FSVP foreign supplier approval process

Documented herein is the approval process that TrueTech Inc will adhere to for the following scenarios

- Approval of new suppliers
- Re-evaluation and continued approval of new suppliers
- Discontinued use of foreign suppliers

Approval of new suppliers

Prior screening

During this phase we will check if the portended supplier is listed on the import alerts list. If the supplier is listed on the import alerts list, verify that supplier has since updated internal processes to rectify issues they have been associated with in the import alert.

We will also review the food safety history of suppliers including warning letters from the FDA.

Visit of foreign facility

The process of physically visiting and inspecting the foreign facility where cacao beans are sourced and processed. This visit aims to assess the facility's overall operations, hygiene practices, equipment, and employee practices to ensure compliance with quality and safety standards. During the visit, a comprehensive review of the facility's layout, processing areas, storage conditions, and sanitation procedures will be conducted. Documentation related to food safety practices, facility layout, and employee training will be examined to evaluate the facility's capability to produce safe cacao products.

Definition of Critical Control Points in facility

Identification and delineation of critical control points (CCPs) within the foreign facility's processing operations. CCPs are specific stages in the production process where control measures can be applied to prevent or eliminate hazards. For cacao processing, CCPs might include harvesting, fermentation, drying, roasting, and packaging stages. Defining CCPs allows for targeted implementation of preventive controls and verification procedures to ensure food safety.

Hazard Analysis at Critical Control Points

A systematic assessment of potential hazards that could occur at identified critical control points. Hazard analysis involves identifying biological, chemical, and physical hazards that may be associated with the cacao processing operations. For example, microbial contamination, allergen cross-contact, and foreign object inclusion are hazards to be evaluated. Reference will also be made to the FDA bad bugs books to identify all possible sources of foodborne illnesses. This analysis informs the development of preventive controls to mitigate the identified hazards.

Establish Preventive Controls at Critical Control Points

The implementation of specific measures at critical control points to prevent, minimize, or eliminate identified hazards. Preventive controls include practices, procedures, and protocols that ensure the safety of the cacao products. These controls are tailored to each critical control point and can involve hygiene practices, temperature controls, sanitation procedures, and allergen management to prevent potential hazards.

Establish Verification of Preventive Control Integrity

The establishment of procedures to regularly verify the effectiveness and integrity of implemented preventive controls. Verification involves ongoing monitoring, testing, and auditing of critical control points to ensure that the intended preventive controls are consistently operating as intended. Verification activities may include microbial testing, allergen swabbing, equipment inspections, and process audits to confirm the adequacy of the preventive controls.

Supplier evaluation and approval

The process of evaluating and assessing the foreign supplier's capability to consistently provide safe and compliant cacao products. Supplier evaluation involves reviewing the supplier's quality assurance practices, food safety certifications, and documentation related to sourcing, processing, and shipping practices. Supplier evaluation helps ensure that the foreign supplier aligns with the required quality and safety standards and can be relied upon for the procurement of safe cacao products. Supplier is approved upon successful evaluation.

Official records

We will utilize the following templates to establish records that we have conducted the above steps as well as our agreement on the processes we will adhere to after the supplier approval event.

- Written letter of assurance for FSVP small importer compliance

- Ongoing Verification process
- Evaluation Declaration

Re-evaluation and continued approval of new suppliers

Events for triggers of evaluation

- 2 year expiry of prior evaluation
- Change in supplier internal process
- FDA recall notice
- FDA Import alert

2 year expiry of prior prior evaluation

When a supplier's prior evaluation has expired, the reapproval process will be initiated. This involves a reassessment of:

- the supplier's processes including critical control points
- Revisit list of associated hazards
- Revisit effectiveness of preventive controls
- Revisit and update verification procedures
- Review regulation compliance local government and US FDA regulations
- Reapproved.

A physical or virtual site visit may be conducted to verify the supplier's operations. Based on the findings, a new evaluation report will be generated, and if the supplier continues to meet the required standards, they will be reapproved for another period of 2 years.

Failure during period verification activity done every 6 months

If a supplier fails the periodic verification conducted every 6 months, immediate action will be taken to address the identified issue. The supplier will be notified of the failure and provided with specific details about the non-compliance. The supplier will be required to

1. implement corrective actions to rectify the issue within a specified timeframe.
2. Once the corrective actions are completed, a reevaluation will be conducted, including a review of the corrective action documentation and potentially another site visit.
3. If the supplier must demonstrate compliance and successful resolution of the issue

4. Revisit effectiveness of preventive controls
5. Revisit and update verification procedures
6. Reapproved.

Change in supplier internal process

If a supplier informs us of a change in their internal processes that could impact the safety and quality of the cacao products supplied, a thorough assessment will be conducted. The supplier will be required to provide detailed information about the change, including the reasons for the change, the nature of the change, and the potential impact on food safety. Our evaluation team will review the information provided and may request additional documentation, such as updated SOPs and testing results. If the change aligns with our safety and quality requirements, the supplier may undergo the re-approval process which involves the following steps.

- the supplier's processes including critical control points
- Revisit list of associated hazards
- Revisit effectiveness of preventive controls
- Revisit and update verification procedures
- Review regulation compliance local government and US FDA regulations
- Reapproved.

FDA recall notice

Upon receiving an FDA recall notice related to a supplier's product, an immediate review will be initiated. The recall notice will be analyzed to understand the nature and severity of the issue. The supplier's involvement and corrective actions taken in response to the recall will be assessed. The supplier will be required to provide detailed information about the recall, including root cause analysis and corrective and preventive actions taken. If the supplier demonstrates a robust response and corrective actions that align with our safety standards, a reevaluation may be conducted to determine their reapproval. This is the process

- the supplier's processes including critical control points
- Revisit list of associated hazards
- Revisit effectiveness of preventive controls
- Revisit and update verification procedures
- Review regulation compliance local government and US FDA regulations
- Reapproved.

FDA import alert

In the event of an FDA import alert being issued for a supplier's products, a thorough assessment of the situation will be undertaken. The reason for the import alert and the specific concerns raised by the FDA will be examined. The supplier will be requested to provide information about their actions to address the FDA's concerns. This may include comprehensive testing, documentation of corrective actions, and changes made to their processes. A reevaluation of the supplier's practices and documentation will be conducted, and if the supplier satisfactorily addresses the FDA's concerns, reapproval may be considered. This is the process

- the supplier's processes including critical control points
- Revisit list of associated hazards
- Revisit effectiveness of preventive controls
- Revisit and update verification procedures
- Review regulation compliance local government and US FDA regulations
- Reapproved.

Discontinued use of foreign supplier

This process is triggered when an exception is triggered for foreign supplier in the below scenarios

- 2 year expiry of prior evaluation
- Change in supplier internal process
- FDA recall notice
- FDA Import alert

Failure scenarios

- Failure to respond within 48 hours when we reach out to them
- Could not resolve the exception after 3 counts
- Could not pass any of the reevaluation of the stages indicated in the re-evaluation process

As president of TrueTech inc I declare the above documented foreign supplier FSVP approval process is hereby in force

Zhiwen Teh
President
TrueTech Inc
(EIN: 88-3411514)

27th August 2023