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**PRODUCE HANDLING ASSURANCE**

**Control Points and Compliance Criteria**

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# 

# INTRODUCTION

1. The Produce Handling Assurance (PHA) Standard sets minimum requirements for the management of food safety of parties seeking certification. The standard sets current good manufacturing practices, hazard analysis and preventive controls, traceability and segregation, and assesses overall food safety management system practices. This includes supplier management, management of food safety related incidents, and additional requirements for the site, personnel, and production practices.
2. GLOBALG.A.P. provides the standard and framework for independent, recognized 3rd party certification of pre-process handling operations based on ISO/IEC Guide 65. Certification of the pre-process handling – packing house, pre-processing, cooling/cold storage, and storage/distribution – of products ensures that only those that reach a certain level of compliance with current Good Manufacturing Practices (cGMP’s) set out in the GLOBALG.A.P. normative documents are certified.

c) FSMA Claims

* + 1. The Produce Handling Assurance (PHA) Standard is designed to include requirements of the USA Food and Drug Administration’s Food Safety Modernization Act (FMSA) Produce Safety Rule (PSR, 21 C.F.R. Part 112) and Preventative Controls for Human Food Rule (PCHF, 21 C.F.R 110) as applicable in the covered handling facilities. The requirements of these two rules are adapted in the control points and compliance criteria, so that the user can make the necessary adjustments to implement the requirements of FSMA. However, every operation should review FSMA for compliance details that may not be covered in this module.
    2. The PHA certificate can be provided to retailers and value-chain participants as evidence of a producer’s efforts toward FSMA implementation. The PHA is not an assurance or guarantee of FSMA compliance, as legal compliance can only be determined by a regulatory authority, such as the United States Food and Drug Administration

1. Legislation relevant to Control Points and Compliance Criteria (CPCC), more demanding than GLOBALG.A.P., overrides the GLOBALG.A.P. requirement. Where there is no legislation (or legislation is not so strict), GLOBALG.A.P. provides a minimum acceptable level of compliance. Legal compliance of all applicable legislation per se is not a condition for certification. The audit carried out by the GLOBALG.A.P. Certification Body is not replacing the responsibilities of public compliance agencies to enforce legislation. Existence of legislation relevant to a specific CPCC does not change the level of that Control Point to Major Must. The CPCC levels have to be kept as defined in the CPCC documents and checklists approved and published in the GLOBALG.A.P. website.
2. Definitions of terminology used in the GLOBALG.A.P. General Regulations and Control Points and Compliance Criteria are available in the General Regulations – Part I, Annex I.4 - [GLOBALG.A.P. Definitions](http://www.globalgap.org/export/sites/default/.content/.galleries/documents/170630_GG_GR_Part-I_Annex_I-4_V5_1_en.pdf).
3. Annexes referenced in the CPCC are mandatory.
4. Only products included in the GLOBALG.A.P. product list, published on the GLOBALG.A.P. website, can be registered for certification. The GLOBALG.A.P. product list is not limited and can be extended based on demand. Requests to add new products to the product list shall be send to the e-mail address: standard\_support@globalgap.org with the following information:
5. Product
6. Scientific name
7. Any additional information e.g. cultivation, use, alternative names, pictures, etc. This can be supplied via a website link as well.
8. The term “shall” is used throughout the GLOBALG.A.P. PHA Standard documents to indicate those provisions which, reflecting the requirements of GLOBALG.A.P., are mandatory.
9. FoodPLUS GmbH and GLOBALG.A.P. approved Certification Bodies are not legally liable for the safety of the product certified under this standard and not liable for the data accuracy and completeness in the GLOBALG.A.P. Database entered by the GLOBALG.A.P. Certification Body. Under no circumstances shall FoodPLUS GmbH, its employees or agents be liable for any losses, damage, charges, costs or expenses of whatever nature (including consequential loss) which any producer may suffer or incur by reason of, or arising directly or indirectly from the administration by FoodPLUS GmbH, its employees or agents or the performance of their respective obligations in connection with the scheme save to the extent that such loss, damage, charges, costs and/or expenses arise as a result of the finally and judicially determined gross negligence or willful default of such person.

Comment:

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| Nº | Control Point | Compliance Criteria | Level | Comment |
| --- | --- | --- | --- | --- |
| 1 | GENERAL | |  |  |
| 1.1 | FOOD SAFETY MANAGEMENT SYSTEM | |  |  |
|  | Policy, Responsibilities, Written Plan, Review, Self-audit  The Food Safety Management System reflects in an unambiguous manner the commitment of the Operation to ensure that food safety is implemented and maintained throughout the product handling processes. | |  |  |
| 1.1.1 | Is a food safety policy in place? | A written policy shall outline a commitment to food safety, in general terms, how it is implemented and how it is communicated to employees, and shall be signed by management. The policy shall confirm management commitment to improve the food safety system. The policy shall be available to employees and displayed in employee areas in the dominant language of the workforce.  No N/A. | Major |  |
| 1.1.3 | Is there a written Food Safety Plan that covers all activities? | The Food Safety Plan shall identify all products, locations and activities of operation and shall cover management procedures for physical, chemical, and biological risks identified in the hazard analysis, including all methods used to comply with regulatory requirements (minimum and maximum thresholds, sampling procedures, etc.). The Food Safety Plan shall include the appropriate procedures, good manufacturing practices, prerequisite programs, corrective actions and resolutions, which minimize or prevent the hazards identified in the hazard analysis. | Major |  |
| 1.1.4 | Is the Food Safety Plan reviewed at least annually? | The operation shall be responsible for reviewing their Food Safety Plan at least annually, documenting the review procedure, and revising the plan as necessary, e.g. when significant changes in products, equipment, or the facility occur, after system failure, etc. Updated or revision dates shall be indicated. | Major |  |
| 1.1.2 | Has management designated individual(s) with roles, responsibilities and resources for food safety functions? | The Food Safety Plan shall designate competent supervisory individual(s) who has the responsibility and authority for food safety, to ensure compliance of the Food Safety Plan by all workers, visitors, contractors, and facility personnel with the hygiene requirements. This includes a provision for the absence of key personnel. Twenty-four hour contact information shall be available for these individuals in case of food safety emergencies. These roles and responsibilities shall be documented and communicated within the organization. The management shall determine and provide the resources needed to implement and maintain the food safety plan in a timely manner. Minimum competency criteria are set in the requirements of section 2.1.3 for individual(s) with supervisory responsibility for implementation of the Food Safety Plan and responsible for carrying out the hazard analysis. Consideration shall be given to the satisfactory ability to carry out this audit as an internal inspection. | Major |  |
| 1.1.5 | Has the operation implemented written procedures to conduct an annual internal audit of all locations included in the Food Safety Plan? | Internal audits of the facility shall be conducted at a minimum annually by an assigned individual who is knowledgeable in this standard, utilizing this standard to assist in the self-audit. All locations of the operation’s Food Safety Plan will be audited and a written record of required corrective actions shall be documented. Management shall review internal audits of the Food Safety Plan and HACCP-based plan to ensure suitability, adequacy, and effectiveness. Records are kept. | Major |  |
| 1.2 | FOOD DEFENSE | |  |  |
|  | Food Defense is the effort to prevent, prepare for, respond to, and recover from acts of intentional adulteration of the food supply. | |  |  |
| 1.2.1 | Has the operation developed a risk assessment for food defense? | Potential intentional threats to food safety in all phases of the operation shall be identified and assessed (e.g. inputs, employees, subcontractors, visitors, etc.). Food defense risk identification shall assure that all input comes from safe and secured sources. Information of all employees and subcontractors shall be available. | Major |  |
| 1.2.2 | Does the food defense plan specify the measures implemented to mitigate risks? | The operation shall have a documented management plan that specifies the measures implemented to mitigate the risks from identified food defense threats. | Major |  |
| 1.3 | FOOD FRAUD | |  |  |
|  | Food fraud may occur when suppliers provide input products/materials that do not match the specifications (e.g. counterfeit cleaning or sanitizing chemicals, non-food grade packaging material, false claims on raw product, etc.). This may cause a public health crisis; therefore, operations should take measures to mitigate these risks. | |  |  |
| 1.3.1 | Does the operation have a food fraud vulnerability risk assessment? | A documented risk assessment to identify potential vulnerability to food fraud (e.g. counterfeit products, post-harvest treatments, non-food grade packaging material) is current and available. This assessment may be based on a generic one, but shall be customized to the scope of the production. Where facilities are required to follow the FSMA Preventive Controls for Human Foods Rule, economically motivated fraud shall be considered. | Minor |  |
| 1.3.2 | Does the operation have an implemented food fraud mitigation plan? | A documented food fraud mitigation plan specifying the measures the operation has been implemented to address the identified food fraud threats shall be available. | Minor |  |
| 1.4 | DOCUMENT CONTROL/RECORDS | |  |  |
|  | Important details of good manufacturing practices shall be recorded and records kept. | |  |  |
| 1.4.1 | Is documentation kept that demonstrates the Food Safety Plan is being followed? | Documents of procedures, standard operating procedures (SOPs), policies and records shall be in place for meeting each of the food safety standards identified in the Food Safety Plan. | Major |  |
| 1.4.2 | Are records in place for meeting each of the food safety standards identified in the Food Safety Plan? | Records comply with prevailing regulations, but shall at minimum include identification of the operation, the date, and if appropriate, the time of the activity documented, the signature or initials of the person performing the activity, and where appropriate, the identity of  the product and the lot code, if any. | Major |  |
| 1.4.3 | Is documentation readily available for inspection? | Documents and records may be maintained on-site, at an off-site location, or accessible electronically (e.g. Safety Data Sheets). They shall be accurate, indelible, and legible, and shall be available for inspection within 24 hours or as required by prevailing regulation. If electronic records are used, operations are responsible for maintaining back-up copies of the information. | Major |  |
| 1.4.4 | Is documentation retained for a minimum period of two years, or as required by prevailing regulation? | Document and record handling policy or procedures require that documentation required by the Food Safety Plan shall be stored securely and retained for a minimum of two years, or as required by prevailing regulation if longer. There is evidence that this document and record handling policy is followed. | Major |  |
| 2 | HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) | |  |  |
|  | Product & Use, Flow Diagram, Risk Assessment/Hazard Analysis, Critical Control Points, Team and Training, Monitoring, Corrective Actions, Records, Verification, Validation, Compliance, Review | |  |  |
| 2.1 | *HAZARD ANALYSIS AND CRITICAL CONTROL POINTS* | |  |  |
| 2.1.1 | Is a product description available for each product or product category? | Product description defines the product or product category, intended use, end-user, shelf life, storing conditions, packaging, and distribution system. | Major |  |
| 2.1.2 | Does the operation have a written, up-to-date flow diagram for each product or product group? | The flow diagram shows each step, inputs, and outputs of/to the process, under the control of the operation. The flow diagram shall be dated and signed, and each Critical Control Point (CCP) clearly identified, if any. | Minor |  |
| 2.1.3 | Is the employee(s) designate who has the responsibility and authority for food safety, competent to conduct the hazard analysis and to ensure compliance of the Food Safety Plan? | The individual responsible for the hazard analysis and the Food Safety Plan is qualified based on education, training, and/or experience appropriate to the responsibilities. Employee must have received training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the products, facility, and employee duties. At minimum, the employee shall have completed a Hazard Analysis and Critical Control Points training whenever critical control points are included in the Food Safety Plan. For qualified produce facilities under FSMA, the employee must have additional training such as the Preventive Controls Qualified Individual Training covering Preventive Controls curriculum where facilities are responsible for implementation of the Preventive Controls Rule or Produce Safety Rule training where facilities are responsible for implementation of the Produce Safety Rule.  If applicable, the operation shall be aware of which FSMA rule the audited facility shall be held to for regulatory standards. | Major |  |
| 2.1.4 | Has a hazard analysis been performed for the product handling activities? | The operation shall have a documented hazard analysis or risk assessment covering physical, chemical (including toxins and radiological) and microbiological contaminants, spillage of bodily fluids (e.g. vomiting, bleeding), and human transmissible diseases, customized to the products and handling activities, as covered by the flow diagram, as well as personnel, personal effects, equipment, clothing, packaging material and product storage (also short-term storage). The hazard analysis shall be tailored to the activities of the operation, the location and adjacent land, the products, the technical level of the business, includes the likelihood and severity of the risk, and prepared in accordance with Codex Alimentarius Hazard Analysis and Critical Control Point (HACCP) Principles and prevailing regulation. The hazard analysis shall be reviewed at least annually and any time changes to the operation occur.  No N/A. | Major |  |
| 2.1.5 | Where Critical Control Points (CCPs) are included in the HACCP Plan, are critical limits defined for each CCP? | Where hazards can be prevented, eliminated, or reduced to an acceptable level, critical control points are documented. For identified CCPs, thresholds must be defined based on legislation, international reference standards, or scientific evidence. Where no critical limits or thresholds are found, the remaining HACCP questions can be skipped.  N/A if No CCPs are identified. | Minor |  |
| 2.1.6 | Where CCPs are included in the HACCP Plan, is training provided to the staff responsible for implementation of CCPs? | Responsibilities of staff are assigned and documented for the monitoring, recording, and corrective actions of each CCP. Training adequate to staff’s functions is provided and records are kept.  N/A if No CCPs are identified. | Minor |  |
| 2.1.7 | Where CCPs are included in the HACCP Plan, have monitoring procedures been established for CCPs? | Specific monitoring procedures shall be established. Monitoring records have been designed to record the CCPs that have been identified. The records shall specify the frequency of monitoring, the person responsible, as well as the date and result of the monitoring activities.  N/A if No CCPs are identified. | Minor |  |
| 2.1.8 | Where CCPs are included in the HACCP Plan, does the operation have a written action plan available when limits do not meet thresholds? | Operation has an action plan when critical limits of CCPs do not meet thresholds defined in the HACCP Plan. Action plan must include determination and correction of the cause of the non-compliance, segregation or isolation of non-compliant product, determination of the disposition of non-compliant product (e.g. rejected or released), who is responsible for implementing the corrective actions, and records kept.  N/A if No CCPs are identified. | Minor |  |
| 2.1.9 | Where CCPs are included in the HACCP Plan, have verification activities been developed for each CCP? | Verification activities related to each CCP are documented. A HACCP trained supervisor or manager shall verify that all CCP monitoring records have been completed in a proper and timely manner, including any corrective action work. Workers may not verify their own work.  N/A if No CCPs are identified. | Minor |  |
| 2.1.10 | Where CCPs are included in the HACCP Plan, are identified critical control limits supported by validation studies? | The operation has documented evidence that the critical control limits are scientifically derived and meet any relevant legal requirements. Internal validation studies may serve this purpose.  N/A if No CCPs are identified. | Minor |  |
| 2.1.11 | Are CCP monitoring activities and frequencies in compliance with the HACCP Plan, where they are included? | On-site verification of CCP monitoring activities and frequencies are in compliance with the HACCP Plan.  N/A if No CCPs are identified. | Minor |  |
| 2.2 | ALLERGEN MANAGEMENT | |  |  |
|  | *When allergens are identified as a hazard through the hazard analysis, the allergen control program aims to avoid inadvertent allergen cross-contamination. The top eight food allergens are soy, wheat, eggs, milk, peanuts, tree nuts, fish and shellfish.* | |  |  |
| 2.2.1 | Where the operation handles or stores allergens, does the operation have a written Allergen Control Program? | The Allergen Control Program lists the allergens in use or storage at the facility specific to country regulations. If applicable, procedures address identification and segregation of allergens during storage, handling, loading, and shipping as based on a risk assessment conducted by the facility. All products intentionally or potentially containing allergenic materials are labeled according to the allergen labeling regulations in the country of production and the country of destination. | Major |  |
| 2.2.2 | Where Allergen Control Program is in place, are workers trained in proper handling of allergens? | Where allergen handling or storage occurs, workers shall be trained in proper handling of allergens per Allergen Control Program. Documentation of training is available. Training materials and the delivery of training shall be provided in language understood by staff. Records are kept. | Major |  |
| 3 | PRODUCT SPECIFICATION AND LABELING | |  |  |
|  | Integrity, Labeling | |  |  |
| 3.1 | Are specifications for all raw material, packaging and packed product available and in place? | Specifications shall be up to date, unambiguous and in compliance with legal requirements and, if existing, with customer requirements. Grading or other written local or federal requirements or guidelines are acceptable. | Major |  |
| 3.2 | Does labeling of packed product comply with customer requirements and current legislation of country of production and country of destination? | A written policy shall be in place to ensure that labeling complies with current legislation of country of production, destination country, and customer requirements. Evidence of grower/shipper agreement of responsibility is acceptable. | Major |  |
| 3.3 | Is the GLOBALG.A.P. word, trademark, GLOBALG.A.P. QR code or logo and the PHA-GGN (GLOBALG.A.P. Number) used according to the GLOBALG.A.P. General Regulations and according to the Sublicense and Certification Agreement? | The producer/producer group shall use the GLOBALG.A.P. word, trademark, GLOBALG.A.P. QR code or logo and the PHA-GGN (GLOBALG.A.P. Number), GLN or sub-GLN according to the General Regulations Annex 1 and according to the Sublicense and Certification Agreement. The GLOBALG.A.P. word, trademark or logo shall never appear on the final product, on the consumer packaging, or at the point of sale. However, the certificate holder can use any and/or all in business-to-business communications.  GLOBALG.A.P. word, trademark or logo cannot be in use during the initial (first ever) inspection because the producer is not certified yet and the producer cannot reference to the GLOBALG.A.P. certified status before the first positive certification decision. | Major |  |
| 4 | SUPPLIER APPROVAL | |  |  |
|  | *Incoming Goods, Packaging* | |  |  |
| 4.1 | Does the Operation have an Approved Supplier program for all incoming materials, including packaging, all items and services (utilities, transport, maintenance, etc.)? | Operation shall have and maintain a current list of approved raw material suppliers and service providers. Approved Supplier program includes a procedure for accepting materials from brokers and alternate sources. Primary (food contact) packaging suppliers adhere to specifications, legal requirements, and include lot coding on all items. Procedures for Approved Suppliers shall be reviewed minimum annually. | Minor |  |
| 4.2 | Does the Operation have a policy and take steps to ensure that all fresh produce that are packed or stored in the operation are grown following good agricultural practices (GAP)? | The operation shall establish, implement and maintain procedures for the evaluation, approval and continued monitoring of its suppliers which have an effect on food safety. The results of evaluations, investigations and follow up actions shall be recorded. Use of non-approved suppliers shall be acceptable in an emergency situation provided the supplier has been assessed and the product meets the specifications. | Minor |  |
| 5 | MASS BALANCE | |  |  |
|  | *The company shall be able to justify consistent mass-balance.* | |  |  |
| 5.1 | Are all incoming product quantities accurately recorded and regularly summarized to facilitate a mass balance audit? | All input quantities of products from approved and non-approved suppliers shall be recorded and an up-to-date summary shall be calculated.  No N/A. | Major |  |
| 5.2 | Are conversion ratios used for mass-balance calculated, validated, and recorded? | Conversion ratios shall be calculated and available for each relevant handling process. The generated product loss and/or waste quantities shall be validated.  No N/A. | Major |  |
| **6** | **CHAIN OF CUSTODY** | |  |  |
|  | *Applicable when the final product(s) is/are sourced from GLOBALG.A.P. IFA certified producers and labeled with a GGN.* | |  |  |
| 6.1 | Are quantities of the GLOBALG.A.P. IFA certified products recorded and summarized to allow a mass balance calculation that shows consistency between input and output of certified product? | The quantities of GLOBALG.A.P. IFA certified products shall be recorded and summarized to facilitate a comparison with inputs of certified product in the same period. The mass balance calculation shows consistency between purchases and sales of certified product. Quantities (including information on volumes or weight) of certified, non-certified, incoming, outgoing and stored product shall be recorded and a summary maintained so as to facilitate the mass balance verification process. Influencing factors such as waste, shrinkage, rejected/returned items, etc. shall be taken into consideration. The frequency of the mass balance verification shall be defined and be appropriate to the scale of the operation, but it shall be done at least annually per product. Documents and/or records to demonstrate mass balance shall be clearly identified.  Sold certified output ≤ certified input – conversion loss – stored amount. | Major |  |
| 6.2 | Are the producers or the suppliers of the certified sources clearly identified and traceable during any stage of the operation? | The operation shall be able to identify the producer (origin) or the CoC certified supplier of all GLOBALG.A.P. IFA certified product during any stage of the operation (e.g.: receipt, handling, packing, storage, or dispatch). | Major |  |
| 6.3 | Are production runs and storage of certified and/or non-certified products segregated? | Production runs and storage of GLOBALG.A.P. IFA certified and/or non- certified products are segregated. | Major |  |
| 6.4 | Does transaction documentation related to GLOBALG.A.P. IFA certified product include the PHA-N of the certificate holder (and additionally the GGN, where it is also a producer) and indicate which product is GLOBALG.A.P. certified? | Transaction documentation (sales invoices, other sales related, dispatch documentation, etc.) related to sales of the GLOBALG.A.P. IFA certified product shall include the ‘PHA-N” prefix followed by the PHA-N of the operation and shall contain a reference to the GLOBALG.A.P. certified status per product.  Where the PHA certificate holder is also a GLOBALG.A.P. IFA certificate holder, the GGN prefix may additional be included (e.g. PHA-N/GGN: xxxxxxxxxxxxx).  Positive identification is enough on transaction documentation. Transaction documents related to non-certified product cannot include the PHA-N or GGN, or indicate the product is certified. | Major |  |
| 6.5 | Is there a system in place to check the validity of the source producer/s certificate when the producer’s GGN is included on the product labeling/packaging? | The GLOBALG.A.P. IFA certification status of the producer can be checked through the GGNs in the GLOBALG.A.P. Database ([www.globalgap.org/search](http://www.globalgap.org/search)). The producer/s GLOBALG.A.P. IFA certificate shall still be valid when the product is labeled with the GGN and when the product is sold as certified. The GGNs might also be linked to lot or batch number.  N/A when the company does not label the product with producers’ (origin) GGN. | Major |  |
| 6.6 | Are all finished goods - when sold as GLOBALG.A.P. IFA certified - labeled with the operation’s PHA-N Number and with the producers’ (origin) GGN? | The PHA-N of the operation that labels the product and the GGN of the producer or the producer group shall be printed in the smallest packed unit that is individually labeled.  The packer, who packs and labels the product, shall be able to identify all the GGNs of the producers (origin) for the smallest packed unit that is individually labeled.  N/A when the finished goods are not sold as GLOBALG.A.P. certified and any further claim of the certified status of the finished good is discontinued. | Major |  |
| 6.7 | Is the Country of Destination on the producer’s certificates checked and does it match with the country of destination where the product is actually marketed? | In case the Country of Destination as indicated on the producer’s certificate is not the same as the actual country where the product is marketed, the company shall inform the relevant customer and shall take additional measures. Additional measures shall include product sampling and laboratory analysis to verify that the product meets the legal limits of the Country of Destination. The Country of Destination on the producer’s certificates can be checked at www.globalgap.org/search using the producer’s GGN. | Major |  |
| 7 | TRACEABILITY | |  |  |
|  | *Traceability facilitates the recall/withdrawal of foods and enables customers to be provided with targeted and accurate information concerning implicated products.* | |  |  |
| 7.1 | Has a documented traceability program been established? | Records shall be maintained that enable reconciliation of raw agricultural commodities and food contact packaging delivered to recipients (one step forward). Records shall include the items, the date of receipt, quantities, lot numbers or other identification (one step back). Additional information, such as farm information may be included. Contents and retention of records shall be consistent with applicable regulations. | Major |  |
| 8 | INCIDENT MANAGEMENT | |  |  |
|  | *Complaints, Corrective Actions, Recall/Withdrawal*  *Management of complaints will lead to an overall better production system.* | |  |  |
| 8.1 | Does the operation have a documented complaint and corrective action procedure that ensures non-conformances and complaints related to the scope of the standard are adequately recorded, studied, and addressed including a record of actions taken? | A documented complaint procedure shall be available to allow that all received complaints and/or non-conformances related to food safety are recorded and followed up on. Actions taken with respect to such complaints and/or non-conformances regarding any GLOBALG.A.P. related products or services are documented. When legal limits (e.g. pesticide residue) have been exceeded, the operation shall have up-to-date records of all cases including investigation, remedial actions, closure of each case, notification to their supplier, to the producer (origin) and to the Certification Body. No N/A. | Major |  |
| 8.2 | Does the operation have documented procedures on how to manage/initiate withdrawal/recall of certified products from the marketplace? | The company must have documented procedures, which identify the type of event that may result in a withdrawal/recall, persons responsible for making decisions on the possible withdrawal/recall of product, the mechanism for notifying customers and the GLOBALG.A.P. certification body, publicly available emergency contact details of the company that is operational 24/7 and methods of reconciling stock and final disposition of product, and where applicable, a product hold and release procedure is defined. The operation shall review the withdrawal and recall procedure annually to ensure it defines responsibility and steps for the specific activities consistent with applicable regulations. | Major |  |
| 8.3 | A trace back and trace forward exercise shall be performed at least once every six months. | The trace back and trace forward exercise shall achieve accurate traceability within 2 hours or as required by applicable regulations. Trace exercise shall achieve 100% reconciliation of product to recipients. Facilities adequately perform product trace back/trace forward (mock recall) exercises at a minimum of twice a year. Operations with less than six consecutive months of operation must have at least one trace back/trace forward exercise per season. | Minor |  |
| 9 | STAFF WELFARE | |  |  |
|  | People are key to the prevention of product contamination. Operation staff and contractors are essential for maintaining the quality and safety of the product. Education and training will support progress toward safe production. This section is intended to ensure good practices to diminish hygiene risks to the product and to ensure all workers understand the requirements and are competent to perform their duties. | |  |  |
| 9.1 | HYGIENE POLICY, TRAINING | |  |  |
| 9.1.1 | Does the operation have a policy for hygiene and health? | Each operation shall establish written policies for their specific operations based on the hazard analysis in section 2.1.4, which shall be in compliance with prevailing regulations for worker health and hygiene practices. | Major |  |
| 9.1.2 | Have all personnel received food safety training, sufficient to their responsibilities? | All personnel shall receive training in the food safety policy and plan, food safety procedures, sanitation, and personal hygiene appropriate to their job responsibilities. All personnel shall receive training at the time of hire and have refresher training at least annually. Training materials and the delivery of training shall be provided in a language understood by staff. Records of training is available. | Major |  |
| 9.1.3 | Are contracted personnel and visitors made aware of and following all personal hygiene practices as designated by the operation? | Operation’s hygiene policies shall apply to all contractors, visitors, buyers, product inspectors, auditors, and other personnel in the operation. The operation shall have procedures and/or records to demonstrate that contracted personnel or visitors whose activities can affect food safety have been informed of and, to the extent that can be verified, are in compliance with the relevant requirements of this standard. | Major |  |
| 9.1.4 | Is all produce handled in a manner not likely to become contaminated? | Operation has a written policy, in compliance with current industry practices or regulatory requirements for the commodity, regarding handling, walking, stepping, or placement on harvested produce, placed or dropped to the ground, food contact surfaces, or packaging materials, or coming in contact with produce that has not been handled in compliance with these standards, or that may otherwise result in contamination. There is visual evidence that workers handle the product in a way that does not pose a risk of product contamination and/or adulteration. | Major |  |
| 9.2 | *PERSONAL HYGIENE* | |  |  |
|  | Clothing, Personal Protective Equipment (PPE), Gloves | |  |  |
| 9.2.1 | Do personnel wash their hands at any time when their hands may be a source of contamination? | Operation has a written policy, in compliance with current industry practices or regulatory requirements for the commodity, regarding handwashing such that personnel shall wash their hands prior to start of work, after each visit to a toilet, after using a handkerchief/tissue, after handling contaminated material, after tobacco use, eating, or drinking, after breaks and prior to returning to work, after touching animals or waste and at any other time when their hands may have become a source of contamination. | Major |  |
| 9.2.2 | Is signage requiring handwashing posted? | Signage in applicable languages and/or pictures shall be provided in a visible place adjacent to hand washing facilities hands and at the workers’ access/entry to the facility, requiring people to wash their hands. | Minor |  |
| 9.2.3 | Is wearing of jewelry, body piercings, and other loose objects in compliance to company policy and applicable regulation? | Operation shall have a written policy that personal effects such as jewelry, watches or other items shall not be worn or brought into areas where fresh fruit or vegetables are exposed. Policy shall be in compliance with current industry practices or regulatory requirements for that commodity. The wearing of plain wedding bands with no stones and medical alert bracelets that cannot be removed can be permitted per evaluation of customer requirements and the applicable food legislation. The following are not permitted to be worn when handling product: false fingernails, long nails, or fingernail polish, ear gages, rings, watches, clothing with sequins or studs, bobby pins, false eyelashes, and eyelash extensions. | Minor |  |
| 9.2.4 | Does the hygiene policy address the risk of cross-contamination from cosmetics, chemicals, perspiration, and medicines applied to the skin? | The operation’s hygiene policy includes provisions to avoid cross-contamination from cosmetics, chemicals, perspiration, and medicines applied to the skin. | Minor |  |
| 9.2.5 | If protective clothing is required by the operation in product handling areas, is it handled in a manner to protect against contamination? | When employees wear protective clothing, such as aprons and gloves, the operation shall have a written policy that the clothing not be left on product, work surfaces, equipment, floor or packaging material, but hung on apron and glove racks or in designated areas. Racks shall be available and located so as to avoid potential contamination. Storage containers or designated storage areas shall be provided to ensure tools used by employees are properly stored prior to entering toilet facilities. | Major |  |
| 9.2.6 | Is the use of hair coverings in compliance to company policy and applicable regulation? | In operations that handle exposed product, the risk assessment and food safety plan must address if employees must wear a hair net and when workers have facial hair, if beard nets and moustache covers are required. This includes packinghouses, coolers and cold storage facilities, if they handle exposed product. Where hair nets are required, caps or other head coverings may be worn, but must be covered with a hair net. Policy must be in compliance with prevailing regulation.  N/A If exposed product is not handled. | Minor |  |
| 9.2.7 | Is protective clothing, including aprons and footwear effectively maintained, cleaned, and worn so as to protect product from contamination? | The operation shall have a written policy that employee protective clothing shall be clean at the start of the day and appropriate for the operation. At minimum, inspection for cleanliness of protective clothing occurs prior to the start of work as part of pre-operational check or cleaned by the operation as part of standard operating procedure. | Minor |  |
| 9.2.8 | Does the operation have a documented glove use policy, if gloves are used? | If rubber, disposable, cloth, or other gloves are used in contact with product, the operation shall have a written glove use policy that specifies how and when gloves are to be used, cleaned, replaced, and stored. When used, gloves must be provided by the facility. Hands must be washed before putting on gloves. Policy shall be in compliance with current industry practices or regulatory requirements for that commodity. Use of Latex and powder-free Latex gloves is prohibited. Cotton gloves may be worn under non-Latex/powder-free non-latex gloves. | Minor |  |
| 9.2.9 | Is there a disciplinary policy for food safety violations? | There shall be a policy that establishes corrective actions for personnel who violate established food safety policies or procedures. | Minor |  |
| 9.3 | *AMENITIES* | |  |  |
|  | *Facilities and Restrooms* | |  |  |
| 9.3.1 | Do workers have access to clean food storage areas, designated rest areas, hand-washing facilities, and drinking water? | A place to store food and a place to eat shall be provided to the workers. Hand washing equipment and drinking water shall always be provided. Break areas shall be designated and located away from food contact/handling zones and production equipment. Break areas shall be designated and located away from food contact/handling zones and production equipment. Single-use items (e.g. paper cups, and paper towels) must be stored, handled, and disposed of appropriately. | Major |  |
| 9.3.2 | Are workers’ personal belongings stored in designated areas? | Workers’ personal belongings shall be stored away from product handling and storage areas. The operation shall have a policy for when and how workers’ personal belongings shall be stored so as not to be a source of product contamination. | Minor |  |
| 9.3.3 | Is smoking, chewing, eating, drinking (other than water), chewing gum and/or using tobacco prohibited except in clearly designated areas? | The operation shall have a written policy prohibiting tobacco use, eating, chewing gum, and drinking other than drinking water except in designated areas. Such areas shall be designated so as not to provide a source of contamination. | Major |  |
| 9.3.4 | Are toilet facilities and restrooms designed, constructed, and located in a manner that minimizes the potential risk for product contamination and are directly accessible for servicing? | The operation shall have toilet and handwashing facilities (restrooms). Restrooms are located during operation and servicing so as not to pose a hazard to the produce or other opportunity for contamination. Restrooms are located away from produce handling areas. Hand wash basins shall be provided immediately near toilet room. Hand wash basins shall be supplied with: i. Potable water supply at an appropriate temperature to facilitate 20 second duration of handwashing; ii. Liquid, unscented soap contained within a dispenser;  iii. Paper towels in a hands free cleanable dispenser or other hands-free drying device in good working condition; and iv. A means of containing used paper towels for disposal. Larger facilities may require additional hand wash sinks.  Antiseptic hand sanitizers or gels may not be used as a substitute for soap and water. For an operation where product is not exposed to employees, such as a cold storage facility or distribution center, restroom only hand washing stations are acceptable. Appropriate temperature shall allow employees to comfortably wash hands (not too hot, not too cold). | Major |  |
| 9.3.5 | Are toilet facilities of adequate number, easily accessible to workers and visitors and in compliance with applicable regulation? | The operation will have verification that the number of toilet facilities and their location relative to workers meets the more stringent of federal, state, or local regulations. At least 1 restroom shall be available for every 20 employees. | Minor |  |
| 9.3.6 | Is the practice of disposing of used toilet tissue on the floor prohibited? | Workers shall be instructed that used toilet tissue only be disposed of in the toilet, where adequate plumbing exists. Where adequate plumbing does not exist, appropriate disposal receptacle is provided (e.g. covered with a “lid”). | Minor |  |
| 9.3.7 | Are toilet and washing stations maintained in a clean and sanitary condition? | Restroom sanitation schedule and records of cleaning shall be available. Restrooms shall be maintained and stocked according to 8.3.4, extra supplies, including toilet paper, shall be provided by the operation. Wash stations shall be located with the restrooms and include hand washing facilities with a tank that captures used hand wash water for disposal. Gray water is plumbed or captured for disposal. Operation shall take appropriate steps to ensure that leaks or spills are corrected. | Major |  |
| 9.4 | *ILLNESS, INJURY, AND FIRST AID* | |  |  |
|  | This section is intended to ensure safe practices in the work place and that all workers and contractors both understand and are competent to perform their duties; and that, in the event of accidents, workers, contractors, and visitors can obtain proper and timely assistance. | |  |  |
| 9.4.1 | Are workers, contractors, and visitors who show signs of illness restricted from direct contact with produce or food-contact surfaces? | Operation shall have a policy that restricts employees, contractors, visitors, buyers, product inspectors, auditors, and other personnel in the operation who show signs of illness (e.g. vomiting, jaundice, diarrhea) from working in activities or areas where they might enter into contact with product or food contact surfaces. Policy shall require that any person so affected immediately report illness or symptoms of illness to management. | Major |  |
| 9.4.2 | Are personnel with exposed cuts, sores or lesions not engaged in handling product? | Minor cuts or abrasions on exposed parts of the body are acceptable if covered with a non-permeable covering, bandage or glove. Bandages on hands shall be covered with gloves in compliance with the operation’s glove policy. | Minor |  |
| 9.4.3 | Does the Operation have a blood and bodily fluids policy? | There shall be a written policy specifying the procedures for the handling/disposal of food or food contact surfaces that have been in contact with blood or other bodily fluids. | Major |  |
| 9.4.4 | Are first aid kits accessible to all personnel? | The kits shall be readily available in the facility(ies) and maintained in usable condition, within expiry dates, and in accordance with prevailing regulation. The kit materials shall be kept in a sanitary condition. | Minor |  |
| 9.4.5 | Is an appropriate number of persons (at least one person) trained in first aid present at the facility? | There is always at least one person trained in first aid (i.e. within the last 5 years) present at the facility whenever workers are present. As a guideline: one trained person per 50 workers. | Minor |  |
| 9.4.6 | Do accident and emergency procedures exist? Are they visually displayed, and are they communicated to all persons within the operation, including subcontractors and visitors? | Permanent accident procedures shall be clearly displayed in accessible and visible location(s) for workers, visitors and subcontractors. These instructions are available in the predominant language(s) of the workforce and/or pictograms.  The procedures shall identify, the following:  - The facility address  - The contact person(s)  - An up-to-date list of relevant phone numbers (police, ambulance, hospital, fire department, access to emergency health by means of transport, supplier of electricity, water and gas).  Examples of other procedures that can be included:  - The location of the nearest means of communication (telephone, radio).  - How and where to contact the local medical services, hospital and other emergency services. (WHERE did it happen? WHAT happened? HOW MANY injured people? WHAT kind of injuries? WHO is calling?).  - The location of fire extinguisher(s).  - The emergency exits.  - Emergency cut-offs for electricity, gas and water supplies.  - How to report accidents and dangerous incidents. | Minor |  |
| 10 | FACILITY | |  |  |
| 10.1 | BUILDING LAYOUT AND MAINTENANCE | |  |  |
|  | Construction: Walls, Platforms, Drains, Cooling Equipment, Lighting, Ventilation, Grounds  This section is intended to ensure that the land, buildings, and other facilities, which constitute the fabric of the operation, are properly managed to ensure the safe production of food and protection of the environment. Where compliance criteria are not applicable to open shed operations, auditors must include justification for exclusion. | |  |  |
| 10.1.1 | Is the facility(ies) located, designed, constructed, and maintained in a manner that prevents contamination of produce during staging, handling, storage, and cooling? | The facility(ies) buildings and structures are located as to enable safe production and prevent contamination and cross-contamination. Buildings and equipment structures and surfaces (floors, walls, ceilings, doors, frames, hatches, etc.) shall be constructed in a manner that facilitates cleaning and sanitation and does not serve as harborage for contaminants or pests. Drop ceilings shall enable cleaning and monitoring for pest activity. Facilities, storage, and loading dock areas shall be appropriately constructed to allow drainage, including flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Roof leaks shall be promptly identified, controlled, and repaired. Overhead structures such as ducts and pipes shall be properly installed and maintained. Drip pans shall be drained as to not pose a risk of contamination. Condensation shall be controlled as to not be a source of product contamination. Drains shall be constructed and located so they can be easily cleaned and not present a hazard. Air intakes shall not be located near potential sources of contamination. Storage of maintenance materials is designated and does not pose risk of cross-contamination. Walls, frames, drop ceilings, etc.  N/A available for open shed operations. | Major |  |
| 10.1.2 | Is equipment installed in a way that provides access for cleaning? | Cooling, packing and other food contact equipment is installed away from walls and otherwise positioned so as not to inhibit access for proper cleaning.  N/A available for open shed operation. | Major |  |
| 10.1.3 | Are catwalks above product zones protected to prevent produce or packaging contamination? | Where workers walk over food contact surfaces, those walkways are solid surface or have catch trays installed, are protected by kick plates, product covers, or other barriers. Walkways over food contact surfaces shall not be made of wood. | Minor |  |
| 10.1.4 | Is cooling equipment maintained so as not to be a source of product contamination? | Cooling equipment (e.g. hydrocoolers, air coolers), shall be inspected, all debris removed, and cleaned and sanitized according to written sanitation SOPs.  N/A available for open shed operation. | Minor |  |
| 10.1.5 | Is adequate lighting provided in all areas? | Lighting in all areas shall be sufficient to provide a safe working environment, enable cleaning of hands and maintenance of personal hygiene, facilitate the changing of personal protective clothing, and enable the cleanliness, sanitation, and repairs of the facility(ies). Where legal requirements are specific, lighting shall meet prevailing regulation. | Minor |  |
| 10.1.6 | Is adequate ventilation provided in enclosed product handling and storage areas? | Ventilation in all areas shall be sufficient to prevent accumulation of dust, odors, condensation, vapors, and noxious fumes. Fans are controlled so as not be a source of contamination.  N/A available for open shed operation. | Minor |  |
| 10.1.7 | Does the facility maintain a grounds program? | The operation shall have written procedures to maintain the grounds surrounding the building in a manner to minimize sources of contamination, such as litter, vegetation, waste culls, debris, and standing water that may be pest attractants or harborages. Vegetation that does not serve as an attractant or harborage is permitted. Operation shall implement a policy to maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. | Minor |  |
| 10.2 | *EQUIPMENT DESIGN AND MAINTENANCE* | |  |  |
|  | *Materials, Preventive Maintenance, Temporary Repairs, Lubricants* | |  |  |
| 10.2.1 | Are all food contact equipment, tools, and utensils designed and made of materials that are easily cleaned and maintained? | The operation shall document and implement handling and storage procedures of all food contact surfaces to reduce and control the potential for contamination. Food contact tools, utensils, and equipment shall be made of materials that can be cleaned and sanitized. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. Where corrosion presents a food safety risk it must be controlled. With the exception of commodities where using wooden bins or equipment is the industry standard, produce must not come in contact with surfaces which are not food grade, not accessible and/or cannot be cleaned, including but not limited to the following: foam rubber, any type of carpet, non food grade plastic, etc. | Major |  |
| 10.2.2 | Does the facility have a documented Preventive Maintenance Program with related SOPs? | There shall be a written preventive maintenance program or schedule for all food and non-food contact surfaces including floors, drains, walls, ceilings and other surfaces that may pose as a source of product contamination. Procedures include frequency, instructions for inspection and persons responsible. Records show that tasks were completed and by whom. | Major |  |
| 10.2.3 | Are any temporary repairs on food contact surfaces constructed of food-grade material? | The operation shall have procedures to ensure temporary repairs are compliant with all food safety requirements, and do not create potential sources of chemical, microbiological, or physical contamination risk in products or for workers. Permanent repairs are implemented as soon as practical. Operation shall establish timelines and responsibilities for completion. | Minor |  |
| 10.2.4 | Is equipment lubrication managed so as not to contaminate food products? | Only food-grade lubricants shall be used on food handling and packaging equipment, or on any other equipment where incidental food contact may occur, unless the equipment manufacturer specifies only a non-food grade lubricant. Lubricant leaks are fixed or catch pans are installed to prevent product contamination. | Minor |  |
| 11 | WATER/ICE | |  |  |
| 11.1 | *WATER SUPPLY AND CONTROLS* | |  |  |
|  | *The quality of post-harvest water, including ice that contacts fresh produce during post-harvest flume transport, cleaning, grading, and surface treatment application is widely recognized as an essential pathogen control point to limit cross contamination of fresh produce.* | |  |  |
| 11.1.1 | Has a water system description been documented? | Water sources and check-valve locations of the operation shall be documented and current. Written description or map is acceptable. | Minor |  |
| 11.1.2 | Has an initial risk assessment been performed and documented that takes into consideration the historical testing results of the water source for cleaning food contact surfaces, hand wash, drinking water, dump tanks, circulated, immersed produce, and rinse water, and ice? | The operation shall have a written risk assessment to address potential physical, chemical, and biological hazards and hazard control procedures for the water distribution system. The water supply must be adequate for the intended operations and must be derived from an adequate source so as not to pose a risk to food safety. A review or new assessment shall be conducted seasonally and any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The operation’s water quality must meet U.S. Environmental Protection Agency (EPA) requirements for drinking water, or similar standards (currently, the Total Coliform Rule and the Surface Water Treatment Rule). The EPA threshold for drinking water samples is zero for total coliforms, whereas any sample with a positive finding of total coliforms must be retested for *E. coli*. And Total Coliforms. Non-US legislation may have different tolerance limits or indicator organisms or more specific guidelines for sampling, however, the results may be no less stringent than zero for total coliforms. | Major |  |
| 11.1.3 | Is the laboratory carrying out the analysis a suitable one? | The operation shall have documented evidence that used laboratories are currently accredited to ISO 17025 or its national equivalent, or a laboratory that can demonstrate via documentation that the laboratory is in the process of gaining accreditation. | Minor |  |
| 11.1.4 | Is a written scheduled assessment of the water system, including delivery equipment, in place? | The water storage and delivery system shall be maintained so as not to serve as a source of contamination of produce, water supplies or equipment with pathogens, or to create an unsanitary condition. The system shall maintain appropriate water temperature monitoring for the commodity. | Major |  |
| 11.1.5 | Where product washing occurs, does the operation’s hazard analysis include the produce washing process? | If produce is washed, an initial risk assessment of the washing process shall be performed. The risk assessment shall take into consideration the commodity, type of wash system, type of sanitizer, and water quality. This can be part of the hazard analysis or be a separate risk assessment. | Major |  |
| 11.1.6 | Where water is re-used, are water-change schedules in place for all uses of water? | Operation shall have procedures for changing water that is re-used, such as recirculated water, flumes and dump tanks. | Major |  |
| 11.1.7 | Where water antimicrobials are used, do they comply with regulatory approval? | Only wash water antimicrobials or antimicrobial systems registered or approved by EPA, FDA or the prevailing regulatory agency for their specific intended use may be used in the dump tank water, on the spray line, or for other food contact purposes. | Minor |  |
| 11.1.8 | Where water antimicrobials are used, does the operation use and monitor them in accordance with established operational procedures and manufacturer instructions? | The operation shall have a procedure that includes limits for antimicrobial in water for food safety. The procedure shall include how to control, monitor and record use of water antimicrobial as needed to assure compliance with minimum and maximum limits. Microbial, physical, or chemical testing shall be performed, as appropriate to the specific operation, to demonstrate that acceptance criteria have been met. Records shall be kept. The operation shall have a procedure as to what corrective actions are taken if criteria are not met. Note: While the use of antimicrobials in water does not constitute a “kill step”, levels must be monitored so that the treated water adequately limits cross contamination. There shall be proof of antimicrobial parameters derivation (e.g. validation study). When required, pH shall be monitored and recorded (e.g. when using chlorine). | Major |  |
| 11.1.9 | Are debris and damaged, and/or visibly contaminated produce removed from wash areas/dump tanks to the extent possible? | The operation shall have procedures to determine how and when debris and damaged produce, and/or visibly contaminated water or produce shall be removed from wash areas/dump tanks to prevent buildup of organic material. | Minor |  |
| 11.2 | *WASTE WATER* | |  |  |
|  | *Waste and gray water cross-connections* | |  |  |
| 11.2.1 | Is the sewage disposal system adequate for the facility and maintained to prevent direct or indirect product contamination? | The human waste and gray water sewage system has sufficient capacity to handle the operation’s peak flows and not cause direct or indirect product contamination. Water installations and equipment are constructed and maintained to prevent back-siphonage backflow and cross connections between food contact water and waste water. Routine checks verify that back siphonage and backflow prevention units are functioning properly (annual or as needed to maintain continuous protection). After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, the operation shall take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate produce, food contact surfaces, areas used for produce handling, agricultural water sources, or agricultural water distribution systems. Records are kept of corrective actions after these events. | Minor |  |
| 12 | AIR SUPPLY | |  |  |
|  | *Employing a maintenance and monitoring program for the compressed air system can mitigate the risk associated with compressed air at points of contact.* | |  |  |
| 12.1 | Compressed air that contacts food or food contact surfaces shall be clean and present no risk to food safety. | Compressed air systems used in the production or packaging steps shall be maintained and the filter regularly monitored for cleanliness. | Minor |  |
| 13 | CLEANING AND SANITATION | |  |  |
|  | *Food Contact Surfaces, Chemicals and Sanitizers, Storage of Chemicals, Cleaning Tools* | |  |  |
| 13.1 | Does the facility have a cleaning schedule, with related SOPs in place? | There is a written cleaning and sanitation schedule for all food and non-food contact surfaces including equipment, floors, drains, walls, ceilings and other surfaces that may pose as a source of product contamination. Procedures include frequency, instructions for cleaning, and persons responsible. Cleaning intervals are defined for lines with continuous production. | Major |  |
| 13.2 | Are food contact surfaces cleaned and sanitized according to the cleaning schedule? | Prior to use, the lines used for washing, grading, sorting, or packing shall be cleaned and sanitized with adequate time for drying, as appropriate per risk assessment or prevailing regulations. Records must include the date, method of cleaning and sanitizing equipment, and completed by whom. When in use, the lines shall be maintained so as not to be a source of contamination. | Major |  |
| 13.3 | Are all cleaning agents approved for their intended use on food contact surfaces? | All chemicals used for cleaning or sanitizing of food contact equipment, tools, utensils, containers and other food contact surfaces shall be approved for that use, according to the chemical manufacturer or supplier and all federal, state, and local requirements, and shall be used in a manner consistent with the approved use. Safety Data Sheets (SDS) shall be available for chemicals in use. | Major |  |
| 13.4 | Are all chemicals stored in a secure, separate area, away from product or product handling areas? | Chemicals, including cleaning and maintenance chemicals and lubricants, are stored away from product handling areas. Food-grade and non-food-grade lubricants are kept separate from each other. All chemicals shall be properly labeled. Empty containers are labeled, segregated and securely stored until disposal, and unused and/or obsolete chemicals are stored secured while waiting disposal by an approved channel. | Minor |  |
| 13.5 | Are cleaning equipment and tools in working order, clean, properly marked or coded, and stored properly away from product handling areas? | The operation shall have an implemented policy for effective identification and storage of cleaning equipment to prevent cross contamination of food contact surfaces. Equipment, utensils, and tools, and single-use items used for cleaning or sanitizing, including food contact and non-food contact surfaces, are maintained in a manner sufficient to avoid becoming a source of product contamination and are stored away from product handling areas. Hoses shall be stored off the floor. | Major |  |
| 13.6 | Are pre-operational hygiene inspections, cleaning and sanitation, and verification activities in place? | Pre-operational hygiene and sanitation inspections shall be conducted to ensure product handling equipment and areas are clean before the start of production. Records are kept. | Minor |  |
| **14** | **MICROBIOLOGICAL TESTING** | |  |  |
|  | *Sampling, Records, Test and Hold, Lab Accreditations, Test Results, Action Plan* | |  |  |
| 14.1 | Where microbiological analysis is required in the Food Safety Plan, are samples collected in accordance with an established sampling procedure? | The operation shall utilize a written sampling protocol when collecting samples for microbiological testing. The written program must identify persons responsible, test type (method), frequency, sampling locations, and actions to be taken if thresholds are exceeded. The written program can be part of the facility’s risk assessment or a separate document/program to verify sanitation effectiveness for food contact and non-food contact surfaces. The risk assessment must include prevailing regulations, customer requirements, where applicable, and other commodity specific guidelines. See Annex 1 – Environmental Monitoring for more information. | Major |  |
| 14.2 | Are test results and actions taken documented? | All results for microbiological testing required in the operation’s Food Safety Plan shall be recorded and the records maintained for two years or as required by prevailing regulation, if stricter. If finished product is tested for pathogens or other adulterants, operation’s procedures require that it shall not be distributed outside the operation’s control until test results are obtained. | Major |  |
| 15 | CONTAINERS | |  |  |
|  | *Primary Packaging, Secondary Packaging, Reusable Plastic Containers, Bins, Pallets, Packing Material, etc.* | |  |  |
| 15.1 | Does the operation have a written container management policy which includes requirements for food contact containers? | Construction of food contact containers and packing materials shall be appropriate to the commodity being handled and suited for their intended purpose. Written specifications from manufacturer which include a statement that product is manufactured from food grade materials is acceptable evidence. | Major |  |
| 15.2 | Are materials that come in contact with the produce clean and in good repair? | The operation’s container management policy includes produce bins, totes and materials that come in contact with the produce or the containers during handling or storage shall be cleaned and, if practicable, sanitized so as not to be a source of contamination. Reusable containers must be on a written cleaning program stating frequency and procedures for cleaning. Records are kept. | Major |  |
| 15.3 | Does the container management policy consider whether food contact containers are permitted in direct contact with the ground? | If produce does not normally contact the ground during production, operation shall have considered and developed written policies, consistent with industry standards, regarding placement of food contact containers directly on the ground, or whether a physical buffer (e.g. buffer bin or slip sheet) is required, or use of containers constructed to prevent contact of the product or food contact surfaces with the ground. | Minor |  |
| 15.4 | Does the container management policy include inspection of food contact containers and bins prior to use? | Food-contact totes, bins, reusable bins, packing materials, other harvest containers, shall be visually inspected for cleanliness, intact, and free of any foreign materials prior to use, and used per shelf-life. Records are kept. | Minor |  |
| 15.5 | Does the container management policy prohibit use of food contact containers for non-product purposes unless clearly marked or labeled for that purpose? | Food-contact totes, bins, and other food contact containers shall not be used for other purposes. Where the same materials are used for non-food contact purposes, the operation shall have a policy or procedure that clearly designates approved non-food contact uses and how the containers are to be marked or labeled for that purpose. Food contact totes, bins, and other packing containers and equipment that are no longer cleanable shall not be used for packing but can be used for other non-food uses if clearly marked/labeled. | Major |  |
| 15.6 | Are pallets kept clean and in good condition as appropriate for their intended use? | Operation inspects pallets prior to use for conditions that may be a source of produce contamination. Pallets that are not cleanable are removed from use. Pallets and other wooden surfaces are properly dried after being washed. | Minor |  |
| 16 | PEST CONTROL | |  |  |
|  | *Policy, Procedures, Type, Location, Records, Assessment* | |  |  |
| 16.1 | Does the operation restrict animals from product handling areas? | Per written procedure, domesticated animals are prohibited from product handling facilities unless procedures are in place for their safe presence. Procedures are in place to exclude wild and feral animals to the degree practical and to monitor for and mitigate contamination from animal excreta. | Major |  |
| 16.2 | Does the operation have procedures to manage pests to the extent appropriate to the operation? | The operation’s written pest control program to ensure control or eliminate the risk of pest infestation shall include policies and procedures applicable to that operation, covers the facility(ies) inside and out. Program includes pest control measures such as screening, traps, etc. where applicable. | Major |  |
| 16.3 | When used, are pest control devices, including rodent traps and electrical flying insect devices, located so as to not contaminate produce or product handling surfaces? | Maps of the location of pest traps at the operation shall be available. Light traps are located away from food contact surfaces. Inside rodent traps are set at maximum distance of 50 feet apart. Outside rodent traps are set at maximum distance of 100 feet apart and shall be located next to exterior doors. Only non-toxic traps and pest control devices are used inside the product handling buildings. | Minor |  |
| 16.4 | Is adequate space maintained between rows of stored materials to allow cleaning and inspection? | Materials shall be stored away from walls and ceilings. Written procedures shall be followed to guarantee the proper cleaning, inspection and monitoring for pest activity in storage areas. | Minor |  |
| 16.5 | Are pesticides and other toxic chemicals used approved for intended use, clearly labeled, and stored? | List of chemicals used and the accompanying Safety Data Sheets (SDS) shall be available. Chemicals are handled and stored in compliance with storage and handling of all chemicals set in section 12.3 and 12.4. | Minor |  |
| 16.6 | Are pesticides and other toxic chemicals used applied by properly trained personnel? | Applications of pesticides (e.g. insecticides, rodenticides) shall be performed by a trained pest control operator and in compliance with local, state, and federal pesticide regulations. | Minor |  |
| 16.7 | Are records of pest control device inspections available? | Operation maintains a pest-control log that includes dates of inspection, inspection report, and corrective actions to eliminate any problems. | Minor |  |
| 16.8 | Does the operation have procedures to prevent pest harborage in any equipment stored near the building? | Equipment stored outside shall be stored away from the building perimeter. Bone yards are located away from the building. Outside equipment storage areas shall be included in pest control program. | Minor |  |
| 16.9 | Are packaging, product, and inside of facility free of infestation of insects, rodents, birds, reptiles and mammals and evidence of them? | The inside of the facility, all product, and packaging shall be free of infestation of insects, rodents, birds, reptiles and mammals and evidence of them, including decomposed pests in pest control devices. | Major |  |
| **17** | **WASTE MANAGEMENT** | |  |  |
|  | *A waste management plan is established to ensure waste is properly managed.* | |  |  |
| 17.1 | Are waste materials and waste removal managed to avoid contamination? | Trash, leaves, trim, culls, waste water, and other waste materials, and adulterated product are removed from the produce handling areas at a written, defined frequency and as needed, sufficient to avoid becoming a source of produce contamination. Outside garbage receptacles/dumpsters are closed or have lids (except for waste collection/cull trailers in active use) and located away from building entrances. Weeds and other pest harborage are minimized around the containers. | Major |  |
| **18** | **FOREIGN MATERIALS** | |  |  |
|  | *Glass, metal, or other extraneous materials are physical hazards which can cause injury or illness in the person consuming the product.* | |  |  |
| 18.1 | Has the operation developed a foreign materials programs to eliminate or control any metal or other extraneous material issues? | Operation maintains a written foreign materials policy including glass and brittle plastic to address adequate measures to protect against the inclusion of metal or other extraneous material in food. All foreign material risks must be either removed and/or accounted for and controlled. Visual inspection is acceptable. Records are kept. | Major |  |
| 18.2 | Are only essential glass and brittle plastic present in the building? | Light bulbs, fixtures, windows, mirrors, skylights and other glass and brittle plastic in the building or in the product path entering or exiting the building shall be of the safety type, or shall be otherwise protected to prevent breakage. If glass or brittle plastic must be used, the written glass and brittle plastic control policy shall include a glass and brittle plastic register. | Major |  |
| **19** | **COOLING AND STORAGE** | |  |  |
|  | *Cold Storage, Controlled Atmosphere, Iced Storage, Equipment* | |  |  |
| 19.1 | Are product storage areas and conditions appropriate to the commodities stored? | Produce storage locations and conditions shall not pose a risk of produce contamination, consistent with industry standards or prevailing regulation, if stricter, including outdoor bulk storage. Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable inspection and cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin. | Major |  |
| 19.2 | Where temperature control is required for food safety, are cooling facilities fitted with temperature monitoring equipment or suitable temperature monitoring device? | Temperature and atmosphere monitoring equipment shall be located so as to monitor the warmest part of the room and be fitted with measurement devices that are easily readable and accessible. | Minor |  |
| 19.3 | Is iced product handled so as not to serve as a source of contamination? | Protective measures are implemented in areas where iced product is stored over packed produce in order to prevent melting ice from contaminating product below. | Major |  |
| 19.4 | Are packaging materials storage areas maintained so as not to be a source of product contamination? | Areas designated to store packaging materials, whether indoors or out, are well ventilated, maintained in a dry and clean manner, free from direct contamination or residues, and designed to protect materials and produce from contaminants. Packaging materials stored in uncovered areas shall be protected from condensate, sewage, dust, dirt, chemicals, allergens, or other contamination. Packaging materials shall be stored off the floor/ground on pallets, slip-sheets or stands and covered where applicable. | Major |  |
| 19.5 | Are all other non-product areas maintained so as not to be a source of contamination for product, packaging materials, or food contact equipment? | Areas designated to store materials, whether indoors or out, such as machine work areas, extra supply warehouses, vehicle parking or charging areas, are maintained in a dry and clean manner, free from direct contamination or residues, and designed to prevent cross contamination to product handling areas. | Minor |  |
| **20** | **EQUIPMENT CALIBRATION** | |  |  |
|  | *All GMP instruments must be calibrated and maintained according to a written program designed to ensure and demonstrate ongoing accurate performance.* | |  |  |
| 20.1 | Are all instruments used to measure temperature, pH, antimicrobial levels and/or other important devices used adequately maintained and calibrated at a frequency sufficient to assure continuous accuracy? | Calibrations for measuring equipment shall be conducted minimum annually. Written procedure and records shall be kept. Methods of verification and acceptable range of variation are documented. If an Oxidation-Reduction Potential (ORP) system is used, an independent measurement shall be used to verify compliance. Test methods or test strips used to monitor requirements shall be appropriate to their use and sufficiently sensitive to their intended purpose and available in adequate numbers for their designated use. Verification procedures shall be based on legal requirements, manufacturer recommendations, or other industry specific guidance for that equipment. | Major |  |
| 20.2 | Are foreign material control devices inspected and maintained at a defined frequency? | Where foreign material control devices are utilized in the food safety plan, devices shall be included as part of a Preventive Maintenance Schedule and maintained to ensure effective operation. Calibration methods are defined in the written procedure and conform to prevailing regulation, manufacturer’s recommendations, or commodity specific guidance. | Minor |  |
| **21** | **TRANSPORTATION** | |  |  |
|  | *Vehicles, Loading and Unloading, Inspections, Records* | |  |  |
| 21.1 | Is transporting equipment maintained to prevent contamination of products being transported? | Loading/unloading equipment, such as pallet jacks, carts, trolleys and forklifts, etc., shall be clean and well maintained and of suitable type to avoid contamination of the produce during transport and are listed on the Preventive Maintenance and/or Cleaning Schedules. | Minor |  |
| 21.2 | Does the Operation have a policy, written procedures, and a checklist to verify cleanliness and functionality of shipping units (e.g. trailer)? | Shipping units shall be clean, functional and free of objectionable odors before loading, in compliance with current industry practices or regulatory requirements for that commodity. Refrigeration units, if used, must be in working order. Procedures include prohibition of raw animal or animal product transport, or other materials that reasonably may be a source of contamination with biological, chemical, or physical hazards. Shipping units shall be washed between loads if prior transport included materials that reasonably may be a source of contamination. Records are kept. | Major |  |
| **22** | **POST-HARVEST TREATMENTS** | |  |  |
|  | *Products, Training, Records, Plant Protection Product Residue Analysis* | |  |  |
| 22.1 | Where biocides, waxes and plant protection products are used for post-harvest protection of the harvested crop, are all label instructions observed? | There are clear procedures and documentation available, (e.g. application records for post-harvest biocides, waxes and plant protection products) that demonstrate compliance with the label instructions for chemicals applied. | Major |  |
| 22.2 | Are all the biocides, waxes and plant protection products used for post-harvest protection of the harvested crop officially registered in the country of use? | All the post-harvest biocides, waxes and plant protection products used on a harvested crop are officially registered or permitted by the appropriate governmental organization in the country of application. They are approved for use in the country of application and are approved for use on the harvested crop to which they are applied as indicated on the labels of the biocides, waxes and crop protection products. | Major |  |
| 22.3 | Is an up-to-date list maintained of post-harvest plant protection products that are used, and approved for use, on crops handled in the facility? | An up-to-date documented list that takes into account any changes in local and national legislation for biocides, waxes and plant protection products is available for the commercial brand names (including any active ingredient composition) that are used as post-harvest plant protection products for produce handled in the facility under GLOBALG.A.P. Certification within the last 12 months. No N/A. | Minor |  |
| 22.4 | Is the technically responsible person for the application of post-harvest plant protection products able to demonstrate competence and knowledge with regard to the application of biocides, waxes and plant protection products? | The technically responsible person for the post-harvest biocides, waxes and plant protection products applications can demonstrate a sufficient level of technical competence via nationally recognized certificates or formal training. | Major |  |
| 22.5 | Is the source of water used for post-harvest treatments potable or declared suitable by the competent authorities? | Water shall be declared suitable by the competent authorities and/or within the last 12 months a water analysis has been carried out at the point of entry into the washing machinery. The levels of the parameters analyzed are within accepted WHO thresholds or are accepted as safe for the food industry by the competent authorities. Water used for post-harvest treatments is considered under section 10 of this standard. | Major |  |
| 22.6 | Are the biocides, waxes and plant protection products used for post-harvest treatment stored away from produce and other materials? | To avoid chemical contamination of the product, biocides, waxes and plant protection products, etc., are kept in a designated secure area, away from the produce. Products are handled and stored in compliance with section 12.3 and 12.4 of this standard. | Major |  |
| 22.7 | Are all records of post-harvest treatments maintained and do they include the minimum criteria listed below?   - Identity of product (i.e. lot or batch of produce);  - Location (if multiple product lines) - Application dates  - Type of treatment  - Product trade name and active ingredient  - Product quantity - Name of the operator - Justification of application | The following information is recorded in all records of post-harvest biocide, wax and plant protection product applications:  - The lot or batch of produce treated. - The product line where the treatment was undertaken.  - The exact dates (day/month/year) of the applications.  - The type of treatment used for product application (e.g. spraying, drenching, gassing etc.). - The complete trade name (including formulation) and active ingredient or beneficial organism with scientific name. The active ingredient shall be recorded or it shall be possible to connect the trade name information to the active ingredient.  - The amount of product applied in weight or volume per liter of water or other carrier medium.  - The name of the operator who has applied the plant protection product to the produce. - The common name of the pest/disease to be treated. No N/A. | Major |  |
| 22.8 | Are all post-harvest plant protection products considered in the hazard analysis for compliance with the MRLs in the country of destination? | Where the MRLs of the market in which the producer is intending to trade the produce are stricter than those of the country of production, the operation or the producer's customer shall demonstrate that during the production cycle these MRLs have been taken into account. | Major |  |

ANNEX 1 GLOBALG.A.P. GUIDELINE | ENVIRONMENTAL MONITORING

**Introduction to Environmental Monitoring**

In any Food Safety Plan, the environmental monitoring must be scientifically based and specific to the hazard analysis of the operation.

The following information contains relevant recommendations for an operation's implementation of an environmental monitoring program. Using this standard, an environmental monitoring program is seen as the verification step of the facility design, employee training program, SOPs and sanitation program, whereas the microbiological hazard is identified in the hazard analysis and the sanitation program is documented as a step to control, reduce, or eliminate that microbiological hazard. The hazard is evaluated based on risk, including characteristics of the product, production methods, equipment, scientific literature and studies, and legal requirements. As example, facilities using wash water that fall under the Preventive Control Rule may be required to adhere to environmental monitoring for *Listeria* (e.g. cantaloupe, tomato). According to FDA definition, ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards. Customer requirements may vary.

Assessment for the need of Environmental Monitoring (FSPCA Preventive Controls for Human Food, Instructor Guide, Appendix A6-1):

* Is the product associated with pathogen contamination?
* Does the product receive a validated process control designed to kill environmental pathogens?
* Is the product exposed to the environment after the kill step and before packaging?
* Is the product a ready-to-eat product?
* Does a refrigerated ready-to-eat product support the growth of *Listeria monocytogenes*?

Draft Guidance for *Listeria* is available here: [https://www.fda.gov/downloads/Food/Guidance Regulation/GuidanceDocumentsRegulatoryInformation/UCM535981.pdf](https://www.fda.gov/downloads/Food/Guidance%20Regulation/GuidanceDocumentsRegulatoryInformation/UCM535981.pdf)

Additional draft guidance for developing the hazard analysis for the product can be found in FDA's 2.4.2.4 Evaluation factors on page 31 of the [Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry.](https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517610.pdf)

FDA recommends an environmental monitoring program designed to detect areas of pathogen harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. FDA recommends the following practices:

* Performing environmental sampling on both food contact and non-food contact surfaces (e.g., drains)
* Determining the appropriate target pathogen, test locations, and frequency of sampling
* FDA recommends that the appropriate target pathogen be the most resistant microorganism of public health significance that is likely to occur in fresh-cut produce.
* Focusing environmental monitoring on an indicator organism, such as *Listeria* spp., which indicates microbial contamination but is non-pathogenic and more easily detectable than a target pathogen, such as *L. monocytogenes*
* Establishing a plan for action in the event that a microbiological test indicates the presence of a target pathogen or indicator organism
* Documenting corrective actions and follow-up for all positive microbial test results within 7 days

The ultimate goal is to show evidence of a controlled environment, that the sanitation program is effective, and that the operation responds to positive findings and trends.

Comment:

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