



Supplier

Guiding Principles

oterra™

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## Social Responsibility, Quality and Food Safety Management

**OTERRA** is a global supplier of ingredients to the food, health and pet food industries, with leading positions in the markets in which we operate. We produce natural colors, coloring foodstuff and dietary supplements. Our market positions are built on our product innovation and applications, production processes, long-term customer relationships and intellectual property.

Oterra is committed to providing high-quality products that satisfy a diverse range of customer needs and applications. With production facilities on multiple continents and products sold in more than 100 countries, we strive to meet and exceed our customers' expectations. Oterra, together with our suppliers, will provide products and services that meet our commitment of delivering high-quality, safe and responsible products to our customers.

To meet these commitments, we will select suppliers which adhere to the principles:

- High food safety standards
- Documented quality and food safety management programs
- Sustainable and responsible processes, products and services

## Introduction

The principles detailed in this document are designed to assist current and potential suppliers in supporting our commitments. Our suppliers are expected to provide goods and services of consistent high quality with food safety and responsible business conduct being of utmost importance.

The principles in this document are Oterra's expectations for our suppliers that will be used for evaluating and auditing our vendors as part of Oterra's vendor management program. These principles are a global standard for Oterra and are based on international standards such as ISO 9001, FSSC 22000, ISO 26000, UN Global Compact and other UN treaties and conventions.

Oterra expects suppliers to have full visibility of their supply chain to ensure the necessary hygienic conditions are in place for producing products that are safe and suitable for our intended use. This begins with understanding primary source of packaging and raw materials and continues through incoming and outgoing transportation, manufacturing, and storage or warehousing prior to delivery and acceptance at an Oterra facility.

It is expected that suppliers are current on technical issues and regulatory changes to ensure all applicable standards are met. It is the responsibility of the supplier to educate and train the employees, so they are prepared to comply with all applicable regulations and Oterra principles.

All Oterra facilities comply with and/or are certified against a standard benchmarked by the Global Food Safety Initiative (GFSI). We expect that all of our raw material and contract manufacturing suppliers will participate in a 3rd party audit program against quality and food safety criteria. A standard benchmarked by the GFSI is preferred but not mandated. Likewise, we will favor suppliers which adhere to our commitments on corporate social responsibility.

We are pleased that you have accepted the opportunity to become a supplier to Oterra. By fully complying with the principles, you will assist us in maintaining our quality reputation and thereby our mutual business success.

If you have any questions or require assistance, please contact your designated Oterra contact.

## Corporate Social Responsibility



**OTERRA** is committed to being accountable to all of our stakeholders.

We strive to be good members of society by actively assuring sustainable development and respecting all local and international regulations and/or legislation.

We expect that our suppliers will contribute to this effort by adhering to the following principles:

### **Laws and regulations**

Suppliers shall respect and comply with applicable local, national and international laws, rules and regulations.

### **Human rights**

Suppliers shall respect the protection of human rights. Additionally, no employees are to be harassed, punished, or discriminated.

### **Forced labor**

Suppliers shall ensure that all employees work out of their own free will. Any kind of forced or compulsory labor shall not be tolerated. Employees shall be free to leave employment after reasonable notice.

### **Working time and remuneration**

Suppliers shall comply with applicable laws, industry standards and any collective agreements on working hours, including overtime and fair remuneration.

### **Child labor**

Suppliers shall not use or permit the use of child labor as stipulated in local and national laws. Suppliers should support the efforts of the International Labour Organization (ILO) concerning the minimum age of admission for employment and concerning prohibition and immediate action for elimination of the worst forms of child labor.



**Freedom of association and collective bargaining**

Suppliers shall respect freedom of association and the right to engage in collective bargaining in accordance with local laws and international conventions.

**Health and Safety**

Suppliers shall comply with applicable laws regarding health and safety. Additionally, suppliers shall provide a safe and healthy work environment to prevent accidents and injuries, and to minimize the causes of hazards.

**Environment**

Suppliers shall comply with all applicable environmental laws and regulations, including the upholding of applicable permits and authorizations. Suppliers shall continuously strive to improve environmental performance.

**Business integrity**

Suppliers must have zero tolerance for any violation of competition, anti-trust and anticorruption laws.



## Management Responsibility

The supplier's executive management shall document, support and maintain functioning Food Safety and Quality Management systems to ensure food safety, quality, and compliance with regulatory requirements and Oterra principles.

Support of these systems shall be evident through appropriate staffing, education and training with routine assessment for effectiveness, and continuous improvement initiatives.

There must be a process in place to communicate the supplier's quality and food safety policy throughout the organization.



## Management Review

Suppliers shall conduct management reviews to analyze their food safety and quality management systems to ensure the effectiveness of the programs and to identify opportunities for continuous improvement.

The management review should include a review of all activities that may impact quality or food safety.



## Employee Awareness

### Education and Training

Suppliers shall have employee training and competency assessment programs in place which support the manufacture of safe, quality products to be used as Oterra raw materials, packaging materials and finished goods.

Employee training must include quality and food safety topics such as food defense, good manufacturing practices (GMPs), food safety awareness, and personnel health and hygiene.

Suppliers shall ensure all permanent, temporary and contract employees are trained, qualified and empowered to perform their assigned responsibilities.

All training shall be documented.

### Personal Hygiene / Illness and Injury

Suppliers must take appropriate measures to ensure that products are not contaminated during handling. Adequate hand washing facilities shall be provided in restrooms, break rooms and at entry points into production areas.

Work attire shall be suitable, adequate and clean; company provided uniforms should be worn, where possible.

Suppliers shall maintain adequate control of employee illness, injury and communicable disease that may result in pathogen transmission through product.



## Notification Requirements

Suppliers are required to notify Oterra under the circumstances outlined below:

### **Food Safety**

In the event that the safety of any product supplied to Oterra is adversely impacted, the supplier must immediately notify their local Oterra contact or Corporate Quality (Denmark) at telephone number +45 35155600.

### **Regulatory Non-Compliance**

In the event of an incident that requires communication to regulatory authorities regarding any product supplied to Oterra, the supplier must notify Oterra concurrent with any communication given to the regulatory authorities.

Copies of any documents or product samples given to regulatory authorities concerning products delivered to Oterra must be made accessible to Oterra if needed.

### **Changes in Manufacturing Process, Formulation or Specification**

Any change to the product specification or manufacturing process that may have an adverse impact on environment, employee health, product quality, or food safety must be communicated to Oterra as soon as reasonably possible.

Any change of the manufacturing site or interruption of product supply must also be communicated to Oterra in a timely manner.

## Good Manufacturing Practices



**SUPPLIERS** shall be able to demonstrate effective control of food safety and quality, including compliance with regulatory and industry-specific standards such as sanitary design and Good Manufacturing Practices (GMP). Such systems are essential prerequisite programs to support the effective operation of a food safety management system.

### Infrastructure

Facilities and equipment used to manufacture, handle or store materials must be appropriately designed, suitable for their intended use and permit adequate cleaning.

Floors shall be constructed to allow adequate drainage to prevent standing water and to allow for cleaning.

Production sites must have established programs for the handling and use of water, lighting, boilers, steam, gas, compressed air, etc. The program shall include monitoring, maintenance, and documentation.

### Manufacturing Environment

#### Waste Management

Suppliers shall establish a program to manage waste collection and disposal to prevent product contamination, pest attraction and hazards to public health. Waste material containers shall be clearly

identified for their intended purpose and remain covered when not in use.

**Chemical control**

Suppliers shall have a chemical control program in place including approved chemical list, Safety Data Sheets (SDS), inventory control and procedures for preparation and use. Chemicals used where there is a potential for product contact, including boiler chemicals and lubricants, must be food grade.

**Pest control**

Suppliers shall have a pest control program in place to effectively manage pest activity in the facility and/or surrounding environment.

The program must include control procedures and frequency of methods by target areas. Pest control activities must be performed by a licensed pest control operator (national equivalent) or internal personnel with comparable qualification. Use of all insecticides, fungicides or rodenticides must be in accordance with current local laws and regulations.

**Cleaning and Sanitation**

Suppliers shall have a cleaning and sanitation program in place that meets all regulatory requirements and ensures the cleanliness of the food handling equipment and the facility.

The program must also ensure that all raw materials, packaging, in process component and finished goods storage areas, and shipping containers are clean and pest-free. Only cleaning and sanitizing chemicals that are approved for use in food manufacturing facilities should be permitted.

A system for verifying and documenting the effectiveness of the cleaning and sanitation program shall be in place.

**Plant Traffic Controls and Product Segregation**

Traffic patterns of people, machines, and materials shall be controlled to prevent contamination. Products, processes and plant areas shall be adequately segregated to prevent cross-contamination. In facilities handling microbiologically sensitive materials, the plant structure shall provide adequate physical separation to prevent contamination. For construction activities an effective plan shall be in place to address segregation and containment to prevent contamination.

The plan shall include enhanced environmental monitoring in and around construction areas.

## Maintenance Practices

### **Preventive/Corrective Maintenance Program**

Suppliers shall have programs in place to provide for the effective and preventive maintenance of the facility, equipment and tools.

Special attention shall be given to all product-related equipment that may have an impact on quality or food safety.

The program must be established for interior and exterior maintenance of the building at a predetermined frequency based on the facility age and environmental conditions.

Facility inspections shall be conducted per a prearranged schedule and all corrective actions should be documented.

### **Calibration**

Equipment that measures or monitors quality or food safety related processes or activities must have a documented calibration program.

The calibration program should ensure traceability to applicable national or international standards and include procedures for monitoring the performance of processing and testing equipment to ensure that the equipment continues to perform between calibrations.

In case of deviation, a documented program must be in place to ensure that any product produced while equipment has been out of calibration is investigated and evaluated for compliance.



## Food Safety Programs



### Hazard Analysis Critical Control Point (HACCP)

Each supplier location must have a food safety program for each producing line and product type that is based upon the 7 commonly accepted principles of HACCP including:

1. Documented hazard analysis detailing chemical (including allergens), physical and biological hazards
2. Identification of Critical Control Points (CCPs)
3. Established critical limits for CCPs
4. Monitoring procedures for CCPs
5. Defined corrective action procedures when Critical Limits are not met
6. Ongoing verification procedures that demonstrate the HACCP system is working
7. Established record-keeping and documentation procedures

The food safety program shall be supported by a multi-disciplinary HACCP Team that meets on a regular basis, with minimum annual review and prior to any significant changes.

The HACCP team must perform risk assessments that include identification of hazards from raw materials, production processes and customer application. It is preferred that the risk assessment is started at the design level. The HACCP plan shall be validated initially and concurrent to any significant changes such as new constructions, new equipment and major process changes.

## Microbiological Control and Environmental Monitoring

An environmental monitoring program including critical acceptance levels for pathogenic microorganisms such as Salmonella and Listeria monocytogenes, or an indicator such as E.coli, must be in place as appropriate for the product type.

Additionally, a procedure shall be in place to respond to adverse events or GMP breaches of the facility, such as roof leaks and drain backups. Positive results must be immediately investigated, and corrective actions taken to prevent reoccurrence. Potential impact on food safety must be evaluated for any products produced since the last time the environment was under control.

## Allergen Control

Suppliers must have an adequate allergen control program in place to prevent cross contamination and secure adequate disclosure of allergen information to Oterra.

The allergen control program must address all allergens that are stated in the Oterra Supplier Declaration of Allergens. Oterra recognizes all allergens mentioned in the EU and US regulation. Product changeovers from one allergen to another or to non-allergen products must be restricted to systems that have validated cleaning procedures.

These systems must also have documented cleaning and changeover procedures.

## Foreign Material Control

Suppliers must conduct a risk assessment to identify potential foreign or extraneous material hazards including metal, glass, brittle plastic, ceramic and wood.

Suppliers must have controls, procedures and equipment in place to prevent foreign and extraneous materials from entering their products. Examples include magnets, screens, metal detection, X-ray, and filtration systems. When glass and brittle plastic exist in the production area, a specific control program shall be in place for the management of these materials.

## Supply Management

Suppliers shall have controls in place to ensure that purchased materials and services comply with specifications and applicable laws and regulations.

Programs shall be implemented to ensure the control of procurement, processing,

transportation, storage and preservation of all raw materials and product contact packaging materials throughout their supply chain.

## **Raw Material and Supplier Approval**

Suppliers shall have programs in place to approve raw materials and suppliers of raw and packaging materials. The program must include identification of primary source of raw materials including country of origin, primary and intermediary processing sites, transportation, storage and warehousing prior to delivery to an Oterra designated facility. The program shall also include documented risk assessments for raw materials and a method for monitoring and evaluating all suppliers. For any Oterra owned formula, changes in raw materials or suppliers must be approved by the appropriate Oterra Quality contact prior to the change.

## **Control of Incoming Raw Materials and Packaging**

Prior to accepting incoming materials, the supplier must verify that delivery vehicles have preserved the quality and safety of the materials during transit. Verification activities must include inspection of internal cleanliness, structural integrity, verification of seals, evidence of pest activity, and verification of temperature for refrigerated or frozen items. Inbound loads suspected of any type of tampering shall be investigated by the supplier. The shipment shall be rejected if tampering cannot be excluded.

Suppliers shall have a program for receipt of materials that ensures that material specifications are met through visual inspection, Certificates of Analysis (CoA) review, and/or product testing. Primary packaging materials shall have a current Certificate of Compliance (CoC) with each shipment or on file.

Lot or batch numbers must be recorded for all incoming raw materials and product contact packaging to ensure traceability.

## **Warehousing and Distribution**

Suppliers shall have programs in place for the handling of raw materials, intermediate products and finished products throughout their supply chain to maintain product quality, integrity, food safety and shelf-life. The supplier shall use designated storage areas or stockrooms to prevent damage to, deterioration of

or tampering with materials.

Storage facilities shall be neat and orderly. When required the supplier shall ensure that products are properly temperature controlled at all times during storage and transportation. Stock rotation should be controlled according to First In First Out (FIFO) or First Expired First Out (FEFO) principles. Oterra shelf life requirements, where specified, must be met. Products not meeting these requirements are subject to rejection by Oterra warehouse personnel.

If the supplier uses third party warehouses to store raw materials, packaging materials, semi-finished or finished products, the supplier shall conduct periodic assessments to ensure that the above principles are met.



## Quality Control and Documentation



### **Document Control and Recordkeeping**

Systems shall be in place for developing, deploying and controlling all paper and electronic documentation, records, and data. Records must be maintained, legible, readily identifiable and retrievable. Procedures, work instructions and forms should be reviewed at predetermined frequencies. All controllable documentation shall be dated and signed or electronically approved by authorized personnel.

Suppliers shall have a document retention policy that includes retention times for paper and electronic records and a system for purging expired documents.

### **Internal Audits**

Periodic audits of the complete quality and food safety system should be conducted by the supplier in order to verify the system's effectiveness as well as to identify opportunities for improvement. Audits must be completed on a routine schedule and corrective actions must be implemented on a timely basis.

### **Hold and Release**

Suppliers shall have a written Hold and Release control program in place for identification, segregation, control, and disposition of all non-conforming raw materials, intermediate products, packaging materials and finished products. The program shall also apply to materials pending QC release. The Hold and Release program shall apply to all materials on the supplier's premises or in second party facilities used by the supplier. Materials that are on Hold must be controlled by a defined and effective system which is intended to prevent inadvertent use and/or movement. Inventory reconciliation must occur to verify quantities of quarantined materials.

### **Lot Code and Date of Manufacture**

All production runs shall be identified with code dates or batch identification/lot numbers which enable the supplier to trace raw materials, product contact packaging materials and finished goods one step back and one step forward in the supply chain.

### **Product Traceability and Mock Recall**

Suppliers must have written recall and traceability procedures in place to record and trace the receipt and usage of raw materials, packaging materials, rework, intermediate and finished products. Procedures shall include up to date 24 hour emergency contact information. Suppliers must be in compliance with all applicable regulatory reporting requirements.

Mock recalls shall be conducted at least once per year to validate the effectiveness of the traceability program. Appropriate corrective actions shall be taken when deficiencies or other opportunities for improvement are identified.

### **Conformance to Specifications**

Raw materials, packaging materials and finished products shall be evaluated and confirmed to meet Oterra specifications as defined by the contract and/or purchase order.

A procedure shall be in place for reviewing and accepting Oterra orders and specifications.

### **Good Laboratory Practices**

All plant and contract laboratories and laboratory personnel shall observe Good Laboratory Practice (GLP) principles based upon common industry standards.

In the absence of such standards, use Good Laboratory Practice (Title 21, Part 58 - United States Code of Federal Regulations), current European Union Good laboratory Practices Guidelines or ISO 17025 as a reference.

Testing laboratories shall use published, recognized and validated testing methods. Where published test methods are not available, internally developed methods may be used but should be validated for their intended use consistent with GLP requirements.

The manner in which the lab is equipped, arranged and managed shall ensure test results are consistent and reliable.

### **Customer Service**

Suppliers shall have an effective program in place for receiving, evaluating, and responding to customer complaints and inquiries. Complaints should be logged, investigated and trends evaluated as part of the supplier's continuous improvement program.

### **Non-Conformance, Corrective and Preventive Action (Continuous Improvement)**

Suppliers shall have a continuous improvement program to routinely detect, analyze and correct quality and food safety issues that cause non-conformance and to maintain compliance with updates/changes in regulations. The program shall include a documented non-conformance process, including root cause analysis and corrective and preventative action planning. The program should be evaluated periodically to drive continuous improvement, and corrective actions that are taken as a result of the program shall be reviewed to ensure effectiveness

## Food Defense



**SUPPLIERS** shall have a food defense program that protects the integrity of raw materials and products throughout their supply chain and minimizes risks to personnel, proprietary information and facilities.

The program should include assessment and implementation of food defense and risk control measures that meet applicable regulatory guidance such as C-TPAT, FDA Bioterrorism Act of 2002 or Authorized Economic Operator (AEO) EU Regulation 1875/2006. The program shall include written security procedures and be managed by a designated individual.

Supplier's employees shall be trained to recognize and respond to evidence of product tampering or other security breaches.

### **Facility, Storage and Transportation Security**

Security measures shall be in place to control access to storage and production facilities to minimize potential contamination and/or tampering. Suppliers shall implement systems and procedures to identify people who are regularly on site (e.g. employees and contractors) as well as to restrict access to sensitive areas to authorized people only.

The documented facility security program should include routine security checks of the premises, new hire background checks, fencing or other perimeter protection, and secure entrances and exits. Actions to take in the event of a security breach or product tampering incident shall be included in a crisis management procedure.

Security measures shall be in place to control access to transportation loading facilities and vehicles to minimize potential contamination and tampering; this includes intercompany transport and storage as well as owned, leased or contracted conveyances for external transport via road, rail, water, or air.

The supplier shall take deliberate steps and implement procedures to monitor and verify the integrity of incoming and outgoing shipments. Records to verify chain of



custody shall be maintained. Raw materials, packaging and finished goods must be supplied in suitable tamper-evident packaging or in appropriately security-sealed bulk containers/conveyances. Security seal procedures shall be implemented for all incoming loads of raw materials and packaging material and all outgoing shipments of finished goods.

## Regulatory and Compliance

### **License to Operate**

The supplier shall maintain registration and/or authorization for manufacturing of all relevant materials and services as per local regulations. This also includes any relevant local permits for environment and occupational health and safety. The supplier shall maintain at the facility records of all regulatory inspections and contacts, including any reports issued by inspectors, facility response, and corrective actions taken, for a period according to local regulatory requirements.

### **Labeling Information Approval**

Suppliers shall ensure that labels are correctly and consistently applied to materials supplied to Oterra, and that labels meet applicable regulatory requirements and Oterra specifications. In particular, the supplier shall verify the accuracy of labels for allergen profile, raw material information, nutritional information, net quantity, hazards, and dangerous goods. The supplier shall provide valid Safety Data Sheets (SDS) in the local language of the Oterra unit delivered.



The terms used to designate requirements and recommendations stated in this document include

**Must** – Used to express food safety related or regulatory requirement that is mandatory.

**Shall** – Used to express other obligation or requirement with no exclusions (i.e., what is mandatory).

**Should** – Used to express a recommendation among other possible options.

**May** – Used to indicate an action which is permissible, but not mandatory.

## Alphabetical list of defined terms:

**Allergen:** Foods or food components known to produce allergic reactions to an at-risk portion of the population. Allergens recognized by Oterra include the United States “Big 9” plus the additional allergens identified by the European Union (EU). The complete allergen profile must be properly identified and communicated to Oterra.

**Calibration:** Calibration is accomplished by a formal comparison to a standard which is directly or indirectly related to national standards, international standards, or certified reference materials.

**Certificate of Analysis (COA):** A document provided by the supplier which indicates results of specific tests/analysis performed on a defined lot of the supplier’s product. The tests are done either by the supplier or an external testing firm, and must be based on published, recognized or validated test methods.

**Chain of Custody:** Documentation that confirms materials are under control and accounted for throughout storage and transport from the supplier to Oterra.

**Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce to an acceptable level.

**Cross-Contamination:** The unintended introduction of a material or product into another material or product. For example, cross-contamination may arise from:

- 1) traces of an allergenic product from a previous production run that have not adequately been removed through cleaning.

2) physical contact at any point in the manufacturing process with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

**Disposition:** The determination of what will be done with a material or product. For example, the disposition of non-conforming product that has been placed on Hold is the determination as to whether to release, destroy, or take other action with the product.

**Extraneous Material:** Any object or matter that may become part of the product being produced, which is not designed to be part of such product. Extraneous material may be a foreign object, foreign material or an anomaly in the product or product ingredient. Examples may include: metal, stones, wood, plastic, glass, paper and matter inherent to raw materials (e.g., bone, nut shells). See also Foreign Material.

**Finished Product:** Product, packaging material or ingredients created by a supplier's manufacturing process for use by Oterra.

**Food Defense:** Steps to safeguard the food supply against intentional acts (or the threat of an act), such as a bioterrorism, vandalism and sabotage.

**Food Regulatory Agency:** Any national or local government body appointed or authorized to oversee activities of the food manufacturing and supply industry. Examples include United States agencies such as Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA); European country specific Food Standards Agencies; and Canada's Canadian Food Inspection Agency (CFIA).

**Food Safety:** The concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

**Food Safety Management System:** Organizational structure, policies, programs and procedures needed to manage food safety.

**Foreign Material:** Any material that is not natural to the product, such as metal, wood, glass, plastic, rock, paper or cloth. See also Extraneous Material.

**Hazard:** A biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect.

**Hold:** A status assigned to a specified product indicating it must be excluded from normal handling processes until further notice. Synonyms include terms such as: quarantined, blocked, segregated, or contained.

**Lot (Lot Number/Batch Number):** A unique identity given to a defined quantity of a material usually based on time and location of manufacture. For continuous processes, a lot may not exceed the amount of material produced in one 24 hour period.

For non-continuous processes, the batch, blend, shift, or other time segment may be used to identify a lot. For materials received in bulk, the lot is usually identified as the contents of the bulk vehicle.



**Mock Recall:** A simulated recall of the manufactured product or item, including the tracing of all components and finished products, to ensure that traceability procedures are adequate in the event of a real recall situation. The mock recall includes a full reconciliation of quantities received, manufactured, stored and shipped including identification of end customers.

**Non-Conforming:** A product or ingredient that fails to meet specifications or regulatory requirements.

**Pathogen:** A food borne microorganism recognized as a public health hazard that can cause illness or death in humans.

**Product Contact Packaging (also “Primary Packaging”):** Packaging which has a surface in direct contact with raw materials, intermediate product, or finished goods.

**Product Contact:** Any physical contact (i.e., solid, liquid, or gaseous exchange) of product with processing aids, utilities, and equipment under actual and foreseeable conditions.

**Quality Management System:** Organizational structure, policies, programs and procedures needed to manage product quality.

**Recall/Product Retrieval:** Any voluntary or involuntary recovery of product that has been released for distribution.

**Rework:** Any product or product component that fails to make it completely through the manufacturing process in its first pass but is suitable to be returned to the process stream.

**Risk:** A function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (death, hospitalization, absence from work, etc.) when exposed to a specific hazard.

**Tamper Evident:** Seals or sealing mechanisms or a feature of a package or container that allows end users, under ordinary conditions of use, to determine whether unauthorized opening or tampering has occurred.