Frequently Asked Questions on Cumin/Allergens

Overview

In October 2014, the Canadian Food Inspection Agency (CFIA) conducted random testing for allergen analysis and found undeclared material from peanuts and almonds in Ortega taco seasoning and a recall was issued. That recall was subsequently expanded to a wide range of other Ortega brand products and a similar recall occurred in the U.S. in November. On December 19, 2014, Reily Foods recalled chili seasoning kits due to undeclared peanut and almond. Reily's notification to its cumin supplier prompted a series of additional recalls. A third company then also notified its customers of the presence of undeclared peanut in its cumin, resulting in additional recalls. In all, FDA reports more than 20 recalls for undeclared peanut on its recall Web site since November. Additionally, there was a recall in Tennessee for paprika that was found to have small amounts of peanut.

There are two very different situations. The initial recalls came after very high levels of peanut were found in ground cumin. It is believed that these were the result of economically motivated adulteration. That subsequently generated significant testing of cumin and very low levels have been found, which are thought to be unintentional cross-contact. That finding is driving customer demands for testing and guarantees of zero allergens and has created a great deal of uncertainty.

ASTA has spoken with numerous ASTA member companies who provided information about their supply chain and testing practices. ASTA has also spoken with staff from the Food Allergy Research & Resource Program (FARRP) at the University of Nebraska-Lincoln. These discussions have helped to build a framework of knowledge about the situation, however, there are still unanswered questions, including the exact source of the peanut contamination in the original recalls.

ASTA is providing the following information in an effort to answer many of the questions that we have received from members and to provide information to allow companies to determine the appropriate course of action for them. The information is broken out into several categories, including allergens and labeling, the specific contamination events and economically motivated adulteration. It is our intent to provide comprehensive information although we realize this may not answer every question you have. Please contact the ASTA office at info@astaspice.org if there are other issues you think should be addressed. These FAQs are updated periodically as additional information becomes available.

Allergens and Labeling

- How are allergens regulated? In the U.S., allergens are regulated under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). FALCPA details the eight major food allergens that require labeling as well as specifics on how the labeling must be done. The intent of the law was to make it easier for people with food allergies to identify and avoid foods containing major allergens. The U.S. Food and Drug Administration (FDA) is charged with enforcement of FALCPA.

- What are the "Big Eight" allergens that require a labeling declaration in the U.S.? Under FALCPA, the "Big Eight" allergens are milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts and soybeans.

- What does FALCPA require? FALCPA does not require foods to be free of major allergens. Rather, the regulation requires that the label clearly note the presence of allergens intentionally added to a product and additionally requires that the allergens be listed by their common or usual name. The source of the allergen must be included when the common or usual name does not include the source. In other words, the presence of peanut in any food, including cumin, doesn't

render the food unusable but requires labeling of the presence of peanut unless the peanut is present as the result of unintentional cross-contact. Certainly, if peanut is intentionally added to cumin or another food or food ingredient, then the presence of peanut in that food requires the declaration that peanut is present to protect those with peanut allergy.

- Why isn't the solution to just label cumin and products containing cumin that they may contain peanut? That approach complies with FALCPA but presents challenges for your customers and consumers. Industrial food companies understandably seek to limit their need to label product for allergens to those products whose recipes require the use of products that are allergens (eg. They actually add peanuts because the recipe calls for peanuts.) Additionally, since consumers with peanut allergy typically will avoid any product that lists the potential for peanut, this approach would severely curtail their food choices and impact their quality of life. For example, they would likely have to avoid all Mexican food.

- Is labeling required for other things people are allergic to? According to FDA, the Big Eight allergens account for 90 percent of all food allergies. While some sensitive individuals may have reactions to other foods, FALCPA does not require that they be labeled. It is important to note that regulated allergens differ in other countries. For example, sesame and mustard are considered allergens in Canada, but do not require labeling in the U.S.

- What is FARRP and what role do it play in this matter? The Food Allergy Research & Resource Program (FARRP) at the University of Nebraska-Lincoln is widely viewed as the expert resource on allergens in the U.S. FARRP was founded in 1995 as a cooperative venture between the University of Nebraska and seven founding industry members. Today FARRP has more than 80 member companies and its mission related to allergens is to "develop and provide the food industry with credible information, expert opinions, tools, and services relating to allergenic foods." FARRP membership is open to food processors, food manufacturers, ingredient manufacturers, equipment manufacturers, suppliers of analytical test kits for allergen residue detection, and other companies directly supplying products or services to the food processing industry and a number of ASTA members belong to FARRP. FARRP has done extensive testing on cumin and provided information to its members as well as to ASTA. They are also supporting ASTA with their knowledge and expertise as we pursue options to resolve some of these issues for the spice industry.

Peanut Protein in Cumin

- How was the peanut found in the cumin? The original undeclared peanut protein was found during routine testing for allergens by the Canadian Food Inspection Agency (CFIA) in Ortega taco mix being imported into Canada. Those findings resulted in recalls of other mixes and sauces by B and G Foods. FARRP confirmed those results, finding up to 5,000 ppm of peanut in the cumin in question. Subsequent testing led to Reily Food Co. finding peanut in its products. That company notified its supplier who then notified several dozen companies to which it had distributed the cumin.

- How much peanut was found in those instances? ASTA has received information that testing detected levels of peanut up to 50,000 ppm. FARRP indicates it detected levels over 100,000 ppm in ground cumin, calculated by analyzing a seasoning blend.

- Why is this believed to be economically motivated adulteration? There has been no conclusive evidence of economically motivated adulteration. However, based on their experience, FARRP has indicated that it seems difficult to believe that unintentional cross-contact resulted in levels up to 100,000 ppm. They have tested other cumin samples and occasionally have found levels between 5 and <40 ppm. Those lower levels are not believed to be economically motivated adulteration.

- What is in the cumin? As peanuts are more expensive then cumin, it would not make sense economically to grind peanuts into a less expensive commodity. There has been speculation that ground peanut shells were mixed into the ground cumin. Peanut shells themselves, if washed, do not contain the protein that triggers an allergic reaction. However, during shelling a small number of peanuts typically fail to be removed and remain behind in the shells, which would result in detectable peanut protein in the ground shells. Laboratory testing has not been able to identify peanut shells in the ground cumin. Furthermore, it seems unlikely that peanut shells could result in the very high levels of peanut found in that initial lot of contaminated cumin. The root cause of that situation remains unidentified. (Updated May 2016)

- What do we know about the cumin? Both instances involve ground cumin imported from Turkey. It is not known if the cumin is Turkish cumin or if it was imported and then ground in Turkey. Based on information that ASTA has received, the two instances involve two different suppliers in Turkey.

- Why won't ASTA name the companies in Turkey that supplied the cumin involved in the recalls? ASTA has received information about the possible suppliers but has not independently confirmed their identity.

- Have there been any illnesses as a result of someone with a peanut allergy consuming cumin containing peanut? FDA has not published any adverse incident reports, however, *Allergic Living* magazine reported that FDA received reports of 32 suspected allergic reactions. One lawsuit was filed and reportedly a confidential settlement was reached. (Updated May 2016)

- Is peanut being found in other cumin? ASTA understands that there has been significant testing of cumin and that low levels of peanut are being found in some instances. FARRP reports that most samples of cumin obtained from whole seed and ground in the U.S. contain no detectable peanut found using an ELISA test (the type of test used to identify peanut protein. There are several types of ELISA tests). However, the FARRP lab has detected low levels of peanut at levels between 5 and <40 ppm in some samples.

- What is the difference between economically motivated adulteration and unintentional cross-contact? Economically motivated adulteration occurs when something is intentionally added to a food to make it seem more valuable than it is. Unintentional cross-contact may occur in a variety of ways. When material is intentionally adulterated one would expect to see a high percentage of adulterant to achieve an economic advantage.

- How does unintentional cross-contact occur? Unintentional cross-contact can occur when crops are grown in close proximity and the allergen comes into contact with the other crop through growing or harvesting. For example, it is our understanding that cumin and peanuts are grown in the same areas in India and we have been told some farmers rotate the two crops in the same field. That could result in unharvested peanuts winding up in cumin. Cross-contact can also occur because of shared transportation, storage, or production equipment.

- How does FDA regulate unintentional cross-contact? FDA has issued guidance to industry on compliance with FALCPA. It contains the following information:

  [Added December, 2005] Is a major food allergen that has been unintentionally added to a food as the result of cross-contact subject to FALCPA's labeling requirements?

  No. 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.

- Has FDA defined a level for trace amounts found through unintentional cross-contact? FDA has indicated in the past that it may consider setting a threshold for food allergens, however, at this point the Agency has not done so. FDA sought feedback in 2013 on possible thresholds for allergens and ASTA submitted comments at that time in support of such action. In a March 2015 meeting between FDA, ASTA and FARRP, FDA expressed a reluctance to set thresholds despite scientific evidence showing they can be safely established. (Updated May 2016)

- Do the low levels present a safety risk to individuals with peanut allergy? FARRP reports that it has conducted numerous quantitative risk assessments based on the analytical level of peanut in the cumin or spice blend, the formulation of the food product to account for the percent of cumin, the consumption of the food product and the known peanut threshold dose dilution. They believe that when peanut is present at levels less than 25 ppm, the risk is essentially zero in some products. They caution that risk does depend on consumption levels. It is important to note that neither FDA nor USDA have voiced an opinion on the acceptability of cumin containing detectable peanut at levels less than 25 ppm. (Updated February 19, 2015)

- What is a risk assessment? FARRP is performing risk assessments based on particular formulations of food. As indicated above, they look at the amount of peanut present in the cumin or spice blend, the percent of that cumin or spice blend included in the formulation, the consumption of the product and the known peanut threshold dose distribution among peanut-allergic individuals. FARRP can perform these risk assessments for any company seeking information on their products.

- Is it possible that all of the low level detection is the result of false positives? FARRP reports that false positives can occasionally occur in ELISA tests but typically are when levels are below 10ppm and they recommend additional testing. FARRP has found numerous cumin samples with no detectable peanut residues and they believe that argues against a false positive from an ELISA test because all cumin samples should be testing positive then. A number of ASTA members participated in a study conducted by FARRP of the various methods in which peanut spiked cumin was tested. Preliminary results indicate there were no false positives found with ELISA tests or Lateral Flow Strips, although there was some degree of variability in the results. The study found that PCR testing produced the greatest variability in results. FARRP has indicated this study will be published and complete results will then be available. (Updated May 2016)

- If cumin, or another spice, is found to have allergens, can the spice be diluted until the allergens are undetectable? No, this is not permitted.

- Is peanut being found in whole cumin? According to FARRP, some of its members import whole cumin seed and they have not seen peanuts being found during cleaning and processing. FARRP reports that most samples of cumin obtained from whole seed and then ground in the U.S. have not contained detectable peanut when tested by ELISA tests. However, they have occasionally detected peanut in those samples with levels between 5 and <40.

- If we find very low levels of peanut in our cumin, are we required to file an RFR and recall it? This is an individual company decision, however, FARRP did send information to its members recommending that if peanut is found at less than 10ppm that further testing be conducted to substantiate that positive result. FARRP notes that the requirements for filing an RFR states that an RFR report is warranted when ingestion of the product is associated with a reasonable probability of serious adverse health consequences or death in humans. A quantitative risk assessment can be used to determine if low levels of peanut in cumin would meet the RFR criteria. In the experience of FARRP, the probability of an allergic reaction occurring from low levels of

peanut in cumin is quite low in most situations but decisions should be made on a case-by-case basis. (Updated May 2016)

- Why doesn't ASTA provide specific advice to its members on actions they should take? It is not possible for ASTA to understand all of the details of member companies' supply chains and specific practices to make a specific recommendation on a course of action. ASTA recognizes that each company makes decisions based on its specific practices, supply chains and willingness to assume risk. That is different for every company and each company needs to make decisions based on a variety of factors only its employees know. ASTA's policy is that it will provide regulatory and other helpful information to members but that it is an individual company decision on how to use the information provided by ASTA. There are significant legal liability issues for ASTA and its Board of Directors associated with ASTA providing specific advice and guidance to its members on matters such as the current issues with adulterated and mislabeled cumin. ASTA General Counsel John Hallagan is able to provide ASTA members with referrals should your company wish to retain legal counsel to assist in these decisions, however, as ASTA's counsel, he cannot provide legal advice as that would be a conflict of interest. (Updated May 2016)

- Our customers are asking for us to ensure there are zero allergens in our spices. How can we comply with that? Again, this is an individual company decision and ASTA is seeing companies take different approaches. It is important for your customers to understand your sourcing practices and your supply chain and to understand the low level of risk associated with the very low level of peanuts. Risk assessments can be a valuable tool in this area.

Economically Motivated Adulteration

- What can ASTA do about economically motivated adulteration? ASTA has published a white paper on Spice Adulteration that is available on the ASTA website. We have also conducted previous educational sessions on adulteration – detection and prevention. The Education and Food Safety Committees are exploring options for educational programming and resources to provide members. ASTA had added a new section to the website on food fraud and adulteration that contains the white paper as well as details about the ASTA Self Regulation Program that members can use to report cases of suspected adulteration. Links to resources on U.S. Pharmacopeia resources on food fraud can also be found in this section. (Updated May 2016)

- What can ASTA members do to minimize the risk of economically motivated adulteration? ASTA members have a shared responsibility to ensure that clean, safe spice is being traded in the U.S. in compliance with U.S. law. Companies are encouraged to know their supply chain, understand the points at which adulteration can occur and ensure their customers understand steps that are taken to prevent adulteration. The Food Safety Modernization Act (FSMA) addresses adulteration in both the Preventive Controls and Foreign Supplier Verification Program and companies will be required to implement steps to ensure adulteration is not occurring. ASTA also recommends you and your customers become familiar with the old adage "it if seems too good to be true, it probably is" as it relates to the price of spices.