

## Distressed Foods, Drugs, Cosmetics and Medical Devices

Foods, drugs, cosmetics, or medical devices that are involved in suspected adulteration or misbranding, transportation incidents or other natural/manmade disasters can be subjected to any number of conditions that could render them unsafe or hazardous to consumers. In these events, it is the responsibility of the environmental health personnel to assess the condition of any food, drug or cosmetic involved in such incidents and to make sound decisions based on public health food protection policies and procedures.

Inspections should be conducted, as soon as possible, after accidents, truck wrecks, train derailments, fires, floods, back up of wastewater in a facility, or when other natural/manmade disasters occur. Every effort shall be made to limit the amount of product that is destroyed, however; decisions to salvage or destroy must be based on food protection policies and procedures without regard to economic concerns.

### Definitions

**Adulteration** – Food is adulterated if it:

- Contains any substance harmful to health;
- Contains any diseased, contaminated, filthy, putrid or decomposed substance;
- Has been produced, prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered diseased, unwholesome, or injurious to health;
- Is missing a valuable constituent;
- Contains any substance that has been substituted in whole or in part; or
- Contains any substance that has been added to increase its bulk or weight or make it appear of better quality or value than it is.

**Misbranding** – Food is misbranded if:

- It has labeling that is false or misleading;
- It is offered for sale under the name of another food;
- The container is so made, formed or filled as to be misleading;
- It does not conform to label declarations for weight, measure or numerical count; or
- It is a food that does not conform to a prescribed definition and standard of identity.

**Embargo** shall be defined as goods held pending the decision whether or not to condemn the product or release to re-enter commerce. *Embargo should not be confused with destruction, as the food is only being held temporarily while a determination is being made as to the status of the product.*

**Condemn** shall be defined as goods found to be or believed to be unfit for human consumption which need to be denatured and disposed or used for non-human product.

**Release** shall be defined as goods allowed to re-enter commerce.

### **Notification Process**

In most instances, the LPHA will be notified of an incident, such as a truck wreck, fire, flood or other natural/manmade disaster involving consumable food products in one of two ways:

1. The Missouri Highway Patrol, Local 911 Center or Fire Department will notify the DHSS Center for Emergency Response and Terrorism (CERT), Disaster Situation Room (DSR) who will in turn notify the LPHA or
2. The Law Enforcement, Local 911 Center or Fire Department will notify the LPHA directly.

Regardless of the method in which the LPHA is notified, the response procedures shall remain the same.

### **Response Procedures**

1. Upon notification of an incident, complete the Emergency Response Information Form. Record the type of food products involved, as well as, the location, date and time the incident occurred. Obtain the name, agency, and phone number of the person who is notifying you of the incident.
2. Upon arrival at the incident site, contact personnel in charge of operations, such as the sheriff, highway patrolman, liquor control agent or insurance agent.
3. Notify the responsible party in writing that the product involved in the incident is under 'embargo' (Goods Embargoed Form) and is not to be removed or disposed of until the DHSS, LPHA or the court gives permission for removal or disposal. The responsible party should sign this document. If the responsible party refuses to sign the Goods Embargo Form, contact the DHSS Food Safety Program Coordinator who will notify the DHSS General Counsel.
4. Inform the legal owner or agent of his legal responsibility to protect the embargoed goods by posting guards or by other means necessary.
5. Conduct a preliminary survey of the food and conditions at the site for environmental contamination factors, such as flood water, smoke, soot, heat, chemical, physical or impact damage. Note the weather conditions (temperature, precipitation, etc.) and its potential affect on the food product at the scene.
  - A. If there is generalized damage, such as a fire in a warehouse full of food product, it is not necessary to inventory each item. Instead, note on the Goods Embargoed Form that all food, drug or cosmetic products are under embargo. If there is a bill of lading, a copy can accompany the embargo form. (This also holds true for subsequent forms, such as Goods Released and Goods Released/Condemned as Unfit for Human Consumption).
  - B. If there is localized damage, such as a pallet of flour infested with bugs, and the rest of the food products appear sound, an exact inventory of the damaged products should be noted on the Goods Embargoed Form. (This also holds true for subsequent forms, such as Goods Released and Goods Released/Condemned as Unfit for Human Consumption).

- (I) In this case, the embargoed product should be placed in a secured area and a DHSS warning tag and seal placed through the door latch.
  - (II) If it is not possible to move the product to a secured place, then at least, a sufficient number of warning tags should be affixed to the embargoed product.
6. Check meats and other perishable products first. Fast action is imperative if readily perishable food is to be salvaged.
  7. Salvageable frozen foods and other perishable items must be transported and stored in approved refrigerated units. It is the responsibility of the salvager to provide or arrange for these facilities before starting the salvage of perishable foods.
  8. Determine whether the food product at the site is salvageable or condemned as unfit for human consumption. This may take some time to occur and should be started as soon as possible.
  9. Whenever possible, all salvageable food should be separated at the site from food that is condemned as unfit for human consumption.
  10. If, after evaluation of the food, it is determined that the product is in sound condition notify the responsible party in writing (Good Released Form or Goods Released/Condemned as Unfit for Human Consumption Form) that the product is released to re-enter commerce.
    - A. Product may be released from an embargo by an environmental health personnel when:
      - (I) It has been determined that the product has not been adulterated or misbranded;
      - (II) The product has been diverted to non-human food uses and has been denatured or de-characterized; or
      - (III) Ordered by the Court.
  11. If, after evaluation of the food, it is determined that the product is not in sound condition notify the responsible party in writing (Goods Released/Condemned as Unfit for Human Consumption Form) that the product is condemned as unfit for human consumption and must be destroyed or denatured. The responsible party must sign that they are willingly surrendering the product for destruction or denaturing.
    - A. If the product is perishable and the responsible party refuses to sign the Goods Released/Condemned as Unfit for Human Consumption Form, the environmental health personnel shall serve the responsible party a written notice directing him/her to hold the product for a period not to exceed three (3) days.
    - B. If the product is not perishable and the responsible party refuses to sign the Goods Released/Condemned as Unfit for Human Consumption Form, the environmental health personnel shall serve the responsible party a written notice directing him/her to hold the product for an undetermined period.
    - C. The environmental health personnel shall then notify the DHSS Food Safety Program Coordinator who will notify the DHSS General Counsel.
    - D. The General Counsel may request assistance from the County Prosecuting Attorney if criminal violations might have occurred.

- (I) The General Counsel will immediately apply to the circuit court, in the jurisdiction in which the product is located, for an order to condemn and destroy the product; and
  - (II) Upon application, the court shall immediately hold a summary hearing and decide to uphold or deny the application.
12. Supervise the destruction of all condemned product, observing local ordinances. Do not permit unsalvageable food to be removed from your jurisdiction.
- A. Destruction and/or denaturing can be accomplished by:
    - (I) Crushing the product with a compactor truck;
    - (II) Crushing the product at a transfer station;
    - (III) Burying the product in a landfill; or
    - (IV) Removing any wrapper/container from the product, disposing of the product in a dumpster and pouring bleach or other chemical over the product.
  - B. Food declared as unfit for human consumption, but permitted for use in animal food, should be denatured and is to be free of salmonella organisms and aflatoxins. Food intended for industrial use shall be denatured.
  - C. Do not permit condemned food to be taken for personal use by the salvager, his employees or anyone else.
13. If salvaged foods, under embargo, are removed from your jurisdiction promptly notify the health authority in the jurisdiction in which the salvaged foods are being transported, providing all available information. The salvaged food shall move under embargo with the vehicle sealed. The seal must only be removed by the regulatory agency once the vehicle has arrived at its final destination.
14. Chapter 196 RSMo mandates evaluation of distressed food, drugs, and cosmetics, however, 196 RSMo does not allow authority over non-food items such as tobacco products, pet foods, cleaning chemicals, paper products or single service utensils. In cases where single service paper products and utensils have become contaminated and are in a foodservice facility (restaurant, tavern, etc.) request that these products be disposed. In cases where single service paper products and utensils have become contaminated and are in a retail sales facility (grocery store, convenience store, etc.) encourage voluntary disposal of such items.
15. Be extremely cautious when responding to a transportation incident, fire, flood or other natural/manmade disaster. Extreme hazards can be associated with traffic conditions, structural integrity of the building, wet or slippery conditions and/or toxic chemicals present in the air. Remember that your safety is the primary concern.
- A. If you must transfer the products to a better/safer location, conduct a preliminary survey and segregate product that is obviously damaged from those products that need further examination.
  - B. Assure that product is not removed or altered during travel by securing the doors on the trailer or rail car with a DHSS warning tag. Record the tag number.

**Response Procedures Dealing with Other Government Agencies**

1. Meat and poultry products should be evaluated as salvageable or condemned as unfit for human consumption using the same criteria as would be applied in evaluating other perishable food items. Salvageable fresh meats and poultry products should be referred to the U.S. Department of Agriculture for reworking or reprocessing at an approved facility. In cases involving salvageable Missouri Department of Agriculture inspected meat and poultry products notify the Missouri Agriculture Meat and Poultry Inspection Program.
2. When liquor is involved, contact your local liquor control agent. Only salvagers with a valid license or permit issued by the Missouri Department of Public Safety, Division of Liquor Control, can salvage alcoholic beverages. Salvaged alcoholic beverages must meet the requirements of 11 CSR 70-2.250 Salvaged Alcoholic Beverages.
3. Drugs subject to salvage should receive special consideration. Class I through Class 5 controlled drugs shall be referred to the DHSS, Bureau of Narcotics and Dangerous Drugs or the Federal Drug Enforcement Administration. Antibiotics subject to salvage shall be referred to the United States Food and Drug Administration for their review.
4. Missouri Department of Agriculture, State Milk Board has authority over bulk milk products. Therefore, no response is necessary by the DHSS or LPHA when a transportation incident occurs involving a bulk milk truck.

**Occasions for Issuing an Embargo**

- When a transportation incident, fire, flood or other natural/manmade disaster occurs involving food, drugs or cosmetics.
- When questionable product or time/temperature abuses are discovered during a sanitation and safety inspection.
- When a recall notice is received from the DHSS, Food and Drug Administration, Food Safety and Inspection Service of the U.S. Dept. of Agriculture or other reliable source.
- When requested from another agency that does not have embargo authority (FDA, USDA, etc).
- When notified of a possible tampering, misbranding or adulteration incident.

**Standards for Determining Food Safety**

Whether it is a fire, flood, truck wreck, wastewater back up or other natural/manmade disaster, the following criteria should be used for evaluating foods:

1. Food Temperatures: Potentially hazardous refrigerated or frozen food must maintain a temperature of 45°F or below. Where temperatures are found to be above 45°F the product should not be considered salvageable.
  - A. Food Temperatures - Truck Wrecks:
    - (I) Upon arrival at the scene, record the time and temperature of all perishable food products. Continue to regularly record the time and temperature of these foods until it is declared unfit for human consumption or released back into commerce.

- (II) When the truck is opened, temperatures shall be taken and recorded at a point nearest to the entrance.
- (III) Temperatures should be taken directly from the product/package. If the product/package is thick or large enough to allow for a variation in temperature, temperatures should be taken from an area one-inch below the outside edge of the product/package.
- (IV) Product temperatures should be taken from the outer edge of the load then progressively toward the center of the load.
- (V) Product temperatures should be taken around any hole or break in the truck.
- (VI) Product temperatures should be taken from each different product in a mixed load.
- (VII) The ambient air temperature in the receiving trailer must be 45°F or below. Every effort should be taken to maintain this temperature during loading operations.
- (VIII) Product that is found to be above 45°F shall be marked for identification as unfit for human consumption.

**B. Food Temperatures - Fires, Floods and Other Natural/Manmade Disasters**

- (I) Upon arrival on the scene and safe entry into the structure, record the time and temperature of all perishable food products. Continue to regularly record the time and temperature of these foods until it is declared unfit for human consumption or released back into commerce.
  - (II) Temperatures shall be taken directly from the product/package. If the product/package is thick or large enough to allow for a variation in temperature, temperatures should be taken from an area one-inch below the outside edge of the product/package.
  - (III) Product temperatures should be taken from the outer edge of the cooler unit then progressively toward the center of the unit.
  - (IV) Product temperatures should be taken from each different product on the scene.
  - (V) Product that is found to be above 45°F shall be marked for identification as unfit for human consumption.
2. Fresh foods, such as produce and exposed food, should not be considered for salvage if it has been subjected to floodwater, sewage, fire, smoke, soot, pesticides, fuel or other automotive fluids, or other contaminants.
  3. Heat-damaged food items, regardless of the packaging material, that are noticeably charred or were in the immediate proximity of the fire shall not be considered salvageable.

4. Products in containers (whether plastic, glass, cardboard or other types of packaging) with screw-caps, snap-lids, crimped-caps, twist-caps, flip-top, snap-open, corks and similar type closures should be closely evaluated and if it is determined that they have been subjected to floodwater, sewage, fire, smoke and/or coated with a film of soot, pesticides, fuel or other automotive fluids, or other contaminants should not be considered salvageable. Often, contamination from water, smoke, soot or other residues will collect under the lid and are virtually impossible to clean.
5. Glass containers subjected to impact conditions, such as would occur as a result of a truck wreck, must be closely evaluated and in most cases should not be salvaged. The extent of damage to the primary packaging cannot always be easily seen and/or identified. Glass containers are subject to fractures and/or glass splintering. Additionally, an impact can result in compromising the container seal.
6. Damaged dry food product containers need to be evaluated according to the criteria below.
  - A. Flexible packages, such as pouches, bags, pur-paks, tetra-paks and plastic tubs constructed of plastic, cellophane, foil or other flexible materials having the following critical or major defects shall be embargoed or destroyed:
    - (I) Packages with bulges or swelling. This may indicate gas formation.
    - (II) Packages with abrasions, cuts, punctures, cracks, fractures or any other visible evidence of loss of hermetic seal.
    - (III) Pull-top containers with obvious fractures or dents on the lid scores lines or in the rivet area.
    - (IV) Packages exposed to smoke and/or coated with a film of soot or chemicals. Many plastics and cellophanes are partially permeable to these agents and depending on the condition can allow contaminants to travel through the packaging material. Additionally, these packaging materials can trap contaminants in seams and splits and are virtually impossible to clean.
    - (V) Packages with a double seam end, when the package has been crushed to the extent the double seam is affected.
    - (VI) Packages exposed to non-potable water such as floodwaters, fire extinguishers and rainwater. It is virtually impossible to remove dirt and to properly clean and sanitize these packages. Dirt has a tendency to collect in the splits and at the seams.
  - B. Cardboard packages having the following critical or major defects shall be embargoed and destroyed:
    - (I) Packages with cuts, punctures, rips or any other visible evidence of exposure of the product to contamination. Note that some products may have double packaging. For example, cereal is often packaged in a sealed inner bag within an outer cardboard box. The cereal may be salvaged if the inner bag has not been damaged or subjected to contamination.

- (II) Packages exposed to smoke and/or coated with a film of soot or chemicals. Most cardboard packages are permeable to these agents and depending on the condition can allow contaminants to travel through the packaging material. Additionally, these packaging materials can trap contaminants and are virtually impossible to clean.
- (III) Packages damaged by or exposed to floodwater, floor drain backup, water or chemicals used in firefighting, precipitation, fuel or other automotive fluids, smoke, pesticides or other contaminants.
- (IV) Packages damaged by physical means, such as an explosion, severe weather, glass shards, etc.

7. Damaged canned foods need to be evaluated according to the criteria below.

- A. Any cans having the following critical or major defects shall be embargoed and destroyed, with the exception of carbonated beverages and dry foods, e.g. ground coffee or powdered beverage mix, provided the container is otherwise intact.
  - (I) Cans with bulged ends. This may indicate gas formation.
  - (II) Cans with bulged lids due to severe dents or buckles with the exception of carbonated beverages and dry foods.
  - (III) Cans with holes or any visible evidence of product leakage. Stained labels may indicate leakage.
  - (IV) Pull-top containers with obvious fractures or dents on the lid scores lines or in the rivet area.
  - (V) Rusted cans with any pits that show a danger or imminent perforation.
  - (VI) Cans crushed to the point where they cannot be stacked or opened with manual can openers.
  - (VII) Cans dented on the score or at the juncture of the side seam and end seam.
  - (VIII) Cans cut or fractured through the metal on the end seam.
  - (IX) Flippers, springers and/or swellers.
  - (X) Cans with deep body dents where the can may be fractured.
- B. Plastic “cans” are usually rigid and more susceptible to permanent damage than metal cans; examine carefully and look especially for split sides and seams.
- C. Foods in hermetically sealed cans (top and bottom double seams) that have been exposed to contamination may be salvageable for human consumption if the owner reconditions and re-labels the product. The labels must first be removed and the containers cleaned with hot soapy water; rinsed with clean water, sanitized by immersing the cans in a solution of an approved sanitizer and air-dried. In most cases the can will need to be recoated to prevent the container from rusting. Finally, all cans must be re-labeled before entering back into commerce.

8. Information labels on all salvaged food containers must be legible and complete prior to entering back into commerce since many consumers are on restricted diets or have life-threatening allergies to certain food products.

**Can Classifications**

1. FLAT – A can with both ends concave; the can remains in this condition even when the can is brought down sharply on its end on a solid flat surface.
2. FLIPPER – A can that normally appears flat, but when brought down sharply on its end on a flat surface, one end flips out. When pressure is applied to this end, it flips in again and can appear flat.
3. SPRINGER – A can with one end permanently bulged. When sufficient pressure is applied to this end, it will flip in, but the other end will flip out.
4. SOFT SWELL – A can bulged at both ends but not so tightly, the ends cannot be pushed in somewhat with thumb pressure.
5. HARD SWELL – A can bulged so tightly at both ends that no indentation can be made with thumb pressure. A hard swell will generally “buckle” before the can bursts. Bursting usually occurs at the double seam over the side seam lap or in the middle of the seam.

**Duties of BERL Staff**

1. Provide consultation and technical advice.
2. Provide training to Regional and LPHA personnel.
3. Act as liaison between DHSS and other governmental agencies and industry.
4. Prevent unfit product from entering commerce.
5. Contact the Office of General Counsel for legal assistance, as needed.
6. Coordinate DHSS and LPHA activities.
7. Provide assistance to LPHA’s when requested.

**Common Responsibilities of Local Public Health Agency**

1. Respond when notified by DHSS (CERT-DSR), Highway Patrol, local law enforcement or other responsible parties, to all transportation incidents, fires, floods, or other natural/manmade disasters involving food, drugs, or cosmetics occurring within their jurisdiction.
2. Conduct on-site inspection(s), complete appropriate emergency response forms and determine condition of product.
3. Contact DHSS regional EPHS and request assistance if needed.
4. Evaluate food, drugs, and cosmetics as to whether they are salvageable and either release product back into commerce or witness voluntary destruction.
5. Embargo product, which may be adulterated.
6. Seek legal assistance from DHSS when needed to prevent unfit product from re-entering commerce.
7. Provide documentation of actions taken to DHSS Food Safety Program Coordinator.

**Common Responsibilities of the Product Owner or Representative**

1. Provide necessary equipment and personnel to protect product from contamination.
2. If needed, provide necessary equipment and personnel to maintain safe product temperatures.
3. If needed, provide necessary equipment and personnel for removal and destruction of product.
4. Dispose of unfit product in a manner approved of by DHSS and LPHA.

**REFERENCE MATERIAL**

E1.17 Emergency Response Information Form

E1.20 State Laws Accompanied by DHSS Rules and Administrative Guidelines Governing the Manufacture and Sale of Foods - Administration Guidelines for Distressed Foods, Drugs, and Cosmetics (Page 2-3)

E1.23 Warning Against Removal of Embargoed Goods

E6.07 Sanitation Observations

E6.11 Goods Released/Goods Condemned as Unfit for Human Consumption

E6.11a Goods Released/Goods Condemned as Unfit for Human Consumption Worksheet

E6.11b Goods Released

E19.0 Goods Embargoed