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# Partners in Quality

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## Supplier Quality Expectations Manual

July 1, 2019  
THE HERSHEY COMPANY

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## About The Hershey Company

A century ago, all we had to offer was a simple kiss. Today, we are among the most respected companies in the world, bringing snacks, community growth, and human opportunity to all corners of the globe.

It all started with Milton S. Hershey, founder of The Hershey Company. He was not immediately successful as a businessman, but he persevered through several failed attempts to establish a confectionery business before he established the Lancaster Caramel Company. In 1893, after visiting the World's Columbian Exposition, Mr. Hershey became very interested in milk chocolate. Through trial and error, he finally established his own formula for milk chocolate. In 1903, he returned to Derry Church, now known as Hershey, to begin construction of the original chocolate factory located at 19 East Chocolate Avenue. By 1905 the factory was complete and in production. The foundation and history of The Hershey Company are firmly grounded on the innovation and persistence of Milton Hershey.

In addition to establishing a viable and growing business, Milton Hershey also provided a model of social responsibility for other businessmen and his successors to follow. Along with building a factory, Milton Hershey set out to establish a town for his workers that went beyond basic housing to include opportunities for entertainment and recreation. He is credited with building Hershey Park, a swimming pool and a ballroom. Later as the depression took grip on the country, Mr. Hershey started the "Great Building Campaign" to provide jobs. This effort yielded some of the town's most prestigious buildings like The Hotel Hershey, the community center and the stadium and firmly entrenched Hershey as a destination town for tourists.

Along with establishing a town with all of the amenities, Milton and Catherine Hershey founded the Hershey Industrial School in 1909. Unable to have children themselves, they channeled their wealth to the school, established for the care of orphaned boys. In 1918, Mr. Hershey gave his entire fortune of \$60 million dollars to the school. Today the school has expanded to serve both girls and boys. The Milton Hershey School is now home to around 1800 students from disadvantaged situations, providing them with housing, education, medical and dental care, opportunities for recreation and the hope of a future without poverty.

Today THC is over one hundred years old and proudly bears the name of its founder. The company has grown from a single factory in Hershey, Pennsylvania to become the largest producer of chocolate in North America and a global leader in confectionery and sugar. Hershey's presence in the marketplace is significant with over \$7.4 billion in sales and products representing 80 brands that are manufactured by facilities across the United States, Canada, Mexico, Brazil, India, Malaysia and China.

Continuing the legacy of our founder, Milton S. Hershey, our commitment to delivering quality products to our customers and upholding ethical business practices is core to who we are. We strive to make sure all of our decisions

— from responsible sourcing of our ingredients and environmental stewardship to fostering diverse work environments and transparency— are guided by our deeply held values.

"Give them quality. That's the best kind of advertising in the world."

*- Milton S. Hershey*

## 1. INTRODUCTION

The Hershey Company views its business partners as an integral part of its success. Our business partners are ingredient and raw materials Suppliers, Contract-manufacturers, Contract-packers, and Food Licensees - collectively referred to as Suppliers. We respect our supply chain network and strive for the development of a relationship with our Suppliers that will continually improve the product quality and safety that our customers and consumers demand.

The expectations set forth in this manual are a comprehensive set of food safety and quality programs that serve as a solid foundation for our Supplier Quality Management system. The Hershey Company (Hershey) is committed to delivering safe, quality foods. We rely on our Suppliers to embrace these programs and implement a culture that continually pursues improvements in food safety.

*This manual does not outline or mandate how to set up or operate a Supplier's facility to meet the expectations set forth by Hershey. Suppliers are solely responsible for operating their facilities in a manner that complies with the requirements mentioned in the manual, Hershey specifications and all-applicable federal, state, and local laws and regulations in both the country of manufacture and country to which any Products provided will be delivered.*

The Hershey Company is committed to building and maintaining a mutually beneficial relationship with Suppliers. Suppliers of ingredients or raw materials should send any questions about Hershey or these expectations to [HersheyQualitySupplierAssurance@hersheys.com](mailto:HersheyQualitySupplierAssurance@hersheys.com). Contract-manufacturers, Contract-packers, and Licensees should send any questions about Hershey or these expectations to their Hershey Quality & Regulatory Compliance Representative. We will attempt to provide assistance and guidance on these expectations as requested and welcome comments and suggestions.

### 1.1 Minimum Standards Overview \ GFSI Certification

The Supplier shall have implemented a written Quality Management System to ensure that the material produced conforms to specified requirements. At a minimum, the Quality Management System shall ensure compliance with each element of this Hershey Company Supplier Quality Expectations Manual, Hershey Specifications for the specific product, and all applicable regulatory requirements of the country of manufacture and the destination to which the products will be delivered and sold.

The Hershey Company continues to move toward industry-accepted certifications. It is a requirement for all Suppliers of Hershey to attain a Global Food Safety Initiative (GFSI) certification. This indicates a Supplier's conformity with an industry-recognized baseline for food safety, demonstrates ongoing commitment to food safety and provides for an independent verification of this commitment. GFSI benchmarks each Food Safety Management Scheme and recognizes those that meet key elements. All GFSI recognized Food Safety Management Schemes are accepted by The Hershey Company. (See – <http://www.mygfsi.com/schemes> )

Specific information on the applicable timeline for meeting GFSI requirements is available from your Hershey Business and Quality & Regulatory Compliance (QRC) partners. If your company is not GFSI certified, you will be asked to provide a detailed plan, which outlines specific activities and milestones for achieving GFSI certification.

In addition, the Supplier's Quality Management System shall specifically include controls to ensure all manufacturing facilities producing Identity Preserved Products shall develop and maintain a program for the identification and processing of Identity Preserved Products. Identity Preserved Products claim special attributes and require segregation and proper labeling to prevent comingling with other products and raw materials that do not have the same attributes (*e.g.*, Kosher, Halal, and organic products, genetically modified organisms (GMO), and products with allergens or sensitive ingredients). Suppliers shall assure the declaration of the identity-preserved status of products complies with all applicable federal, state, and local laws and regulations.

Suppliers shall retain a statement of the status claimed by all Identity-Preserved Products, including, but not limited to, finished products, raw materials, ingredients, preservatives, additives, processing aids, and flavorings. Raw material specifications for Identify Preserved Products shall include requirements for their handling, transport, storage, and

delivery prior to use. Manufacturers producing Hershey Finished products with specifications for Identity-Preserved Products shall include requirements for their handling, transport, storage, and delivery and any additional customer requirements concerning Identity Preserved Products.

## 1.2 Brokers/Distributors/Traders

In cases where materials are being procured through brokers, distributors and traders, the following requirements must be followed:

- Only buy from Hershey approved Suppliers (approval is ingredient and site specific). The Supplier Manufacturing Locations shall be disclosed to the Hershey Contracting Representative to assure that materials are only sourced from locations meeting Hershey requirements for quality and food safety.
- Notify the Supplier that the specific material will be delivered to The Hershey Company.
- Ensure the Hershey Company *SQE Manual* is communicated to Supplier and provide evidence to Hershey of agreement to the requirements by the Supplier.
- The broker/distributor/trader has responsibility to ensure that Supplier complies with those requirements
- The broker/distributor/trader shall be required to notify Hershey of any Manufacturing Location changes. New sites and new lines must be approved prior to use
- The broker/distributor/trader must demonstrate that traceability of materials to Manufacturing Location is maintained.

## 1.3 Confidentiality

The confidentiality provisions contained in contracts between the Hershey Company and Supplier shall govern the disclosure of sensitive information shared between the companies. All personnel should avoid sharing confidential or otherwise sensitive information unless such a contract is in place between the companies.

Assessors (Hershey or persons acting on behalf of the Hershey Company) shall not be asked or required to sign confidentiality agreements as a prerequisite to gain access for assessments prior to or at any time during a quality assessment. The standard confidentiality agreements between supplier and The Hershey Company will suffice. Dates of assessments must be disclosed prior to assessment date so proper documentation can be signed. Assessors cannot sign day of assessment- the assessment must occur on schedule.

## 1.4 Notifying The Hershey Company of Significant Events

Communication in the supply chain is critical when events occur that could impact food safety, quality, or processing. The Supplier must establish procedures to ensure Hershey is immediately and adequately notified of these occurrences.

The Supplier must notify Hershey by a phone call with a live person **and** by email. A voicemail, even coupled with an email, is not adequate. The Hershey Contracting Representative shall be the primary contact for any interaction or notification required by this document.

The Supplier shall notify The Hershey Company Contracting Representative immediately of any of the following occurrences. This list is not inclusive:

- Systematic product quality defect or process control deviation on raw materials, ingredients or finished products supplied to Hershey.
- Discovery of potentially defective or adulterated ingredients or raw material associated with product in distribution.
- Inadvertent release from Hold of any material produced for The Hershey Company.
- Routine and non-routine Regulatory Authority investigations, testing, sampling, reporting, or other contact or action with the potential to affect material produced for Hershey.
- Any event that leads the Supplier to suspect that a non-conformance (specification, Regulatory, etc.) exists in product already shipped to The Hershey Company.
- Product tampering or threat of tampering.
- Event or substance that could threaten ingredient or product integrity.

- Notification by law enforcement or other authority of a potential product safety event.
- Identification of an unlabeled allergen in material produced for Hershey.
- Any change to a Supplier's processes, manufacturing facilities and/or sourcing of ingredients that could have an impact on materials supplied to Hershey.
- Manufacturing changes: The Supplier must notify Hershey of its intention to make any change that may affect the safety, quality, security, shelf-life, ingredient statement, allergen profile, nutritional labeling or functionality of material produced for Hershey – such as changes in material formula, raw materials, production line, Manufacturing Location or processes – and any change shall be approved by Hershey before being implemented. The Hershey Company must be notified of such changes in writing.
- Inability to deliver materials that meet Hershey Specifications
- If any of the Supplier sites manufacturing products for Hershey loses GFSI certification.

## **2 LEADERSHIP AND COMMITMENT**

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Suppliers shall cultivate a strong food safety and quality culture across all levels and functions of the organization. Establishing and building a culture begins at the top of the organization where leaders have the responsibility to set the food safety vision for the organization. When leaders demonstrate a commitment to food safety and quality through their decisions and behaviors, the rest of the organization can follow. Everyone in the organization needs to understand his or her role in upholding food safety and quality.

### **2.1 Commitment**

#### **Policy Statement**

Suppliers shall develop and maintain a policy statement that includes, but is not limited to, the following:

- Commitment to supply safe, quality food products
- Methods used to comply with customer and regulatory requirements
- Commitment and methods used to continually improve its food safety and quality management system
- Commitment to establish and review food safety and quality objectives
- Commitment to maintain an effective GFSI certified food safety and quality management system

This policy statement shall be:

- Signed and dated by senior management
- Made available in language(s) understood by all employees
- Displayed and communicated to all employees

### **2.2 Organization and Resourcing**

Suppliers shall maintain an organizational structure that identifies employees with responsibility for food safety and quality and describes their interrelationship. This organizational structure shall be dated, reviewed and updated periodically, and communicated within the organization. Suppliers shall provide adequate resources for the implementation and effective management of their Quality Management System.

### **2.3 Roles and Responsibilities**

#### **2.3.1 Food Safety & Quality Responsibilities**

Suppliers shall identify employees with responsibility for food safety, quality and regulatory, define their duties, and communicate their interrelationship in the organization. Suppliers shall inform employees of their responsibility to report food safety and quality problems to management.

### 2.3.2 Training

Suppliers shall define and document the responsibility for establishing and implementing the training needs of the organization's employees to assure they have the required competencies to carry out those functions affecting product legality, safety, and quality.

### 2.4 Communication

Communication between The Hershey Company and its Suppliers is an essential element of a thriving and respectful partnership. The routine exchange of information provides the best opportunity to effectively plan and implement food safety and quality initiatives.

## 3 AUDITS AND ASSESSMENTS

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The Hershey Company shall perform an initial food safety assessment of Suppliers as part of the Supplier approval process. Additional assessments may be conducted based upon Supplier performance, risk evaluation, and other factors determined by Hershey. Suppliers should complete corrective actions in a timely manner. Suppliers should acknowledge receipt of report within 5 business days, provide Corrective Action/Corrective Action Preventative Action (CA/CAPA) within 30 days of report issuance.

### 3.1 Assessment Requirements

All Suppliers of The Hershey Company shall be assessed and approved prior to the production and shipment of any materials. The frequency and type of approval assessment required by Hershey is dependent on the type of material or product supplied and may be conducted by:

- Second Party Assessing Supplier on behalf of Hershey or
- a Hershey employee

Suppliers shall permit The Hershey Company or its representatives to assess its establishment manufacturing, storing or supplying materials for Hershey, upon prior communication. This would be a pre-arranged and agreed to date. The assessment frequency requirements are prioritized based upon the experience with the Supplier and the type of material produced for Hershey at that location, using a risk-based assessment tool. To become and remain an approved supplier, the assessment results and response to corrective and preventative actions must be acceptable to Hershey. These food safety and quality assessments evaluate key food safety programs and manufacturing controls, which may include, but are not limited to HACCP validations and verifications of Critical Control Points, Allergen controls and Pathogen Environmental Monitoring.

### 3.2 Internal Audits

The Supplier shall establish and maintain written procedures for conducting internal audits to verify whether their Quality Management System and food safety programs, including the relevant content of this SQE Manual, are adequately implemented. Supplier's management shall review audit results, corrective actions and follow-up as part of regular meetings. Suppliers shall train all employees conducting internal audits on internal audit procedures.

### 3.3 Corrective and Preventive Action (CAPA)

Suppliers shall develop and maintain a corrective actions program to describe methods for investigation, resolution, management, and control of corrections and corrective actions. This program shall include the identification of the cause and resolution of noncompliance of critical food safety and quality parameters. Suppliers shall document all investigations and resolutions of corrections and corrective actions.

All programs mandated by this *SQE Manual* require that Corrective and 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.



### Corrective Action Preventative Actions (CAPAs)

Hershey will issue the final assessment report within 2 weeks of the assessment date. Suppliers shall acknowledge issuance of report within 5 business days, CAPAs within 30 days, providing a timeline for items that require longer than 30 days.

The effectiveness of the corrective action shall be verified, and additional actions must be implemented where necessary. The audit must be completed and closed-out within an established timeframe.

Corrective and Preventive Actions are required for all non-conformances raised- this includes any findings from an internal audit, Hershey assessment, notification by Hershey, regulatory visits, consumer complaints, process and food safety monitoring deviation.

Supplier shall have a procedure for handling and correcting non-conformances in food safety and quality management system.

Where a non-conformity is related to a risk to product safety, legality or quality, investigation shall be conducted, including;

1. Clear documentation of non-conformity
2. Root cause identification
3. Assessment of non-conformity impact on product or process
4. The action to address immediate issue
5. Appropriate corrective action with timeframe
6. The responsibility for correction
7. Verification of correction for its effectiveness

Supplier must have a procedure for root cause analysis. At a minimum a root cause analysis shall be deployed to prevent recurrence of non-conformities when:

1. Trends shows significant increase in non-conformities
2. A non-conformity places safety, quality and legality of product at a risk

## 4 INCIDENT MANAGEMENT

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### 4.1 Hold & Release (this section applies where appropriate to the materials being provided to or as specified by Hershey)

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 product 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. Inventory reconciliation must occur to verify proper control.

The program shall include controls for non-conforming raw materials, materials pending testing (e.g., pathogen testing, sterility testing or Certificate of Analysis (COA) 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 Hershey is either inadvertently released from hold or is suspected of having a non-conformance but has already been shipped to The Hershey Company, the Hershey Contracting Representative shall be immediately notified (see [Section 1.4 - Notifying The Hershey Company of Significant Events](#))

Prior to release, evidence shall be documented to demonstrate one of the following:

- Evidence that control measures have been effective beyond the monitoring system (i.e. analytical or microbiological testing results).
- The control measures (i.e. CCP) comply with the performance intended of that product (CCP charts, retest data, evidence of rework).

- The results of sampling, analysis and/or other verification activities demonstrate that the product complies with the identified acceptable levels for the food safety hazard(s) concerned.

#### **4.2 Control and Disposition of Non-Conforming Products**

Suppliers shall develop and maintain a documented Supplier nonconformance program to communicate and track noncompliance issues with their Suppliers. The program shall require corrective action responses from identified Suppliers addressing the nonconformance issues.

Disposition of materials on Hold that do not comply with specific approved Hershey Specifications must be effectively controlled and documented. 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.

Rejected material shall be clearly identified. The reason for rejection of the material, code dates, 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.

#### **4.3 Regulatory Actions\Product Retrieval\Recall\Withdrawal**

Suppliers shall notify The Hershey Company immediately of regulatory actions or product retrievals involving materials manufactured for Hershey. If finished products manufactured for Hershey are sampled under regulatory action or retrieval, Suppliers shall immediately place those products on hold and take duplicate samples. Suppliers shall not release these materials without Hershey approval. Samples shall remain at the Supplier's facility until a disposition is provided by Hershey.

Suppliers shall develop and maintain a documented recall and withdrawal program that includes written retrieval procedures to promptly and effectively respond to product issues. Suppliers shall maintain documentation and records of all recalls and withdrawals. Suppliers shall investigate all recalls and withdrawals to determine the cause. Suppliers shall document and communicate to Hershey all actions taken because of the investigation.

The retrieval system shall be tested on an annual basis and after any major system changes to confirm (1) the accuracy of all product and contact data and (2) the continuing effectiveness of procedures and traceability systems. The results of these tests and any corrective actions necessary shall be documented.

## **5 FOOD SAFETY AND QUALITY**

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### **5.1 Food Safety and Quality Policies and Procedures**

Suppliers shall develop and maintain specific programs as part of an overall Quality Management System to assure the materials provided:

- Meet all specifications, standards, and requirements established by The Hershey Company.
- Conform to all applicable federal, state, and local laws and regulations and industry standards
- Are free from any physical, chemical, or biological hazards

At a minimum, Suppliers' food safety and Quality Management System shall comply with GFSI standards and include:

- Food Defense
- GMPs
- SSOPs
- HACCP
- Environmental monitoring procedures (EMP)
- Allergen and sensitive ingredient control
- Pest elimination
- Foreign material prevention and control

- Receiving and inventory management
- Product and process evaluation
- Product traceability and mock recalls
- Packaging and labeling
- Storage and shipping
- Analytic records and laboratory support
- Employee training

Suppliers shall outline how they control potential hazards and assure food safety, including, but not limited to:

- The results of a hazard analysis conducted to identify food safety hazards in raw materials, packaging materials, and the process; including but not limited to- processing aids, food contact atmospheric modifiers, desiccant packs, and packaging material.
- Control points and/or critical control points in production to monitor food safety and identify when a process is deviating from set parameters

## **5.2 HACCP**

Suppliers shall develop and maintain a HACCP plan to identify and control hazards associated with the material and/or process. Suppliers shall provide the HACCP flow chart for each product or process to The Hershey Company. Suppliers may provide a copy of the HACCP plan and at a minimum, allow Hershey to view the plan at the Supplier's facility.

For products and processes with no CCPs, Suppliers shall perform a hazard analysis and maintain a flow chart, the hazard analysis, and supporting documentation to justify the decision not to have a CCP. Suppliers shall review the hazard analysis, supporting documentation and flow chart at least annually or when the process, product, equipment, and/or other food safety related areas are changed. Suppliers shall perform verification and validation of all prerequisite programs used to justify decisions in the hazard analysis to support the absence of CCPs. Led by a trained individual, Supplier HACCP Teams shall develop, monitor, review, and validate the HACCP plan.

### **5.2.1 Monitoring**

Suppliers shall monitor critical limits for each CCP at a frequency defined in the HACCP plan to assure implementation of and compliance with the program. Employees responsible for monitoring activities shall sign and date each monitoring record. A master sheet may be used to clearly align signatures to employees' names and titles. Suppliers shall maintain legible, thorough monitoring records. Suppliers shall assure measuring instruments used to monitor CCPs, if any, are appropriate for and capable of measuring the critical limit(s) and are to be calibrated.

### **5.2.2 Verification**

Suppliers shall establish methods, identify responsible employees, and develop criteria for verifying the effectiveness of monitoring activities to assure they achieve their intended purpose. The HACCP plan shall describe who performs verification activities, how the activities are performed, and how often the activities are performed.

### **5.2.3 Validation**

Suppliers shall establish methods, identify responsible employees, and develop criteria for validating prerequisite programs, critical limits, and other food safety limits to assure they achieve their intended purpose. Suppliers shall document all validation activities.

### **5.2.4 Review and Reassessment**

Suppliers shall review the HACCP plan at least annually and when the process, product, equipment, and/or other food safety related areas are changed. Suppliers shall document the review process and maintain records of reviews and the review process (e.g., meeting minutes, records of changes).

**5.2.5 Documentation**

At a minimum, Suppliers shall:

- Maintain a current, signed copy of the HACCP plan for each Hershey product line
- Assure the plant manager or plant authority signs the HACCP plan upon creation and with each change
- Develop a HACCP plan for each type of product or process
- Include a plant layout showing product flow in the HACCP plan
- Assure a current flow chart, identifying CCPs, is available upon request
- Summarize CCPs, if any, in the HACCP plan with critical limit(s), monitoring activities, corrective actions, and verification activities; include documentation of process capability to demonstrate the critical limit(s) is compatible with plant process capabilities
- Assure management maintains control of the product and process when deviations occur
- Document all deviations and corrective actions to demonstrate control of the affected product
- Maintain a deviation log
- Document the justification for monitoring and verification frequency in the HACCP plan
- Document verification and validation of prerequisite programs listed in the HACCP plan

**5.3 Thermal Processing (Treated/Pasteurization Process)**

Suppliers providing thermally processed foods shall comply with all applicable federal, state, and local laws and regulations. Suppliers shall develop and maintain documented programs to assure the products have a minimum 4-log reduction of Salmonella. Reduction varies for different materials. For example:

<b>Product</b>	<b>Target Microorganism</b>	<b>Log Reduction Required</b>
Almonds	<i>Salmonella spp</i>	4-log
Peanut products	<i>Salmonella spp</i>	5-log
Pistachio products	<i>Salmonella spp</i>	5-log
Hazelnut	<i>Salmonella spp</i>	5-log
Cashew	<i>Salmonella spp</i>	5-log
Seeds	<i>Salmonella spp</i>	5-log
Coconut	<i>Salmonella spp</i>	5-log
Cocoa beans	<i>Salmonella spp</i>	6-log
	Total Plate Count	3-log (micronized nibs) or 5-log (whole beans)

This requirement applies to all manufacturing processes that have a defined time temperature requirement, either as pathogen kill step and/or as a process step.

Suppliers shall maintain all production and processing records. Records shall include thermal mapping studies, establishment of process, control of deviations, and evaluations of products.

The Supplier having expert knowledge of thermal processing shall validate the thermal processes. Suppliers should have appropriate facilities and equipment for collecting heat penetration data. Suppliers shall process products based on thermal processes established by the thermal mapping. Suppliers shall conduct frequent checks of critical factors to assure they are within the limits specified in the scheduled process.

Validation studies that are based on the log reduction of total aerobic bacteria, must provide references of relevant peer reviewed scientific studies that establish the equivalency between the log reductions of the target pathogen and total aerobic bacteria.

The defined process shall include, but are not limited to, the following:

### **5.3.1 Process Deviations**

The Supplier shall review records of all thermal process deviations and disposition them using established scientific methods. If Hershey branded product was made, the Supplier shall review the recommendations with The Hershey Company for final disposition of the product.

### **5.3.2 Record Review**

Suppliers shall conduct record review no later than the next working day after processing. Record review shall include, but is not limited to, the review and verification of all relevant production and processing records, tests, and inspections to assure only safe and stable product is shipped into commerce.

### **5.3.3 Product validation**

Suppliers shall conduct validation studies following installation of new lines and development of and/or changes to a process, package, or product as deemed necessary by Hershey. Suppliers may use a qualified third-party facility (*e.g.*, universities, outside laboratories) to conduct these incubation studies.

### **5.3.4 Post Processing**

Suppliers shall develop and maintain a documented post processing operation program. The program shall include procedures to protect against post process contamination.

## **5.4 Prerequisite Programs and Preventative Controls**

Suppliers shall establish and maintain prerequisite programs, preventive controls, and corrective action procedures, including, but not limited to, the monitoring of corrective actions taken, to support the HACCP program.

### **5.4.1 Employee Practices**

Suppliers shall develop and maintain documented GMP programs that control conditions to protect and maintain food safety and quality. These GMPs include, but are not limited to, the following:

- Employee training
- Product and material receiving, handling, and storage
- Employee hygiene and hygienic practices
- Control of employee illness and communicable disease

These GMP programs shall comply with the Codex Alimentarius Commission's recommendations on general principles of food hygiene, where applicable.

Employees shall wash hands before beginning operations and after each absence or activity where hands are potentially soiled (*e.g.*, using the restroom, handkerchief/facial tissue use, handling dirty material, smoking, eating, and drinking). If gloves are used, employees shall maintain hand-washing practices. Employees directly handling product or product contact surfaces should clean and sanitize their hands after touching any non-food contact surface and prior to donning gloves.

- Clothing: Clothing worn by employees should not present a contamination risk to the product. Employees shall wear clean clothing at the start of the shift. Employees shall change soiled clothing if it presents a product contamination risk. If shirts or smocks have pockets above the waist (or lower if exposed product is below the waist), Suppliers should assure pockets are sewn shut or enforce a policy that prohibits storing items in those pockets.

Employees shall change disposable gloves and aprons after each break, upon re-entry, and when damaged. Employees shall store non-disposable gloves and aprons under conditions that will not result in

contamination when not in use.

- Visitors: Visitors shall wear suitable clothing and footwear when entering any food processing or handling area. Visitors shall enter and exit food processing and handling areas through proper staff entrance and exit points and shall comply with all hand washing and personal hygiene requirements. Suppliers should have documented GMP requirements for visitors.

#### 5.4.2 Employee Training

Suppliers shall develop and maintain a documented employee training program to assure regular training on food safety and quality. Suppliers shall determine the necessary competence for employees performing work affecting food safety, food defense, and product quality across all functions that encounter materials and finished product. Suppliers shall train new and temporary employees before they begin working in production. The training program shall include refresher training.

#### 5.4.3 Allergen Control Program

The Supplier shall have an effective program to identify, evaluate, and control food allergens to ensure that specific allergens are not inadvertently incorporated as an undeclared component of any product. The information provided by the Supplier should allow for an unambiguous determination of the need for allergen declaration in The Hershey Company product.

An Allergen Assessment shall be carried out as part of HACCP Plan development to identify, review, and document allergens likely to be present. The Allergen Assessment shall consider possible sources of allergens related to the formulation, process, and site-specific practices, including: raw materials/ingredients, processing aids, rework addition and potential for cross contact in manufacturing, storage or shipment practices. The program shall also identify potential avenues for cross-contamination, including, but not limited to rework, trimming, reprocessing and equipment cross contact.

The Allergen Assessment must consider all allergens on The Hershey Company Allergen Category List as well as any others identified in local regulations and regulations of the countries to which the product is shipped. Suppliers are not responsible for product being shipped to other countries without supplier knowledge.

- Egg and egg products
- Milk Products (Whey, Casein, Butter, Dairy)
- Wheat and wheat products
- Non-wheat gluten-containing ingredients, such as rye, barley and their derivatives
- Soy lecithin\*
- Soy protein\*
- Peanuts\*
- Tree Nuts\* (almonds, Brazil nuts, cashews, chestnuts, coconut, hazelnuts [filberts], macadamias, pecans, pine nuts, pistachios, shea nuts, walnuts)
- Other nuts (beech nuts, butternut, chinquapin, ginkgo nuts, hickory nuts, lychee nuts, pili nuts)
- Crustacean/shellfish (Shrimp, Lobster, etc.)
- Mollusk (Clams, mussels, scallops)
- Fish
- Sesame seeds
- Mustard
- Celery root, stalk and leaves (not Seeds)
- Lupine
- Sulfites if greater than 10 ppm
- Latex

\*The Hershey Company considers the refined, bleached, and deodorized oils derived from these foods non-allergenic.

Where possible, allergens must be “designed out” of the product, making labeling unnecessary. This may be achieved by reformulation or by avoiding manufacturing cross-contact (via proper rework handling, product sequencing,

changeover cleaning or change-over flushing). Avoiding the introduction of allergens through cross-contact from other lines (no common equipment) or other production areas shall be strictly managed through raw material handling (e.g., use of color-coded utensils and work tools), rework handling, GMP and employee allergen awareness training. Allergen-containing materials shall be stored in a manner that will prevent cross-contact. Rework product containing allergens as an ingredient shall be used only in products, which contain the same allergen as an ingredient.

Controls shall be in place to make sure that The Hershey Company is notified of all allergens present (as ingredients or traces). Where a new allergen is identified in a product where it was not previously present, and is therefore not labeled (e.g., discovery of an allergen cross-contact or change to the allergen profile of a raw material), The Hershey Company must be notified immediately (see *Section 1.4- Notifying The Hershey Company of Significant Events*).

Allergen training must be provided so that all involved personnel are equipped with essential information and skills relative to their job responsibilities and the site allergen risk profile. This includes identifying ingredients and products that contain allergens, knowing the process steps where allergens could be introduced to the product inadvertently and understanding the control methods applied.

#### **5.4.4 Physical Contamination Control**

The Supplier shall perform a risk assessment to determine potential sources of extraneous matter. Suppliers shall develop and maintain programs for foreign material prevention and control. The program shall describe maintenance, set-up, verification, and frequency of testing for all foreign material prevention and/or detection devices used by the Supplier. The program shall include guidelines for the prevention of contamination and disposition of materials with suspected or known contamination. Suppliers shall maintain documentation of foreign material findings with root cause and corrective actions.

Suppliers shall develop and maintain a program to control glass and hard/brittle plastic. The program shall identify equipment and other areas containing glass and hard/brittle plastic. The program should restrict the use of glass and hard/brittle plastic devices and supplies. Facilities packing materials in glass shall properly clean the containers and provide shielding to protect materials and ingredients in the event of glass or hard/brittle plastic breakage during production.

All materials manufactured for The Hershey Company shall undergo a foreign material prevention and/or detection step appropriate for the process and material in question (e.g., x-ray, metal detectors, filters, screens). Sensitivity (e.g., detection limits, screen sizes, magnet strength) of the foreign material prevention and/or detection step shall be appropriate for the process and material in question. Suppliers shall optimize the degree of detection, prevention, and mitigation based on the best available technology for the specific application.

##### **5.4.4.1 Metal Detection Requirements**

The detection limit for an end-point metal detector will depend on type of product, package, and the detection equipment. Detection equipment settings shall be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination.

Hershey "Finished product" (unpacked or packaged) metal detectors shall be installed to provide the greatest probability of consistently detecting the smallest ferrous, non-ferrous and 316 series stainless steel metal contaminants which could be hazardous to the health of a consumer.

Typical Hershey installations achieve minimum sensitivity standards for consistent detection and rejection of the following test pieces:

0.8 mm ferrous

1.0 mm non-ferrous

1.2 mm 316 series, non-magnetic stainless steel

#### **5.4.5 Equipment Calibration**

Suppliers shall develop and maintain a documented calibration program to evaluate the performance of operational

measuring devices (*e.g.*, metal detectors, thermometers). The program shall include documentation of corrective actions to address the use of a non-calibrated or inaccurate measuring device.

#### **5.4.6 Cleaning and Sanitation**

The Supplier shall have implemented a written Sanitation program that ensures cleanliness of the food production environment, equipment (including tankers inbound and outbound) and tools. The program shall address:

- Master sanitation schedules; including but not limited to, equipment, areas, structures to be cleaned, cleaning methods, monitoring, and verification procedures.
- Correct use of appropriate sanitation equipment and tools
- Equipment disassembly and re-assembly
- 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
- Inspection procedures
- Verification of Sanitation effectiveness
- Hygiene (non-pathogen) monitoring programs
- Recordkeeping, record review, and corrective action plans

##### **5.4.6.1 Assurance of Sanitation Effectiveness**

Suppliers shall perform and document visual inspections to assure cleaning effectiveness. Suppliers shall also verify cleaning effectiveness (*e.g.*, bioluminescence monitoring or swabbing of food contact surfaces at the end of the cleaning cycle, but before sanitizing) and document or record the results. The program shall address recleaning and documentation of corrective actions when deviations occur. Suppliers shall assure food processing areas, food contact surfaces, equipment, and employees' sanitary facilities are clean before production.

##### **5.4.6.2 Traffic Controls**

- Suppliers shall mitigate risks posed by employee's movement (*e.g.*, on foot, forklifts, hand jacks) between Ready-To-Eat (RTE), Non RTE, and common areas, where applicable; using traffic patterns and product flow charts.
- Suppliers providing microbiologically sensitive materials to The Hershey Company shall consider maintaining foot sanitizing stations (*e.g.*, footbath, foaming) and hand washing and sanitizing stations, or hygiene junctions into the high-risk area.

##### **5.4.6.3 Hygienic Restoration**

Suppliers shall develop and maintain a documented program to address hygienic restoration, defined as corrective actions to maintain the hygienic condition of the processing environment and to assure the production of safe, wholesome foods after an event that could compromise food safety (*e.g.*, roof or overhead leaks).

This program shall address immediate and long-term actions required to determine potential product impact and prevent potential contamination of the processing area.

Suppliers shall place any product that could have been contaminated by an event that could compromise food safety on hold. Suppliers shall perform environmental monitoring of the area during hygienic restoration. Suppliers of ingredients shall notify The Hershey Company if the product has left supplier control, or supply to The Hershey Company may be affected. For co-manufacturing/co-packaging/licensing- Suppliers shall notify The Hershey Company if any products manufactured for The Hershey Company are involved in this type of incident.

##### **5.4.6.4 Environmental Microbiological Monitoring Program (EMMP)**

Suppliers that manufacture or handle microbiologically sensitive materials for The Hershey Company shall have implemented an Environmental Microbiological Monitoring Program (EMMP). The EMM program shall verify that the controls put in place during the *Hygienic Zoning* assessment are effective at preventing potential cross-contamination —



between different Hygienic Zones. The rigor of the plant program depends on the product and process risk evaluation, and the likelihood of pathogen(s) to survive or grow in the finished products during storage and distribution.

All suppliers must have a risk-based environmental monitoring program in place for pathogens and hygiene indicators. At a minimum, these shall include all production areas with open and ready-to-eat products. The environmental monitoring program shall also identify any potential risks in the production and open-product areas so that they can be appropriately managed and prevented from becoming the source of product contamination.

The design of environmental monitoring program shall be based on risk and at a minimum include;

- Sampling protocol
- Identification of sample locations based on zoning concepts
- Frequency of tests
- Target organisms (e.g. pathogens, spoilage organisms and/or indicator organisms)
- Scientifically valid test methods
- Recording and evaluation of results
- Correction and corrective actions in case of positive result
- Annual review of the environmental monitoring program
- Monitoring plan for events that may induce cross contamination risk (construction, roof leaks, etc.)

Justification shall be provided for areas that are not included in EMMP zoning.

#### **5.4.7 Chemical Control Program**

Suppliers shall develop and maintain a chemical approval and control program to assure the safe use and storage of chemicals, including those used in the pest elimination program. The program shall assure only approved food grade chemicals are used in food and food contact packaging material production.

Suppliers shall lubricate equipment located over product or product conveyors with food grade lubricants. Suppliers shall use non-toxic paint in food handling areas and only on non-food contact surfaces. Suppliers shall maintain physical separation of food grade and non-food grade lubricants in storage areas and cabinets to prevent potential contamination. Suppliers shall clearly label grease guns for food grade or non-food grade lubricants.

Suppliers shall provide Safety Data Sheets (SDS) for all materials provided to The Hershey Company upon request. If an SDS is not appropriate for the material provided to Hershey, Suppliers shall provide a letter explaining the regulatory rationale used to determine that an SDS is not required.

#### **5.4.8 Integrated 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. If pesticides are used, the Supplier shall ensure that they are used in accordance with local regulations and those pesticides residues do not exceed limits established by the law of both the Location of the facility and the Location where Hershey will receive the material. The Supplier shall ensure that appropriate measures are taken to prevent pesticides from contaminating foodproducts.

Licensed Pest Control Operators (PCOs) or trained employees shall document each inspection and address deficiencies with corrective actions. Suppliers shall document deficiencies and all corrective actions.

Suppliers should train all employees to increase awareness of the pest elimination program and actions that should be taken if employees are exposed to elements of the pest elimination program (*e.g.*, bait stations, traps, pesticide application).

#### **5.4.9 Food Defense and Food Fraud**

Suppliers shall establish and maintain a documented food defense and food fraud prevention program that specifies measures implemented to identify the food defense and food fraud vulnerabilities, mitigation strategies and their management.

#### **5.4.9.1 Food defense and food fraud prevention plan**

The site's food defense plan shall include methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident, it shall also include measures to secure incoming ingredients. The sites food fraud prevention plan shall include the methods, responsibility and criteria for identifying the site's vulnerability to food fraud. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution and counterfeiting which may adversely impact food safety.

#### **5.4.10 Facilities**

##### **5.4.10.1 Plant Structure**

The Manufacturing Location shall be of adequate design and construction to ensure production of safe and high-quality materials. The facility, including utility fixtures, shall be designed to prevent potential contamination sources from affecting materials manufactured for supply to the Hershey Company. The plant structure shall provide adequate physical separation to prevent any cross contamination (e.g. raw and processed, allergen and non-allergen). Facility grounds must be maintained to address food defense considerations. The Location and design of waste bins, toilets and hand washing, drying and sanitizing facilities shall be adequate to comply with GMPs. The Supplier shall ensure that the facility is satisfactorily maintained.

##### **5.4.10.2 Maintenance**

Suppliers shall develop and maintain a program to assure maintenance is performed in a manner that minimizes the risk of product, packaging, or equipment contamination. The program shall include, but is not limited to, preventive maintenance, installation, and repairs. Suppliers should maintain a preventive maintenance schedule to cover building, equipment, and premises critical to food safety and quality. Maintenance employees shall inform management if repairs and/or maintenance poses a potential threat to product safety.

If duct tape or plastic is used as a temporary repair pending permanent repair, Suppliers maintain the temporary repair in a sanitary condition. Under no circumstances may temporary repairs be used long term. Management shall respond appropriately to protect product, which may include performing repairs outside processing times.

Suppliers shall provide dedicated maintenance tools for use in the RTE area, where and when appropriate. All contractors and Suppliers shall meet the requirements of the GMP program while working on the premises.

##### **5.4.10.3 Utilities Management**

The Supplier shall have implemented programs to ensure safe provision of Utility Services in food production areas. Utility Services include environmental air, compressed air, water, steam, and centralized hydraulic systems. Suppliers shall develop and maintain effective programs for the management and control of the utilities including utilities corrective action standards. All utilities testing standards shall be set for applicable areas based off a risk assessment. The environmental/compressed air, steam, and water shall be monitored on a periodic basis. Applicable corrective action limits shall be defined and followed for all out of specification test results. Recordkeeping and record review shall be in place for corrective action plans

##### **5.4.10.4 Waste Disposal**

Suppliers shall remove waste effectively and regularly from the premises. If waste is held on site prior to disposal, Suppliers should use a separate storage area, which is suitably fly-proofed and contained to prevent potential food safety and quality hazards. Suppliers should routinely clean and sanitize disposal equipment, bins, and storage areas to avoid attracting pests. During daily, documented hygiene inspections, Suppliers should review waste management.

## 6 PROCESS MANAGEMENT

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### 6.1 Purchase

All materials (raw materials, ingredients and packaging) used to manufacture The Hershey Company finished products shall come from approved Suppliers, who are selected based on their ability to meet and maintain compliance with The Hershey Company requirements.

#### 6.1.1. Supplier Approval

The Supplier shall buy materials only from Suppliers who are approved through a documented program designed to manage their quality and food safety. The Supplier shall develop and document quality expectations, requirements and/or specifications for purchased goods, using risk-based assessments, similar to the programs in this SQE Manual and provide them to their Suppliers.

Elements of an acceptable Supplier approval program include but are not limited to the following:

- Specifications
- Risk analysis of materials provided
- Risk analysis of incoming supplier site
- Evaluation of Supplier food safety and quality programs
- Process for assessing high risk ingredients and determination of hazard control (for example – a kill step)
- Method of Supplier approval
- Audit of Supplier facility and warehouse(s)
- Ongoing Supplier verification activities which may include
  - Onsite audits
  - Sampling and Testing
  - Review of the Supplier's relevant food safety records
  - Review of applicable Supplier performance indicators
- Certificates of Analysis or Compliance

#### 6.1.2. Specifications – Raw Materials, Ingredients & Packaging

Suppliers shall develop and maintain documented and current raw material, ingredient, and packaging specifications. Suppliers shall maintain a register of raw material, ingredient, and packaging specifications.

##### 6.1.2.1. Certificates of Analysis/Guarantees

Suppliers shall maintain Certificates of Analysis, Letters of Guarantee, Continuing Pure Food Guarantees, or equivalent documents for all incoming raw materials, ingredients and food contact packaging.

##### 6.1.2.2. Label Verification

Suppliers shall develop and maintain a documented label control program to assure correct labels are received and stored properly. All labels must comply with applicable laws, regulations, and The Hershey Company purchasing specifications and requirements.

At a minimum, the program shall address:

- Label review upon receipt against regulatory approvals, where applicable, and internal specifications. Label review and verification may include accuracy of allergen statement, ingredient information, nutritional information, net quantity, kosher symbol and specific claims.
- Storage and use of labels

Suppliers shall assure labels for USDA-inspected products that are subject to sketch approval are approved by the USDA. Documentation of both sketch and generic approvals shall be maintained.

### **6.1.3. Material Monitoring Program**

The Hershey Company requires that some specific incoming raw materials and ingredients be part of a Material Monitoring Program. This Program was designed to check for potential contaminants from the supply chain and attest that materials consistently meet The Hershey Company expectations regarding specification, chemical food safety, and compliance with all applicable Regulatory requirements for the designated country of The Hershey Company receiving Location. Materials are selected for the Program at the discretion of The Hershey Company.

Under the Program, Suppliers must submit samples representative of The Hershey Company specified materials to a designated laboratory approved by The Hershey Company for testing of the potential contaminants. This testing is in addition to tests that are required for The Hershey Company Specification compliance and may include test parameters additional to those required by Specification. Test results will be released to Suppliers and The Hershey Company, simultaneously.

### **6.1.4. Supplier Non-Conformance**

Suppliers shall develop and maintain a documented nonconforming material (*i.e.*, raw materials, ingredients, packaging, finished products, and equipment) management program to assure any material that does not meet specifications is appropriately managed to prevent inadvertent use or shipment of the material.

### **6.1.5 Receiving**

Suppliers shall develop and maintain a receiving procedure. The program shall address the cleanliness, integrity and security of the carrier equipment. Additionally, the program shall include the inspection and handling of the materials (raw materials, ingredients, WIP and packaging) that are transported.

### **6.1.6 Inventory Management**

Suppliers shall develop and maintain a documented inventory management program (first-in first-out (FIFO) or first-expired-first-out (FEFO) principles) to assure the timely use of stored raw materials, ingredients, and packaging and to prevent stored raw materials, ingredients, and packaging from becoming a source of contamination. Suppliers shall document lot tracking from receipt through usage for raw materials, ingredients, and food contact packaging to maintain full traceability.

### **6.1.7 Contract Service Providers**

Suppliers shall define and document expectations for all contract services affecting food safety. These expectations shall include a full description of the service and detail relevant training needs.

## **6.2 Manufacturing**

### **6.2.1. Product Specifications**

For Hershey finished product The Supplier shall ensure that The Hershey Company Product Quality Specifications are implemented at the manufacturing location and that appropriate plant personnel have access to the latest specifications for finished product supplied to The Hershey Company. Additionally, Suppliers shall develop and maintain a program to assure they have and comply with the most current Hershey Company specifications.

The Supplier must deliver materials that meet The Hershey Company specifications. If the Supplier anticipates that it will not be able to meet the specification, The Hershey Company Contracting or QRC Representative shall be notified immediately (see [Section 1.4- Notifying The Hershey Company of Significant Events](#)).

Licensees must provide The Hershey Company with a Product Quality Specification, which specifies product components and ingredient percentages, monitoring instructions (analytical and microbiological), weight control

requirements, coding instructions, warehousing storage and shipping instructions and product and packaging appearance standards.

### **6.2.2 Process Flow**

Suppliers shall design and organize the process flow to prevent cross-contamination and maintain a continuous flow of product through the process (*e.g.*, separation between raw and RTE areas).

Consideration shall be given to the following:

- Sensitive areas in which foods have undergone a “kill” step, a “food safety intervention,” and/or are subject to post process handling should be separated from other processes, raw materials, or staff that handle raw materials to assure cross-contamination is prevented.
- Staff access points should be located, designed, and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination and cross-contamination.
- Product transfer points should be located and designed to avoid compromise of segregation and minimize cross-contamination.

### **6.2.3 Sampling, Inspection, and Analysis**

Suppliers shall develop and maintain programs for sampling, inspecting, and/or analyzing raw materials, ingredients, WIP, and finished products to assure raw materials, ingredients, WIP, and finished products comply with relevant specifications and regulatory requirements and are true to label.

Suppliers shall use methods approved for the intended food type by the AOAC (current edition), current methods of the US FDA or USDA, methods approved by The Hershey Company, or alternative methods validated as equivalent to the accepted methods noted here for all analyses, whether performed by the Supplier or a third-party laboratory. Suppliers shall document and maintain records of all inspections and analyses.

### **6.2.4 Packaging**

Suppliers shall develop and maintain a documented packaging program to assure finished product packages and shipping containers are properly closed and sealed, with tamper evident seals, and protect the finished product from environmental and shipping conditions. Material in contact with the food must meet appropriate regulatory requirements for food contact materials.

Suppliers shall ensure that the label and all packaging components being used match each other and the finished product being manufactured.

### **6.2.5 Net Weight, Liquid Measure, and Piece Count Control Program**

Suppliers shall develop and maintain a net weight, liquid measure, and/or piece count control program to assure that weight, content, and/or quantity requirements are met for all finished products manufactured for The Hershey Company. The net weight control program shall include the application of statistical process controls, routine scale verification, periodic calibration, corrective action plans and guidelines for handling non-compliant product. Suppliers shall maintain documentation of testing and methods used to assure proper weight, count, and/or quantity control

Sampling criteria for all packaging lines shall be specified in the net weight control plan. Data must be collected routinely and across the compliance lot. Package tare weights shall be verified on an ongoing basis to assure no significant changes have occurred in package weights.

The program shall comply with all applicable laws and regulations and should follow guidelines of the most recent edition of NIST Handbook 133: Checking the Net Contents of Packaged Goods or FSIS Net Weight Labeling of Meat and Poultry Products, as applicable.

Out of compliance lots must be held for further evaluation and disposition (see [Section 4.1- Hold &](#)

## **6.2.6 Changeovers**

Suppliers shall develop and maintain a changeover program, including line clearance, pre-start up inspection, and code date changes. The program shall assure all printed packaging and labels are removed from line equipment at the end of the run, including partial cases and/or cases on conveyors before palletizing. Suppliers shall inspect the equipment and area and document said inspections.

## **6.2.7 Rework**

The Supplier shall have implemented a written program to control the use of rework materials (WIP and Finished Product) in any product supplied to The Hershey Company. If rework is to be reincorporated into product as an 'in-process' step (not simply repackaging or re-casing finished product), then the conditions for use of rework must be clearly set out in the product formula and/or specifications, and equivalent local documents (e.g. Manufacturing recipe, rework matrix) with prior approval from The Hershey Company.

The conditions of use of rework must include: the type and quantity of rework that can be added to the target product, conditions of storage, reprocessing steps in which it will be added, method of addition, identification of allergens, shelf life, special handling requirements and lot number identification for traceability. If rework is identified as potentially containing allergens, it must be segregated, controlled, and incorporated only into the same and/or appropriately labeled product. Rework inventory and usage controls shall include stock rotation practices to ensure that the oldest rework is used first

Suppliers shall maintain records of all rework operations to maintain traceability. Suppliers shall include rework on the HACCP plan hazard analysis and flow chart. If rework is not used, Suppliers shall add a note to that effect in the HACCP plan.

## **6.3 Storage**

### **6.3.1.1 Storage of Raw materials, Ingredients, Packaging, WIP, and/or Finished Products**

Suppliers shall assure that facilities used to handle or store raw materials, ingredients, packaging, WIP, and/or finished products are of suitable and appropriate design for holding and storage of such items and are maintained and secured to prevent potential contamination.

Raw materials, ingredients, packaging, WIP and finished products shall not be stored adjacent to any materials that have strong odors or adjacent to chemicals, whether hazardous or non-hazardous. Suppliers and carriers shall hold raw materials, ingredients, packaging, WIP and finished products at conditions (temperature and relative humidity) recommended by the manufacturer during all stages of storage and transportation.

Suppliers shall conduct a risk analysis when holding raw materials, ingredients, packaging, WIP, or finished products under alternative storage conditions to assure there is no risk to the integrity of those items, no contamination, and no adverse effect on food safety and quality.

### **6.3.1.2 Storage of Equipment and Receptacles**

Suppliers shall store equipment and receptacles in rooms designed and constructed to allow for the hygienic and efficient storage of equipment and receptacles. Suppliers shall not store processing utensils or packaging in areas used to store hazardous chemicals and/or toxic substances. Equipment and pallets should not be stored outside. If outside storage cannot be avoided, Suppliers shall store materials in a sanitary manner to prevent pest harborage and develop a program to clean equipment and pallets before re-entry into the building.

### **6.3.1.3 Storage of Hazardous Chemicals and Toxic Substances**

Suppliers shall store hazardous chemicals and toxic substances in such a way that they do not present a hazard to staff, raw materials, ingredients, packaging, WIP, finished product, product handling equipment, or areas in which

product is handled, stored, or transported.

## 6.3.2 Shipment

### 6.3.2.1 Product Release

Suppliers shall develop and maintain a documented finished product release program. The program shall assure finished product is only released for loading/shipment by authorized employees and after all inspections and analyses are successfully completed and documented (*e.g.*, quality holds, pre-shipment review, microbiological testing).

### 6.3.2.2 Loading and Shipment

Suppliers shall develop and maintain a documented loading and transport program. At a minimum, the program shall:

- Describe acceptable and unacceptable equipment and shipping container conditions (including pipes and loading/unloading equipment). Load locks, air bags or a pin wheeling loading pattern may be used to eliminate excess space and load shifting in transit. Wood should NOT be used.
- Address temperature-controlled vehicles and on-board temperature monitoring devices
- Address bulk tanker construction (stainless steel), frequency and conditions for equipment sanitation, tanker logs, and cleaning certificates, and approval of wash stations.
- Where Hershey is directing transit, Hershey is directing transportation protocol and approval of wash stations. Carriers must be washed at an approved Hershey wash station.
- Require documented inspections of shipping containers (*e.g.*, trailers, tankers, trucks)
- Require proper stock rotation (*i.e.*, product to be shipped by first expiration date)
- Include the handling of returned and/or brought back finished products

Suppliers should design loading and unloading programs to minimize unnecessary exposure to conditions and to maintain raw material, ingredient, packaging, and finished product integrity.

### 6.3.2.3 Seals

Suppliers shall develop and maintain a seal policy to assure no product has been tampered with or lost while under the carrier's control. Suppliers shall assure materials sent to external providers for repackaging, reprocessing, or other handling are sealed or locked appropriately during transport to and from the external provider location.

Containers shall have intact seals upon arrival at The Hershey Company or co-manufacturers and the vehicle seal number shall match the original seal number applied at the original shipping point.

Shipments that cross borders or are opened by Customs or regulatory personnel (scale personnel, police, border patrol, etc.), require a replacement seal on the door or hatch opened. In addition, the new seal number must be documented on the BOL along with the regulatory person's name and ID or badge number. The original seal should be retained by the driver and provided to Hershey's receiving personnel to compare against the BOL. If a Customs official opens an individual product container (case, drum, tote, etc.), the container shall be resealed, and the driver should document that the container was opened on the BOL. (PLEASE NOTE: Truck drivers shall obtain new seals from Hershey's customs brokers or be equipped with extra seals when moving across U.S. borders). If product containers are taken by Customs, the number of missing units shall be noted on shipping records, along with the signature or badge number of agent. Extra seals may be required for shipments to Mexico.

Chemicals, whether hazardous or non-hazardous, or materials with strong odors should not be shipped on the same truck/trailer with finished products destined for The Hershey Company. While LTL shipments are not required to have a seal or continuous seal form because of the inherent nature of LTL shipments, Suppliers shall have the shipper secure trailers with a lock and the carrier shall assure that no product has been tampered with or lost while under the carrier's control.

## 6.4 Document Management and Control

Suppliers shall develop and maintain a document control and records retention program that effectively demonstrates the implementation of food safety and quality systems. At a minimum, the program shall:

- Identify employees responsible for monitoring, verifying, maintaining, retaining and disposing of records
- Assure records are readily accessible and securely stored to prevent damage and deterioration
- Establish record retention timeframe requirements in compliance with periods specified by applicable laws and regulations

### 6.5.1 Product Identification

Suppliers shall develop and maintain a product identification program, specifying employees responsible for identifying product, including raw materials, ingredients, packaging, WIP, and finished products, during all stages of production and storage. At a minimum, the program shall assure:

- Product is clearly identifiable during all stages of receipt, production, storage, and transportation
- Finished product labels comply with customer specifications and all applicable laws and regulations
- If applicable, product labels contain the appropriate Kosher or Halal symbol of their Kosher or Halal religious authority.
- Product identification records are maintained

### 6.5.2 Lot Coding and Lot Size

A lot is defined as a unit of raw material, packaging, or finished product that is clearly delineable in the context of an intervention or other controls that would allow any subsequent action on the product (*e.g.*, a recall) to be unquestionably limited to that unit. Lot definitions facilitate internal controls, provide clear boundaries around incoming raw materials and packaging, and potentially minimize the impact of a recall should a problem arise. Suppliers assign a lot through coding, which is an identification number assigned to products indicating the batch or lot in which the product was manufactured or processed.

#### 6.5.2.1 Coding

Suppliers shall have the ability to apply a multi-digit alphanumeric date code as well as Best By designator to all retail units that can be sold as individual units. Product traceability and distribution requirements necessitate accurate, legible date coding be applied to each unit. Multiple-line, alphabetical and numerical characters are typically utilized. Best by or Expiry statements may also be required. International coding requirements vary by country of origin and destination. Suppliers using their own date code format shall provide a code interpretation document to The Hershey Company upon request.

Co-Manufacturers and Co-Packers manufacturing finished product shall use lot codes and code dates in the required The Hershey Company format on individual retail units and shipping cases. The Hershey Company shall provide this information as part of The Hershey Company specification. Exceptions shall be pre-approved and documented.

Suppliers shall assure all raw materials, ingredients, packaging materials, WIP, and finished products have traceable lot codes that follow the item from receipt through storage and use. Blending and mixing records shall show times, quantities, and lot identification of raw materials and ingredients used.

#### 6.5.2.2 Lot Size

No lot size should exceed 24 hours of production. Larger lot sizes must be supported by scientific/operational data and preapproved by The Hershey Company.

Suppliers shall provide an interpretation of the lot size (*e.g.*, cleanup to cleanup, 2 hours of production, shift) to The Hershey Company.

### 6.5.3 Traceability and Mock Recalls

Suppliers shall develop and maintain a documented traceability program, which is capable of effectively tracing specific lots of raw materials, ingredients (including bulk ingredients), packaging, and finished products through shipping and



distribution channels. At a minimum, the program shall:

- Assure finished product is traceable from the Supplier (one back) and to the customer (one up)
- Specify processes to trace raw materials, ingredients, packaging, WIP, carryover product, rework, and finished products
- Detail methods to trace finished products back to the received raw material, ingredient, and packaging lots
- Include records of product transportation and destination
- Include methods (mock recall) to validate the traceability programs at least annually. Target turnaround time to complete full traceability is 4 hours, with a maximum of 8 hours and 100% ( $\pm 1\%$ ) effectiveness.

#### **6.5.3.1 Emergency Contact Information**

Suppliers (corporate and site levels) shall provide emergency contact information allowing The Hershey Company to reach emergency contacts 24 hours a day, 7 days a week, and 365 days a year.

## **7 COMPLIANCES**

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### **7.1 Laboratory Compliance Criteria**

- All internal & external laboratories used for analyses critical to safety (pathogen), or legality of products need to be accredited to ISO 17025 or an equivalent national standard.
- All internal & external non-accredited laboratories will require successful completion of Hershey assessment.

### **7.2 Regulatory Compliance**

Suppliers shall maintain appropriate documentation to verify the regulatory status of all materials provided to The Hershey Company. Appropriate documentation may include, but is not limited to, GRAS conditions for use statement, a third-party opinion, or a Code of Federal Regulations (CFR) reference. In all cases, Suppliers shall maintain this documentation and keep it up to date during the entire time the material is provided to The Hershey Company.

Suppliers shall provide regulatory documentation certifying the legal status of materials immediately upon request by The Hershey Company and make this documentation available to The Hershey Company, third party, and regulatory auditors as needed.

Suppliers shall comply with all applicable federal, state, and local voluntary and required laws, regulatory programs, and rules.

### **7.3 Quality or Economic Adulterants and Other Chemical Hazards**

Suppliers shall provide materials that are not adulterated in any way, either accidentally or intentionally, and are of high quality and implicit safety. Suppliers shall develop and maintain programs to assure the quality of materials. The program shall assure materials comply with the following:

- Global regulations and/or Codex Standards for heavy metals levels in the material
- Global regulations and/or maximum residue limits (MRLs) for pesticide residues in the material
- Tolerance limits levels for veterinary residues, hormones, and growth stimulants, where applicable.
- Mycotoxin limits, where applicable.

Suppliers shall develop and maintain an ongoing chemical management policy to assure potential chemical adulterants and reasonably anticipated chemical contaminants are monitored and are within regulatory requirements and The Hershey Company specifications. The Hershey Company reserves the right to test any materials for chemical contaminants including economic adulterants periodically.

## 7.4 Proposition 65

Suppliers providing material containing a chemical or chemicals listed by the State of California pursuant to the Health and Safety Code Section 25249.5 et. sec. (commonly called "Proposition 65") shall notify The Hershey Company in writing of the material name, listed chemical(s) involved, expected concentrations, and the warning statement the Supplier provides with the material. If the material is not expected to contain such chemicals at a concentration requiring a warning, Suppliers should provide a statement to that effect.

## 7.5 Certifications/Specialty Programs

Suppliers must comply with the requirements of the certifying body specified on the ingredient or raw material or the final Hershey Company product. Certifying organizations include, but are not limited to Kosher, Halal, Organic and Certificate of Origin. Where required by Hershey, Suppliers shall ensure conformity with legislation, religious rules or distinctions regarding certified products.

Specialty programs or label declarations require additional procedures to meet requirements for the programs such as non-GMO, Sugar Free, Gluten Free and Peanut Free.

# 8 CUSTOMER AND CONSUMER FOCUS

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## 8.1 Customer and Consumer Feedback Trend Analysis

Suppliers shall develop and maintain a documented procedure for tracking, reviewing, trending and resolving consumer and/or customer complaints.

## 8.2 Certificates of Analysis (COA)

Ingredient and raw material Suppliers shall provide lot specific COAs to The Hershey Company plants and Co-Mfg. plants before or with delivery of the raw material or ingredient verifying the lot complies with the specification. Parameters required on the COA are specified in the Ingredient Specification under Certificate of Analysis requirements.

A COA for finished product must provide pathogen results at a minimum. Additional analytical and microbiological test results required on the COA shall be outlined by The Hershey Company.

In addition to the required test results, the COA shall include, but is not limited to, the following:

- 8.2.1 Manufacturer name
- 8.2.2 Broker or distributor name, if applicable
- 8.2.3 Manufacturing plant address
- 8.2.4 Name of material
- 8.2.5 The Hershey Company material or item number
- 8.2.6 Purchase order number
- 8.2.7 Lot number(s)
- 8.2.8 Date of COA
- 8.2.9 Date of manufacture
- 8.2.10 Tests performed
- 8.2.11 Test methods
- 8.2.12 Unit of measure/reporting unit (*i.e.*, amount tested)
- 8.2.13 Test results
- 8.2.14 Name and/or signature of person certifying the lot

In addition to the above information, COAs from third party laboratories, brokers, and distributors shall include the name and address of the laboratory, broker, or distributor as well as the original Supplier's name and manufacturing

facility address.

If the Product Quality Specification only contains guidelines, Suppliers shall provide a document with the above information along with the results of all tests performed as part of the Supplier's regular analysis of the lot.

## 9.0 CONTINUOUS IMPROVEMENT

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Suppliers shall establish and document processes to improve the effectiveness of its food safety and quality management systems continually. Proper measurement shall be established to demonstrate the results. Supplier shall be proactively engaged in sharing best practices on improvement of the food safety and quality management systems.

## APPENDIX A: DEFINITIONS AND ABBREVIATIONS

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AOAC	Association of Official Analytical Chemists
BAM	FDA's Bacteriological Analytical Manual
Bioterrorism Act of 2002	Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Calibration	Confirmation of standardization of a measurement device or system against a known reference
CAPA	Corrective Action Preventive Action -
CBP	Customs and Border Protection
CCP	Critical Control Point
CFR	Code of Federal Regulations
COA	Certificate of Analysis
Codex	Codex Alimentarius Commission
Co-Manufacturer	Production of goods by one firm, under the label or brand of another firm under a purchase order, supply agreement, or contract
EMP	Environmental Monitoring Program
EMMP	Environmental Microbiological Monitoring Program
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
Finished Product	Item purchased by Hershey from a Supplier
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Modernization Act
GFSI	Global Food Safety Initiative
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practice
HACCP	Hazard analysis critical control points
High Risk Processes	A product in which there is the potential for metal contamination and where metal detection of the finished product is not possible
Hygienic Restoration	Corrective actions to maintain the hygienic condition of the processing environment and to assure the production of safe, wholesome foods, after an event that could compromise food safety ( <i>e.g.</i> , roof or overhead leaks)
Ingredient	A raw material, incidental additive, or processing aid used to manufacture a finished product
ISO	International Organization for Standardization
Legality	national, federal, state, and local regulations in the country of manufacture and intended markets
Licensee	A company that enters into a business agreement whereby it is granted a license.
Licensing	A business arrangement in which one company gives another company permission (a license) to manufacture its product and use its trademark for a specified payment (royalty).
LTL	Less than truckload
Materials	Any raw material, ingredient, packaging material, incidental additive, or processing aid that is used as part of the manufacturing process

MRL	Maximum Residue Limit
MSS	Master Sanitation Schedule
NIST Handbook 133	National Institute of Standards and Technology Handbook 133: Checking the Net Contents of Packaged Goods
NRTE	Not Ready to Eat; also, Ready to Cook (RTC)
Packaging	Packaging or containment devices that contain the finished product and/or the finished product shipping case or tray.
PCO	Pest Control Operator
Potable Water	Fit or suitable for drinking; water supplies that have been tested and determined to meet or exceed the appropriate health authority standards for drinking water
Proposition 65	Health and Safety Code Section 25249.5 et. sec.
Raw Material	An ingredient, incidental additive, or processing aid used to manufacture a finished product
Rework	Any combination of components or work-in-process that is held for later use from when it was originally combined, processed or manufactured
RTE	Ready to Eat
SQF	Safe Quality Food, a GFSI standard
SSOP	Sanitation Standard Operating Procedures
Supplier	Any company that delivers materials or services to a Hershey site also referred to as a raw material or ingredient provider, co-packer, re-packer, licensee, co-manufacturers, and other quality partners
USDA	United States Department of Agriculture
WIP	Work in Process; Work in Progress

## 10 CHANGE LOG

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<u>DATE</u>	<u>MODIFICATION</u>	<u>NAME</u>
June 28, 2019	Revised document; removed CTPAT, revised EMMP, thermal processing sections.	A. Patil, T. Askey, A. Moses
November 11, 2017	Original document	R. Toews, T. Askey

