



Contract Manufacturing

General

## Food Safety and Quality Expectations Manual



**Version 2**

**2019**

**Global Supplier Quality**

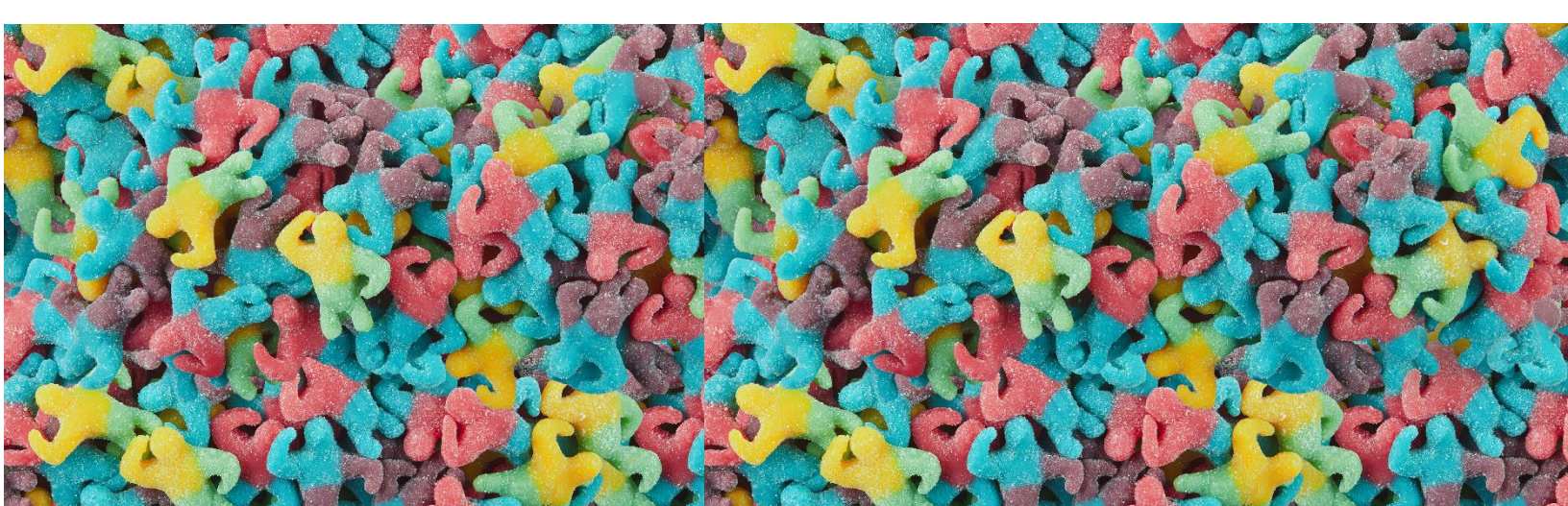
Dear Ferrara Contract Manufactures,

Ferrara Candy Company (“Ferrara” or “FCC”) is committed to sharing delight in every bite. We intend to achieve this goal through consistent programs and continuous improvement of food safety and quality. Ferrara Candy views Contract Manufacturers as an extension of our company. Ferrara requires our Contract Manufacturers to comply with regulatory requirements.

Resources for Contract Manufacturers, including this manual, may be found on the following link: [www.ferrarausa.com/suppliers](http://www.ferrarausa.com/suppliers). It is the responsibility of each Contract Manufacturer to review the webpage regularly for changes and updates to the expectations manual. We respect our supply chain network and strive for the development of a relationship with our Contract Manufacturers that will continually improve the product quality and safety that our customers and consumers demand.

It is Ferrara’s stance that all Contract Manufacturers should understand the requirements so they can better understand our culture. Contract Manufacturers who apply our standards and best practices to their processes reduce the consumer’s overall food safety risk and improve the business prospects for both of us. The expectations outlined in this document are essential to effectively manage food safety and quality to our standards at Ferrara. In order to effectively do this, we at Ferrara believe we must work together to ensure our customers receive a great tasting, safe product. We look forward to working with you.

– **Ferrara Global Supplier Quality**



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## Evaluation and Qualification of Contract Manufacturers

Ferrara Candy Company welcomes new and innovative ideas. All companies interested in joining the Ferrara Contract Manufacturing network should understand that they must go through an approval and contracting process prior to manufacturing/packing/filling any product. Contract manufacturers are required to formally agree to Ferrara and regulatory requirements by signing an acknowledgement of the requirements in this manual. To ensure that safe quality food is produced, approval is conducted on a site level. Key Process Indicators may be developed with each Contract Manufacturer. Technical and process capabilities may be assessed and improvement programs required. A Contract Manufacturer may be required to subscribe to an electronic data management system if approved.

### **a. Document request, initial information, and/or audit**

- i. Each prospective Contract Manufacturer must undergo a food safety, quality, and regulatory compliance review. Ferrara, among other things, uses questionnaires, review of documentation, government data, 3<sup>rd</sup> party food safety certifications, Ferrara on-site audits, product testing and review of specification conformance capability to assess Contract Manufacturers ability to meet our requirements.

### **b. Pre-Qualification Corrective Action Plans**

- i. If Ferrara identifies a failure on the part of the prospective Contract Manufacturer to comply with our requirements in the initial audit and verification phase, the Contract Manufacturer must develop a corrective action plan prior to manufacturing product for Ferrara. Ferrara will review the corrective action plan for appropriateness prior to determining final qualification status. Failure to effectively close non-conformances may result in a disqualification status by Ferrara.

## Management Commitment

- a. The Contract Manufacturer site producing goods for Ferrara must have a documented policy that states the site's commitment to producing safe food and food product products in line with legal requirements
- b. Senior management of each Contract Manufacturer must have clear objectives that support a food safety and quality culture. Management must meet annually to review their site's food safety and quality programs. Meetings notes must be taken along with the inputs and outputs of the meeting. The scope of the meeting includes but is not limited to:
  - ii. Results of audits
  - iii. Customer complaints
  - iv. Incidents
  - v. Effectiveness of the Food Safety Plan
  - vi. Resource requirements

- c. Senior management must be present at the opening and closing of Ferrara audits. They must provide resources to ensure gap closures and continuous improvement plans are achieved for Ferrara products.
- d. The site must ensure responsibilities are defined, documented and communicated within the company. They must ensure that programs are established and will continue in the event of personnel or company changes.

## Food Safety and Quality Management Systems

A Food Safety System shall be developed by each Contract Manufacturer and managed by a multi-disciplinary food safety team having specific knowledge of the type of Food Safety Management system being applied, based on the requirements of the region it operates in as well as knowledge related to the product, processes, and associated food safety hazards. Preventive Controls-based food safety teams shall be led by a Preventive Controls Qualified Individual (“PCQI”). Hazard Analysis and Critical Control Points (“HACCP”) teams must have a designated and qualified team leader who shall be able to demonstrate competence relative to HACCP. Team records shall be maintained and demonstrate competency of team members.

The Food Safety Plan must be prepared in accordance with the requirements specified by the U.S. Food and Drug Administration, outlined in 21 Code of Federal Registrar 177.126(b) as may be revised or superseded from time to time.

### **The site must:**

- a. Establish, implement, document and maintain food safety and quality management systems.
- b. Demonstrate programs are effective via documented processes, controls measures, and audit results.

### **Documentation Requirements**

- c. The site must have documented policies, methods, and programs in the form of a printed or electronic food safety and quality manual.
- d. Documents that are required for food safety and quality must be controlled and available upon the request of Ferrara or any applicable regulatory authority.
- e. Records must be maintained, legible, and retrievable. The site must have a documented procedure to establish the controls instituted for identification, storage, retrieval, retention, and disposition of records.
  - i. Documents relating to production for Ferrara must be maintained for shelf life of product plus one year, but in no event less than 3 years.

### **Regulatory Requirements**

- f. The site must have a regulatory inspection procedure that outlines requirements if production samples or swabs are taken.
- g. It is the site's responsibility to assure compliance with applicable laws and regulations throughout their supply chain. Contract Manufacturers may be required to comply with additional certification requirements (e.g. organic, kosher) for specific products or regions of the world.
  - i. Management at the site must ensure that employees are properly and sufficiently trained to manage regulatory inspections and that Ferrara is immediately notified if product released into commerce does not comply with regulatory requirements or contractual specifications.
  - ii. Ferrara must be notified within 24 hours if regulatory authorities inspect product or documents that pertain to Ferrara or would impact Ferrara. If product samples are taken, the lot must be placed on hold until the results are released.

### **Sensory**

- h. The site must ensure that product meets Ferrara specification requirements for taste, texture, odor, and appearance (size, shape, color, etc.). Appearance includes product and packaging.
- i. The site must have a program in place to show compliance with Ferrara specification requirements. It is recommended that sensory checks are conducted throughout each production run.

### **Retention Samples**

- j. Contract Manufacturers must maintain retention samples for at least the shelf life of the product plus one year, or such longer period as agreed to in the supply agreement with Ferrara. Retention samples must be one quarter pound per lot of bulk packed product, or two finished goods in finished packaging.



## Crisis Management

Contract Manufacturers must have a documented crisis management plan, including a product recall/withdrawal plan. The plan must include current contact information and be tested at a minimum annually. Ferrara must be contacted promptly in the event of a product recall/withdrawal or other crisis, which may affect Ferrara product.

- a. The crisis management plan must include at least the following:
  - i. Communication plan
  - ii. Documented contingency plan
  - iii. Implementation requirements involved in crisis management
  - iv. Checklist of required activities including an assessment of impact to product/site/equipment
  - v. Root cause analysis and corrective actions post incident

## Third Party Food Safety and Quality Accreditation

Ferrara requires that Contract Manufacturers maintain certification for a food safety certification program recognized by the Global Food Safety Initiative (“GFSI”). A minimum acceptable score will be determined and is required by Ferrara and will be conveyed to the Contract Manufacturer by the appropriate Ferrara personnel. The certificate must be sent to Ferrara on an annual basis. Once accreditation is achieved Ferrara must be notified immediately if certification lapses.

## Good Manufacturing Practices

All of Contract Manufacturer's employees, visitors, and contractors at sites handling product for Ferrara must comply with current Good Manufacturing Practices (cGMPs) established by laws, regulations, and internal requirements. Building, ground, equipment and process must meet cGMP requirements. The site must conduct a cGMP audit at minimum once a month and records must be available for review. Staff facilities must be sufficient to accommodate the required number of personnel. The facilities must be maintained in good and sanitary condition.

### Personal Hygiene Practices

- a. Contract Manufacturers must maintain personal hygiene standard designed to minimize the risk of product contamination from personnel. The Codex Alimentarius Commissions recommendation on personal hygiene shall be followed.
- b. Jewelry, watches, false eyelashes, false fingernails, perfume or aftershave are not permitted in food production areas.
- c. Health screenings must be in place for new and existing employees and visitors where permitted. Procedures in place for managing illnesses and communicable diseases must be established and communicated throughout the company.

### Training

- d. The site must ensure that all personnel performing work pertaining to food safety and quality are competent to carry out their activity through training, work experience, or qualification.
- e. Personnel engaged in activities relating to critical control points or preventative controls must go through a competency assessment prior to commencing work.
- f. Records of training must be maintained and training must be completed by a qualified individual.

### Facility and Grounds

- g. The site must be suitable in size, and location and maintained in order to facilitate the production of safe and legal products.
- h. The site must have reasonably designed systems in place to prevent unlawful or malicious actions from affecting the products and premises.
- i. The site layout, flow of processes and movement of personnel should be sufficient to prevent the risk of product contamination and comply with relevant legislation.
- j. The interior of the site (floors, wall, drains, ceilings, lights, etc.) must be of suitable construction and not present a hazard to the product.
- k. Waste must be adequately segregated and disposed of in a manner that prevents contamination of the product and the surrounding environment.

## Equipment and Utensils

- l. Equipment and utensils must be assessed as suitable prior to use.
- m. Equipment and utensils must be suitable for the intended purpose and of hygienic design. They must be properly maintained and cleaned to protect the product from contamination including allergen cross contact. Cleaned and sanitized equipment and utensils must be stored in a manner that is protected from potential contamination and allergen cross contact.
- n. The site must have a documented preventive maintenance program in place to protect against equipment failures and contamination. Records of preventative maintenance must be maintained.
- o. A documented calibration program must be in place for measuring equipment. Records of calibration and verification of equipment must be maintained.



## Food Safety Plan, Traceability, and Date Coding

### Food Safety Plan

The site must have a fully implemented and effective food safety plan that complies with Ferrara and applicable regulatory requirements. The food safety plan must be verified at, minimum, once every 3 years, or when any material change occur.

- a. The site must have a food safety team who are trained in HACCP and have relevant knowledge of the products and processes
- b. Prerequisite programs must be established and maintained including but not limited to: Training, purchasing, maintenance, sanitation, pest control, storage, transportation, and allergen controls
- c. A process flow diagram must be completed.
- d. A hazard analysis must be completed that evaluates and identifies potential hazards that are reasonably expected to occur at each step of the flow diagram. Control measures must be put into place to prevent or eliminate identified hazards.
- e. A hazard analysis must be completed for raw materials including packaging (primary, secondary, and tertiary)
- f. Monitoring, verification, and validation (as applicable) activities must be in place for critical control points and/or preventive controls.
- g. Product descriptions must be on file for each product or product category. Product descriptions must include shelf life, storage and transportation, ingredients, packaging and intended customer.
- h. The site must have a minimum of one PCQI.

### Traceability

- i. The site must maintain a current, documented product traceability and recall program. The program must be tested at minimum annually for Ferrara product (upstream and downstream).
- j. The traceability program must ensure that all ingredients, finished product, and product packaging can be traced from production to distribution.
- k. The site must meet regulatory requirements related to traceability and recall/withdrawal.

### Date Coding

- l. All coding information must be clear and legible
- m. All Ferrara requirements on coding, labeling and graphics must be met. These will be communicated to the Contract Manufacturer's personnel by the appropriate Ferrara personnel.

## Delivery

All deliveries must comply with FCC specification and requirements. A representative from Ferrara will reach out and provide the requirements.

- a. International suppliers must have and provide an FDA registration number to FCC. The number must be maintained and provided to FCC on an annual basis. All international suppliers must comply with the Foreign Supplier Verification Program (FSVP) as outlined in the FSMA, and make all necessary evidence of compliance available to FCC.
- b. Ferrara Candy Company requires products received from Contract Manufacturers to have a minimum remaining shelf life at time of receipt:
  - i. Producers: Product must have 70% shelf life remaining.
  - ii. CoPackers/RePackers: Product must have 50%, but not less than 6-months, remaining shelf life.
- c. Ferrara conducts an inspection upon receipt of materials. Ferrara maintains the right to reject/not accept product within 72 hours of receipt. The vendor will be notified if product is not accepted.
- d. A Certificate of Analysis (COA) is required for every material lot shipped to FCC. COA's must be provided at time of receipt or prior to shipment for each lot of product contained in the shipment. Each COA must include, at minimum:
  - i. Co-Man Name
  - ii. Manufacturing Facility Address
  - iii. Product Name
  - iv. Co-Man Material Number
  - v. Lot Code
  - vi. Manufacture Date
  - vii. Expiration Date
  - viii. Ferrara Material Number
  - ix. Analytical and Microbiological Tests
    1. A Ferrara employee will specify the required test
  - x. Test Results
  - xi. Test Method
  - xii. Co-Man Quality Contact
- e. The case label requirements will be shared by the appropriate Ferrara employee but must contain the following, at minimum:
  - i. Ferrara Candy Company
  - ii. Brand Name and Item Description
  - iii. Item Number
  - iv. Net Weight
  - v. Country of Origin

- vi. Lot Code
- vii. Best By Date
- viii. Storage and Transportation information
- ix. Allergen Statement
- f. The Bill of Lading must contain at minimum, the following information:
  - i. Unit of Measure in Net Quantity
  - ii. Number of Units
  - iii. Lot Number
  - iv. Ferrara Material #
  - v. Ferrara Purchase Order Number
  - vi. Quantity Delivered by Lot and Product Description
  - vii. Date of Production for Each Product

## Foundation Requirements

### Pest Management

- a. The site must have a documented pest management protect to prevent and eliminate pests. The site must have resources available to rapidly respond to any issues, which occur to prevent the risk to product.

### Foreign Material Prevention

- b. The potential presence of foreign material must be considered in all hazard analyses. All necessary steps must be taken to prevent the introduction of foreign material into product and written procedures must be established. Where applicable and/or available, technology options shall be used to detect foreign material.



### Chemical Control

- c. All chemical used at the site must be purchased, labeled, stored and used in compliance with all applicable laws, regulations, and internal site requirements. Each site must have a written

chemical approval and management program. Chemicals must be stored appropriately to prevent contamination. Safety Data Sheets (“SDS”) must be on file for all chemicals used at the site.

### **Water, Air, Ice and Gas**

- d. Water, air, ice, steam, and gas that comes into contact with food product, food contact surfaces, or food packaging must be safe and suitable for the intended use. It must be monitored and records must show compliance with applicable law, regulations, and internal site requirements.

### **Cleaning and Sanitation**

- e. The site must have a documented cleaning and sanitation program. The program must include the following:
  - viii. Responsibility of cleaning
  - ix. Areas/Items to be cleaned
  - x. Frequency of cleaning
  - xi. Method of cleaning
  - xii. Cleaning chemicals and concentration
  - xiii. Cleaning Materials
  - xiv. Records of cleaning and verification
- f. The site must perform pre-operation inspections, verify and monitor cleaning and sanitation results, and implement corrective action plan for deficiencies.
- g. Cleaning equipment must be properly designed and suitable for the intended purpose. It must be stored in a clean and hygienic manner to prevent contamination.
- h. Cleaning procedure be validated and reviewed annually. The procedures must be re-validated when changes occur.

### **Environmental Monitoring**

- i. The site must have a risk based environmental monitoring program in place for pathogens or spoilage organisms. Ferrara must be allowed to review the environmental monitoring program prior to acceptance as a Contract Manufacturer.

### **Allergen Control**

- j. Where applicable, the site must have systems in place to control and prevent allergen cross contact and to ensure proper allergen labeling of product. The site must maintain a list of allergen containing items.
- k. Where the site has a risk of allergen cross-contact, the site must have validated cleaning procedures in place. The validation must be reviewed by Ferrara QA prior to approval.

### **Good Laboratory Practices and Testing**

- l. Programs must be in place to ensure reliability of laboratory results for testing done on product and material produced for Ferrara. Ferrara must be allowed to review and approve testing completed on products and materials.
- m. Unless agreed to in writing, Contract Manufacturers will not ship product with test results pending.
- n. Controls must be in place to prevent potential contamination of product by laboratory personnel or laboratory reagents.
- o. A laboratory with at minimum ISO 17025 accreditation must be used for microbiological testing.

### **Product Handling, Storage, and Transport**

- p. Contract Manufacturers must adhere to “First To Expire, First Out” inventory management.
- q. Product should be stored and transported according to applicable temperature ranges. A Ferrara representative will provide the appropriate storage and transportation temperatures.
- r. Product must be handled, stored, and transported in a manner that prevents contamination.
- s. Product shipped to Ferrara must have a seal. The seal number must match the number on the bill of lading. Less Than Truck Load’s (LTLs) must be locked.

### **Holding Material**

- t. Contract Manufacturers must have document programs and systems in place to prevent the shipment of nonconforming product to Ferrara.

### **Notification of Changes**

- u. Contract Manufacturers must conform to Ferrara’s Change Management procedures. The Ferrara change management form must be used. This includes notifying Ferrara of any changes or modifications to the production location, product specifications, product inputs, and/or process steps.



### **Internal Audits**

- v. The site must conduct internal audits at planned intervals at their facility based on risk to determine compliance with their food safety, quality, and regulatory programs. The program must include monitoring and completion of internal audit findings.

## **Supplier Qualification**

- w. Contract Manufacturers must have a supplier qualification program in place. A program must be in place for approval and monitoring of suppliers based on risk.
- x. A list of approved suppliers per site must be kept on file with the Contract Manufacturer.

## **Specification**

- y. Product specifications must be agreed to between the Contract Manufacturer and Ferrara. Systems must be established and implemented to demonstrate that product released meets the requirements specified in the agreed to specification

## **Net Quantity**

- z. The frequency and methodology of quantity checking must meet Ferrara and applicable legal and regulatory requirements. Records of checks must be maintained to insure lot compliance where declared on packaging. The site must have a procedure in place for the verification of net quantity (weight and count).
- aa. In no case shall packages which are outside of allowable regulatory or customer limits or guidelines be shipped. Packages not meeting requirements must be reworked or discarded.

## **Process Validation and Capability**

- bb. All production lines are expected to operate within established process control and monitoring parameters. These parameters must be documented, validated, and verified at a frequency based on risk.

## **Pallet Requirements**

- cc. Contract Manufacturers must have a pallet management program that includes inspection for damage, infestation, mold, splinters, etc. Grade A pallets must be used.
- dd. The use of slip sheets is required for finished product pallets
- ee. Product imported to the United State must be heat treated and be stamped with HT.

# **Continuous Improvement and Complaint Management**

## **Complaint Management**

- a. Contract Manufacturers must have programs in place to manage consumer and customer complaints and respond with corrective actions at Ferrara's request. Process must be established to analyze and identify improvement opportunities. Customer complaints will be shared with an appropriate contact at Ferrara.

## Continuous Improvement

- b. Contract Manufacturers must have processes in place to improve the effectiveness of their food safety and quality programs. Measurements shall be in place to demonstrate the results.

## Plant Trials and Samples

If a Contract Manufacturer is required to complete a plant trial or send samples, this requirement will be communicated to the Contract Manufacturer. A plant trial, where product is intended for sale, may not occur until the site has received an acceptable food safety status.



## Ferrara Food Safety and Quality Status Classifications:

A Contract Manufacturer will be awarded one of the following statuses by Ferrara. Ferrara retains the right to change a Contract Manufacturer's status at any time.

### Approved

Ferrara may use a Contract Manufacturer who is in "Approved" status. To be in "Approved" status the Contract Manufacturer must comply with Ferrara standards. To remain in status the Contract Manufacturer must ensure that documentation is updated as required and they are continually meeting Ferrara standards.

## **Conditionally Approved**

Ferrara may use a Contract Manufacturer that is “Conditionally Approved” status upon:

- a. Verification that corrective action plan has been developed and mutually agreed upon timeline for close is in place
- b. An acceptable plan is developed and implement to mitigate any perceived risk

## **Not Approved**

Ferrara will not use a Contract Manufacturer who is in “Not approved” status. A Contract Manufacturer who wish to achieve an “Approved” status must develop and implement with a corrective action plan. Once reviewed and approved by Ferrara, a verification will be completed to ensure compliance, this may be in the form of an on-site audit. Ferrara will determine, based on the corrective action plan and verification, if the Contract Manufacturer is ready to be moved to “Approved” status.

## **Restricted**

“Restricted Status” is a direct result of unresolved issues that may put FCC products at risk. Continued sourcing to FCC is allowed; however no future business opportunities will be considered. To be reevaluated as a supplier to Ferrara, the Contract Manufacturer must develop a corrective action plan and fully implement. Ferrara must review the Contract Manufacturer corrective action plan and verify effectiveness to ensure compliance. A facility audit may be required. For a probationary period of 3 months, no non-conformities are to be observed.

## **Disqualified**

Ferrara will not use a Contract Manufacturer who is in “Disqualified” status. A “disqualified” status reflects that a Contract Manufacturer has a severe gap in its food safety and quality programs and/or does not otherwise comply with Ferrara standards. If a Contract Manufacturer wishes to achieve an “Approved” status they must go through the Ferrara approval process.

## **Ongoing Monitoring and Management**

Ferrara’s ongoing monitoring and management of Contract Manufacturers has the following components: Periodic audit and corrective action plan; Ongoing monitoring; triggering event management; updates to Status Classification

### **a. Audit**

Ferrara audits, as appropriate, will require corrective and preventive action plans with closure due dates.

### **b. Monitoring Performance**

Ferrara will monitor Contract Manufacturer ongoing performance utilizing various methods. Ferrara will advise each Contract Manufacturer of the methods and other information that is required for

monitoring of the Contract Manufacturer. Some examples of documentation and other information that may be required are listed below:

- Microbiological testing results
- Contamination testing results
- Monthly reports on Key Performance Indicators
- Third Party Audits
- Food Safety and Quality Questionnaire/Assessments
- Management of Change records
- Complaints
- Batch Records
- Process Control charts (Targets/Ranges)

c. Triggering Event Management

A “Triggering Event” is an event or circumstance that might cause Ferrara to change the Food Safety and Quality status or another component of the management of the Contract Manufacturer. This may be a positive or negative event. Examples of triggering events include, but are not limited to, the following:

- Product Retrieval Incident
- Repeated failure to meeting specification
- Trends in Key Performance Indicators
- Audit Results
- Change in Regulations or Regulatory Enforcement
- Escalated Complaint

## Exceptions

Exceptions to the program may be made on a case-by-case basis and as be authorized and allowed by Ferrara Director of Global Supplier Quality in the Director’s sole discretion.



## **Contract Manufacturers**

### **Food Safety, Quality and Regulatory Acknowledgement**

The undersigned Supplier represents to Ferrara Candy Company ("Ferrara") that it has received, read, and agrees to abide by the Supplier Food Safety and Quality Manual in its dealings with Ferrara and further agrees as follows:

1. The Products supplied by Contract Manufacturer will be suitable for use in food and fully comply with the specifications and other requirements agreed to, in writing, by Contract Manufacturer and Ferrara as such specifications may be revised from time to time. The Products supplied by Contract Manufacturer will comply with (and be produced in compliance with) all applicable legal and regulatory requirements.
2. The Products supplied by you will be produced and managed in accordance with the Ferrara Food Safety, Quality and Regulatory Requirements set forth in Ferrara Supplier and Contract Manufacturer Requirements Manuals, as amended from time to time.
3. The Products will be produced only at the manufacturing location(s) approved by Ferrara, in writing.
4. Ferrara will be allowed to enter all manufacturing location(s) producing, holding, and/or storing product to be supplied to Ferrara at any time.

Accepted and Agreed

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

