To assure the achievement and maintenance of the integrity and quality of our products, Nutrishus Brands Inc. (NBI) has the expectation that the requirements regarding quality, sensory, food safety and other parameters are met on an ongoing basis by the contracted manufacturing facility. All our contract manufacturers are expected to meet the regulatory requirements- local, state and federal- including compliance with the Food Safety Modernization Act regulations.

Below are requirements for contract manufacturers/co-packers involved in the production of products for NBI:

Management

- Besides the normal duties of management of a food production facility, NBI requires that management at all levels receives continuing education in food safety. This training must be documented.
- Management must provide the resources (manpower, time, etc.) for support of food safety requirements and initiatives.
- Management must commit to achieving certification to one of the GFSI quality and food safety schemes. Refer to NBI policy ***NBPOL005 Global Food Safety Initiative Certification*** for details on compliance with the NBI policy.
- There must be an up-to-date organization chart delineating those responsible for food safety, quality and food defense.

Quality System

- Plant QA systems
    a) Must be defined, with responsibilities and authority assigned.
    b) There must be a written quality procedures manual available for plant and QA staff.
    c) Documentation, monitoring and verification activities must be clearly defined, with frequencies included.
    d) A written Hold/Release procedure is in place, and release authority is assigned. The system must be designed to prevent unreleased items from entering the production stream and/or being shipped to the market.
    e) A formal documented system for receiving, evaluating, and tabulating complaints is in place, with management reviews of the complaint information.
- There must be a procedure in place to handle 3rd party and regulatory audits.
- There must be a written and implemented document/record control system. NBI requires access to all documents related to the production of NBI products.
- All testing and inspection is to be completed and documented prior to any release for shipment. Material determined to be out of compliance is to be placed On Hold and NBI notified. NBI will provide the disposition for On Hold material.
- Where microbiological evaluation is required, no product is to be shipped until notification by NBI.

Training

- Trainers must be certified and have received external training and/or have thorough experience in the topics in which they are training. Certificates, training records and work experience of the person(s) performing training are current and available for review by NBI.
- The contract manufacturer is to provide new hires with an orientation that outlines company quality policy, philosophy and expectations, and food safety programs – including GMPs, HACCP/Preventive Controls and Food Defense. Documentation must be available and show that the training took place before the new hire started working in the facility.
- The contract manufacturer must provide ongoing training in food safety, GMPs, HACCP/Preventive Controls and food defense for all employees, including management and non-production staff. Documentation showing the training was provided must be available for review by NBI or designated representatives.
- Where training is required to meet NBI quality and food safety requirement, documented training must be provided by the contract manufacturer. NBI may assist upon request.
- Temporary personnel are not to be employed on NBI production runs unless they have been fully trained the same as regular employees of the contract manufacturer. Documentation must be available to NBI.

Product Inputs / Incoming Material Control

- NBI retains the right to determine the sourcing, grade and quality of the inputs – ingredients, raw materials and packaging. NBI has the option to also act as the purchaser of these inputs.
- Vendor Approval / Certification Programs are documented and implemented. Supplier approval program with appropriate verification activities is required by 21CFR117 Subpart G.
- Specifications are to be on file and available for use. They must be current and incorporate the appropriate food safety requirements for each raw material and ingredient purchased for use in NBI products.
- Have on file the appropriate Letter of Guarantee that all regulatory and NBI requirements are met on a per lot basis. These documents are to be renewed, at a minimum, every three years.
- Incoming carrier vehicles and incoming raw materials are inspected. Where a manufacturer has certified a supplier and does not normally inspect the raw materials from that supplier, NBI reserves the right to make a determination to inspect or not for those materials being used for NBI products.
- Substitutions of type of ingredients is not acceptable. Proposed substitution of grade and quality of an ingredient will be managed through NBI policy ***NBPOL004 Change Control Policy.***
- Emergency substitutions due to external factors such as severe weather, transport issues, etc., must also be addressed through NBI policy ***NBPOL004 Change Control Policy.***

- Incoming raw materials and ingredients are lot-coded and properly rotated using FIFO standards. FIFO is to be linked to the supplier date of manufacture.
- Tankers used for bulk ingredients are dedicated for the specific use intended, are transported and received under seal, and have appropriate documentation verifying, they have been properly cleaned and sanitized.
- There must be a program in place to ascertain the safety of incoming raw materials and ingredients. Certificates of Analysis (COA) must be received for items to be used in the production of NBI products.
- A program of monitoring must be in place for the storage areas of raw materials and ingredients. This includes ambient, refrigerated and frozen storage areas.
- Raw materials and ingredients On Hold or Rejected are to be appropriately segregated from acceptable material and clearly marked to avoid inadvertent use.
- Raw material containers must be labeled, covered and in good condition.
- Ingredient, raw material and packaging storage areas are to be in good condition and repair, with appropriate sanitation procedures implemented for cleanliness and to prevent any cross-contamination. The same housekeeping and food safety controls used in production areas must also be in place in storage areas.
- A program must be in place and documentation available to NBI for the review of off-site warehouse and storage facilities for raw materials and ingredients and finished product. Inspection and audit of the policies and programs in place of the off-site facility to assure compliance with GMPs and other food safety and quality requirements for NBI products.

<u>Process Equipment / Maintenance</u>

- The processing equipment employed in the production of must be constructed of material that is readily cleanable and sanitizable. The potential for cross-contamination of allergens and previous non-compatible ingredients and raw materials is a critical concern of NBI.
- The equipment should be suitable for the process activity for which it is to be used. Equipment configured beyond its designed purpose- often termed “jerry-rigging”- and the use of temporary fixes (tape, cardboard, wire, etc.) is not acceptable for the production of NBI items.
- A documented preventive maintenance program must be in place and implemented.
- A documented, corrective maintenance program must be in place for employees to identify items that require repair
- The Maintenance function must have a current maintenance procedures manual avail for use by facility staff.
- String, wire, tape, etc., are not to be used for temporary repairs.
- Process make-up air is properly cleaned and filtered. Records of the cleaning and changing of filters, including pore size, must be maintained.

Process Methods

- The methods and practices employed in the production of NBI products must meet the requirements of NBI as contracted. If on-site observation by NBI staff or a third-party group designated by NBI determines that a method and/or practice is not acceptable, NBI will enter into discussion with the contracted manufacturer to determine if the method and/or practice is to continue or cease during NBI destined production. Agreement or rejection is to be in writing.
- Any process method and/or practice which is found to be non-compliant with the current GMP (21CFR117 Subpart B) must immediately cease. NBI will require material produced while the non-compliant method/practice to be placed On Hold and not shipped until NBI determines the disposition for the material.
- All process methods and instructions must be in writing and available to the appropriate staff of both the contract manufacturer and NBI.
- Adherence to formulas is critical to the success of NBI. Refer to NBI policy ***NBPOL003 Formulation Control and Verification*** policy for details concerning formulas for NBI items.
- All containers of in-process ingredients, raw materials and finished product must be properly labeled, covered, and cleaned between fillings.
- Waste containers are identified by color coding and/or labeling, and waste is removed from production/processing areas at appropriate intervals and not allowed to accumulate to a level which presents a hazard to food safety.
- Sanitary GMP procedures must be used for opening raw material and ingredient containers to avoid contamination.
- All monitoring equipment (scales, thermometers, pressure gauges, etc.) must be checked and calibrated routinely by a 3rd party or using NIST traceable equipment. Documented methods and records of calibration must be in place.

The potential for allergen and non-NBI formula ingredient cross-contamination is of critical concern to NBI and must be fully addressed to the written satisfaction of NBI during planning for NBI production runs.

As a contracted partner, NBI has the expectation that all required process steps will be carried out as designed, and that the contracted manufacturer will provide the services required to produce a high-quality product for NBI.

Plant Facility

- Any opening in walls must be sealed properly. Materials used for sealing must be approved for use in a food production environment.
- Floors must be smooth, free from cracks, pitting and rough surfaces and are readily cleanable.
- Floor drains must be clean, covered and trapped.
- Walls, ceilings, exposed structural supports, partitions, equipment, etc., are clean, free of flaking paint, stickers, rust, loose insulation and be in good repair.

- No leakage or condensation is observed from roof, ceiling, or overhead conduits or pipes.
- Drip pans are installed where needed, cleaned and properly drained.
- Exhaust fans to the exterior are adequately screen and equipped with self-closing louvers.
- Adequate hand washing facilities are available with water at the proper temperature (approx.100°F), with soap and disposable sanitary toweling. “Wash Hands” signs are to be clearly posted in appropriate languages at all hand wash stations.
- Separate and properly labeled sinks for hand washing, product and utensil washing are available.
- Rest room, locker/changing rooms and break rooms are to be neat, clean and well lit. These room must not empty directly into production, processing or food storage areas. These areas are to be vented to the outside and have self-closing doors. “Wash Hands” signs are to be clearly posted in appropriate languages at the exits of these areas
- All hose stations are equipped with backflow / back siphoning devices.
- Surplus and unused equipment must not be stored in production areas.
- Ladders and walkways above exposed product lines must be protected to avoid foreign material adulteration.
- Air in Ready-To-Eat (RTE) areas are tested for air flow and quality at least annually.
- Hoses or nozzles (i.e., openings or nozzles) do not lie directly on the floor.
- Hand tools and knives are in good repair and stored in a sanitary manner between uses.

<u>Sanitation</u>

- A documented Pre-Operational Program must be in place to assess sanitation and equipment readiness prior to production. Methods such as ATP swabbing are to be used to verify cleaning at least several times per week beyond visual inspection normally employed.
- Regular GMP and Sanitation audits must be performed, covering all plant areas and the exterior grounds, with nonconformances documented and corrective actions performed and documented.
- A complete sanitation procedures manual must be in place and available to Sanitation staff and others tasked with cleaning and sanitation activities.
- A Master Sanitation Schedule must be in place with records of compliance maintained.
- All general chemicals, lubricants, cleaners, and sanitizers must be approved for food contact. Checks of sanitizer concentrations must be performed and recorded to avoid using concentrations beyond the EPA labeled amounts.
- Appropriate controls must be in place to prevent pathogen cross-contamination (handling procedures, etc.).
- Food contact surfaces and equipment in product zones must be cleaned on a regular basis. The cleaning is to be documented.
- Food contact surfaces and equipment must free of cracks, pits, crevices and show no sign of corrosion and rust.

- Equipment used in cleaning and sanitizing activities must be clean, in good repair and appropriate for use in a food production facility. Wood handled items are not allowed.
- Racks, carts and totes are clean and in good repair. If used for both raw and finished product they must be identified and segregated to avoid cross-contamination.
- Raw materials, ingredients and in-process material must be protected during cleaning activities.
- All cleaners, sanitizers, general chemicals and lubricants must be securely stored in appropriate areas when not in use.
- Sanitation equipment should be color-coded to avoid misuse. For example, items used in rest room sanitation must be identified so they will not be used in production areas.

Personal Hygiene

- A written employee hygiene policy must be in place and enforced. Requirements for regulatory compliance are per 21CFR117 Subpart C.
- Appropriate hair and beard coverings are to be used on personnel and visitors in areas where food is exposed and stored. These coverings are to be sanitary, of a size to completely cover exposed hair and beard, and be disposable.
- Fingernail polish, false eyelashes and/or fingernails, watches and jewelry are not to be worn in production and warehouse/storage areas.
- All people must wash and/or sanitize their hands (and gloves if required to wear them) upon entering any exposed product area, starting work, after breaks, after using the rest room, touching the mouth or nose, wiping sweat away, when dirty or contaminated.
- Eating, drinking, chewing gum or using tobacco products or storage of personal items is not allowed in production areas.
- Employees must wear clean and suitable clothing for the work being done.

Pest Control

- There must be a written pest control program in place. It must be detailed and followed with activities documented.
- All service and inspection reports must be available for review by NBI, including corrective actions taken. These reports should be periodically audited as part of the GMP/Sanitation audit.
- The pest control applicator must be trained and licensed and a certificate of insurance must be on file.
- Pest control chemicals must be used according to label instructions and only by the trained, licensed pest control applicator. Copies of the chemical labels and MSDS sheets are to be part of the pest control program.
- A map of the premises showing the location of both interior and exterior pest control devices is to be kept current. No pest control chemicals are to be used in interior traps. Traps should be checks- with records kept- at a minimum of once a week when NBI products are being produced.

- Outer doors and windows (to the exterior) are to be tight-fitting and adequately screened.
- No evidence of pests, vermin and/or birds is to be found in production areas, warehouse areas, employee lockers, vending machines and rest rooms.
- Items in warehouse and storage areas must be off the floor and at least 18 inches from walls.
- Any on-site pesticides are to be stored in a locked storage area segregated from any manufacturing area.
- Exterior areas are to be kept free of trash, litter, unused equipment, pallets, etc. Brush and grass must be cleared away from the exterior walls of the facility.
- The must be adequate disposal facilities for trash and recyclable waste. Dumpsters must be kept covered.

Finished Product

- A material tracking system must be in place to allow tracing of raw materials, ingredients and packaging from receipt through storage and shipment. This includes rework and carryover material.
- Individual units and outer cases must have clear, legible identification and coding readily visible.
- Finished product is properly stored to meet or exceed temperature requirements. For freezer < 0°F, for refrigerator < 40°F, and for dry materials, at temperatures and humidity sufficient to prevent clumping, mold and mildew. Storage conditions require monitoring with documented results and appropriate frequencies.
- NBI will determine the type, frequency, methods and equipment to be used to evaluate NBI products.
- NBI will provide through contract the specifications- measurements such as dimensions and weights, color, visual appearance, organoleptic values for taste/aroma evaluation- to be met for each NBI item.
- It is the expectation of NBI that the contract manufacturer will investigate testing failures and institute corrective action to prevent recurrence
- Shipping and tracking systems for finished products must include code date.
- On Hold and Rejected Material systems must be in place to avoid inadvertent shipment of these products.
- Returned goods must be properly identified and segregated from acceptable material.
- Outgoing carrier vehicles for finished product must be inspected according to documented procedures and sealed. Records of all inspections must be maintained.

Initial Production Runs

- Prior to the initial run of a NBI product, NBI will assess through either second or third party the intended process steps and inputs for the run. This will be performed on-site.
- NBI representation will also observe the initial run from start to finish. Any issues which might arise during the run are to be discussed during the on-site visit. Product

in which deviations which could affect the legality and/or the integrity of the NBI product are to be placed On Hold pending determination of disposition by NBI.
- Initial runs are not to be released until instructions to do so are received from NBI.

Packaging and Labeling
- Packaging must be per contract. Any proposed changes are to be addressed through NBI policy ***NBPOL004 Change Control Policy*****.**
- All labeling and package imprints are to be as approved by NBI. No deviations are allowed unless approved by NBI through the Change Control policy stated above.
- Cross contamination of allergens is to be prevented in the packaging process through scheduling, cleaning, separation of personnel and other methods.

Food Safety
- An environmental pathogen testing program (i.e., Salmonella / Listeria) must be in place with records available for review by NBI. There must be a documented program that monitors the plant environment (i.e., floor drains, standing water, non-food-contact equipment, wall/floor junctions, etc.). The program must show or state specific locations for testing and the frequency of testing.
- Pathogen control programs are in place for Ready-To-Eat products where appropriate. Any program must be in line with current regulations and guidelines issued by the FDA and state agencies.
- Effective measures must be in place (production scheduling, space, partitions, air flow, etc.) to prevent cross-contamination between raw materials and finished products.
- Potable water, ice and steam must be safe for its intended use and appropriate documentation available to prove its safety. Water testing must be done at least annually.
- There must be adequate documentation on cooked/baked process parameters to support the baking kill step control. In Preventive Controls, validation is required.
- Product must pass through a properly calibrated and functioning metal detector.
    - A written metal detection program must be available for review by NBI.
    - Calibration and verification of calibration with ferrous, non-ferrous, and stainless-steel standards at the rated sensitivity of the detector. If calibration and verification is not performed using all three types of metals, then documentation from the manufacturer of the detector or validation testing must be available showing that test wands used have correlation to size and types of metal not being tested.
    - Metal detectors must have calibration verified by placing the specified test unit (wand or card) into the center of the product. This is done to simulate the ability to detect metal in the center of the product.
    - Adequate documentation must be available of the detector's operation.
    - The detector must have a properly functioning reject system in place.
    - There must be an action plan in case of system failure and for rejected product.

- Glass and brittle plastic must be controlled in the facility. Only properly setup x-ray detection units can detect glass in a product.
    - All glass and brittle plastic items in the facility have been identified and inventoried.
    - There must be a written policy available that includes procedures for handling glass and brittle plastic incidents. Full documentation of incidents with corrective actions are to be readily available to NBI.
    - Documentation (e.g., map) where all glass and brittle plastic items are in production areas and warehouse/storage areas, including forklift lights/gauges, clocks, processing equipment, computer monitors, etc.) must be maintained.
    - Documentation of glass/brittle plastic audits must be performed at defined frequencies, with corrective actions taken.
    - No unprotected glass (e.g., light bulbs, thermometers) are allowed in production and warehouse/storage areas.
- For all sifters, filters, and magnets:
    - A written policy must be available.
    - There must be documentation of inspections and examinations with results and corrective actions recorded.
- A written product recall and withdrawal system must be in place.
    - Training of the recall team must be documented.
    - The recall plan must conform to 21CFR117 requirements.
    - Full documentation of any recall event must be performed and maintained.
    - For recall events on NBI products, refer to NBI policy ***NBPOL002 Product Recall and Withdrawal Policy*** for details and guidelines in performing a recall.
    - NBI will review the recall and withdrawal policy and procedures of the contract manufacturer during on-site visits.
    - A mock recall must be performed on a raw material/ingredient and a finished product at least annually.
- Allergen control measures must be implemented to prevent cross-contamination of allergenic materials during any phase of reception, production, storage and shipment.
    - The allergens to be controlled are the top eight designated by the United States, plus any of the allergens required to be controlled by a country in which the NBI product is to be marketed.
    - The allergen control plan must be written and available for review.
    - Contract manufacturer staff must have documented training in the allergen control plan. These records are to be available for review by NBI.
    - A documented review of the labels of incoming raw materials and ingredients must be performed to determine the allergens being received into the facility.
    - A procedure must be in place for the storage of allergen containing items. Detailed instructions are to be included, i.e. store allergen items below non-allergen items.
    - A documented procedure must be implemented concerning reaction and recovery from spills of allergen containing materials.

  - Production changeover methods to include scheduling and sanitation must be in place. Verification of sanitation must be documented.
  - Finished goods labels must be reviewed to assure that any allergen material used in the product is also in the allergen warning and ingredient statement on the label.
  - Sanitation methods for cleaning equipment and lines to remove allergens must be designed, implemented, verified and validated.
  - Validation is to employ ELISA test kits where they exist for the allergen involved.
  - Any repacking and reworking operations must be designed to provide adequate prevention of allergen cross-contamination.
- Hazard Analysis and Risk-Based Preventive Controls
  - This is a new set of regulations under the Food Safety and Modernization Act (FSMA) and can be found on 21CFR117 Subparts C and G. It goes into effect for most food manufacturing firms in September 2016.
  - A hazard analysis similar to traditional HACCP methods must be undertaken. It must be assumed that there are no controls in place such as baking, pre-requisite programs, etc., when making determinations of the likelihood and severity of a hazard in relation to public health concerns, as well as the hazards themselves.
  - For any hazard with a likelihood of a public health issue, there must be a preventive control designed.
  - There must be a monitoring system for the preventive control with details on:
    - How to monitor
    - Who will monitor
    - What will be monitored
    - How frequently will the monitoring take place
    - What to document
  - Pre-determined corrective actions need to be designed and implemented.
  - Preventive controls must be verified periodically, but no more than 7 days from the date of the monitoring event.
  - Only a Preventive Controls Qualified Individual (PCQI) can set up the food safety plan, the preventive controls, the Supply Chain program (if required) and also perform or oversee verification and validation of the controls. The PCQI must successfully pass a training course having the curriculum designed and approved by the FDA.

This is a very extensive set of regulations, with each one taking effect at various dates. The information shown here is a small section of the regulations. As stated, only a PCQI can perform or oversee the actions required to become fully compliant to the Preventive Controls requirements.

<u>Shipping and Transportation</u>
NBI will determine with the contract manufacturer the provision of transportation, type (ambient, refrigerated or freezer), and shipping firm. This determination will be in writing.

Waste and Reject Products

During any production run there may be wastage such as spilled ingredients and raw materials not compliant with the NBI specifications. NBI has the right to determine the disposition of these items.

Waste and Reject Products from NBI production runs are to be handled as follows:

- Waste ingredients and raw materials: Discard either as trash or for use as animal feedstock. FDA GMP regulations on the handling of waste human foods for animal feedstock have been changed as of the year. NBI requires that the contract manufacturer be compliant with these regulations.

- Post-production pieces out of specification; these pieces are to be either disposed as trash or as animal feedstock (see above concerning updated regulations for this use).

- NBI will not allow donations or other disposition of NBI items unless expressly approved in writing by NBI.