Ontex Supplier Quality Expectations Manual

Contents

1 Introduction

1.1 Our suppliers

Ontex recognizes the very important role our suppliers play in the value we offer to our customers and consumers. As an extension to our own operations, we rely on our suppliers to provide materials, products, and services which meet all of the requirements as stated in our specifications and the quality management requirements outlined herein.

1.2 Purpose

The purpose of this manual is to inform Ontex suppliers of the core expectations we have regarding the supplier quality management system (QMS), design requirements, and manufacturing process controls required for the purpose of doing business with Ontex.

1.3 Scope

This manual applies to all suppliers providing Ontex with raw materials, packaging, finished goods and trading goods purchased by and delivered to Ontex by the supplier or by any of its affiliates or sub-contractors.

1.4 Expectations

In this manual, the terms “shall” and “must” mean that the described action is mandatory. ”Should” means that the described action is necessary and expected with some flexibility allowed in the method of compliance, and “may” means that the described action is permissible or optional.

2 Prerequisite programs

Prerequisite programs are defined as the universal procedures used to control the conditions in the plant environment, which contribute to the overall safety of the product.

All persons entering the supplier facility (plant personnel, visitors, and outside contractors) shall comply with these requirements.

Prerequisite programs must be in writing and available to all personnel.

2.1 Premises

2.1.1 Plant structure and utility systems

The facility shall be of adequate design and construction to ensure production of safe and high-quality materials, and satisfactorily maintained. The facility, including utility fixtures, shall be designed to prevent potential contamination sources from affecting the products produced or handled. The location and design of waste bins, toilets, and hand washing, drying and sanitizing facilities shall be adequate to comply with good manufacturing practice (GMP). Construction materials used for the structure (e.g., floors, walls, ceilings, overheads, and drains) must be completely compatible with the product, environment, cleaning materials used, and the method of cleaning.

Further specific requirements include the following:

- The internal and external structure shall be free of cracks, holes, openings, and pest entry, or nesting areas. The roof must not leak.
- All exterior doors shall be self-closing and must form an adequate seal when closed. Loading docks shall be protected to prevent pest entry. Entrance of air shall be limited by vestibules or air curtains as appropriate.
- Windows present in production areas that can be opened must be adequately screened. All vents and fans shall also be adequately screened.
- Doors, windows, and other openings shall prevent access by unauthorized people.
- Floors shall be sealed, in good repair, sloped adequately to avoid standing water, and pitched to a drain.

- Dust in the air shall be minimized and cross-contamination shall be prevented.
- The plant shall provide adequate space and separation from adjacent structures and equipment to prevent cross-contamination and to facilitate cleaning.

2.1.2 Building and ground security

Suppliers shall develop specific procedures to secure their product, to deter and prevent intentional contamination, and shall have protocols in place to quickly and accurately identify, respond to, and contain threats or acts of intentional contamination. Likewise, suppliers will ensure that their suppliers adopt similar protocols and implement appropriate controls.

Suppliers shall incorporate product security awareness, including information on how to prevent, detect and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including temporary, contract, and volunteer staff.

2.1.3 Utilities management

The supplier shall have implemented programs to ensure safe provision of utility services in production areas. Utility services include environmental air, compressed air, water, and steam.

The supplier shall control access points for the above referenced utility services, as well as electricity, heating, and ventilation. Access shall be controlled by any means deemed effective, such as locked facilities which only authorized employees can open. Further specific requirements include the following:

2.1.3.1 Compressed air

Compressed air for general applications shall be dry, oil free and filtered to remove foreign particles.

Compressors that provide air for direct or indirect product contact should be of oil free design. Where air from existing oil lubricated compressors is used for direct or indirect product contact, the following requirements apply:

- only food grade oil shall be used or it shall be evident that it is suitable for the purpose (hygiene products),
- vapor and odor filters must be installed prior to use where possible,
- air pressure gauges must be installed and monitored, and
- oil and filter changes must be captured in the preventive maintenance program.

Preventive maintenance of air filters to manufacturer specifications is of prime importance and shall be documented.

2.1.3.2 Water

The potable water supply system shall meet all applicable local and national regulatory requirements.

The site shall have effective programs to control water microbiological quality and to verify that water meets specified requirements. Microbiological and other test data from water testing shall be trended and reviewed by appropriate personnel. The plant water program shall describe the sampling locations, action limit, methods, corrective actions, and responsible personnel.

Microbiological tests shall be performed periodically, based on product/process sensitivity. The sampling plan shall cover all water circuits, and branches from main circuits. Microbiological tests also shall be performed after maintenance or repair. Incoming water from municipal source shall be analyzed yearly. Certification from the municipal source is accepted.

The extraneous matter risk of incoming municipal water shall be subject of a HACCP assessment based on historical data.

For surface or well water sources, a visual turbidity assessment shall be carried out regularly. Testing shall also be carried out following any event which may adversely affect water quality, such as abnormally heavy rain or flooding.

Water systems must not have cross connections between treated and untreated supplies. Incoming water lines must be fitted with one-way valves or a header tank.

2.2 Personnel, training program

Exceptions linked to chapter 2.2.1 to 2.2.4 need to be based on a documented risk assessment.

2.2.1 Personnel practices

- Carrying objects above the belt or waistline (e.g., pens, flashlights, thermometers) is not allowed in GMP areas.
- Badges and clip-on identification cards, if used, must be worn below the waist. Visitor identification badges are permitted but must not be a source of contamination at the plant.
- Jewelry and visible piercings are not allowed in GMP areas.
- Smoking and vaping are only allowed in designated areas.
- Nail varnish, false nails and false eyelashes are not allowed in GMP areas.
- Glass, brittle plastics and sharp tools, such as knives and blades are not permitted in GMP areas, in case they are not avoidable, they must be reduced to the minimum and controlled/registered.
- Consumption of food, including chewing gum, and beverages is only allowed in designated areas. The only exception is water without additives, like sugar, sweetener, and flavors, in resealable plastic bottles.
- Food must not be stored in employee lockers.

2.2.2 Clothing and personal equipment

- All clothing must be kept in good repair. Employee clothing shall not be a source of contamination.
- Restricted uses: Work wear, including shoes dedicated to GMP areas, are not permitted outside the plant premises (e.g., way from work to employees' home).
- Ear protection devices must be secured to prevent product contamination (e.g., ear plugs attached by string or with a rigid attachment worn around neck, and earmuffs attached by headband).

2.2.3 Hands

- Personnel working in GMP areas must wash their hands before entering a GMP area; upon re-entering the GMP area; after each visit to the toilet facility, and/or lunch and break room facilities; prior to touching product or product contact surfaces; or any time when hands have become soiled or contaminated.
- Personnel working in a sensitive area must sanitize their hands after proper washing and after touching non-product contact surfaces. If soil is observed on hands, hands must be washed prior to re-sanitizing.
- Hand lotions must not be used if hands are in direct contact with product or product-contact surfaces.
- Personnel with minor cuts or injuries on hands must be able to protect the wound and will be allowed to work on production lines. Adhesive bandages must be metal detectable.

2.2.4 Hair

Hair must be maintained as follows in GMP areas:

- Hair curlers, hair combs, and bobby pins are not allowed.
- Hair nets/restraints covering all hair and the ears must be worn in GMP areas.
- If safety or bump helmets are used, they must be worn over appropriate hair restraints.

Facial hair must be maintained as follows in GMP areas:

- Employees must be clean-shaven or cover the exposed hair with a beard restraint.

2.2.5 Personnel training

The supplier shall ensure that all employees receive appropriate training for their job functions and shall maintain records of training. Specific training requirements are as follows:

- **GMPs:** All employees, including temporary and seasonal personnel, must receive GMP training (including on employee illness and communicable diseases) as part of the orientation process. All employees shall also receive refresher training or verification of GMP knowledge at defined intervals. In addition, specific training programs to instruct personnel on the requirements of this document shall be provided as required and applicable.
- **Production personnel:** Training for supplier personnel who work in production areas must include the following principles: Quality, HACCP, and foreign object prevention.
- **Critical control point (CCP) monitors**: Employees monitoring CCPs must receive further specific training on monitoring, documentation, verification, and corrective actions if critical limits are not met.

Training shall be provided to new employees before starting work in production. Refresher training on these topics shall be provided. The supplier shall maintain records of personnel education, training, skills, and experience. The supplier shall also periodically evaluate the effectiveness of its training programs.

The supplier shall provide visitors and contractors with site specific training programs, as necessary, prior to performing activities which may affect product safety or quality.

2.2.6 Employee illness and communicable diseases

The supplier shall establish written instructions for the control of employee illness and communicable diseases. These instructions shall be available and communicated to all applicable personnel, visitors, and contractors.

The instructions shall, at a minimum, include information for the recognition of symptoms of communicable diseases such as diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice, as well as symptoms associated with region-specific diseases as defined by local medical experts.

2.3 Health and safety recalls

2.3.1 Hold and release

The supplier shall have a written “hold and release” control program that clearly establishes roles and responsibilities for effective implementation. The hold and release program shall apply to products on the supplier’s premises or other 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 movement.

The program shall include controls for non-conforming raw materials, materials pending testing (e.g., performance testing or certificate of analysis verification), packaging, labels, semi-finished product (work-in-progress), finished product and rework. The supplier must maintain records sufficient to enable reconstruction of each hold event (e.g., quantities, code dates, lot numbers, product numbers, reasons for hold and/or release, investigative information, disposition, and traceability information).

If any material produced for Ontex is either inadvertently released from hold or is suspected of nonconformance but has already been shipped to Ontex, the Ontex contracting representative shall be immediately notified.

2.3.2 Control and disposition of non-conforming products

The supplier shall have written procedures for the identification, documentation, evaluation, segregation (where practical) and determination, and execution of the final disposition of non-conforming products. Disposition of materials on hold that do not comply with specific approved Ontex specifications must be effectively controlled and documented.

Rejected material shall be clearly identified. The reason for rejection of the material, code dates, and quantities involved, and its disposition shall be noted on the batch/lot record. Records of

actions and outcomes shall be maintained (for example, certificates or other evidence of product destruction or burial). Disposition shall be completed in a timely manner.

Any labeled material, including semi-finished products with the brand name on it, that are dispositioned for destruction must be disfigured, or destroyed or disposed of, in a manner that provides assurance trademarks cannot be reused in any manner.

2.3.3 Product retrieval

The supplier shall have written retrieval procedures in place that promptly and effectively respond to product issues that represent an unacceptable risk to Ontex and/or the consumer.

Product retrieval procedures must include:

- Notification procedures, including contact lists and customer contacts.
- Protocol for retrieval and disposition of all affected product, with designated authority and assigned responsibilities to ensure that sufficient controls are followed to allow for complete retrieval of product.
- Identification of delivery points, dates and quantities for affected product delivered further into the supply chain or to customers.
- Protocol for isolation of affected stocks and/or materials remaining under control.

The retrieval system shall be tested on an annual basis and after any major system changes to confirm the accuracy of all product and contact data and the continuing effectiveness of procedures and traceability systems. The results of these tests (mock recall/recall simulation) and any corrective actions necessary shall be documented.

2.3.4 Corrective and preventive action (CAPA)

All programs mandated by this manual require that corrective and/or preventive actions be taken in the event of non-conformances. The supplier shall have an effective CAPA program tracking such actions to ensure that non-conformances in any program are addressed in an appropriate and timely manner. After closure of CAPA, the supplier shall inform Ontex and provide objective evidence that actions have been closed out (from audit or other source).

The CAPA program shall address proper means of managing Incoming customer contacts to enable an accurate, appropriate, and timely response.

An effective CAPA program shall include the following steps:

- Identification of CAPA opportunities
- Determination of immediate action(s) to be taken (including responsibility and timing)
- Root cause analysis and quantification of the problem (prioritization)
- Identification of long-term (permanent) solutions (including responsibilities and timing) When required, resources (e.g., personnel, equipment) must also be identified
- CAPA plan implementation
- Further analysis of data to validate if the desired results were achieved (e.g., was the plan effective in resolving the root cause)
- Periodic review of CAPA by the management team

The CAPA program shall include procedures for analysis of effectiveness of corrective actions for, at a minimum, each of the following:

- Out of specification process or product
- Products found to deviate from critical limits of a CCP
- Customer/consumer feedback, including complaints
- Failure to meet external, regulatory or customer requirements
- Issues arising from internal audits, external audits, and regulatory inspections/contacts
- Product retrieval
- Supplier performance measures

2.4 Equipment maintenance

The supplier shall ensure that equipment and materials used for production are suitable for the purpose intended and in good repair. The supplier shall have implemented a written program for preventive and corrective maintenance.

The preventive maintenance program shall include all devices used to monitor or control the product safety hazard.

Corrective and preventive maintenance shall be carried out in such a way that production on adjacent lines or equipment is not at risk of contamination.

Temporary fixes shall not put product safety at risk.

Lubricants with a potential direct product contact shall be food grade or it shall be evident that they are suitable for the purpose (hygiene products).

The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in the sanitation procedure, and pre-use inspection.

Maintenance personnel shall be trained in the product hazards associated with their activities.

2.5 Sanitary design: Plant structure and equipment design

2.5.1 Plant structure

The facility shall be of adequate design and construction to ensure production of safe and high-quality materials, and satisfactorily maintained. The facility, including utility fixtures, shall be designed to prevent potential contamination sources from affecting the products produced or handled. The location and design of waste bins, toilets, and hand washing, drying and sanitizing facilities shall be adequate to comply with GMPs. Construction materials used for the structure (e.g., floors, walls, ceilings, overheads, and drains) must be completely compatible with the product, environment, cleaning materials used, and the method of cleaning.

Further specific requirements include the following:

- The internal and external structure shall be free of cracks, holes, openings, and pest entry or nesting areas. The roof must not leak.
- All exterior doors shall be self-closing and must form an adequate seal when closed. Loading docks shall be protected to prevent pest entry. Entrance of air shall be limited by vestibules or air curtains as appropriate.
- Windows present in production areas that can be opened must be adequately screened. All vents and fans shall also be adequately screened.
- Doors, windows, and other openings shall prevent access by unauthorized people.
- Floors shall be sealed, in good repair, sloped adequately to avoid standing water, and pitched to a drain.

2.5.2 Equipment design

The supplier shall ensure that equipment design is adequate for the production of materials that meet the agreed quality parameters. Equipment shall be constructed and maintained to sustain “cleanability” (reduce bacterial survival, growth, and reproduction; reduce the risk of chemical cross-contamination; and reduce the risk of extraneous matter contamination). Equipment must be accessible for maintenance, cleaning, and inspection.

2.6 Sanitation

The supplier shall have implemented a written sanitation program that ensures the cleanliness of the processing environment, equipment (including tankers inbound and outbound), and tools.

The program shall address:

- Sanitation schedules, methods, and frequencies
- Correct use of appropriate sanitation equipment and tools
- Use of food grade cleaning, sanitizing, and disinfecting products
- Chemicals to be used and how they are to be used including chemical concentrations, contact time, temperatures, frequencies, and rinsing procedures

- Equipment disassembly and re-assembly
- Verification of sanitation effectiveness
- Hygiene monitoring programs
- Inspection procedures (including visual inspections)
- Recordkeeping, record review, and corrective action plans

Proper tools and materials must be used to prevent extraneous matter, microbiological and/or chemical contamination of the product. Items that are known to be potential sources of contamination must be prohibited.

2.7 Pest management

The supplier shall have implemented a written pest management program to monitor and control pest activity in the facility and the surrounding area effectively. The pest management program shall include:

- Pest management plans, methods, schedules
- Inspection procedures and frequencies
- Required documentation of pest activity log and analysis of records for trends in activity
- Corrective actions for increased trends /activity
- Training requirements
- A map showing the location of pest control devices, such as indoor rodent traps, glue boards, insect light traps, outdoor bait stations, and pheromone traps
- Records of application of pesticides

Exclusion shall be the first line of defense and primary method of controlling pests. Efforts must be made to keep pests out of the building by using good exterior controls. If pesticides are used, the supplier shall ensure that they are used in accordance with local regulations.

The supplier shall ensure that appropriate measures are taken to prevent pesticides from contaminating products. Residual insecticides shall not be applied as a fog or an aerosol. Pesticide use and application shall be strictly controlled and in accordance with the label.

Non-chemical methods, such as traps or glue boards, are preferred to control rodents inside manufacturing facilities and warehouses. Rodenticides should be avoided.

When using pesticides, the following practices shall be followed:

- Pesticide type shall be documented on usage records to assure traceability.
- All pesticide labels and material safety data sheets (MSDS) or equivalent material addressing safety precautions shall be available at the facility where the pesticide is used.
- Disposal of unused pesticides and of empty pesticide containers must comply with applicable regulatory requirements.
- Baits shall be used in situations where a specific pest is the target. Where used, bait must be placed in secured bait stations (e.g., securely anchored to the ground or building). Throw packs and loose rodenticide baits such as pellets and meals are not permitted. Old bait shall be discarded periodically and replaced with fresh bait.

Insect light traps (ILT) shall be utilized as surveillance devices to monitor flying insect activity. They are not considered a control method. Light bulbs from the insect light traps must be kept clean and be replaced regularly (minimum annually) to ensure maximum efficiency. The insect light traps shall be installed in the receiving or warehouse areas close to entrances, but shall be located so as not to attract insects into the building. Trap contents must be evaluated monthly. ILT lamps shall be shatter-proof.

3 Quality management and product safety management

3.1 Quality management system

As a supplier to Ontex, a quality management system in accordance with ISO 9001 is a fundamental requirement. Other standards such as EDANA QAP, BRC, IFS, or similar are advisable.

The supplier shall have implemented a written quality management system (QMS) to ensure that the material produced conforms to our specified requirements. At a minimum, the quality system shall ensure compliance with all applicable regulatory requirements of the production country and the destination to which the products will be delivered.

The quality system shall clearly set out the source of each product safety and quality requirement. The quality system shall also set forth the specific personnel responsible for compliance with each requirement through use of an organizational chart. The supplier shall review the quality system on a regularly scheduled basis.

The supplier shall maintain records sufficient to show effective implementation of the quality system. Records must be legible. The quality system will clearly identify the records that must be maintained to show effective implementation, and controls needed for identification, storage, protection, retrieval, retention, and disposition of records. The minimum retention time shall be 5 years.

In addition to the requirements set out above, the supplier's quality system shall specifically include controls to ensure the following:

- **Outsourcing:** The supplier shall notify the Ontex contracting representative of any ingredient which is produced or processed in a plant not entirely owned or operated by the supplier. Any outsourced process that affects material or ingredients produced for Ontex shall comply with the same requirements and be managed by the supplier.
- **Manufacturing changes**: The supplier must notify Ontex of their intention to make any change that may affect the safety, quality, security, shelf-life, ingredient statement, allergen profile or functionality of the material produced for Ontex—such as changes in material formula, raw materials, production line, production facility or processes—and any change shall be approved by Ontex before being implemented. Ontex must be notified of such changes in writing. Ontex will assess whether a new approval is needed.

3.2 Product safety management

3.2.1 Risk assessment framework

Before developing the hazard analysis and risk assessment, the company shall have implemented all necessary good manufacturing practices/best practices which are commonly used in its scope of activity.

The basis of the company's product safety management system shall be a fully implemented, systematic, and comprehensive risk management system. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The hazard analysis and risk assessment shall be adequate and implemented at each production site.

The hazard analysis and risk assessment shall cover all raw material groups, products or product groups, as well as every process (included outsourced processes) from incoming goods until the dispatch of final products, including product packaging material management.

The company shall ensure that the hazard analysis and risk assessment shall be based upon scientific literature or technical verified specifications relating to the manufactured products and procedures. This information shall be maintained in line with any new technical and scientific process development.

3.2.2 Risk assessment team

The risk assessment team shall be multidisciplinary and include operational staff. Personnel appointed as risk assessment team members shall have specific knowledge of hazards and risks associated to products and processes. Where competent knowledge is not available, external expert advice shall be obtained.

Those responsible for the development and maintenance of product safety management system shall have received adequate training in the application of the risk management principles based on the risk assessment tool (risk matrix, FMEA, HACCP, RPN, etc.) which the company uses.

The risk assessment team shall have senior management support and shall be well known and established within the company.

3.2.3 Hazard analysis and risk assessment

3.2.3.1 Describe the product

A full description of the product shall be documented and maintained and shall contain all applicable relevant information on product requirements, at a minimum:

- composition (including rework when applicable),
- physical, chemical and microbiological parameters,
- methods of treatment,
- packaging,
- durability (shelf life), and
- conditions for storage, methods of transport and distribution.

3.2.3.2 Construct flow diagram

A flow diagram shall be documented and maintained for each product or product groups, raw material groups, and for all variations of the processes and sub-processes (including rework, outsourcing, and reprocessing). The flow diagram shall determine every step and clearly identify each critical control point and other control measures. It shall be dated and in the event of any changes, the flow diagram shall be updated.

3.2.3.3 Conduct a hazard analysis and risk assessment for each step

A hazard analysis shall be conducted covering all possible and reasonably expected physical, chemical (including allergens), and biological hazards. A hazard analysis and a risk assessment shall be conducted for each step of the process from raw materials to the finished products. The analysis shall include also hazards linked to materials in direct contact with the product.

The hazard analysis shall consider the likely occurrence of hazards and severity of their adverse health effects. Consideration shall be given to the specific control measures that shall be applied to control each hazard. The methodology for assessing the risk shall be documented.

The determination of relevant CCPs and other control measures shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.

For each critical control point critical limits shall be defined and validated to identify when a process is out of control.

Specific monitoring procedures in terms of method, frequency of measurement or observation and recording of results shall be documented, implemented, and maintained for each CCP to detect any loss of control at that CCP. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records.

Records of CCP monitoring shall be verified by a responsible person of the company and maintained for a relevant period.

The operative personnel in charge of the monitoring of CCPs and other control measures shall have received specific training/instruction.

The control measures other than CCPs, shall be monitored, recorded, and controlled by measurable or observable criteria.

In the event that the monitoring indicates that a particular CCP or control measure other than a CCP is not under control, corrective actions shall be documented and implemented. Such corrective actions shall also take into account any action taken relating to non-conforming products and identify the root cause for the loss of control of CCPs.

Procedures of verification shall be documented, implemented, and maintained to confirm that the hazard analysis and risk assessment are effective. Verification activities of the hazard analysis and risk assessment include for example:

- internal audits
- testing
- sampling

- evaluations
- deviations and non-conformities
- complaints

The results of this verification shall be performed at least once within a 12-month period or whenever significant changes occur and shall be incorporated into the hazard analysis and risk assessment.

3.3 Notifying Ontex of significant events

Communication in the supply chain is critical when events occur that could affect product safety, quality or processing. The supplier must establish procedures to ensure Ontex is immediately notified of any occurrences, but not limited to:

- Systematic product quality defect or process control deviation which could lead to a voluntary or involuntary recall or withdrawal of a Ontex finished product.
- Discovery of potentially defective or adulterated ingredients or packaging materials associated with product in distribution.
- Event that leads the supplier to suspect that a non-conformance exists in a product already shipped to Ontex.
- Product tampering or threat of tampering.
- Event or substance that could threaten product security. Notification by law enforcement or other authority of a potential product security event.
- Changes to the supplier's processes and/or facilities that could have an impact on materials supplied to Ontex.
- Inability to deliver materials that meet Ontex specifications.

The supplier must notify Ontex by a phone call with a live person and by email. Voicemail, even coupled with an email, is not adequate. The Ontex contracting representative shall be the primary contact for any contact or notification required by this document. However, if the representative is not available in cases of emergency, contact the Group Product Stewardship team.

3.4 Inspection, measures, tests, and quality system requirements

The supplier warrants that its measuring and test equipment is capable, reliable, and periodically serviced and/or calibrated according to written procedures. The supplier is responsible for providing the necessary resources for compliance with any applicable specifications, quality procedures, GMPs, and regulatory requirements. The supplier warrants that the necessary foreign objects detection devices (e.g., metal detectors) are installed, properly calibrated, and cover 100% the produced/delivered materials.

A consistent quality level can only be achieved through a stable and statistically reliable manufacturing process. Therefore, the supplier must use suitable control methods such as records generated parallel to continuous production. Evidence of the achieved process capability shall be provided on Ontex first request.

4 Definitions

Accuracy:
The repeatability of closeness to the target value of a certified reference or other standard.

Calibration:
The adjustment of measuring and monitoring equipment to assure that 1) for equipment that measures across a range of values, the measurements are accurate across the entire range to the degree of accuracy stated, 2) for equipment that is used to measure a single point, that the measurement reaches the degree of accuracy stated.

Carry-over:
Traces of product from the previous product run, which cannot be adequately cleaned from the product line due to technical limitations.

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 conducted either by the supplier or an external testing firm and must be based on protocols/methods that have been approved and agreed by technical experts within Ontex.

Critical control point (CCP):
A point at which control can be applied to prevent, eliminate, or reduce a safety hazard to an acceptable level.

Declaration of compliance:
A written statement describing the migration potential of the packaging material. Where content is not legally defined, it shall contain at minimum the following elements: identification of the business operator and the material manufacturer, applied legislation, information about all potential migrants and their restrictions and conditions suitable to use the material safely.

Disposition:
The determination of what will be done with the object of the determination. For example, the disposition of a 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 matter:
Any object or matter that may become part of the product being produced, which is not designed to be part of such product. Extraneous matter may be a foreign object, foreign material, or an aberration in the product or product ingredient. Examples include metal, stones, wood, plastic, paper, and matter inherent to raw materials.

HACCP:
Hazard analysis and critical control points (HACCP) is a systematic preventive approach to product safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe and designs measures to reduce these risks to a safe level.

Hazard:
The potential to cause harm to human health. Hazards can be biological, chemical, or physical.

Lot (lot 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 shall 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.

Manufacturing location:
The supplier facility where the ingredient or packaging material is produced and/or packaged into the final product that is sent to Ontex locations. This includes blending operations, chopping and any direct handling of the ingredient with the potential to introduce physical, microbiological, or chemical risks.

Mock recall:
A simulated recall process. This exercise helps to ensure that traceability procedures are adequate and identify opportunities for improvement in the event of a real recall situation.

Our:
Belonging to Ontex.

Packaging component:
All elements of packaging including adhesives, labels, inks, dyes, and stabilizers.

Pesticides:
Compounds classified as such by the regulatory authorities of the location where materials or products are produced and the destination to which they may be delivered. These include, but are not limited to fungicides, insecticides, rodenticides, and herbicides.

Primary packaging:
This includes any physical contact (i.e., solid, liquid, or gaseous exchange) between packaging and product under actual and foreseeable conditions. It includes packaging which has a surface in direct contact with the product, and/or a surface in air contact with the product (e.g., material touching another packaging component that is not hermetically sealed (airtight) or that has low barrier properties, and/or a surface in contact with the product after opening).

Product defense:
Steps to safeguard the product supply against intentional acts (or the threat of an act), such as a mass contamination or product tampering.

Product withdrawal:
Any voluntary or involuntary retrieval of a product that has been released for distribution.

Recall:
Removal of a product from commerce because it is believed to be in violation of applicable law or regulations (e.g., misbranded or adulterated).

Recycled material:
A pre- or post-consumer use material that has been treated, salvaged, refurbished, or otherwise reworked for re-use.

Release:
The action to discharge a product from hold status for use after the cause of the hold has been investigated, and disposition determined.

Risk:
An estimate of the likely occurrence of a hazard or illness.

Sanitation:
All actions dealing with cleaning or maintaining hygienic conditions of the facility. This ranges from cleaning/sanitizing specific equipment to periodic cleaning activities throughout the facility, including plant and grounds cleaning activities.

Tolerance:
Allowable deviation from the target value of a certified reference or other standard.

Traceability:
The ability to track materials on a lot number basis up and down the distribution chain, for example to trace a specific lot of ingredient/component from the supplier who delivered it to the product that contains it, and to track a finished product to the primary external customer(s) or destination(s).