
Investigator’s Desk Aid to the FDA Food Safety Modernization Act (FSMA) Whistleblower Protection Provision

Section 1013 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 399d

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This Desk Aid represents the Occupational Safety and Health Administration’s (OSHA’s) summary of the scope of coverage and protected activity and the procedures for investigating and adjudicating retaliation complaints under the FD&C Act, as amended by the FDA Food Safety Modernization Act, and as of the “last revised” date listed below. This Desk Aid is intended for OSHA’s use and the guidance herein is subject to change at any time. This Desk Aid is not a standard or regulation, and it neither creates new legal obligations nor alters existing obligations. Furthermore, there may be a delay between the publication of significant decisions or other authority under this whistleblower protection provision and modification of the Desk Aid. The Federal Register, the Code of Federal Regulations, and decisions of the Department of Labor’s Administrative Review Board remain the official source for the views of the Secretary of Labor on the interpretation of this whistleblower protection provision.

Abbreviations Used in this Desk Aid:

FSMA	FDA Food Safety Modernization Act (used in this Desk Aid to refer just to the Act’s whistleblower protection provision)
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act (a statute enforced by the FDA; FSMA amended the FD&C Act)
USDA	U.S. Department of Agriculture

I. FSMA in a Nutshell

FSMA protects employees from discharge or other retaliation by their employers for making complaints about food safety or other violations of the FD&C Act.

Under FSMA, no covered entity may discharge or otherwise retaliate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee), whether at the employee's initiative or in the ordinary course of the employee's duties, engaged in any FSMA protected activity.

A. Covered Entity

Covered entity:

FSMA applies to any entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food.

What does “manufacture, processing, packing, transporting, distribution, reception, holding, or importation” mean?

The whistleblower provision does not include definitions of manufacture, processing, packing, transporting, distribution, reception, holding, or importation. The FDA has defined some of these terms in other contexts, such as in the regulations pertaining to the FDA's registration requirements for food facilities. Although those definitions do not directly apply to the whistleblower provision, OSHA can use the FDA's definitions for guidance in interpreting these terms for purposes of the whistleblower provision. *See, e.g.*, 21 C.F.R. §§ 1.227, 1.328. These definitions include the following:

- “Manufacturing” or “processing” means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients.
Examples of manufacturing/processing activities include baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.
- “Packing” means placing food into a container other than packaging the food. “Packing” includes activities performed for the safe or effective packing or re-packing of that food, such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing. (“Packaging” means placing food into a container that directly contacts the food and that the consumer receives.)

- “Holding” means the storage of food and includes activities performed incidental to the storage of a food, such as fumigating food during storage. “Holding” also includes activities performed as a practical necessity for the distribution of that food (e.g., breaking down pallets). Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

What businesses are covered entities? Are restaurants and retail food establishments covered entities?

Many types of businesses that deal with food at every step of production and distribution—including shipping, storing, and cooking—are covered entities. Restaurants, grocery stores, other retail food establishments, farms, food testing laboratories, and food-safety inspection services are covered entities.

Although farms, restaurants, and retail food establishments are exempt from some FD&C Act registration and recordkeeping requirements,¹ the FSMA whistleblower protection provision contains no similar statutory exclusions and, as of publication of this Desk Aid, Department of Labor ALJs and the ARB have decided several FSMA cases involving restaurants,² retail food establishments,³ and food inspection/testing services.⁴

What is “food” under FSMA?

The FD&C Act defines “food” as anything used for food or drink for people or animals, chewing gum, or any component or ingredient of those things. This definition of “food” includes items that are commonly thought of as food, such as apples, lettuce, pizza, and cereal, as well as products like dietary supplements, beverages, infant formula, animal feed, and live food animals. *See, e.g.*, 21 C.F.R. §§ 1.227.

¹ The FD&C Act requires certain food facilities (excluding farms, restaurants, and retail food establishments) to register with FDA. 21 U.S.C. § 350d(a)(1), (c) (registration requirements apply to “any facility,” but the term “facility” expressly “does not include farms; restaurants; [or] other retail food establishments”). In addition, different recordkeeping requirements apply to different types of entities, including farms for some records. *See, e.g.*, 21 C.F.R. § 112.161 (general requirements for farm records under the Produce Safety Rule); 21 U.S.C. § 350c(b) (certain recordkeeping requirements apply to “persons (excluding farms and restaurants)”).

² *See, e.g., Phox v. The Savoy at 21c*, 2019-FDA-00014, slip op. 20-21 (OALJ May 25, 2021) (noting that hotel and restaurant holding food for public consumption is a covered employer under FSMA whistleblower protection provision).

³ *Courtney v. The Kroger Co.*, 2013-FDA-00001, slip op. at 28-29 (OALJ Aug. 12, 2015) (explaining that retail food establishments are covered employers under the FSMA whistleblower protection provision); *see also Brischle v. Super 1 Foods*, 2021-FDA-00006 (OALJ Mar. 4, 2022) (denying summary decision for grocery store employer in case involving food safety complaints by deli manager); *Roldan v. PSK Supermarkets, Inc.*, 2015-FDA-00006, slip op. at 14 (OALJ Oct. 17, 2016) (noting that company operating supermarkets is a covered employer under FSMA whistleblower protection provision).

⁴ *Byron v. I.E.H. Laboratories*, ARB Case No. 14-087 (ARB Sept. 28, 2016) (holding food testing laboratory was a covered employer under FSMA whistleblower protection provision).

Are any entities engaged in the manufacture, processing, packing, transportation, distribution, reception, holding, or importation of food exempt from FSMA coverage?

FSMA does not apply to an entity that is subject to USDA's mandatory inspection authority (e.g., a meat, poultry, or egg product processing facility) if that entity does not also manufacture, process, pack, transport, distribute, receive, hold, or import food that is regulated by the FDA. Live animals intended for food fall within the definition of food under the FD&C Act and are not subject to the carve-outs granting exclusive inspection authority to the USDA. Furthermore, producers of live animals, such as farms that raise hogs, cattle, sheep, goats, and chickens, typically engage in holding or distributing animal feed, which would subject them to coverage under FSMA.

If coverage questions arise, investigators should first consult with a supervisor and then confer with the Directorate of Whistleblower Protection Programs (DWPP) or the Regional Solicitor's Office (RSOL) for assistance in determining whether coverage exists.

Examples:

- An employee of a local grocery store that sells a range of fresh and packaged foods as well as salads, sandwiches, and baked goods prepared on-site, files a FSMA complaint. **The grocery store is a covered entity.**
- An employee at a factory that manufactures only nail polish and mascara complains that chemicals used to make those products have gotten into the sandwich she brought to work to eat for lunch. **The factory is not a covered entity** because it does not engage in the manufacture, processing, packing, transporting, distribution, reception, holding or importation of food; so, she does not have a claim under FSMA.
- A farm raises chickens from hatchlings under contract with a poultry producer. An employee of the farm claims the chickens intended for food use have been treated with unapproved new animal drugs. The farm is a covered employer since the chickens are intended for human consumption and it stores and handles animal feed.
- An employee of a chicken processing plant files a FSMA complaint. According to Attachment 1, the USDA has jurisdiction over poultry products in a plant subject to mandatory USDA inspection. **Investigators, after consulting with a supervisor, should contact DWPP or RSOL for assistance in determining whether the respondent is a covered entity.**

B. Protected Activity

Protected Activity:

An employee is protected from retaliation under FSMA if the employee:

1. Provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of the FD&C Act or any order, rule, regulation, standard, or ban under the FD&C Act;
2. Testified or is about to testify in a proceeding concerning such violation;
3. Assisted or participated or is about to assist or participate in a proceeding concerning such violation; or
4. Objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other person) reasonably believed to be in violation of any provision of the FD&C Act, or any order, rule, regulation, standard, or ban under the FD&C Act.

Complaints to whom?

Complaints to an employer, the Federal Government, or the attorney general of a State are protected. Other forms of objection to potential violations, such as complaints to state, county, or other local health departments may also be protected.

Complaints about what?

An employee is protected from retaliation for providing information about, objecting to, or refusing to participate in any activity that is, or that he or she reasonably believes to be, related to a violation of the FD&C Act. Attachment 2 to this Desk Aid is a summary of the FD&C Act meant to help assess whether a complaint is about a possible violation of the FD&C Act. In general, the most common allegations of FD&C Act violations raised in whistleblower complaints relate to the adulteration or misbranding of food.

Attachment 2 provides more detail about the adulteration and misbranding of food under the FD&C Act. Food is adulterated if it was made or stored in insanitary conditions such that it is, or may be, contaminated or dangerous to health in some way. Food may also be adulterated if it contains any harmful substance. As a rule, food is misbranded if its labeling is false or misleading in any way. Therefore, a complaint about the safety or contamination of food, or a complaint that food labeling contains false or misleading statements, representations, or omissions will (provided that the other coverage requirements are met) likely be protected by FSMA.

FSMA protects activity related to *any* violation of the FD&C Act. As explained in Attachment 2, the FD&C Act not only contains standards regarding food, but it also regulates drugs, medical devices, cosmetics, and tobacco products. It is important to remember, however, that an employer must manufacture, process, pack, transport, distribute, receive, hold, or import food to be covered under the FSMA whistleblower protection provision.

Does the employee need to mention the FD&C Act or FSMA when engaging in protected activity?

An employee does not need to mention the FD&C Act or FSMA when engaging in protected activity to be protected under FSMA. An employee also does not have to be correct that the information that he or she provided relates to an actual violation of the FD&C Act. Furthermore, an employee's complaint can take any form. For example, it can be in person, on the phone, or in an email.

What is a reasonable belief that a violation of the FD&C Act has occurred?

FSMA requires that a report or refusal to work relate to something that the employee "reasonably believes" is a violation of the FD&C Act, or any order, rule, regulation, standard, or ban under the FD&C Act. To have a "reasonable belief," an employee must have a *subjective belief* (i.e., actually believe that a violation has occurred, is occurring, or is likely to occur), *and* the belief must be *objectively reasonable* (i.e., it must be possible that a reasonable person in the employee's position would share this belief).

In determining whether these two requirements are met, the employee's experience and educational background are relevant. An experienced employee who handles food safety issues for a food processing company and routinely meets with FDA inspectors, for example, may be held to a higher standard of reasonableness. But many complainants may be unfamiliar with the FD&C Act. An employee in that position is protected from retaliation for reporting conduct that does or might violate the FD&C Act, such as the contamination of food with a dangerous substance. Importantly, the employee need not report an *actual* violation; the employee will be protected from retaliation so long as a reasonable person with the same training and experience could also believe that the relevant conduct is a violation, even if that belief is mistaken.

Examples:

- An employee of a grocery store is asked to put sandwiches in the display case for sale. The employee believes that the cheese in the sandwiches has been left out of the refrigerator for more than 24 hours. The employee refuses to put the sandwiches in the case because he believes that it is not safe for customers to eat them. The employee's refusal is protected if the employee reasonably believes that the sandwiches are not safe for customers to eat.
- An employee of a produce distributor with no expertise in the FD&C Act calls the FDA to complain that the distributor is shipping lettuce that has been sprayed with a chemical that is shipped to her worksite in boxes marked "Caution—poisonous contents." Even if the FD&C Act does not actually prohibit the use of the chemical on produce, her complaint is protected activity if it is reasonable for her to believe that applying the substance to lettuce makes the lettuce unsafe to eat.

- An employee responsible for testing food for a food testing lab that contracts with a peanut butter manufacturer complains to the director of his department that the process used to test samples of peanut butter for salmonella is flawed and does not adequately detect salmonella in the samples. The employee’s complaint is protected if the employee has a reasonable belief that the process is inadequate to detect salmonella.
- An employee of a food manufacturer complains to his supervisor that the manufacturer has not included on the label on the packaging of cookies made by the manufacturer that the cookies contain milk, a food allergen that must be listed on the label. The employee’s complaint is protected if the employee reasonably believes that the cookies contain milk and that the presence of milk in the cookies has not been properly disclosed on the label.

Does FSMA contain any explicit exceptions to protection?

FSMA does not protect employees who, acting without express or implied direction from the employer (or the employer’s agent), deliberately cause a violation of any requirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under the FD&C Act. Under analogous whistleblower protection laws, this exception to protection is an affirmative defense that the employer must raise and requires an element of willfulness. In other words, for the exception to apply, the evidence must show that the employee knew or acted with reckless disregard for whether his or her conduct violated the law.

II. Procedures for Handling FSMA Complaints

Procedures for handling FSMA complaints are contained in [29 CFR Part 1987](#). Below is a summary of the procedural provisions most relevant to the OSHA investigation. More information is also available in the “[What to expect during an OSHA Whistleblower Investigation](#)” section of OSHA’s website, the [OSHA Whistleblower Investigations Manual](#), and the [Filing Whistleblower Complaints under the FDA Food Safety Modernization Act](#) fact sheet.

A. Complaint

Who may file: An employee who believes that he or she has been retaliated against in violation of FSMA may file a complaint with OSHA. The employee may also have a representative file on the employee’s behalf.

Form: The complaint need not be in any particular form. Oral or written complaints are acceptable. If the complainant cannot make a complaint in English, OSHA will accept a complaint in any language.

Timing: The complaint must be filed within 180 days of when the alleged adverse action took place. Equitable tolling principles may extend the time for filing in limited circumstances, consistent with the guidance in OSHA’s Whistleblower Investigations Manual.

Distribution of complaints and findings to partner agencies: Complaints and findings in FSMA cases should be sent to the FDA.

B. Investigation

Upon receiving a complaint, OSHA will evaluate the complaint to determine if the complaint contains a prima facie allegation of retaliation. In other words, the complaint, supplemented as appropriate with interviews of the complainant, must allege that:

1. The employee engaged in FSMA-protected activity;
2. The respondent knew or suspected that the employee engaged in FSMA-protected activity;
3. The employee suffered an adverse action⁵; and
4. The circumstances were sufficient to raise the inference that the protected activity was a contributing factor in the adverse action.

If the complaint meets this requirement, OSHA will ask for a position statement from the respondent and proceed with the investigation. If it does not, and the complainant does not agree to administrative closure of the complaint, OSHA will dismiss the complaint with notice to the complainant and the respondent of the right to request a hearing before a Department of Labor administrative law judge (ALJ).

FSMA is a “contributing factor” statute. Thus, following the investigation, OSHA will find that retaliation occurred if it determines that there is reasonable cause to believe that FSMA-protected activity was a contributing factor in the decision to take adverse action against the complainant and the respondent has not shown by clear and convincing evidence that it would have taken the same action in the absence of the protected activity. A “contributing factor” is a factor which, alone or with other factors, in any way affects the outcome of a decision.

If OSHA finds reasonable cause to believe that retaliation occurred, it will issue findings and a preliminary order stating the relief to be provided. The relief may include an order requiring respondent to provide reinstatement, backpay, compensatory damages, other remedies for the retaliation (such as a neutral reference), and reasonable attorney fees and costs.

If OSHA does not find reasonable cause to believe that retaliation occurred, it will issue findings dismissing the complaint.

If the complainant and respondent agree to settle the case during the investigation, they must submit the settlement agreement for OSHA’s review and approval.

⁵ An adverse action is an action that might dissuade a reasonable employee from engaging in FSMA-protected activity. Examples of adverse actions include (but are not limited to) firing, demoting, denying overtime or a promotion, or disciplining the employee.

C. Administrative and Judicial Review

Either the complainant or the respondent may object to OSHA's findings within 30 days and request a hearing before an ALJ. Filing objections will stay OSHA's order for all relief except reinstatement, which is *not* automatically stayed. If no objections are filed, OSHA's findings become the final order of the Secretary of Labor not subject to review.

The ALJ proceeding is a *de novo*, adversarial proceeding in which both the complainant and the respondent have the opportunity to seek documents and information from each other in discovery and to introduce evidence and testimony into the hearing record. OSHA does not typically participate in the ALJ proceeding. Documents and other information submitted to OSHA during the investigation do not automatically become part of the record in the ALJ proceeding.

However, both the complainant and the respondent may introduce evidence that they obtained or used during OSHA's investigation into the ALJ proceeding. The ALJ may hold a hearing or dismiss the case without a hearing if appropriate. Either the complainant or the respondent may appeal the ALJ's decision in the case to the Department of Labor's Administrative Review Board (ARB), which may either accept or reject the case for review. The ARB's decision is subject to discretionary review by the Secretary of Labor. A complainant or a respondent may obtain review of an ARB decision or an ALJ decision which the ARB has declined to review by the appropriate U.S. Court of Appeals.

D. Kickout Provision

FSMA permits a complainant to bring a *de novo* FSMA action in federal district court if the Department of Labor has not reached a final decision on the complainant's FSMA claim within 210 days of the filing of the complaint with OSHA and the delay is not due to the bad faith of the complainant, or within 90 days after receiving OSHA's findings.

Attachment 1: FDA and USDA Jurisdiction (from FDA’s Investigations Operations Manual (2022))

The table below provides a simplified summary of the overlapping jurisdiction of the FDA and the USDA in certain establishments and may provide a useful reference for OSHA investigators. However, OSHA investigators should not rely on the table below as a substitute for a full analysis of FSMA whistleblower coverage in each case using the standards described above (see pp. 2-3), and should be aware that outside of the establishments subject to USDA’s mandatory inspection authority, USDA-regulated products are also subject to the FDA’s jurisdiction under the FD&C Act (for example, in retail establishments).

EXHIBIT 3-1

INVESTIGATIONS OPERATIONS MANUAL 2022

This table summarizes information concerning jurisdiction overlap for human food products regulated by either or both FDA and USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc.

FDA JURISDICTION	USDA JURISDICTION		
<p>21 USC 392(b) Meats and meat food products capable of use as human food shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals and all members of the deer family including elk (wapiti) and moose)). FDA responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese. For products not intended to use for human food this exemption does not apply. Any ingredient, including meat and meat food products, used in animal food is regulated by FDA.</p>	<p>The Federal Meat Inspection Act regulates the inspection of the following amenable species capable of use as human food: cattle, sheep, swine, goats, horses, mules or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001</p>	<p>The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001</p>	<p>The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs.)</p>
<p>Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or less than 30% fat, tallow or meat extract, alone or in combination. Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat and poultry meat (limited to less than 2%) in any combination. * Closed-face sandwiches. Any meat or meat food product used in or for animal food is regulated by FDA, regardless of %</p>	<p>Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or 30% or more fat, tallow or meat extract, alone or in combination.* Open-face sandwiches.</p>	<p>Products containing 2% or more cooked poultry; more than 10% cooked poultry skins, giblets, fat and poultry meat in any combination.*</p>	<p>Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction.</p>
<p>FDA is responsible for shell eggs and egg containing products that do not meet USDA’s definition of “egg product.” FDA also has jurisdiction in establishments not covered by USDA; e.g. restaurants, bakeries, cake mix plants, etc. Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.</p>			<p>Products that meet USDA’s definition of “egg product” are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.</p>
<p>Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), meat flavored spaghetti sauce with mushrooms, (2% meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor</p>	<p>Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie</p>	<p>Chicken sandwich (open face), chicken noodle soup</p>	<p>Homogeneous cheese and meat products, e.g., cheese balls with pepperoni, must contain more than 50 percent meat to be amenable to USDA inspection. Cheese products that contain 50 percent or less meat are considered products of the dairy food industry and, thus, are exempt from USDA inspection. When cheese and meat are separate components in a package, the packaged product is amenable, provided, it contains 2 percent cooked meat.</p>

Jurisdiction for products produced under the School Lunch Program, for military use, etc. is determined via the same algorithm although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200 and 567.300 provide additional examples of jurisdiction. IOM 3.2.1 and 2.7.1 provide more information on our interactions with USDA and Detention Authority.

* These percentages are based on the amount of meat or poultry product used in the product at formulation.

Attachment 2: Summary of the FD&C Act

The following is intended to provide a broad and simplified summary of the FD&C Act for use by OSHA investigators in deciding whether a complainant has a reasonable belief that there is a violation of the FD&C Act. This summary is not an official source of regulatory information regarding the FD&C Act. The FD&C Act is a complicated statute, and has been frequently amended, so investigators should refer to the statute itself (along with its implementing regulations) for a current and more comprehensive statement of legal authority.

Background

The FD&C Act contains provisions about:

- Food,
- Drugs,
- Medical devices,
- Biological products, such as blood and blood products,
- Dietary supplements,
- Cosmetics,
- Food and color additives, and
- Tobacco products.

The statute (Chapter 9 of Title 21 of the U.S. Code, 21 U.S.C. § 301 *et seq.*) and its implementing regulations (Chapter 1 of Title 21 of the Code of Federal Regulations, 21 C.F.R. § 1.1 *et seq.*) contain many specific provisions regarding each of these types of products. OSHA's whistleblower investigation focuses on whether the complainant reasonably believed that the complaint arose out of a violation. However, if the complainant is a food safety expert, the investigator may need to consult the applicable statutory and regulatory provisions.

Food

The FD&C Act prohibits the adulteration or misbranding of food in interstate commerce, or the receipt, introduction, or delivery for introduction into interstate commerce of any food that is adulterated or misbranded.

What makes food adulterated?

The FD&C Act addresses adulterated food under 21 U.S.C. 342. Here is a summary of several of these provisions:

Made in unsanitary conditions. Food is adulterated if it has been prepared, packed, or held in unsanitary conditions in which it may have become contaminated with filth or made harmful to health.

Poisonous or deleterious substance. Food is adulterated if it contains any added poisonous or harmful substance which may render it injurious to health.

Filthy, putrid, or decomposed substance. Food is adulterated if it contains any filthy, putrid, or decomposed substance or is otherwise unfit for food.

Unapproved additives. Food is adulterated if it contains an unapproved food additive or color additive.

Economic fraud: The adulteration of food may also occur if a valuable constituent has been omitted or if any substance has been added to a food that diminishes its quality, strength, or value.

Examples of situations where food may be adulterated include:

- The existence of live and dead insects in and around spices, spice blends, seeds, herbs, and sauces.
- The failure to prevent roof tar from dripping on food products and food-contact surfaces.
- The use of unshielded lighting over unpackaged food products.
- Storing food in a warehouse that is accessed by rodents.
- The failure of employees to wear appropriate hair coverings while working in a food processing plant.
- The lack of hot water for employees to wash their hands in a food processing plant.
- The addition of beet sugar, pulpwash, and other additives in juice marketed as 100% juice from concentrate.

What makes food misbranded?

The FD&C Act addresses misbranded food under 21 U.S.C. 343. In general, food is misbranded if it contains false or misleading labeling or if it otherwise fails to comply with labeling requirements in the FD&C Act or the FDA's regulations. Statements, graphics, and other representations made in labeling, as well as facts omitted from labeling, may be misleading and render the food misbranded. Examples of situations in which food may be misbranded include:

- Offering the food for sale under the name of another food or failing to state in the labeling the common or usual name of a food, if there is one.
- The container of the food is made, formed, or filled as to be misleading.
- The food is in package form and fails to state the name and place of business of the manufacturer, packer, or distributor.
- The food contains any artificial flavoring, coloring, or chemical preservative but does not bear labeling stating that fact and the FDA has not established an exemption.
- Failing to prominently display information required under the FD&C Act and its implementing regulations, such as nutritional and food allergen information.

Other Products Regulated under the FD&C Act

In addition to food, the FDA regulates the following:

- Drugs, including:
 - Prescription drugs (both brand-name and generic)
 - Non-prescription (over-the-counter) drugs
- Vaccines, blood products, and other biological products for humans
- Medical devices, including:
 - Common or non-high risk devices (like tongue depressors)
 - Complex or higher-risk devices (such as heart pacemakers)
- Electronic products that give off radiation, including:
 - Microwave ovens, X-ray equipment, laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps
- Cosmetics (including components of cosmetics)
- Dietary supplements
- Food additives
- Veterinary products, including:
 - Livestock feeds
 - Pet foods
 - Veterinary drugs and devices
- Tobacco products

(From <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>)

Attachment 3: Optional Worksheet: Analyzing FSMA Whistleblower Complaints

In order to issue merit findings, answers 1 to 9 must be “yes” and answer 10 must be “no.”

	Yes	No
Timeliness		
1. Was the complaint filed within 180 days of the alleged adverse action (or tolling applies)?	<input type="checkbox"/>	<input type="checkbox"/>
Coverage – (See Desk Aid pp. 2-3 and Attachment 1.)		
2. Does respondent manufacture, process, pack, transport, distribute, receive, hold or import food? (Reminder: restaurants, retail food establishments, farms, & food testing/inspection services are covered)	<input type="checkbox"/>	<input type="checkbox"/>
3. Do respondent’s activities relate to food that is at least in part regulated by the FDA?	<input type="checkbox"/>	<input type="checkbox"/>
Protected Activity (See Desk Aid pp. 4-6 and Attachment 2.)		
4. Has complainant (pick at least one):		
a. Provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government or the attorney general of a State information regarding conduct that the employee reasonably believes violates the FD&C Act or any order, rule, regulation, standard or ban under the FD&C Act (e.g., information concerning adulteration or misbranding of food)?		
b. Testified or is about to testify in a proceeding involving such a violation?	<input type="checkbox"/>	<input type="checkbox"/>
c. Assisted or participated or is about to assist or participate in a proceeding about such a violation (e.g., an FDA inspection)?		
d. Objected to or refused to participate in any activity, policy, practice or assigned task that the employee reasonably believed violates the FD&C Act or any order, rule, regulation, standard or ban under the FD&C Act?		
5. For items 4a. or 4d., does the complainant have a subjective, good faith belief that the conduct complained of violated the law?	<input type="checkbox"/>	<input type="checkbox"/>
6. For items 4a. or 4d., could a reasonable person with similar training, knowledge, and experience believe that a violation occurred, is occurring, or is likely to occur?	<input type="checkbox"/>	<input type="checkbox"/>
Employer Knowledge		
7. Did respondent know or suspect that complainant engaged in the protected activity? (Remember that knowledge may be imputed to respondent using a cat’s paw theory or the small plant doctrine if warranted by the evidence.)	<input type="checkbox"/>	<input type="checkbox"/>
Adverse Action		
8. Did respondent discharge or take other adverse action against the employee? (Adverse action is any action that could dissuade a reasonable employee from engaging in FSMA-protected activity. Common examples include firing, demoting, or disciplining the employee.)	<input type="checkbox"/>	<input type="checkbox"/>
Nexus (Contributing Factor)		
9. Was complainant’s FSMA-protected activity a <i>contributing factor</i> in respondent’s decision to take adverse action against complainant? Evidence that protected activity contributed to an adverse action includes, but is not limited to:		
• Close timing (temporal proximity) between the protected activity and the adverse action.		
• Evidence of hostility towards the protected activity.	<input type="checkbox"/>	<input type="checkbox"/>
• Disparate treatment of complainant as compared to other employees following the protected activity.		
• Changes in respondent’s treatment of complainant after the protected activity.		
• Indicators that respondent’s stated reasons for the adverse action are pretext.		
Affirmative Defense		
10. Is there clear and convincing evidence that respondent would have taken the same action against complainant absent the protected activity?	<input type="checkbox"/> No	<input type="checkbox"/> Yes