidance documents specify the use of the Monier-Williams method to detect sulfites. There is a problem with that methodology, however, when testing garlic, onion, and other substances that have naturally occurring sulfur compounds and another method must be used to detect sulfites in these products.

What is the status of sesame as an allergen in the U.S.?

Sesame is not currently considered a major allergen in the US and is not subject to allergen labeling, but this situation may be changing. Although sesame is not considered an allergen in the US, under the current FDA Compliance Policy Guide, sesame seeds should not be labeled under the generic declaration of "spice(s)" and should always be labeled as sesame.

In 2018, FDA issued a request for information on sesame allergies to determine if it should be regulated similarly to other allergens in the United States. ASTA provided comments to the FDA about this potential change. ASTA's position on this regulatory action is that we would support labeling of sesame if it is determined to be a major allergen.

In 2020, the U.S. Congress passed two separate bills that would have designated sesame as a major allergen. Although both were called the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, and both would have declared sesame a major food allergen, the House bill, HR 2117, would have given FDA the power to designate major food allergens going forward, while the Senate bill, S 3451, reserved that power for Congress. Both bills died at the end of the Congress without becoming law. The next Congress is expected to again address the issue.

Additionally in 2020, the FDA issued Draft Guidance for Industry: Voluntary Disclosure of Sesame as an Allergen. The guidance recommends that manufacturers, as a voluntary matter, clearly declare sesame in the ingredient list. For example, sesame would be declared parenthetically when declared in a food and labeled as "spice" or "flavor," or other scenarios in which the ingredient is not clearly declared as sesame.

Are there limits or thresholds for allergens?

In the United States there are currently no regulatory limits for the major 8 allergens, aside from the limit of 20ppm has been established for gluten for the purposes of supporting a "gluten-free" claim. At this time, it is unlikely that the FDA will publish threshold levels for allergens.

What are precautionary statements and are they allowed to be used on spices?

Precautionary statements (also known as advisory labeling) refer to language such as "may contain [allergen]" or "manufactured on shared equipment with [allergen]". FALCPA does not address use of precautionary statements, which allows manufacturers to include warnings on labels regarding the possible presence of allergens. It is important to note that precautionary statements may not be a replacement for adhering to good manufacturing practices (GMPs), and use of the statements must be

truthful and not misleading. FDA has stated that it is considering ways to best manage the use of these types of statements by manufacturers to better inform consumers.

Importantly, the use of precautionary labels is not likely to protect the company from needing to issue a recall in the event that the product is found to contain the allergen. Furthermore, non-governmental organizations representing consumers with food allergens have spoken out against the widespread use of precautionary statements. This community has voiced complaints that this form of labeling is often unclear and may unnecessarily limit food choices.

What does the FDA Food Safety Modernization Act (FSMA) require related to management of allergens?

Allergens are considered a chemical hazard under the Preventive Controls for Human Food rule. If allergens are determined through a hazard analysis to be a "hazard requiring a preventive control," allergen preventive controls may include cleaning and sanitation procedures, scheduling decisions, and labeling practices. These controls must have associated monitoring, corrective actions, verification, and record-keeping.

Additionally, this regulation revised FDA's current Good Manufacturing Practice (cGMPs) regulations to specifically address allergen cross-contact. The updated cGMPs require that equipment, utensils, and food contact surfaces are maintained in a manner to prevent allergen cross-contact. This includes ensuring that cleaning, sanitation and storage practices are conducted in a manner that protects food from allergen cross-contact.

FDA has indicated that a guidance document on allergen control within the preventive controls rule is forthcoming, but has not yet been released.

What are the regulatory implications of a product containing an undeclared allergen being introduced to the U.S. market?

Failure to properly label a food product containing a major food allergen will deem it misbranded under the FFDCA and may result in the product being subject to a recall. Undeclared allergens are the leading cause of recalls in the United States. Furthermore, a company and its management may be subject to civil sanctions, criminal penalties, or both under the FFDCA if one of its packaged food products does not comply with the FALCPA labeling requirements. FDA may also request seizure of food products where the label of the product does not conform to FALCPA's requirements.

Additionally, the presence of an undeclared allergen may result in required reporting to the reportable food registry (RFR). Food facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. are required to report to the RFR within 24 hours for any incidents for which there is a "reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals." Undeclared allergens are a leading cause for RFR reports and recalls.

Section 2: Risk Assessments of the Spice Supply Chain

How can I manage the risk if my supplier uses allergens in their facility?

If a supplier is using allergens in their facility, it does present a potential risk for downstream users of the ingredients. Companies must conduct risk assessments of their suppliers in order to understand the risk of the presence of an allergen in the product.

Under FSMA requirements, companies must have supplier verification procedures in place to determine how the supplier is controlling the allergen. These verification activities may include onsite audits, third party audit, and reviewing allergen control programs. Depending on the risk, it may also be prudent to implement testing as well.

As much as possible, it is important to be very familiar with the spice supplier and the practices they use to grow their crop. Ideally, the supplier should use sound Good Agricultural Practices (GAPs), be educated as to which allergens are of concern, and ensure compliance with avoiding cross-contact with crops containing these allergens. For example, crops grown in close proximity or rotated on an annual basis can cause cross-contact of an unwanted allergen. For example, this occurs in India where some farmers grow cumin and peanuts in close proximity and often rotate these crops in the same field, which may cause unharvested peanuts to inadvertently end up in a cumin harvest.

Spice manufacturers should ensure that their suppliers:

- Are familiar with the major allergens of concern
- Take care when rotating crops to avoid any inadvertent cross contact with a previous allergenic crop
- Ensure that there is a suitable gap in harvest time when potential allergenic crops are grown in close proximity to avoid cross contact
- Since additional spices (*e.g.,* sesame, mustard, celery) have possible allergenic properties, ensure that there are suitable clean-down systems to avoid carry over between spice crops
- Do not use any peanut-related products to process spices or lubricate processing equipment (*e.g.*, ground nut oil)
- Keep spices separate from cereal products, which may contain sensitizers such as gluten (wheat) or allergens such as soybeans or tree nuts
- If using recycled bags for shipping spices, have a robust control system in place to ensure that the bags have not been previously used for potentially allergenic food products
- Have a suitable cleaning operation in place to avoid cross contact in trading yards where spices and allergenic foods are handled

I outsource some of my process, i.e. packaging and sterilization. How can I ensure there is no allergen cross contact during this time?

Similar to supplier verification, risk assessments must be conducted for contract manufacturers. The potential risk will depend on the process that is being conducted as well as mitigating techniques, such

as packaging, scheduling, etc. For example, sterilizing in packaging generally would have limited risk, but if bulk product is being treated, there could be a significant risk.

What does a documented risk assessment for allergens entail? What are the key areas and measures I should consider when I make a risk assessment for allergens?

In the food industry, risk assessments are conducted to evaluate the potential health risk of chemical or microbiological contaminants to the public. This type of assessment can also be applied to food allergens and be used to develop risk management approaches (*e.g.*, advisory statements, labeling).

The assessment of health risk relating to food allergens can be broken into 4 elements:

1. **Hazard Identification**.
    - Identify the allergen (one of the 8 major allergens listed by the FDA)
    - Include data on the prevalence and severity of allergenic reactions
    - Identify potential residues that may produce allergenic responses (*i.e.*, undeclared food allergens may be considered an identified hazard)
    - Consider the mitigation measures and process controls available, including segregation, sanitation, and scheduling
2. **Hazard Characterization**
    - Use of oral food challenge studies to develop safe exposure levels for allergenic individuals (*i.e.*, threshold dose)
    - Estimate of a no-observed-adverse-effect level (NOAEL) on a population basis (*i.e.*, the highest consumption level at which no allergenic reactions occur within a defined population of individuals with food allergies)
    - Use of probabilistic modelling with individual NOAELs and LOAELs (lowest-observed-adverse-effect levels) (*i.e.*, dose distribution) to predict acceptable risk levels
    - Acceptable risk levels defined by identifying a reference dose ("describes the daily dose that is likely to have no deleterious effect even if continued exposure occurs over a lifetime")
    - A reference dose for food allergens would carry some level of risk (*e.g.*, mild allergic reactions that could be controlled with pharmaceutical intervention) that would need to be defined and presented as an "acceptable" risk
    - Currently, the FDA has not provided a threshold for food allergens
3. **Exposure Assessment**
    - The risk to the consumer is primarily due to unintended addition (*i.e.*, contamination due to cross-contact) to food product
    - Identify the amount of contamination (*i.e.*, concentration)
    - Identify the amount of food ingested containing the allergen
    - Use quantitative risk assessment (QRA) to produce an allergen intake distribution
4. **Risk Characterization**
    - Combines hazard identification/characterization with exposure assessment to "assess the likelihood of risk even in cases where a reference dose or maximum level has not been established"

- Use of individual threshold dose-distribution with intake distribution and contamination distribution to estimate an action level (*e.g.*, use of precautionary labeling if the contaminant level is above the action level)
- Use of probabilistic modeling by applying statistical distributions (*i.e.* Monte Carlo simulation) with allergen thresholds, consumption patterns and contamination results to "predict objective allergic reactions in an estimated fraction of the population with food allergy" and then to estimate the allergic population's risk and the overall population's risk

What is the VITAL system?

VITAL (Voluntary Incidental Trace Allergen Labelling) is a standardized risk-based methodology for food producers to use in assessing the impact of allergen cross-contact to indicate appropriate precautionary allergen labelling. More information is available at http://allergenbureau.net/vital/.

What would an example of what a risk assessment for allergens in spices could look like?

"Risk" associated with specific levels of a food allergen in a product may be calculated by knowing the prevalence of the food allergy, the allergen threshold, the consumption of a specific food product, and the concentration of the allergen in the food product. Joe Baument of the Food Allergy Research & Resource Program (FARRP) at the University of Nebraska presented an approach for how spice companies could calculate risk of peanut in cumin during the 2014 ASTA Annual Meeting.

For example, if one knows that there is 5000 ppm peanut in cumin and that a finished food product contains 2% cumin and the serving size of this product is 100 g, one can calculate the exposure to peanut:

5000 ppm (or µg/g) peanut x 2% cumin x 100 g serving = 10 mg of *peanut (2.5 mg peanut protein based on 25% protein in peanut)*

Using clinical threshold studies (*i.e.*, studies examining what levels of a food allergen cause reactions in human subjects), FARRP estimated that 5.5% of the population allergic to peanuts would react after exposure to 10 mg of peanut.

Risk at low levels of a food allergen such as peanut in cumin (*e.g.*, 5-25 ppm) resulting from unintentional cross-contact can also be calculated using quantitative risk assessment, based on:

- Threshold levels of specific food allergens within the overall population (*i.e.*, clinical threshold studies)

- Statistical dose distribution modeling (exposure/consumption data)
- Determination of the probability of an allergic reaction occurring following exposure
- Integration of the variability and uncertainty of data into the model to provide a more realistic estimate of potential risk

This risk can be expressed in a number of ways:

- User population risk (assumes the entire population is allergic and consumes the product = "users")
- Allergic population risk (assumes the entire population is allergic but only a certain percent of the population consumes the product)
- Overall population risk (assumes a certain percent of the population is allergic and a certain percent of the population consumes the product)

Section 3: Managing Allergens Within a Production Facility

Do I need to have dedicated equipment and utensils for processing allergens?

Dedicated equipment is ideal, but may not always be practical or economically viable in all situations. Where it is not feasible for manufacturers to use dedicated equipment, preventive controls can be put in place to mitigate cross-contact risk. For example, scheduling and sanitation procedures should be in place. Additionally, there should be validation and verification of the control measures, including testing to make sure sanitation is effective.

While it may be more economically challenging to dedicate equipment, typically utensils should be able to be dedicated. Use of specifically colored utensils is a common practice to denote utensils used for allergens from those that are not to be used with allergens.

My staff is bringing their own food. Is there a risk of allergens I should consider even if the break room is far from production?

A common industry practice is that no outside food should be allowed to be brought into the plant. However, if allowed, facilities should have policies in place to mitigate the risk of cross-contact from allergens in food brought by employees. Companies should follow basic cGMPs, including handwashing and changing clothes to mitigate risk of transfer of allergenic proteins from outside food. Staff should also be trained on how to mitigate cross-contact of allergens.

How should allergen waste be managed?

It is prudent to manage allergen waste separately from non-allergen waste. A strategy related to the management of allergen waste may entail using different colored waste bins that are clearly labeled and easily identifiable, ensuring waste bins are covered, and removing waste immediately after production.

I have to do a rework that contains allergens. What should I consider?

Manufacturers must ensure to be reworking “like” into “like”, meaning that allergen rework may only be reworked in allergen-containing product. Basic allergen management procedures to handle rework include clear labeling, clear tracking of allergenic product, and storage in a separate area.

Do I need to have separate cleaning supplies for allergens?

Separate color-coded systems are recommended to be used for cleaning supplies used on equipment used to process allergens. This is especially important in a “dry cleaning” process, where dust build up may result in a cross-contact. For example, brushes with different colors clearly denote which are to be used on equipment used to process allergens.

How can I validate that my allergen cleaning system is effective and continually verify that my allergen cleaning procedure is working all the time?

Manufacturers using sanitation as an allergen control should initially validate that the cleaning and sanitation procedures are effective at removing the allergen of concern, and also conduct verification on an ongoing basis to ensure that the validated process is being consistently applied.

To validate the sanitation process, the manufacturer must design a study to determine the effectiveness of the removal of the allergen of concern. This study would entail first cleaning and sanitizing the equipment and then conducting specific allergen testing using surface swabs specific for the allergen used on the equipment. The samples may then be tested with an allergen test kit.

Once the sanitation process is validated, then the manufacturer must use ongoing verification methods to ensure the validated process is being used each time. This may include monitoring and documentation of the sanitation process and/or testing. Adenosine Triphosphate (ATP) assays are one form of testing, and allow for a quick measurement that measure any build up, and can be a general quick check of overall effectiveness of cleaning (though they are not allergen-specific). As usual, it is recommended to swab the most difficult to clean areas. It is noteworthy that testing rinse water may not be sufficient since the water can dilute allergens to non-detectable levels.

How should manufacturers manage labeling of allergen information?

Labeling is an essential part of allergen management. Mislabeling of allergens is the leading cause of recalls in the United States. Every company should set up their own process to monitor, document, and

verify that the correct label is used on the correct package every time there is a changeover. Employees should be trained on the importance of proper labeling. It is also important to have inventory controls in place, such as review of incoming labeling, and discarding out of date labels in a timely process.

Furthermore, it is important that there be a process to approve labels for new products and product changes. For example, labels should be reviewed whenever there is a product formula change, as well as when there is a change in the supplier or country of origin. It is also a good idea to revisit specs at least every three years to check that there have been no changes that would impact labeling.

Section 4: Allergen Testing

What methods are available to detect allergens in spices?

The standard analytical method used to measure food allergen residues in food and on equipment is ELISA (enzyme-linked immunosorbent assays) or ELISA-based technology. Commercial ELISA kits are available for most of the common allergens, and there are ELISA methods that have been validated through AOAC and other method-validation certification bodies. ELISA assays are specific and sensitive, with rapid analytical assessment times from 10 minutes to 1 hour.

Lateral Flow ELISAs, which are strip tests or dipsticks that have a 5 ppm detection limit depending on the test matrix and a 10-minute assay time, are qualitative assays used primarily for assessing sanitation but can also be used for food product testing. Lateral flow offers advantages for quick in-house testing.

Other methods may be considered for allergen testing if ELISA technology lacks sensitivity. For example reverse transcription-polymerase chain reaction (RT-PCR) may be a useful alternative in certain scenarios for detecting some source material DNA when allergenic proteins are denatured or hydrolyzed during processing, but not be able be used with in highly processed products that do not contain enough DNA. Chromatographic methods, such as LC-MS/MS, may be useful to detect mixed allergens in a sample or when allergenic proteins are complexed in a product matrix that masks protein detection by ELISA.

Where can I find information about limitations and capabilities of common allergen detection methods, including considerations related to validation of methods and matrices?

This information will be specific to the allergen of interest, the testing methodology used, and the target commodity of interest. The manufacturers of the tests are a valuable source of information and should be able to provide limits of quantification, limits of detection, and other details about the testing method. Methods of choice should be fit for purpose and validated for products and residues of interest. For example, ATP or protein swabs may not provide results that are correlated with allergen presence.

What is the best course of action to take in the case of a presumptive result?

In the event that an allergen is detected above the limit of detection, all potentially impacted product should be placed on hold until the test result is confirmed.

ELISA is not infallible. It is possible for cross-reactivity to occur between different proteins. For example, pea protein has been shown to test positive for peanut protein in certain ELISA assays. To confirm a presumptive positive, it is advisable to follow a protocol developed by FARRP, which involves conducting tests with two additional different test kits. If two out of three methods come back positive, then the positive is confirmed.