Bulk Repacking of Non-ready-to-eat Dry Product For Charitable Distribution Guidance Document





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Introduction

Providing protein rich, shelf stable food to non-profit food distribution organizations for relief to food insecure individuals and families within the US is a large need that can be met by charitable organizations utilizing volunteers to repack bulk ingredients into smaller packages. This Guidance Document is designed to provide safe packing conditions to enable non-profit organizations to provide millions of meals to food insecure people in the US. This Guidance Document creates a simplified set of standard operating practices to ensure that this certain kind of meal may continue to be produced by volunteers and non-profit organizations for distribution within the US.

Generally, the meals within the scope of this Guidance Document, include dried, shelf stable ingredients such as: rice, soy, beans, noodles, dried vegetables, dried pasta, and vitamin powder, with some variations. The meals must have a kill-step and must be cooked by boiling in water prior to consumption.

Currently, there is confusion between packagers (non-profits organizations who organize volunteers to pack the meals), food banks, (non-profits who collect food to be redistributed to food pantries), and governmental regulatory agencies as to what Guidance Documents, rules or best practices should be followed for these unique volunteer food packaging events to operate. There is a general consensus that these type of meals (dry good with a kill step) are extremely safe and desperately needed in domestic charitable food relief.

The goal of this Guidance Document is to ensure that safe, clean and sanitary food will be delivered to every recipient while allowing volunteers to continue to participate in the process of providing the food through non-profit organizations that implement and follow these guides and best practices.

This Guidance Document is limited in scope to the non-profit volunteer repacking segment that produce packages of meals that contain only dry ingredients from government regulated facilities that when combined would not be eaten without first being boiled in water. This Guidance Document is not intended to replace any current government regulatory requirements that may exist, but can be applied to a relatively small segment of the charitable food supply program where operational standards do not exist.

This Guidance Document will affect millions of people by making it possible for charitable organizations to meet the need of food insecure individuals. The hope of this Guidance Document is to make it possible for all participating organizations to do their part in helping serve our fellow humans in a safe, sanitary way.

Development of this Guidance Document was a collaborative effort of the following organizations:

- Association of Food & Drug Officials (AFDO)
- Feeding America
- Youthfront (Something to Eat[™]) in Kansas City
- Harvesters Food Bank in Kansas City
- Feeding Children Everywhere in Orlando
- Meals of Hope, Naples, FL
- Pack Shack, Rogers, AR
- Outreach Program, Union, IA

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- Youthfront (Something to EatTM), Kansas City
- Meals of Hope, Naples, FL
- Outreach Program, Union, IA

Section 1: Scope and Intent

1-102 Scope (Who this applies and doesn't apply to)

- (A) This Guidance Document only applies to non-profit organizations that do NOT package and/or sell the finished food product for a profit and intend to distribute the final packaged food in a charitable manner to domestic food banks, food pantries, and charitable feeding organizations like homeless shelters.
- (B) This Guidance Document only applies to the bulk repacking of dry ingredients purchased only from commercial vendors who package the dry bulk ingredients under appropriate government regulatory rules and regulations and in a government regulatory inspected and approved facility. All ingredients, when combined, require a Kill Step, like boiling in water, before being consumed.
- (C) This Guidance Document only applies to any organization, packing system, or event whereby staff and/or volunteers repack dry bulk ingredients whether it is in a facility designed for food production or in a facility not designed for food production, but still clean, such as a school cafeteria, classroom, or multi-purpose room.
- (D) This Guidance Document does NOT apply to any charitable food production, repackaging, or salvage efforts for any kind of fresh food, meat, produce, or any food that would have a limited shelf life.

1-(102) Definitions

For the purpose of this Guidance Document:

- (A) **Food Contact Surface**: means any surface, equipment, utensil with which Food normally comes into contact.
- (B) **Food**: any food whether in its bulk form or broken down for final packaging including the packaging itself.
- (C) **Bulk Dry Ingredients**: the food product that is purchased from a government regulated facility and originally packaged under government regulations in bulk form for the purpose of being broken down into smaller measured units and combined with other similar Bulk Dry Ingredients for the purpose of creating a protein rich, shelf stable meal that would only be eaten after boiling in water. Any bulk dry ingredients that can or would be eaten WITHOUT being boiled in water is not covered by this Guidance Document and therefore would fall under other established government regulatory requirements or the Model Food Salvage Code (AFDO 2017). Examples of Bulk Dry Ingredients would include products such as soy meal, uncooked (non-instant) rice, dehydrated vegetables, uncooked pasta and uncooked beans, all of which need to be boiled in order to be consumed.





(D) **Supervisor**: any person employed by a non-profit company for the purpose of over-seeing these Bulk Food Repacking events. This person would be the individual who has the highest level of training and signs off

- that all procedures and systems outlined in this Guidance Document were adhered to. The Supervisor does not have to be paid, but is an agent for the non-profit organization to ensure adherence to these guidelines. The Supervisor will inspect, enforce and verify that the Packaging Process is done properly.
- (E) **Volunteer:** any person who participates or handles, or in any way comes in contact with, Food whether they are paid or not. A person must be a minimum age of eight (8) before being allowed to participate in the touching in any way of the Bulk Dry Ingredients. An adult must supervise all Participants under the age of eighteen (18). Employee(s), Personnel, Participants, and Volunteers, are all used interchangeably and refer to the people involved in all aspects of these Packaging Events.
- (F) **Enforcement Agency**: State and/or local authority or authorities having responsibility for enforcing this any relevant codes.
- (G) **Consumer**: the human individual who intends to prepare by boiling and eating the packaged dry ingredients. Consumer is not necessarily a purchaser. Pets are not covered by this document.
- (H) **Sanitize**: the application of chemicals to the Food Contact Surface so that it is 99% clean.
- (I) **Distributor**: the non-profit entity that distributes the food to the consumer or distributes the food to the person who distributes to the consumer in a charitable way.
- (J) **Packaging Event**: the event, place, and time where volunteers repack bulk dry food ingredients into smaller, properly labeled packages, sealed, given a unique lot number, and then boxed to be distributed to consumers who will mix with boiling water in order to create a protein rich meal. All Packaging Events have a Supervisor who is employed by the supervising charitable organization.
- (K) Supplier: a person or company that supplies the dry bulk ingredients, or the packaging, or the utensils used in the packaging. All Suppliers of dry food ingredients must be government inspected and regulated producers or are a middle-man deliverer of government inspected and regulated products. Because many suppliers only deliver by truck-load, there are middle-man warehouses that buy the truck-load and then sell smaller lots of bulk product to charitable organizations. Assuming all products are produced and packaged in a government inspected and regulated facility, that all packages are undisturbed and in the original sealed packaging, and that all packages can be fully tracked through manufacturing tracking numbers, this is permissible under this Guidance Document.
- (L) **Vehicle**: any truck, car, bus, railcar, aircraft, boat, ship, or other means by which the bulk dry ingredients or the final Packaged Food is transported from one location to another.
- (M) Packaging Line: the lines that are used by volunteers to systematically measure the proper amount of bulk dry ingredients that are dumped, typically through a funnel, into the pre-printed bag. When all ingredients are combined and properly weighed, they are sealed by a thermal sealer and boxed for distribution. This "Packaging Line" is usually made up of volunteer groups of 8-10 people working on sanitized smooth folding

tables. All parts of the Packaging Line before the scales are considered Food Contact Surface.





(N) Intermediary Containers: the containers used to break the largest bulk dry ingredients into small tubs that Participants then measure the proper amounts of ingredients for the final package. These are typically tubs on a packaging line. This is considered a food contact surface. All Intermediary Containers must be made of flexible plastic and not include any glass, ceramic, or brittle plastics.



(O) Thermal Sealer: the final step of packaging line before boxing and its purpose is to seal the package in an airtight manner before being boxed for distribution. Each package should be checked for proper seal making sure sealers are properly adjusted to seal without burning the package.



- (P) **Other Utensils**: the Scoops, Cups, Tub Liners and Scales used in a typical volunteer packaging system and are considered food contact surfaces.
- (Q) **Supervising Organization**: a non-profit entity, overseen by a board of directors that adopts these rules into the minutes of duly called board meeting with a proper quorum at least once per year. The charitable organization establishes the policy for, supervises, and ensures compliance of, the Supervisor for all Packaging Events.
- (R) Packing Personnel Verification Form: the form that each volunteer will fill out and sign prior to participating in any Packaging Event. The name of the form may change, but will include contact information, verification of health, and verification on minimum training and cleanliness standards. This form stored by the Supervising Organization for a minimum of three (3) years after each Packaging Event.
- (S) Packaging Event Checklist and Verification Form: the form that each Supervisor will fill out and sign during and after each Packaging Event. The name of the form may change, but will include the name of the Supervising Organization, contact information of the supervisor, verification of minimum levels of training of all participants, verification of cleanliness standards, verification that proper Packaging Event process were followed, verification of food tracking systems, and verification that no unsanitary conditions were observed during the Packaging Event. This form will be stored by the Supervising Organization for a minimum of three (3) years after each Packaging Event.

- (T) Standard Operating Procedures (SOP): a user-friendly checklist or stepby-step instructions of how to set up and execute a packaging event. The checklist includes steps for Pre-set up, Set-up, the Packing Event itself, and Teardown.
- (U) **Registration Head Person**: the person who is designated to be in charge of making sure all of the participant's register, read, fill out and sign the Packing Personnel Verification Form, and that all personal belongings are stored in the designated area.
- (V) Line Table Head Person: the person on a packaging line who is designated to be in charge of that packing line(s). It is possible for this person to supervise more than one line. This person must at least 16 and with the most experience. This person will listen to instructions on starting and stopping and will intentionally watch the table for any food safety violations. (i.e. if someone sneezes, coughs, or comes into contact with a contaminated surface such as a cell phone, the table head will instruct them to re-wash and change to new gloves).
- (W) Sealing Table Head Person: the person sealing tables who is designated to be in charge of that the sealing process. It is possible for this person to supervise more than one sealing process. This person must be at least 16 and with the most experience. This person will listen to instructions on starting and stopping and will intentionally watch for any food safety violations. (i.e. if someone sneezes, coughs, or comes into contact with a contaminated surface such as a cell phone, the table head will instruct them to re-wash and change to new gloves). Additionally, this person would make sure sealers are working effectively.
- (X) **Boxing Station Head Person**: the person at the boxing station who is designated to be in charge of the boxing process. It is possible for this person to supervise multiple boxing operations. This person must be at least 16 and with the most experience. This person ensures proper boxing, taping, labeling and stacking of completed boxes and is double-checking that sealers are working effectively.
- (Y) **Received Delivery Verification Form**: the form that is used when a delivery of raw product is received. It verifies that the raw product is in good condition, the lot numbers and that there is no obvious evidence of contamination. This will be stored for three (3) years.
- (Z) **Delivered Packages Verification Form**: the form used when delivery final packages to the next distributor. It should be signed by the receiver, and it verifies final food packages were delivered in good condition and had no obvious signs of contamination. This will be stored for three (3) years.

Section 2: Participants

2-101 Health of Employees, Supervisors, and Volunteers

The non-profit organization shall exclude any Participants including the supervisor, any employees, and any volunteers from any contact with food or close proximity to food contact surfaces if the person:

- (A) Has been recently (last two (2) days) diagnosed with, or lives in the same household with a person diagnosed with or exposed to Salmonella typhi, Shigella spp, Escherichia coli 015:H7, or Hepatitis A Virus, or
- (B) Has been exposed to an outbreak caused by Salmonella, E-coli, or Hepatitis A; or
- (C) Has had in the past two (2) days symptoms of illness such as diarrhea, fever, vomiting, sore throat with fever, or jaundice; or
- (D) Has a lesion containing pus, such as a boil or a wound that is open or draining, that may be exposed to Food contact surfaces unless it can be adequately protected and covered by an impermeable cover.

Documentation of the health of all volunteers will be written on the Packing Personnel Verification Form, signed by the participant, and stored for a minimum of three (3) years by the supervising organization.

2-102 Cleanliness

All Participants whether they be supervisors, employees or volunteers shall practice hygienic practices necessary to protect the Food from contamination and cross-contamination.

- (A) Participants, while working in direct contact with Food or Food contact surfaces, shall maintain a high degree of personal cleanliness, wear clean outer garments, have fingernails trimmed and clean; wear hair restraints such as hair nets, headbands, caps or snoods.
- (B) Participants shall wash their hands and exposed portion of their arms thoroughly in an adequate hand-washing facility utilizing warm running potable water, hand soap and clean, single-use disposable towels before starting work, and as often as may be necessary to remove soil and after any activity that may contaminate hands or gloves.
- (C) As a replacement for warm water hand washing, Participants may use the three-step cleaning method outlined below:
 - a. Step one: Cleanse the hands and arms with an alcohol based, hand sanitizing solution.
 - b. Step two: Dry hands and arms with a single use disposable towel.
 - c. Step three: Re-sanitize hands and arms with an alcohol based, hand sanitizing solution, allowing to air dry.



- (D) Participants shall not resume work after visiting the toilet room without first washing their hands as outlined above.
- (E) No person shall eat food, drink beverages, or use tobacco in any form in area where Food is exposed or in areas used for washing equipment or utensils.
- (F) When gloves are used in any activity where the Food or its immediate container is directly contacted, they shall be clean and intended for singleuse. They shall be replaced anytime they contact an unsanitary surface or develop holes or tears.

2-103 Supervision

(A) The Head Supervisor is responsible for identifying, sorting and putting into intermarry containers and supervising packaging events. They should have a background education or experience to provide a level of competency necessary for handling of a clean a safe product. The Head





Supervisor shall have completed training that has allowed them to obtain the following:

- 1. A passing grade or satisfactory completion for a nationally recognized food handler or food managers training course. Records of this must be maintained by the supervising charitable organization for minimum of three (3) years.
- An understanding of warehouse management, and the concept of clean safe storage of food and ensuring a first-in first-out inventory management system.
- 3. An understanding of transportation of food and the necessary steps to ensure the delivery of a clean, safe, product without cross contamination.
- 4. A thorough understanding of tracking Packaged Food in a manner such that a recall, if issued from either one step before, or one step after, could be executed to the final distributor.
- (B) All Food, whether stored or transported, must have a direct supervisor who is responsible for ensuring the on-going process whereby Packaged Food is stored and delivered in a clean and safe manor.
- (C) Each Packaging Event must have a direct supervisor who ensures that:
 - 1. Communication is given in advance to all Participants as to the limits in age, any health situations, and dress code.
 - 2. The set-up of Packaging Lines is done properly and that each Food Contact Surface, including tables are adequately cleaned with a sanitizing solution.
 - 3. That only intermediary containers, scoops, cups, and funnels are recently cleaned and sanitized and that no utensils come in contact with anything unsanitary.
 - 4. That tracking labels are accurate and printed with the unique tracking number for the event and to be affixed to only the packages being filled in that particular event.
 - 5. Ensure that each person participating has filled out and answered the Packing Personnel Verification Form and questionnaire and understands the steps necessary to maintain a sanitary condition for handling the Food.
 - 6. That no tobacco, snacking foods, or other products unassociated with the repacking process are present or near the packaging area.
 - 7. Communication is done verbally to the group reviewing the health requirements and the proper procedures to package in a clean way.
 - 8. Training is done for the Head Registration Person, Head Packing Line Person, Head Sealing Table Person, and Head Boxing Station Person for their area.
 - 9. At the end of the packaging event, each of the intermediary containers are properly sealed and packaged with leftover bulk dry ingredients to be transported properly.
 - 10. That all contact surface including containers, scoops, cups and funnels are packaged and labeled in such way that they must be rewashed and sanitized before next use.

- 11. That all spillage is cleaned and disposed of properly ensuring that no spillage can come in contact with the Packaged Food.
- 12. That all final boxes for distribution are properly sealed and labeled with the packaging date, expiration date, and tracking information.





13. That finished boxes are stacked properly to prevent breakage.

- (D) Each Head Supervisor will fill out and sign in written form of verification of the process that was followed for each Packaging Event. This form must be archived by the supervising charitable organization for minimum of three (3) years. This entire process will be overseen by a board of directors for the charitable organization.
- (E) Registration Head Person is a minimum age of 16, who is most qualified to supervise the registration table and make sure each participant registers, gives basic verbal instructions pointing way to washing facility, hands out single use Gloves and Hairnets, and gives instruction to leave personal belonging in designated area.
- (G) Packing Line Head Person. is a minimum age of 16, who is most qualified to supervise each packaging line table and makes sure everyone at the table understands the food safety requirements, understands the proper way to fill scoops and cups and fill the bag, watches the table for any contamination instructing anyone who contaminates a surface to re-glove or sanitize, and to make sure all product that falls is disposed of and if any scoops or cups are contaminated that they are replaced and the table is cleaned properly.
- (H) Sealing Table Head Person is a minimum age of 16, who is most qualified to supervise each sealing table and make sure everyone at the table understands the food safety requirements, makes sure all sealers are set to the proper heat setting, makes sure no food safety protocols are violated, and inspects final packages for proper seal.
- (I) Boxing Station Head Person is a minimum age of 16, who is most qualified to supervise the boxing station and make sure all boxes are properly preassembled and sealed on the bottom with packing tape, making sure the proper number of completed packages is in each box using the supplied counting board, makes sure top of all boxes are properly sealed with packing tape with proper tracking labels affixed or written on the outside of at least two panels of the completed box and that all boxes are stacked properly on a pallet or otherwise to ensure that boxes don't collapse or break due to excessive weight and then wrapped.

2-104 Training

All Participants must be trained by the Head Supervisor or area supervisor in verbal forms of all the important sanitizing and packaging techniques and limitations due to age, and health.

Section 3: Exclusions

- 3-101 Food that may not be included in this guidance document.
 - (A) Meats, poultry, fish, or eggs. These foods are highly perishable and handling of them fall under the stricter guidelines under the USDA that this guidance document does not contemplate.



(B) Fresh produce. These foods are highly perishable and cannot be used under this guidance document.



(C)Frozen food or refrigerated food. If food must be frozen or refrigerated to keep it from perishing, it cannot be used under this guidance document.



- (D)Known allergens. This includes products such as nuts, peanuts, or peanut products that a larger percentage of the population is allergic to. This does not include gluten if the label states that it is not a gluten free product.
- (E) Poisonous or toxic materials.
- (F) Medical goods, or medicated food products.



(G)Any ingredient that would not be considered a dry ingredient with a lengthy stable shelf life at room temperature and humidity.

3-102 Contamination Protection.

(A) When separating, intermingled food, reasonable care shall be taken at all to times to prevent cross-contamination.

- (B) Any container, scoop, cup or funnel that is broken, or leaking must be disposed of immediately and all containers, scoops and cups, must not be made of any glass, ceramic, or brittle plastics.
- (C) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held and stored in a manner that protects against contamination of food, food contact surfaces, or food packaging materials.

Section 4: Equipment and Utensils

4-101 Design

All equipment including funnels, scoops, cups, intermediary containers, shall be designed, installed, and maintained to ensure adequate cleaning, shall be made of non-toxic, non-corrosive materials and cleanable materials, and not be made of glass, ceramic, or brittle plastics and should withstand repeated cleaning and sanitizing.





Tables must not be wood or of a porous material. All food contact surfaces must be able to be cleaned by a liquid sanitizing solution. If a tabletop is made of porous material, a smooth non-permeable covering may be used.

Section 5: Cleaning

Utensils and food contact equipment and surfaces shall be thoroughly cleaned and sanitized no less than seven (7) days prior to use with a dishwasher or three-compartment sink and stored in such a way to ensure no contamination.

5-102 Handling

- (A) During the packaging event food contact surfaces shall not be exposed to contamination from any other processes, via drift, dripping, splashing, or any other airborne method of contamination.
- (B) Participants' personal items such as medications, food, cosmetics, and tobacco product shall not be utilized or stored where food processing equipment is handled, cleaned, or stored.
- (C)All single-service articles such as gloves, hairnets, and tub liners shall be only used once.

5-103 Storage

- (A) Cleaned and sanitized equipment and utensils shall be stored in a manner that protects them from contamination when not in use.
- (B) Unused single-service articles used in processing consumer commodities, such as gloves, tub liners, cloths, paper cups, and paper towels shall be handled and stored in a manner that will protect them against contamination.

Section 6: Facilities

6-101 Water and Sewage

The water supply shall be from a municipality and safe for drinking and cooking. Sewage should be through the normal plumbing system and not exposed in any way to food or food contact surfaces.

6-102 Toilets

Each facility shall provide the Participants with properly installed, clean, and conveniently located toilet adequate to the size and duration of the Packaging Event with a notice posted instructing all Participants to wash hands before returning to work or to the handling food.

6-103 Hand Washing

Each organization shall provide adequate hand washing facilities conveniently located to the packaging area for its participants, with single-use sanitary towels or approved hand-drying devices or use the accepted three-step hand washing technique using alcohol-based sanitizer which is out-lined above.

If using traditional water-based hand washing facilities, reusable towels will not be permitted and a notice shall be posted instructing all participants to wash hands before returning to work or handling food.

If using the three-step alcohol-based method ensure that there is an adequate supply of bottles of hand sanitizer and single use towels easily accessible by any person before during and after touching food, that instructions on the method are posted as well as instructions to all participants to re-sanitize hands before returning to work or handling of food.

6-104 Garbage and Refuse

(A) All organic refuse shall be in a leak proof, non-absorbent container which shall be kept covered with a tight-fitting lid when filled or stored. Such containers shall be covered and vermin-proofed. Paper, cardboard, unused equipment, and non-organic refuse shall be stored in containers, rooms, or

- areas in such a manner to prevent it from becoming a source of contamination or pest harborage.
- (B) All refuse shall be disposed of with sufficient frequency and in a manner to prevent contamination of food, Food Contact Surfaces, and surrounding processing areas.

6-105 Insect and Rodent Control

No pests, rodents, birds or other animals shall be allowed in any area where food is stored or processed.

- (A) Effective measures shall be taken to exclude pests, rodents, birds or other animals from the processing and storage areas and to protect against the contamination of food. Proper rodent and pest control procedure should be performed by a licensed pest control company with an understanding of pest control in a food storage and/or processing facility.
- (B) The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food contact surfaces, and packaging materials. Application of insecticides and rodenticides should be directed and maintained by a professional pest control service.
- (C) If, at any time, any bulk dry ingredient comes into contact with a pest or rodent, it is to be separated from all other food and disposed of immediately.
- (D) Pests that should be excluded from storage or packaging areas include pets such and dogs or cats, and non-pets such as birds and flying insects.

Section 7: Packaging Facilities

Due the uniqueness of this guidance document for bulk repacking of dry food for charitable distribution, and due to the fact that all the dry ingredients come from a commercial FDA regulated producer and due to the fact that an average consumer would not consume the product without first combining it with boiling water, exceptions exist to make packaging events doable in a variety of facilities. For this kind of packaging event, it does not have to be conducted in an FDA sanctioned "clean room", or "cleaner room". However, it is required that all facilities where packaging events occur have the facility controls listed in Section 6 above.

7-101 Separation of processing rooms

The area used for the purpose of processing the food shall be separate from other rooms where perishable, or highly perishable food is processed and separate from any room where refuse or materials are stored that would contaminate the food or food contact surfaces.

7-102 Floors

- (A) The floor surfaces in all rooms and areas in which the food is to be processed must be cleanable by a broom, mop or vacuum sweeper. It is not permissible to do a packaging event on a dirt or grass surface or any surface that cannot be cleaned by these methods.
- (B) The floor is not a Food Contact Surface and therefore any product that touches or comes in contact with the floor will be contaminated and must be disposed of.
- (C) Prior to each Packaging Event, it must be reasonably ascertained by the Head Supervisor that these conditions will continue to exist during the Packaging Event.
- (D) After the Packaging Event, the Head Supervisor must certify, in writing, that these conditions did continue to exist during the Packaging Event and that if any food or utensil contacted the floor, it was considered contaminated and immediately taken out of service.

7-103 Walls and Ceilings

- (A) The walls and ceilings are not a Food Contact Surface and therefore any food that touches or comes in contact with the wall or ceiling will be contaminated and must be disposed of.
- (B) All walls and ceilings shall be kept clean and in good repair. Walls or ceiling that are not reasonably clean, such as a live-stock barn, or outside would not be permissible.
- (C) If any substance falls from the ceiling, all of the food in that area will be considered contaminated and must be disposed of immediately and all contact surfaces, equipment, and utensils must be cleaned and sanitized.
- (D) Prior to each Packaging Event, it must be reasonably ascertained by the Head Supervisor that these conditions will continue to exist during the Packaging Event.
- (E) After the Packaging Event, the Head Supervisor must certify, in writing, that these conditions did continue to exist during the Packaging Event and that if any food or utensil made contact with the walls or ceiling, or if anything fell from the ceiling, it was considered contaminated and immediately taken out of service.

7-104 Lighting

Adequate lighting shall be provided in hand washing areas, toilet rooms and in all areas where Food is processed, stored, or where equipment or utensils are cleaned.

- (A) Light bulbs, fixtures, skylights, or other glass suspended over exposed Food in any step of processing shall be designed to prevent contamination in case of glass breakage.
- (B) Prior to each Packaging Event, it must be reasonably ascertained that these conditions will continue to exist during the Packaging Event.

- (C) In the event that a packaging event must take place under an exposed light bulb or glass fixture, the Head Supervisor may certify that no glass breakage occurred during the packaging event on the Packaging Event Checklist and Verification Form in Section 13.
- (D) If any glass or substance falls due to glass breakage, all of the Food in that area will be considered contaminated and must be disposed of immediately and all contact surfaces, equipment, and utensils must be cleaned and sanitized.

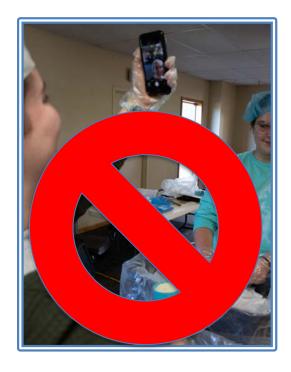
7-105 Ventilation

All Food storage rooms and processing areas shall be well ventilated. Ductwork shall be designed to prevent condensation from dripping into Food.

7-106 Clothing and Personal Belongings

An adequate location outside or away from the Food processing area must be designated for the orderly storage of Participants clothing, food and beverages, and personal belongings that cannot be in the processing area.

With proper training and supervision by the Head Supervisor and Head Line Person, it is possible for limited personal belongings such as purses and cell phone to be put under the table and out of reach by participants. If any personal items are touched, re-cleansing of the hands and arms is required before handling Food.





7-107 Housekeeping

- (A) All rooms, areas, and premises shall be kept clean and free of trash. Cleaning solution and chemicals should not come in contact with Food.
- (B) No Food processing areas should be used as a lounge, living area or sleeping quarters.
- (C)Soiled towels, coats, or aprons shall be kept in suitable containers until removed for laundering.

7-108 Transportation

Vehicles used to transport Food shall be maintained in a clean and sanitary condition to protect Food from contamination.

- (A) The floor, walls and ceiling of a vehicle transporting Food are not considered a Food contact surface and therefore any product that touches or comes in contact with the floor, walls, or ceiling of a transportation vehicle will be contaminated and cannot be used in the final Food package.
- (B) Vehicle must not have been used to haul dirt, animals, or been exposed to farmland or animal dung without proper washing and sanitizing.
- (C) Vehicle must not leak outside liquid.
- (D)A Delivery Form should be used to verify in writing for both incoming product to the warehouse as well as delivered final product to the next charitable distributor.



7-109 Verification

Verification that the facilities where a packaging event takes place complies with all facility and control guidelines will be performed, inspected, and signed off on by the Head Supervisor as specified in Section 2-103 on the "Packaging Event Checklist and Verification Form" or similar sample in found in Section 13.

Section 8: Packaging, Labeling and Tracking

8-101 Packaging

The inside of packaging is considered a Food contact surface and must be clean and sanitized as to ensure no contamination to the Food. Other requirements of the packaging are:

- (A) The material of the package must be made of a non-permeable material that can be sealed to ensure that no liquid can penetrate the packaging and is manufactured suitable for food storage.
- (B) The package size should be commensurate with the amount of Food put into the package.

8-102 Labeling

Food labeling must be truthfully and accurately labeled and such labels shall comply with applicable labeling requirements¹. The label must be on the outside of the package, must be clear and legible, and must be accurate as to what is inside the package. The goal of all labeling and packaging is to ensure that any reasonable person will boil the contents before consuming. All labeling must meet the requirements of the Federal Food, Drug, and Cosmetic Act, Fair Packaging and Labeling Act, and regulations promulgated under these Acts for products in interstate commerce. Each label at a minimum should include:

- (A) The name of the final product and it must be that largest type on the front panel of the package.
- (B) A label with ingredient and nutrition facts, printed to FDA approved specifications, must be printed on the package that contain:
 - 1. Serving size and number
 - 2. Servings per package (cooked)
 - 3. Standard Amount per serving in grams and % of Daily Value of:
 - a) Calories
 - b) Calories from fat
 - c) Fat
 - d) Saturated Fat
 - e) Trans Fat
 - f) Cholesterol
 - g) Sodium
 - h) Total Carbohydrate
 - i) Dietary Fiber
 - j) Sugars
 - k) Potassium

 $\label{lingNutrition} $$ $ https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm $$ $ https://www.fda.gov/Food/GuidanceRegulatoryInformation/Ucm2006828.htm $$ $ $ https://www.fda.gov/Food/GuidanceRegulatoryInformation/Ucm2006828.htm $$ $ https://www.fda.gov/Food/GuidanceRegulatoryInformation/Ucm20$

¹ Labeling requirements can be found on the FDA website at:

Additionally, many computer based applications and companies exist to ensure food labeling is done properly and accurately according to the ingredients of a package.

- I) Protein
- 4. A list of vitamins present given in % of Daily Value
- 5. A declaration of what a daily caloric intake is assumed.
- 6. Any other requirement by proper FDA labeling that may be adjusted in the future that clearly signifies the nutritional contents of the package.
- (C) Directions for cooking the product properly.
 - 1. Instructions for preparing and cooking properly should be written in English. In cases where distribution is in another country an insert with instruction in the local language may be included.
 - 2. Directions for preparing and cooking properly should be in picture form so that any person who cannot read can understand.
- (D) A list of every ingredient listed in order of largest quantity to smallest quantity.
- (E) The statement "Contains: Milk, Soy, Wheat, Eggs, Fish, Tree Nuts, Peanuts" (if the ingredient(s) is used) must be clearly printed on the package.
- (F) The statement "Not packaged in a peanut free environment" must be clearly printed on the package.
- (G)If there are any other commonly known allergens contained in the package, they must be clearly stated on the package. The common allergens are Milk, Soy, Wheat, Eggs, Fish, Tree Nuts, and Peanuts.
- (H) The name and address of the person or entity doing the packaging must printed on the package in such a way that a consumer could contact the packaging organization easily.
- (I) Net Weight of the entire package must be printed in grams and ounces at the bottom of the package.
- (J) A unique tracking number must be affixed to each package



(K) A suggested expiration date or a "Best Used by" date affixed to each package.

8-103 Carrier Boxes

Finished packages will be packed in a suitable box that will not easily break with the given content and weight and the labeling on the box shall include:

- (A) The name and address of the organization that package the Food.
- (B) The net weight of the entire box listed in imperial and metric conversion.
- (C) The date of packaging.
- (D) The tracking number of the packages in the box.
 - 1. All packages in a box must have the same tracking number.
- (E) The suggested expiration date or "Best use by" date of the packages in the box.





8-104 Accuracy of Contents

Every effort shall be made to ensure that the contents of each package is as identical to the label as possible by:

- (A) Providing cups and scoops that are proven accurate.
- (B) Providing a weighing method whereby the final net weight is accurate to within 3 grams of the stated net weight, being adjusted by the bulkiest product that affects the nutritional content the least (such a rice or dry pasta).



- (C) Giving clear instructions and supervision to Participants who are scooping and weighing ingredients
- (D) If any package spills or loses Food between the final weighing and the sealing, it must be discarded and not sealed since it is now inaccurate.

8-105 Tracking

Every finished package of a Food must be given a tracking number that will be accurate enough to conduct a recall of the product if the recall comes from the commercial vendor of the bulk dry ingredients, by a person or incident during the packaging that require a recall of all the packages from that event, or if a recall is ordered due to an end-consumer becoming sick or discovering contamination. The tracking number will contain:

- (A) A number that is unique to that packaging event. This number can contain a date but also must be unique to the packaging event in a given location. Each number must be able to be tracked by the packaging organization to:
 - a. The lot numbers of each original bulk dry ingredient used in the packages at that event.
 - b. The date of the packaging.
 - c. The location of the packaging.
 - d. The list of personnel who participated in the packaging or handling of the Food through the "Packing Personnel Verification Form"(s).
 - e. The "Packaging Event Checklist and Verification Form" signed by the Supervisor on file.
 - f. The distributors (food banks) or users (food pantries) where the finished product was distributed.
- (B) A date when best used by.
- (C) This label must be unique to the event and not pre-printed on the package.
- (D) Each new packaging event, or packaging day, must contain a new and unique tracking number.



(E) Two (2) filled, sealed, samples of a final package, with appropriate tracking number, from each packaging event must be retained and stored by the supervising organization for a minimum of three (3) years after the Packaging Event.

8-106 Recall Audit

Each Packaging Organization must do a mock recall at least once every two (2) years to ensure that proper records, organization of records and sample packages, and accurate quick recall of said records/sample packages, and hence affected product, can be tracked at least one step up the chain and one step down the chain from the Packaging Organization.

Section 9: Records

9-101 General

Written records shall be retained by the non-profit organization for inspection by the Enforcement Agency if needed. Records documenting bulk repacking and distribution shall be maintained such that traceability of lots, ingredients and expiration dates are recorded and such records can be used to verify adequate handling and for the purpose of recall should that become necessary. Other records that must be filed, archived and available for inspection are:

- (A) A list of lot numbers of the bulk dry ingredients from commercial suppliers including the name and address of the manufacturer or supplier, and the date received.
- (B) A "Received Delivery Verification Form" that verifies product received was in good condition with no obvious signs of contamination.
- (C)A list of all Participants who were present at any packaging event that include their name and basic contact information with a written acknowledgment of minimum health and clothing requirements.
- (D)A list of distributors such as food bank and food pantries where finished Food were distributed including lot and tracking.



- (E)A "Delivered Packages Verification Form", signed by the receiver, that verifies final packages delivered were in good condition had no obvious signs of contamination.
- (F) A "Packaging Event Checklist and Verification Form" signed off on by the supervisor before, during and after the event.
- (G)Any proper documentation including an IRS Final Determination letter and/or audit ensuring that the packaging organization is non-profit and is distributing the Food in a charitable way.
- (H)An IRS Form I-990 (as per public inspection guidelines) for the most recent year that lists the board of directors.

All records must be retained on the premises of the supervising organization for a period of three (3) years following the final distribution, must be organized in such a way for quick recall, and must be open for public inspection during normal business hours.

Section 10: Permits

Occasionally a permit to execute a packaging system will be sought by the most appropriate local authority. If this Bulk Repacking Guidance Document is followed closely, the appropriate authority may issue a permit to conduct the packaging process according to this guideline, thereby making it acceptable to food banks and food pantries that are required by their governing body to accept reasonably safe food.

Section 11: Inspection and Enforcement

The most appropriate local authority always has the right to inspect not only the packaging process without prior announcement but also to inspect the storage facility and transportation methods. The appropriate inspection personnel have the authority to issue an injunction, temporary shut-down, or complete closure according to their accepted methods. Appeals, remedies or rectification of problems will be done according to the local inspection authorities' methods and policies.

Section 12: Checklists For Supervisors of Packaging Events

This Guidance Document for the bulk repacking of dry Food goods for the charitable distribution requires a list of procedures, check-lists, and verifications, that when accomplished and backed by a charitable supervising organization, ensure that the food, designed for charitable creation and distribution is as close as reasonably possible to being safe for the end user. These checklists and verification forms should make it possible for the local enforcement agency to certify the packaging process. Although this Guidance Document is not foolproof

to prevent someone from intentionally causing harm, it is reasonable and allows people who desire to help the food insecure, do so safely.

All of these Checklist and Procedures samples can be found in the next section and they include:

- (A) A list of documents that must be maintained by the supervising organizations to prove it is non-profit such as 501(c)(3) final determination letter, supervisory structure, board policies, company in good standing, and inspection and certification certificates.
- (B) A Standard Operating Procedure (SOP) for each packaging event.
 - 1 This is a list of everything that must take place before, during and after a particular packaging event. This document takes this Guidance Document and makes it user friendly.
 - 2 The contents and checklists of the SOP would be verified by the Head Supervisor on the Packaging Event Check-list and Verification Form.
- (C) A Packing Personnel Verification Form
 - 1 This form is for the express purpose of documenting contact info, basic health screening, and the minimum training for each person who participates in a packaging event and is clearly legible and not considered "fine print".
 - 2 Enough time must be given for participant to read and fully understand the contents of the form and they should be signed and archived by the supervising organization for a minimum of three (3) years.
- (D)A Packaging Event Check-list and Verification Form
 - 1 This is a very important form that the appropriate local authority will rely heavily on in order to certify local packaging events.
 - 2 This form is a checklist and verification that the most essential parts of this Guidance Document are adhered to during the set-up, execution and clean up from a packaging event.
 - 3 This form must be personally signed and verified by a trained Head Supervisor who is an agent of the charitable supervising organization.
 - 4 This signed verification form must be filed and archived by the supervising organization for a minimum of three (3) years.
- (E) A "Received Delivery Verification Form"
 - 1. This form verifies that product received from FDA regulated production facilities was received in good condition with no obvious signs of contamination and can be used to track incoming lot numbers.
 - 2. This form should be signed by the warehouse supervisor and delivery person/company and archived
- (F) A "Delivered Packages Verification Form"
 - 1. This form verifies that final product packages/boxes were delivered to the next charitable distributor is in good condition with no obvious

- signs of contamination and can be used to track out-going lot numbers.
- 2. This form should be signed by the packaging organization delivering as well as the receiving organization, and archived.

Section 13: Sample Documents and Checklists

A) Sample Packing Personnel Verification of Health and Minimum Training.

The following form is a sample form that must be filled out and signed by each personnel over the age of eight (8). It must be filed and archived by the supervising charitable organization for a minimum of three (3) years.

Packing Personnel Verification Form

Name:	Address:
Contact Phone:	Contact E-mail:
diagnosed with or expose Virus, or have been expo	have not been diagnosed with, or live in the same household with a personed to Salmonella typhi, Shigella spp, Escherichia coli 015:H7, or Hepatitis A osed to an outbreak caused by Salmonella, E-coli, or Hepatitis A; or have as diarrhea, fever, vomiting, sore throat with fever, or jaundice.
· · · · · · · · · · · · · · · · · · ·	g pus, such as a boil or a wound that is open or draining, that may be exposed equately protected and covered by an impermeable glove.
True Not True	If untrue, explain:
on my person in any way	ndy, tobacco products, or have any food or drink with me, in my pockets, or . I understand that handling any food, touching my mouth, face, covering a ing any unsanitary surfaces such as a cell phone, may contaminate the food.
True Not True	If untrue, explain:
event to use the bathroom	ed my hands and arms and will continue to do so if I need to leave the packing or if I come in contact with any unsanitary surface such as covering a sneeze anitized hand or touching a cell phone. I will leave all personal belonging in ckaging lines.
True Not True	If untrue, explain:
The above is a true statem	nent and as best I understand I am safe to package this food for consumption
Signed:	Date: /

B) Sample Packaging Event Checklist and Verification Form.

The following form is a sample form that must be filled out and signed by the supervisor at the conclusion of each packaging event. The supervisor must meet the minimum requirement outlined in Section 2-103 of this Guidance Document. The final original completed form must be filed and archived by the supervising charitable organization for a minimum of three (3) years following the packaging event.

Packaging Event Checklist and Verification Form

Supervising Organization:	Contact phone:
	Location:
Event Tracking Detail:	Supervisor:
I verify that the following is true during the abo	ove-identified Packaging Event.
I am current with my ServSafe® certificated All tracking numbers for raw ingredients. All tubs, funnels, scoops and utensils were to transport product chemical contamination. There were no bathroom facilities with a disingular clean tub liners were used in all bulk contamination. All tables were wiped down with a disingular clean tub liners were used in all bulk contained at Veryone must wash their has been cannot be anything in the Everyone must leave all personal contained and signed at Veryone must leave all personal contained anything in the cannot be anything in the cannot be no dangling or the can be no dangling or the can be no dangling or the cannot be anything in the cannot be anything in the cannot be anything in the cannot be no dangling or the cannot be anything in the cannot be anything in the cannot be no dangling or the cannot be anything in the cannot be no dangling or the cannot be no dangling or the cannot be anything in the cannot be no dangling or the cannot be no dangling or the cannot be anything in the cannot be no dangling or the cannot be not contained to the cont	ation. Is used have been recorded for tracking purposes. It washed prior to this event. It was clean and with no obvious dirt, animal dung or doors that opened directly into the room of the Event. If ecting agent. Intainers. It is intainers. It is intainer for each participant which included: It is and disinfect. It is onal items in holding area. It your pockets, no food, no cell phones. It is intained area. It is packaging area. It is loose jewelry It, or coughing, please leave the packing line. It is gloves at all times. It is other to ensure compliance. It is not the packaging area. It is not coughing, please leave the packing line. It is not coughing, please leave the packing line. It is not coughing, please leave the packing line. It is not coughing.
proper method of weighing	e of scoops, leveled ingredients and the each package to within 3 grams.
Instructions given on prope There were no lights or light fixtures tha	
A tracking tag was applied to each pactracking number.All products spilled onto the floor were of the f	kage created and all packages in a box have the same
All boxes were labeled with tracking and	l best used dates.
Ç .	e" by the Supervisor, please explain in detail below.
Signed:	

- C) Sample Standard Operating Procedures for a Packaging Event.
 - (1) The following form is a sample form that must be followed in pre-event, setting up, executing and cleaning up a packaging event. This form is a written check-list that is unique to each supervising organization and may be adjusted depending on the type of meal being packaged.
- (3) There may be set-up diagrams included.
 - (4) The purpose of this Standard Operating Procedure (SOP) is for the inspecting or certifying authority to be able to endorse a process that follows the procedures outlined in this Guidance Document and to ensure that each packaging event is supervised by properly trained and certified personnel.
 - (5) Each set of Standard Operating procedures must contain steps for Preevent, Set-up, The Packing Event, and Clean-up.

Standard Operating Procedures for the Packaging Event For: Cheesy Rice and Vegetables Meal

These procedures and diagrams will change depending on room size, meal prepared, and local requirements.

Pre-Event

- 1. Wash all cups, scoops, bins, and lids shortly before the event.
- 2. Inventory that all supplies are needed for each packing line. (this may be its own check-list)
- 3. Collect raw product needed for the size of the packaging event.
- 4. Record all appropriate tracking numbers from raw product.
- 5. Properly package and load onto clean truck/vehicles.

Set up

- 6. Completely clean the room of obvious trash, tripping hazards, and dust.
- 7. Ensure the room is adequately lighted checking to make sure all light fixture are in working order and that nothing is dangling or on the verge of falling from the ceiling.
- 8. Set up two smooth (non-wood or porous) folding tables for each packaging line in such a manner that finished bags are all coming off at the same end. See room diagram provided by the supervisor.
- 9. Set-up a long row of folding tables for the sealing stations. See room diagram provided by the supervisor.
- 10. Set up registration tables in such a way that all participants must register and fill out health verification form before entering. Have plenty of paper and pencil/pens available. Identify registration and personal belongings storage area with signage in such as way that it is visible and clear at the entrance. As soon as food is exposed all participants must have registered, filled out the verification form and must have adequate food safety protection (washing, gloves, hairnet etc.).
- 11. Establish an area away from food packing lines for pallets and/or raw product bags.
- 12. Establish an area away from food packing lines for box assemblage and packing of boxes with complete meal packages. Identify with signage.
- 13. Establish an area away from packing lines for contaminated scoops, cups and containers to be stored for rewashing after the event. Identify with signage.
- 14. Establish a space, outside the packaging area for personal belongings to be stored. Identify with signage.
- 15. Completely clean and disinfect each table with a chorine based antibacterial agent. See diagram for the following:
- 16. Set one funnel, one funnel stand and one funnel catch basin at the head of each packing line.
- 17. Set scales and transport bin on the opposite end of each packing line.
- 18. Set one sealed tub for rice, one sealed tub for soy, and one sealed tub for dehydrated vegetables on three sides of the funnel. Do not open until all participants have been trained and are properly protected.
- 19. Set vitamins and cheese packet tub on remaining corner of the funnel.
- 20. Set empty new bags next to funnel.
- 21. Set appropriate scoops and cups on clean table next to the correct tub.
- 22. Set Intermediate bag holder and rice weight control container and small scoops next to scales.

- 23. Set intermediate bag transport bin at the end of the line beyond the scales.
- 24. Run extension chords to sealing stations. Tape down with gaff type tape any extension chords that could be a tripping hazard.
- 25. Set sealers and counting boards on sealing tables.
- 26. Set appropriate and correct tracking labels (or machine) on the sealing tables.
- 27. Set tape machines, box tracking labels and pallet plastic wrap in boxing area.
- 28. For any empty tubs, install a clean new tub liner.
- 29. Fill tub and liners with product. All food, and liners must be handled by properly cleaned Participants. (Washing, gloves, hairnets etc).

From this point on, all participants in the food packaging area must have registered with the Participant Verification Form and be properly protected for food safety (washing, gloves, hairnets etc.)

The Packing Event

- 30. As participants enter, establish one person on each line to be the Line Table Head who is in charge of watching for food safety protocols. This should on of the people on the funnel with the easiest job, such as inserting the cheese packet, is over 21 and has experience.
 - A) The table head watches to see if anybody coughs, sneezes, or comes into contact with a contaminated surface such as a cell phone, or an unsanitized hand and ask the person to stop and change to new gloves.
 - B) Watches for any scoops or cups that may fall or come into contact with a contaminated surface and make sure it is replaced with a new one.
 - C) Make sure that any packages that spill are removed and properly discarded.
 - D) Make sure no one starts packing until after instruction have been given.
- 31. Establish a Table Head of the sealing tables. This person should be above 21 and the one with the most experience.
 - A) Since food may still be temporarily exposed the sealing table head also watches for food safety violations.
 - B) Watch to make sure all sealers are working and bags are being fully sealed without burning.
 - C) If a sealers stops working, take it out and replace with a working sealer.
 - D) Watch to make sure bags are being collapsed with as little air as possible.
 - E) Watch for any bags that spill or are contaminated in any way and remove them to be discarded.
- 32. Establish a head boxing station person. This person should be above 21 and the one with the most experience.
 - A) This person ensures that the proper number of bags are put into each box.
 - B) Ensures that each box is properly taped
 - C) Ensures that each box has a tracking label attached.
 - D) Ensures that the pallet is stacked properly so boxes don't collapse under the weight.
- 33. Quiet the room and the supervisor gives instructions including the following:
 - A) Instruct the room not to start until all directions are finished
 - B) Review the Participant Verification Form and the importance of accuracy and good health.
 - C) Instruct that no jewelry should be hanging and nothing should be in anybody's pockets in a way that may fall out.
 - D) Review the importance of properly washing, gloving up, putting on hair and beard nets.

- E) Review the importance of not touching anything contaminated like covering a sneeze, cough, touching a cell phone or shaking an unsanitary hand.
- F) Instruct that the line table head person is in charge of the table and that he/she will be instructing the table on starts and stops, communicating to the supervisor(s), and will be watching for any food safety violations.
- G) If a food safety violation occurs, the line table head will point it out and instruct to put on new gloves.
- H) Have all participants review each other for good food safety protocols (check for gloves, hair nets, jewelry etc.).
- I) Give instruction and demonstration for the proper way to will a bag including the order of ingredients and how each scoop/cup should be filled for accuracy.
- J) Begin packing.
- 34. Periodically during the event, review all of the previous instructions.
- 35. As tubs of product get low, fill with clean new product. All handlers of food must be registered and using all proper food safety protocols.

Clean-up

- 36. As lines finish, consolidate all remaining product into tubs with liners that can be sealed.
- 37. Collect all clean container bags and consolidate them into clean containers.
- 38. Collect all used bins, funnels, scoops, and cups and consolidate them for washing.
- 39. Collect all other materials (funnel stands, scales, sealers, extension chords) and put them in appropriate clean containers for transporting. Clean all trash from room and discard, including any product that was contaminated.
- 40. Wipe down tables and clean any other surfaces.
- 41. Load the truck/vehicles in a such a way that nothing will come loose, break or shift.
- 42. Take down tables, do final cleaning and leave with a smile!

- D). Sample Received and Delivery Verification Forms.
 - (1) The following form is a sample form that must be followed when receiving or shipping Food products and must be archived for a minimum of three (3) years and must be quickly available in case of a recall.

Receiving/Delivery Verification Form

Date:/	Receiving Product: Delivery of Product:
Name of Outside Organization: _	
Address:	State: Zip:
Contact Phone:	Contact E-mail:
List of Incoming product:	
	Lot #:
Exceptions/Issue/Problems:	
I certify that the above product	is delivered as stated above.
Deliverer:	, Printed Name / Title:
Receiver:	, Printed Name / Title:

Section 14: Summary and Conclusion

Creating a model Guidance Document that is outside of the norm of food production processes has been the goal of this project. There are many examples in our society where food preparation, because of its unique nature, such as food salvage, microbreweries or boutique bakeries, requires a model Guidance Document designed for that specific production.

The purpose of this Guidance Document has been to give local regulatory and food inspectors the tools needed to approve a process. This is outside the norm because the process is not tied to a specific location, room, or vehicle such as a food truck. Instead, the inspector is relying on a well thought out system that relies on approved individuals who will sign off on the accurate execution of the event. It is believed that with proper record keeping and supervision a process can be approved to the satisfaction of all.

Approving a process that is not tied to a location has not been a common practice for food and drug officials. It is much easier to certify a warehouse, a production room, or even a mobile kitchen than a process. This model Guidance Document is unique in this regard for the following reasons:

- 1. 100% of the raw ingredients addressed by this Guidance Document is produced in FDA approved and inspected facilities and is dry to the extent that all the ingredients must be boiled in order to be palatable to humans.
- 2. All food is produced by non-profit entities and is given out to food insecure individuals in charitable places like food banks, food pantries, or homeless shelters. None of the regulations in this Guidance Document will give any business the ability to make more profit over competitors who follow more stringent guidelines.
- Although it is impossible to protect from every single contaminant and even more impossible to protect against someone who intends to harm, all agree that these regulations will produce a product that is more than 99.99% safe for food insecure individuals.
- 4. We need this! Food insecurity is a growing problem here in the USA and around the world. The desire and need for protein rich, shelf stable, palatable food for food pantries and food banks is massive. People are willing to donate time, money, and energy to meet this need. It behooves us to make it possible for them to serve their fellow man.

In conclusion, this Guidance Document is a working document that will be reviewed from time-to-time as new best practices come to light. If you are a professional in the food protection, charitable creation, or charitable distribution arena and you learn of better way to do this, get involved and do it. If you could speak into the next version of this Guidance Document, please contact the AFDO and get involved. This works because we all work together. The desire for all us is to serve and protect people the best that we possibly can.

For additional copies of the Model Bulk Repacking for Charitable Distribution of Food Guidance Document order online at AFDO.org/Publications.

Appendix A

Following is a list of collaborating organizations in creating this Guidance Document for review and adoption by the AFDO.

- (A) Youthfront / Something to Eat. Topher Philgreen, COO. 4715 Rainbow Blvd, Shawnee Mission, KS 66205 (913) 262-1700. www.youthfront.com/somethingtoeat
- (B) Feeding America Food Distribution Network, Wayne Melichar and Mitzi Baum, Food Safety and Agency Compliance. 38 East Wacker Drive, Suite 2000, Chicago, IL 60601. 800-771-2303 www.feedingamerican.org
- (C)The Pack Shack. Bret Raymond, CEO, 5211 S 43rd Street, Rogers, AR 72758. 479-466-3646. www.thepackshack.org.
- (D)Outreach Inc.. Floyd Hammer, CEO. 301 Center Street, Union, IA 50258. 800-513-0935. www.outreachprogram.org.
- (E) Feeding Children Everywhere. Dave Green, CEO. 830 South Ronald Reagan Blvd. Longwood, FL 32750. 888-891-6447. www.feedingchildreneverywhere.com
- (F) Meals of Hope. Steve Popper, CEO. 2221 Corporation Blvd, Naples, FL 34109. 239-537-7775. www.mealsofhope.org
- (G)Harvesters Community Food Network of Kansas City. Steve Davis, COO. 3801 Topping Ave, Kansas City, MO 64129. www.harvesters.org
- (H) Mid-Ohio Food Bank.

AFDO is an international leader and trusted resource for building consensus and promoting uniformity on public health and consumer protection issues related to the regulation of foods, drugs, devices, cosmetics and consumer products.

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