Distressed Foods

Section 196.030, RSMo mandates the Department of Health and Senior Services (DHSS) and its representatives to embargo foods, drugs, cosmetics, or medical devices that are involved in suspected adulteration or misbranding, transportation incidents, or other natural/manmade disasters. 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 policies and procedures.

Evaluations should be conducted, as soon as possible, after accidents, truck wrecks, train derailments, fires, floods, back-up of sewage in a facility, or when other natural/manmade disasters occur. Every effort shall be made to limit the amount of product destroyed, however; decisions to salvage or destroy must be based on public health food protection policies and procedures, not economic concerns.

Definitions:

Distressed – A food product is distressed when handled or held under abnormal conditions that potentially render the product unsafe. Distressed foods may or may not be reconditioned. A food product is distressed if it:

- Has the label missing, defaced, or obliterated;
- Is not readily marketable due to appearance, freshness, grade, surplus, or other considerations but has not been rendered unsafe or unsuitable for food use;
- Has been subjected to possible damage due to accident, fire, flood, adverse weather, or to any other similar cause; or
- Is suspected of having been rendered unsafe or unsuitable for food use.

Adulterated – A food product is adulterated when it meets one of the twelve conditions specified in 196.070 RSMo. In summary, 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.

Misbranded – A food product is misbranded when it meets one of the eleven conditions specified in 196.075 RSMo. In summary, food is misbranded if it:

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

Embargo - Goods held pending the decision whether to condemn the product or release the product to re-enter commerce as specified in 196.030 RSMo. Embargo should not be confused with destruction, as the product is only being held temporarily while a determination is being made as to its status.

Occasions for Issuing an Embargo

- When a transportation incident, fire, flood or other natural/manmade disaster occurs resulting in adulterated food, drugs, or cosmetics;
- When a product is deemed questionable based on observations 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. Department of Agriculture or other reliable sources and is not voluntarily removed from sale;
- When notified of a possible tampering, misbranding or adulteration incident; and/or
- Other circumstances by which food has been held under unsanitary conditions and may have become adulterated.

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

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

Notification Process

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

- The Emergency Response Center (ERC) or SEMA's Missouri Information Analysis Center (MIAC) will notify the on-call Bureau of Environmental Health Services (BEHS), Environmental Public Health Specialist (EPHS). They will evaluate the circumstances and determine the appropriate response; or
- 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: Initial Response, Assessment of Product, and Final Disposition

Initial Response:

- 1. Upon notification of an incident, complete the Emergency Response Information form. Record the type of food products involved; the location, date, and time the incident occurred; as well as, the name, agency, and phone number of who notified you of the incident.
- 2. 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. Use caution, each incident is unique. Response time may be delayed when site conditions are hazardous or under investigation.
- 3. In cases typically involving inclement weather, an over-the-phone embargo may be utilized as an interim measure if access to the incident/scene is too hazardous. This method of embargo should not be used lightly, as it is difficult to track product inventory and 196.030 RSMo mandates a tag be affixed to embargoed product.
- 4. In cases involving power outages, a large number of food establishments may simultaneously be impacted.
 - A. Contact the utility company, county emergency operations center, or other appropriate agency to determine the boundaries of the power outage.
 - B. Contact the power company that covers the affected area to assess the anticipated duration of the outage. Ameren Missouri and many other electrical cooperatives have a website containing this information.
 - C. The water supply may be lost or placed under boil order restrictions when power is lost. Contact the water supply district, municipal water supply utility or county emergency operations center to determine the status of the water supply serving the area.

Assessment of Product:

- 1. In cases involving an over-the-phone embargo, the LPHA should follow up and physically tag product within 24 hours or as soon as conditions permit.
- 2. In cases involving power outages or boil orders/advisories, the LPHA should begin an assessment of each establishment by telephone calls or site visits to confirm whether the establishment's electricity has been lost; water supply compromised, if they are operating; and their disposition of perishable foods, such as moving food to another location or using back-up generators.
 - A. Priority should be given to full scale grocery stores, high risk food establishments, and food establishments with poor compliance histories. If the scale of the event prevents the LPHA from addressing these types of facilities in a timely manner, contact your Regional EPHS for assistance.
 - B. During telephone calls, safe food handling guidance should be discussed with the owner/operator. As time permits, site visits of each food establishment should be conducted.
 - C. During site visits, safe food handling guidance should be discussed, disposition of food products assessed, and if appropriate a Power Outage Notice and/or Boil Order Advisory provided.

D. Adulterated food products shall be embargoed or voluntary disposed of appropriately.

- 3. For all emergency incidents, upon arrival, contact the owner/operator or their agent of the food product(s) and personnel in charge of the scene, such as, the sheriff, highway patrolman, or towing company.
- 4. 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, such as the temperature and precipitation and its potential effect on the food product at the scene.
 - A. For 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 Order of Embargo 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 and subsequent forms, such as the Final Disposition of Embargoed Goods.
 - B. For localized damage, such as a pallet of flour infested with bugs, an exact inventory of the damaged products should be noted on the Order of Embargo form and subsequent forms.
 - The embargoed product should be placed in a secured area and a DHSS warning tag and seal placed through the door latch.
 - If it is not possible to move the product to a secured place, a sufficient number of warning tags and "do not use" tape should be affixed to the embargoed product.
- 5. Conduct possible, take photographs of visual observations of the establishment, embargoed products, and/or site to document evidence of the event and circumstances.
- 6. Notify the responsible party, using the Order of Embargo form, that the product involved in the incident is under 'embargo' and is not to be removed or disposed of until the DHSS LPHA or court gives permission for removal or disposal. The responsible party should sign this document. If the responsible party refuses to sign the form, document the refusal, and contact your Regional EPHS V or BEHS on call EPHS.
- 7. Affix an embargo tag to the product(s) suspected of being adulterated or misbranded warning all persons not to remove or dispose of the food products until permission for removal of disposal is given.
- 8. Inform the legal owner or his agent of his legal responsibility to secure the embargoed goods by posting guards or by other means necessary.
- 9. Section 196.030 RSMo, mandates evaluation of distressed food, drugs, and cosmetics. However, this section of statute does not grant authority over non-food items such as tobacco products, pet foods, cleaning chemicals, paper products or single service utensils. In case where single service paper products and/or utensils have been contaminated, request these products be disposed/encourage voluntary disposal.
- 10. Determine whether the food product at the site is salvageable or condemned as unfit for human consumption. Salvageable food should be separated from food that is condemned as unfit for human consumption. Section 4.4: Standards for Determining Food Safety provides in depth criteria for evaluating foods.

- A. Meats and poultry products should be evaluated as any other perishable food item.
- B. Alcoholic beverages should be evaluated as any other food item. It is recommended you contact your <u>local liquor control agent</u> to notify them of the incident. An agent may or may not be present on site.
- C. Contact the Missouri Department of Agriculture, <u>State Milk Board</u>, when bulk milk and other dairy products, such as cream being hauled in a tanker truck, are involved in a transportation accident. They have regulatory authority. DHSS and LPHAs should not respond to incidents involving only bulk milk and other bulk dairy products.
- D. Special consideration needs to be made when drugs are involved; see section 4.5: Distressed or Adulterated Drug and Pharmaceuticals.
- 11. If foods under embargo, are to be transported to another local or jurisdiction, you must notify and provide all available information to the regulatory agency in that jurisdiction prior to the embargoed foods being moved.
 - A. Conduct a preliminary survey and segregate product that is obviously damaged from those products that need further examination.
 - B. The food shall move under embargo with the vehicle sealed by securing the doors on the trailer or rail car with a DHSS seal. The seal must only be removed by the regulatory agency once the vehicle has arrived at its final destination.
 - C. Record the seal number on the Order of Embargo form.
 - D. Contact your Regional EPHS V or BEHS on call EPHS prior to allowing embargoed products to leave the state. In most circumstances embargoed food should not leave the state.
- 12. When food product is determined to be in sound condition, notify the responsible party in writing that the product is released to re-enter commerce using the Final Disposition of Embargoed Goods form. Product may be released from an embargo when:
 - A. The product has not been adulterated or misbranded; or
 - B. Ordered by the Court.
- 13. When food product is determined not to be in sound condition, notify the responsible party in writing that the product is condemned as unfit for human consumption and must be destroyed or denatured. The responsible party must sign they are willingly surrendering the product for destruction or denaturing.
 - A. If the product is perishable and the responsible party refuses to sign the Final disposition of Embargoed Goods form, serve the responsible party a written notice directing him/her to hold the product for a period not to exceed three (3) days. At the end of the three (3) day period either a final disposition agreement needs to be in place or a new notice will be issued.
 - B. If the product is not perishable and the responsible party refuses to sign the Final Disposition of Embargoed Goods form, serve the responsible party a written notice directing him/her to hold the product for an undetermined period.

- C. Food declared as unfit for human consumption may be permitted for use in animal food pending approval by the Missouri Department of Agriculture or U.S. Food and Drug Administration.
- D. Notify the Regional EPHS V or BEHS on call EPHS. E. Request assistance from the County Prosecuting Attorney if criminal violations occur.

Final Disposition:

- 1. Supervise the destruction of all condemned product, observing local ordinances. Do not permit distressed and/or unsalvageable food to be removed from your jurisdiction.
 - A. Destruction and/or denaturing can be accomplished by crushing the product with a compactor truck; crushing the product at a transfer station; burying the product in a landfill; or removing any wrapper/container from the product, disposing of the product in a dumpster and denaturing by pouring bleach or other chemical over the product.
 - B. Do not permit condemned food to be taken for personal use.
 - C. Food intended for industrial use shall be denatured.
 - D. Section 196.030, RSMo does not grant DHSS or LPHAs seizure authority. It is imperative that the health authority never takes possession of food products for later disposal.

Standards for Determining Food Safety

Regardless of the incident, the following criteria should be used for evaluating foods:

- 1. Food Temperatures
 - Refrigerated or frozen potentially hazardous foods must maintain a temperature of 41°F or below.
 - 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. Caution should be exercised to minimize opening doors of malfunctioning refrigeration units. Opening refrigeration doors releases cold, conditioned air.
 - Product temperatures should be taken randomly from each unit on the scene.
 - 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.
 - Cold-held potentially hazardous foods found to be above 45°F shall be marked for identification as unfit for human consumption. Exceptions may be provided on a limited basis for raw meat products subject to heat treatment and retail facilities that utilize an approved Emergency Action Plan as described in section 4 below.
 - Once the truck/trailer is opened, temperatures shall be taken and recorded at the point nearest the entrance.
 - Product temperatures should be taken from the outer edge of the load/cooler then progressively toward the center of the load/unit.
 - Product temperatures should be taken around any hole or break in the truck.
 - Prior to reloading salvageable foods, the ambient air temperature in the receiving trailer shall be 45°F or below. Every effort should be taken to maintain this temperature during loading operations.
- 2. Unsalvageable Items include:
 - Fresh foods, such as produce and exposed foods subjected to floodwater, sewage, fire, smoke, soot, pesticides, fuel or other automotive fluids, or other contaminates.
 - Heat-damaged food items regardless of packaging that are noticeably charred or were in the immediate proximity of the fire.
 - Whether plastic, glass, cardboard or other type of packaging, products in containers with screwcaps, snap-lids, crimped-caps, twist-caps, flip-top, snap-open, corks and similar types closers subjected to floodwater, sewage, fire, smoke, soot, pesticides, fuel or other automotive fluids, or other contaminates.
 - Glass containers subjected to impact conditions, such as the result of a truck wreck. Glass containers are subject to fractures and glass splintering; the extent of damage to the primary packaging cannot always be easily seen and/or identified.
 - Food items exposed to extreme hot or cold temperatures that impact the package integrity such as a liquid freezing and rupturing its container.

- Cardboard packages having the following critical or major defects:
 - 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.
 - Exposure 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 contaminates to travel through the packaging material. Additionally, these packaging materials can trap contaminates in seams and splits and are virtually impossible to clean.
 - 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.
 - Damaged by physical means, such as an explosion, severe weather, glass shards, etc.
- Canned foods having the following critical or major defects (with the exception of carbonated beverages and dry foods, such as ground coffee or powdered beverage mixes, provided the container is otherwise intact):
 - > Bulges. This may indicate gas formation.
 - Bulging lids due to severe dents or buckles.
 - Holes or any visible evidence of product leakage. Stained labels may indicate leakage.
 - > Obvious fractures or dents on the pull-top lid score lines or in the rivet area.
 - Rusting with any pits that show a danger or imminent perforation.
 - Crushed to the point where they cannot be stacked or opened with manual can openers.
 - > Dented on the score or at the juncture of the side seam and end seam.
 - > Cut or fractured through the metal on the end seam.
 - > Flippers, springers, and/or swellers (see diagram at the end of this subsection).
 - > Deep body dents where the can may be fractured.
- 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:
 - > Bulges or swelling. This may indicate gas formation.
 - Abrasions, cuts, punctures, cracks, fractures or any other visible evidence of loss of hermetic seal.
 - > Obvious fractures or dents on the pull-top lid scores lines or in the rivet area.
 - Exposure 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 contaminates to travel through the packaging material. Additionally, these packaging materials can trap contaminates in seams and splits and are virtually impossible to clean.
 - > Double seam end crushed to the extent the double seam is affected.

- Exposure 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 splits and at the seams.
- Product held under unsecured conditions whereby product integrity may have been compromised by pests, unauthorized persons, or environmental conditions, such as:
 - ➤ A breeched or unlocked trailer left unsupervised at the scene of an accident.
 - > A storm-damaged food establishment left unsupervised.
 - Uncovered product held overnight in a temporary food event tent.
- 3. Salvageable Items include:
 - Foods in hermetically sealed cans 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 relabeled before entering back into commerce.
 - Information labels on all salvaged food containers must be legible and complete prior to entering back into commerce.
- 4. Emergency Action Plan. During times of disasters/incidents causing an interruption of electrical services, it may be beneficial to have temporary alternative processes in place to protect the public's health. The Conference for Food Protection, in response to growing demands, developed a model <u>Emergency Action Plan</u> (EAP) to assist retail food establishments in preparing for, responding to, and recovering from an emergency.

Responsibilities of the Owner/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 by the DHSS and LPHA.

Distressed or Adulterated Drugs and Pharmaceuticals

Section 196.015, RSMo, prohibits the manufacture, sale or delivery, holding or offering for sale any food, drug, device or cosmetic that is adulterated or misbranded. It is the responsibility of the Department of Health and Senior Services (DHSS) to evaluate these goods for adulteration.

Many of the processes and procedures to evaluate and handle adulterated drugs and pharmaceuticals are similar to those used to handle adulterated food. DHSS on-call and Regional Environmental Public Health Specialist (EPHS) are available to assist with decision making processes on distressed drugs.

Definitions

Drugs fall into three categories: over-the-counter (OTC), prescription drugs, and controlled substances. These categories influence how drugs are evaluated and handled.

<u>OTC drugs</u> are purchased directly by the consumer from the store shelves and do not require a prescription. Aspirin, cold remedies, and vitamins are common examples.

A <u>prescription drug</u> is a medication that can be purchased or given only with a written instruction from a licensed health care provider. Birth control pills, blood pressure medicines, and antibiotics are common examples.

A <u>controlled substance</u> is a drug or other substance that comes under the jurisdiction of the Federal Controlled Substances Act of 1970. Narcotics, depressants, stimulants, hallucinogens and anabolic steroids are common examples.

Determination of Adulteration:

Drugs, regardless of the incident, should be evaluated for adulteration using the same criteria detailed in section Standards for Determining Food Safety in this manual with the exception of temperature. Although many drugs must be held in a narrow range of temperature and humidity, our evaluation for adulteration will not include these factors. No generalized temperature range has been established by which all drugs must be held. Therefore, during an incident, a visual inspection shall be conducted.

A visual inspection is used to assess physical changes to the product that could affect its strength, quality, and/or purity. This includes but is not limited to a lack of uniformity in the product's shape, color, or texture; excessive condensation within the product container; freezing/melting due to weather conditions at the scene; obvious changes in homogeneity; leaking; compromised seals; and breaks, cracks, or other impact issues to glass containers. If these physical changes are observed, the product should be considered adulterated in accordance with 196.095 RSMo.

Special Circumstances:

For incidents involving OTC drugs, the evaluation for adulteration should be conducted on scene or at the facility. When OTC drugs are determined to be adulterated, the owner must determine the method of disposal and arrange for secure holding and transport to the disposal site.

A higher level of security is needed when dealing with prescription drugs and controlled substances and for that reason the owner or his representative must be on scene prior to any evaluation of product.

In a fixed facility like a pharmacy, prescription drugs and controlled substances are typically held in a restricted area or in locked cabinets/storage inaccessible to the general public. Trucks transporting prescription drugs or controlled substances normally carry these products in sealed totes. These totes should not be opened on the scene of a transportation accident as adequate security cannot be assured. If conditions at the scene indicate these drugs may have been adulterated; then all of the involved product should be placed under embargo and arrangements made with the owner to evaluate the product at a secure site.

It is common for the owner to want the product moved out of the county or state where the incident occurred, without the involvement of the health authorities. DHSS embargo authority gives us the authority to deny these requests until an evaluation is complete. Individual circumstances will dictate the best course of action.

Companies may wish to have a representative on site during the evaluation and sorting, this should be welcomed. Companies may decide to dispose of product without an evaluation of adulteration. If so, the company's decision must be documented. It is still the LPHA's responsibility to oversee the disposal of the product.

Final Disposition of Adulterated Drugs:

It is DHSS' responsibility to assure that adulterated product is removed from commerce. It is the responsibility of the owner of these products to assure that proper drug disposal methods are used. This applies to all quantities and classes of drugs. In most instances, disposing of OTC drugs, prescription drugs or controlled substances in a landfill or flushed into wastewater treatment systems is unacceptable as they pose a groundwater contamination hazard.

Best practice for disposing of drugs is to send them to a "reverse distributor" or company that specializes in drug disposal. When a reverse distributor or drug disposal company is used, the product must be transported under embargo. The owner is responsible for providing DHSS or the LPHA written assurance that all of the adulterated drugs were received and disposed of appropriately.