PrimusGFS Standard

V2.1-2 – Nov 2015

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Introduction

The PrimusGFS Standard has been designed with a HACCP based system that includes the measures that need to be taken in the pre-requisite programs of the Agricultural production, both in the farm and facility operations. The intention of describing these requirements is to have the producers assess the risk of their operations and implement the controls to maintain food safety in their process.

This Standard document should be used according to the instructions described in the "PrimusGFS – General Regulations".

The PrimusGFS Standard details the requirements the operation should comply with in order to obtain the certification. Additionally to this, there is a document named "PrimusGFS - Questions and Expectations" that is used in conjunction when performing the certification audits.

1 Food Safety Management System (FSMS)

1.1 Management System

a. There should be a documented food safety manual or other documented food safety management system that covers the scope of the certification and includes the procedures for food safety processes.

b. There should be a food safety policy detailing the company's commitment to food safety. The documented Policy should include a clear statement and detailed objectives of the company's commitment to meet the food safety needs of its products.

c. The company should have a documented organizational structure that specifies job functions and responsibilities for workers whose activities affect food safety. A food safety committee should be established and records of their meetings should be kept as proof of the company's ongoing commitment to the food safety program. Senior management should be involved in the meetings.

d. A verification of the food safety management system should be undertaken and documented at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This verification should be reviewed by senior management.

e. The company should have evidence that senior management is aware and committed to provide the resources needed to implement and improve the food safety related processes.

1.2 Control of Documents and Records

a. There should be a written document control procedure describing how documents will be maintained, updated and replaced.
b. All records should be stored for a minimum period of one year or for at least the shelf life of product if greater than a year or longer if there are customer or legal requirements applicable.
c. Food safety related documents and records should be stored and handled in a secured manner, with access control and backed up in the case of electronic files. In the case of paper files, they should be generated using ink not pencil, and if changes are made to records after initial entry, changes should be clearly legible and tracked, avoiding the use of corrective fluid.
d. Records should be maintained in an organized and retrievable manner.

1.3 Procedures and Corrective Actions

a. There should be a written document that describes how to create SOPs when required to cover any food safety related activities performed in the operations. This should include the SOPs to detail what is to be done, how it is done, how often, by whom, what records are required and any immediate corrective action to perform when deficiencies occur.
b. Documented procedures should be available to relevant operators involved in performing the related activities described in the procedures.
c. Written procedures should include the corrective actions to be taken in case of any deficiency affecting food safety is identified in the organization. Corrective actions should include the review of the non conformance, the determination of the causes, the establishment of an action plan to address such non conformances and prevent future occurrences, the implementation of corrective actions to and the follow-up to ensure the actions have solved the problem.
d. Unusual occurrences should be recorded including the corrective actions taken.

1.4 Internal and external inspections

a. There should be a documented program for internal audits to be performed at the operations, covering all processes impacting food safety and the related documents and records. The internal audits should cover the inspection of the sites, the practices in place, the related documents required and the records generated. The program should include the checklist to use for the audits, the frequency of the internal audit and identification of responsible person(s) for conducting the internal audits.
b. Written procedures for handling regulatory inspections should be available. Records of regulatory and/or contracted inspections should be kept on file, including company responses and corrective actions taken.
c. Calibration procedures should be available for the equipment used for measuring and monitoring processes related to food safety. Records of calibration should be kept to ensure correct and accurate operation.

1.5 Rejection and release of product

a. A documented procedure should exist to explain how product is going to be handled when it has either been rejected or placed on hold. The procedure should include details on how the affected product is separated in terms of identification and any other physical separation to ensure that affected product is not commingled with other goods. Release of product by authorized personnel should be included in the procedure.
b. There should be records of the handling of on hold or rejected products kept on file.
c. Product release procedures (for the release of all product that is shipped) should be documented and implemented and all related records should be kept.
d. There should be a documented system for dealing with customer and buyer food safety complaints. Records of any related incident should be kept on file, along with company responses and corrective actions.

1.6 Supplier Control

a. There should be documented specifications for all products, ingredients, materials and services purchased that have an effect on the product safety. Specifications should be

reviewed when needed but at least annually. Documented specifications should be easily accessed to users.

b. There should be a written procedure detailing how suppliers are evaluated, approved and monitored.
c. There should be a list of approved suppliers and where exceptions are made, approval from management should be documented.
d. There should be documented evidence to ensure that all suppliers of products, ingredients, materials or services comply with the approval requirements and that they are being monitored as defined in the procedure.
e. If the organization is outsourcing any processes that may affect food safety, such services should be identified, documented and monitored within the food safety management system.
f. If tests and/or analysis within the scope of food safety are performed by external laboratories, they should be accredited against ISO 17025 or licensed by National Regulations or State Departments in the country of production. Documented evidence of this license and/or accreditation should be current and available.

1.7 Traceability and Recall

a. There should be a document that indicates how the company product tracking system works. The system should be able to trace back to the supplier(s) of materials including commodities, packaging, ingredients, processing aids, work in progress, etc., and also trace forward to indicate which customer(s) received products. The traceability system should be in evidence when touring the operation and also when checking paperwork. The written traceability system must match the system that is being used in the operation.
b. The operation should have a documented recall system that details the procedures to follow in case of a recall including applicable laws, as well as any related information required to perform these procedures.
c. Testing of trace back and recall procedures should be performed and documented at least every 6 months.

1.8 Food Defense

a. The company should have a documented food defense policy that outlines the organization security controls necessary based on the risk associated with the operations.
b. The company should have available a current list of emergency contact phone numbers for company management, law enforcement and appropriate regulatory agencies.
c. Visitors to the company operations should be required to adhere to food safety and security policies.

2 GAP and GMP Options

GAP Option (from 2.01 to 2.15)

2.1 General GAP

a. There should be a designated person assigned responsibility for the food safety program in the field.
b. There should be a documented evidence of the internal audits performed to the

operations, detailing findings and corrective actions. Internal audits should be conducted at least once

before starting the production season and ideally another one during the production season for each field operation.

c. The operation should have the necessary food defense controls implemented for preventing intentional contamination.

2.2 Site Identification

a. Growing area(s) should be identified or coded to enable trace back and trace forward in the event of a recall. This system should be documented.

2.3 Ground History

a. The grower should know if the growing area(s) was used for the production of crops for human consumption the previous season.
b. Land previously used for non-agricultural activities should have a soil analysis to confirm that the soil is free of contaminants and/or comply with the levels of pollutants present in the soil.
c. Land previously used for animal husbandry or as grazing land for livestock should have a documented risk evaluation including details of the animal grazing (commercial or domestic) and any risk reduction steps.
d. There should be no evidence of animal activity in the growing areas. In case of finding evidence of animal activity in the growing area, actions should be taken based on the risk. The risk should be evaluated considering all the factors involved, including at least the type of animal, the type of activity (tracks, feather, fecal, etc), the extent of activity (frequency and/or quantity of events), the proximity to the crop itself, the maturity of the crop and how all these factors can affect the contamination of the edible part of the crop.
e. If flooding from uncontrolled causes occurred on the growing area(s) since the previous growing season there should be:
    i. Documented evidence (archived for 2 years) that corrective measures were taken to affected land and product.
    ii. Soil test results on file for the flooded area(s) showing soil was negative or within an appropriate regulatory agency's approved limits for contaminants.
f. Operations growing under organic principles should have current certification by an accredited organic certification organization on file.
g. A risk assessment of the growing area should be performed and documented. This should include assessment of microbial, chemical and physical risks, covering at least: previous use of the growing area, adjacent land, water sources (chemical hazards e.g. heavy metals, perchlorate, etc. and microbial hazards e.g. E. coli), fertilizers, crop protection chemicals, worker hygiene, equipment and tools used for harvest, storage, transportation and any other applicable areas. If risks are identified in the assessment, actions to minimize them should be taken and recorded.

2.4 Adjacent Land Use

a. The land adjacent to the growing area should not be a possible source of contamination from intensive livestock production (e.g. feed lots, dairy operations, poultry houses, meat rendering operation). If there is evidence of intensive livestock production, corrective actions and/or prevention measures should be taken and be effective.
b. There should be no evidence of domestic animals, wild animals, grazing lands, etc., in proximity to the growing operation. If domestic animals, wild animals, grazing lands, etc.,

are in proximity to the growing operation, there should be effective measures (e.g. buffer zone, physical barrier, ditch, etc.) in place to restrict animal or potential contaminant movement. There should be a written policy supported by visual evidence that domestic, livestock or wild animals are not allowed in the growing area as well as any packaging, sanitizer or equipment storage areas. There should be measures in place to reduce or limit the animal intrusion (i.e., monitoring field perimeter for signs of intrusion).

c. There should be no evidence of untreated animal manure piles, compost, biosolids, or non- synthetic amendments stored and/or applied on adjacent land. If there is evidence, there should be effective measures (e.g. buffer zone, physical barrier, ditch, etc.) in place to restrict potential contaminant movement. In the case of adjacent landowners using biosolids, they should supply biosolid class information.
d. The growing area should not be situated in a higher risk location where contamination could occur from nearby operations or functions (e.g. leach fields, runoff or potential flooding from sewers, toilet systems, industrial facilities, labor camps). If any case of this exists, there should be effective measures in place to mitigate risk.
e. There should not be evidence of human fecal matter in the adjacent land and if found, it should not represent a high risk to the crop for contamination due to lack of barriers or access controls.

2.5 Pest and Foreign Material Controls - *Applicable for greenhouses only*

a. There should be a documented policy, supported by visual evidence that domestic and wild animals, livestock, or birds are not allowed in the growing facility.
b. All entry points to growing facility(ies), storage and packaging areas should be protected to prevent entry of rodents or birds.
c. Based on the pest activity of the area and the risk to the crop and growing area, the grower should determine if a pest control program is needed, if so, the proper devices and controls should be implemented in the growing facilities.
d. If used, pest control devices (inc. rodent traps and electrical fly killers) should be:
    i. Located away from exposed food products. Poisonous rodent bait traps should not be used within the growing facility or inside any storage or packaging areas.
    ii. Maintained in working condition and marked as monitored on a regular basis.
    iii. Placed in the doorways and at an adequate distance.
    iv. Identified by a number or other code.
    v. Properly installed and secured.
    vi. Identified on a schematic drawing of the facility.
e. There should be service reports created for pest control checks detailing inspection findings, application records and corrective actions.
f. All foreign material risks should be removed and/or accounted for and controlled.
g. There should be a documented glass management policy and procedures for handling glass items or structures in the operation.
h. The growing facilty(ies) including grounds and any packaging and storage areas should be clean and well maintained.
i. If applicable, the compost and/or substrates should be received and stored separated from crop production and packaging and other storage areas.

2.6 Growing Media (Substrate) Use - *Applicable for greenhouses only*

a. If a hydroponic system is used, and excess solution is recycled, there should be records detailing how the solution is treated for recycling.

b. If substrates are used (e.g. sand, gravel, vermiculite, rockwool, perlite, peat moss, coir, etc.) and they are sterilized, there should be records of the location, date of sterilization, time/temperature readings, operator's name and pre-plant interval.

2.7 Fertilizer/Crop Nutrition

a. Untreated human sewage sludge should not be used in the growing operation.
b. Compost, biosolids and/or untreated animal manure should not be applied during the growing season and should be incorporated into the soil.
c. Non-synthetic treatments that contain animal products or animal manures should not be applied to the edible portions of crops.
d. Intervals between application and harvesting of treatments that contain animal products or animal manures should comply with national and/or local legislation/guidelines where they exist, if they do not exist, international guidelines should be used.
e. Certificates of analysis should be available for each lot of compost, biosolids and other non- synthetic crop treatments used. Tests should include microbiological/heavy metal analyses.
f. Biosolids or untreated animal manure should not be applied to crops where the country of production regulations/guidelines ban the use such materials.
g. There should be records of organic and/or inorganic fertilizers applications. The records should be legible and detail (at least) date of application, type of fertilizer, amount, method of application (drip, bulk, etc.), and operator name.
h. Where soil amendments that do not contain animal products are used, appropriate controls should be in place for the application and to guarantee the material.
i. There should be a Certificate(s) of Analysis (COA), letters of guarantee or some other documents from the inorganic fertilizer supplier(s) that specifies all the ingredients, including inert materials.
j. The fertilizers and/or fertilizer containers should be stored in a manner to prevent contamination to the growing area(s) or any water sources.

2.8 Irrigation/Water Use

a. There should be microbial water testing including generic *E.coli* for all water sources used for irrigation, crop protection/fertilizer and frost or freeze prevention programs.
b. Water samples from all sources should be collected and tested according to risk assessment and/or expected frequencies. Minimum requirements:
    i. Samples for microbial testing should be taken at a point as close to the point of use as practical.
    ii. Samples should be taken prior to use each source and ideally monthly or at a frequency relative to the water associated risk.
    iii. There should be documented procedures covering proper sampling protocols including sample identification information.
    iv. There should be written procedures (SOPs) covering corrective measures for unsuitable or abnormal water test results.
    v. There should be documented corrective measures if there are unsuitable or abnormal results of a microbiological test.

c. Well(s), reservoir(s), canals or other water sources should be built, designed and maintained to prevent contamination.
d. The well(s), reservoir(s), canals or other water sources should be free from contamination issues and measures should be taken to minimize contamination.

e. Water sourced from rivers, canals, etc., should be under the direction of a water authority or district.
f. There should be records of inspections and treatments of all water sources used for irrigation, crop protection/fertilizer and frost or freeze prevention programs.
g. Animals (domestic, livestock, or wild) should not have access to the water source(s).
h. There should be a separation between untreated manure and well(s), reservoir, canals or other water sources. The distance of this separation should depend on the risk variables e.g. topography (uphill or downhill), amount of material stored, location of storage, type of water source and others.
i. If reclaimed water is used, reclamation process should be under the direction of a water reclamation management or authority and water should be subject to applicable local and national regulations and standards. Prior to using this water for agricultural purposes growers should check with regulatory bodies to determine the appropriate parameters and tolerances to be used. Records should be kept.
j. Check valves, anti-siphon devices, or other back flow prevention systems should be in place where the water distribution system has the potential of back flowing.
k. Irrigation equipment that is not in use should be stored in a hygienic manner, free of pest contamination and clean.

2.9 Crop Protection

a. There should be a documented procedure for the mixing/loading of crop protection materials. The mixing, loading, or the dilution of crop protection materials should adhere to procedure and label instructions.
b. There should be a documented procedure for the application of crop protection products. The application of crop protection products should adhere to the procedure and the requirements of the labels.
c. There should be a documented procedure describing how to perform the rinsing and cleaning of crop protection equipment (measuring containers and devices, mixing containers, application equipment, etc). The procedure should include to adhere to the requirements of the crop protection product labels (e.g. disposal of spray mixture and rinsate, etc). The actual rinsing and cleaning of the crop protection equipment should be performed adhering to the procedure and the requirements of the labels.
d. There should be documented evidence that the individual(s) making decisions for crop protection applications are competent.
e. Current valid certificates, licenses, or other documentation recognized by prevailing national/ local standards and guidelines should be available for supervisors/workers handling, mixing/loading/and applying crop protection products.
f. There should be a crop protection products application record keeping program that at least includes the following information: Date and time of application, crop name, treated area (must be traceable), crop protection product trade name, crop protection product code (e.g., EPA Registration number in the U.S. - different systems are used in different countries), active ingredient, amount applied (rate/dosage), applicator name, pre-harvest interval and any other information required by local regulations. Ideally, records should also include: equipment used, target pest and size of treatment area.
g. Grower should be aware of the crop protection products registered and/or authorized by a government agency for use in the target crops in the country of production and have the information available.
h. Crop protection applications should be restricted by the guidelines established by the product label, manufacturer recommendation, or by prevailing national/ local standards and guidelines.

i. Where harvesting is restricted by pre-harvest intervals (as required on the crop protection chemical product labels, manufacturer recommendations and/or by prevailing national/ local standards) the grower should adhere to these pre-harvest intervals time periods.
j. In the situation that the country of production has no or a partial legislative framework covering plant protection products and the use of crop protection products that are registered for the target crop in another country (extrapolation) is not prohibited, the grower must have information for the plant protection products in the country(ies) of destination.
k. There should be evidence available that the grower is taking all the necessary measures to comply with the country(ies) of destination expectations regarding the crop protection products used.
l. Crop protection containers stored on the property (even temporarily) should be stored in a manner to prevent contamination and disposed of responsibly according to the product label, manufacturer recommendation or by prevailing national/ local standards or guidelines.
m. There should be documented policies and/or procedures for the monitoring and maintenance of crop protection application equipment.
n. The equipment used for crop protection applications should be in good working order.

2.10 Field Worker Hygiene *(Applies to on-farm or greenhouse workers not harvesting workers)*

a. There should be a written policy supported by visual evidence that workers who appear to be physically ill or become ill while working, with exposed boils, sores, infected wounds or any other source of abnormal contamination are prohibited from contact with product. This policy should require workers to immediately report illness or symptoms of illness to the management.
b. There should be a written policy supported by visual evidence that workers with exposed boils, sores, infected wounds, or any other source of abnormal contamination should be prohibited from contact with product.
c. Written procedures should be in place describing the disposition of product that has come into contact with blood or other bodily fluids.
d. There should be a written policy supported by visual evidence that eating (including chewing gum, drinking (other than water) and tobacco use is restricted to locations away from the growing area(s).
e. There should be a formal training program for new and existing workers covering current hygiene policies, procedures and requirements of the company. Training should take place at the start of the season and then at least quarterly, ideally monthly. Training materials and hygiene requirements should be available.
f. Toilet facilities should be available for workers:
    i. Located within ¼ mile or 5 minutes walking distance of all workers.
    ii. In a suitable location to prevent contamination to product, packaging, equipment and growing area.
    iii. A minimum of one toilet facility should be provided for each group of 20 workers.
    iv. Toilet facilities should have visuals or signs, written in the appropriate languages, reminding workers to wash their hands before returning to work.
    v. Toilets should be maintained in a clean and sanitary condition with records showing regular toilet cleaning, servicing and stocking.
    vi. Toilet catch basins should be designed and maintained to prevent contamination (e.g. free from leaks and cracks).

vii. For self contained toilets, there should be a documented and implemented procedure for emptying, pumping and cleaning in a manner that prevents product, packaging, equipment, water systems and growing area contamination. The procedure should include a documented response plan for major leaks or spills for the sanitation units.

g. There should be no evidence of human fecal contamination in the growing area, proximity to the growing area, or any of the storage areas.
h. There should be operational hand washing facilities provided:
   i. Located within ¼ mile or 5 minutes walking distance of all workers.
   ii. Clearly visible and easily accessible to workers.
   iii. Properly stocked with soap, paper towels and trash can.
   iv. Designed and maintained to properly to capture or control rinse water.
   v. There should be a documented and implemented policy and procedure in place requiring workers to wash their hands prior to beginning work, after breaks, after toilet use and whenever hands may be contaminated.
i. Fresh potable drinking water should be provided for workers on site. Water containers should be maintained in a clean condition.
j. There should be a first-aid kit available and accessible to workers, stocked with inventory.
k. Trash cans should be available and placed in suitable locations.
l. There should be no foreign material issues that are or could be potential risks to the product in the growing areas (e.g. jewelry, glass items, etc).
m. There should be a written policy supported by visual evidence that infant or toddler aged children are not allowed in the growing operation as well as in or around any packaging, chemical or equipment storage areas.

2.11 Harvesting Inspections, Policies and Training

a. Self-audits should be done for the harvesting operation to identify problems and/or situations which need improvement. Frequency of inspections should be established depending on the type of harvesting activity associated risk pressures. Records should show where corrective actions have been taken.
b. A pre-harvest block inspection should be performed on the block being harvested There should be documentation indicating the blocks have been inspected and cleared for harvest. Where pre-harvest inspection issues arise, buffer zones should be clearly identified and respected.
c. There should be records with corrective actions of daily pre-operation inspections that check key aspects of equipment and tool hygiene, personal hygiene, etc.
d. There should be a documented and implemented policy that when commodities (excludes root crops) are dropped on the ground they are discarded.
e. There should be a formal training program for new and existing workers covering current hygiene policies, procedures and requirements of the company. Training should take place at the start of the season and then at least quarterly, ideally monthly. Training materials and hygiene requirements should be available.
f. There should be a documented and implemented policy stating action if harvesting staff find evidence of animal intrusion e.g. fecal material. The policy should include recorded training, potential corrective actions and recording correctives actions.

2.12 Harvesting Worker Activities & Sanitary Facilities *(Applies to harvesting workers)*

a. Workers should follow appropriate hygiene practices including:

i. No harvesting workers with exposed boils, sores, wounds, symptoms of foodborne illness or any other source of abnormal contamination. All bandages should be covered with a non-porous covering such as non-latex or plastic gloves.
ii. No eating and drinking (other than water) in active harvest areas, areas yet to be harvested, near harvested product or storage areas.
iii. No use of tobacco products in active harvest areas, areas yet to be harvested, near harvested product or storage areas.
iv. Harvester's clothing should not pose a cross contamination risk.
v. No wearing loose objects (e.g. jewelry) above the waist. Jewelry should be confined to a plain wedding band.
vi. Gloves should be appropriate for the type of harvesting, in good condition/repair and latex-free.
vii. Any protective clothing (e.g. gloves, aprons, sleeves) should be removed prior to using restrooms, going on breaks, etc.
viii. Secondary hand sanitation stations should be provided and located near hand washing areas. Stations should be well stocked.

b. Toilet facilities should be available for workers:
i. Located within ¼ mile or 5 minutes walking distance of all workers.
ii. In a suitable location to prevent contamination to product, packaging, equipment and growing area.
iii. Separate toilet facilities provided for men and women in groups larger than 5 workers.
iv. A minimum of one toilet facility should be provided for each group of 20 workers.
v. Toilet facilities should have visuals or signs, written in the appropriate languages, reminding workers to wash their hands before returning to work.
vi. Toilets should be supplied with toilet paper and the toilet paper should be maintained properly.
vii. Toilets should be maintained in a clean and sanitary condition.
viii. Toilets should be constructed of light colored, non-porous materials that are easy to clean and sanitize.
ix. For portable toilets, there should be a documented and implemented policy covering emptying and cleaning; waste should be disposed of properly and the units cleaned at an appropriate location.
x. There should be cleaning records available and for portable toilets, servicing records.
xi. Toilet catch basins should be designed and maintained to prevent contamination (e.g. free from leaks and cracks)
xii. Toilet catch basins should be emptied / pumped in a manner to avoid contamination to product, packaging, equipment and growing areas.

c. There should be no evidence of human fecal contamination in the harvesting area.
d. There should be operational hand washing facilities provided:
i. Located within ¼ mile or 5 minutes walking distance of all workers.
ii. Clearly visible (situated outside the toilet facility) and easily accessible to workers.
iii. Properly stocked with non-perfumed soap, single-use paper towels and trash can.
iv. With extra supplies readily available so that toilets can be restocked quickly in the event of running out of toilet materials (e.g., water, soap, toilet tissue, paper towels).
v. Designed and maintained to prevent contamination i.e. rinse water is captured / controlled, free of clogged drains, etc.
vi. Workers should be washing their hands prior to beginning work, after break periods, after using the toilet and whenever hands may be contaminated.

vii. Corrective action should be taken when workers fail to comply with hand washing guidelines.

e. Fresh potable drinking water and single-use cups should be provided for workers. Water containers should be maintained in a clean condition.
f. There should be first-aid kits available and accessible to workers, stocked with inventory.
g. There should be a documented and implemented policy and procedure in available and followed stating that any commodities that come in contact with blood should be destroyed.
h. Waste and garbage should be disposed of properly from the harvesting areas.
i. Garbage containers should be provided in the field for the disposal of trash. The containers should be constructed and maintained in such manner that protects against contamination of the crop and harvesting areas (e.g. covered or closed to prevent pest attraction).
j. Metal, glass, plastic or other potential contamination issues should be controlled.
k. Infant or toddler aged children should be restricted to areas away from production including chemical or equipment storage areas, to prevent contamination of product or packaging.

2.13 Harvest Practices

a. The harvesting area should be free of evidence of animal presence and/or animal activity and of any evidence of systematic animal fecal contamination.
b. Where the product is packed in the final packing unit in the field:
    i. The packing material (e.g. cartons, bags, clamshells, sacks, RPCs) intended for carrying product should be used for that purpose only and should be free from evidence of pest activity, foreign materials and other signs of hazardous materials.
    ii. The packed product should be free from evidence of pest activity, foreign materials, hazardous materials and any adulteration issues.
    iii. The product and packing material should be free from exposure to the ground and or any handling contamination.
    iv. Packaging materials should be inspected prior to use and after the packing process; when contamination issues are found, corrective action should be recorded.
    v. If packing materials are left in the field overnight they should be secured and protected.
    vi. Finish product containers, cartons or other packing material should display information about recommended storage conditions and usage. Applicable labeling regulations should be observed.
c. Where grading and packing tables are used:
    i. The surface(s) should allow for easy sanitation.
    ii. The grading and/or packing tables should be subject to a documented cleaning program detailing the frequency of cleaning and sanitizing procedures.
    iii. An anti-microbial solution should be used to sanitize surfaces after cleaning has occurred.
    iv. Records of cleaning and sanitation for grading and/or packing tables should be kept.
d. Where re-usable containers are used:
    i. Re-usable containers should be made of easy to clean materials.
    ii. The re-usable containers should be subject to a documented cleaning program detailing the frequency of cleaning and sanitizing procedures.
    iii. An anti-microbial solution should be used to sanitize the re-usable containers after cleaning has occurred.
    iv. Records of cleaning and sanitation for re-usable containers should be kept.
    v. Re-usable containers should be free from any handling contamination.

e. Where tools (e.g. knives, clippers, scissors, etc.) are used in harvesting:

i. They should be made of non-corrosive and easy to clean materials (no wood or fabric parts).
ii. Should not be taken into break or toilet areas or used for any other purpose other than product harvesting.
iii. Should be free from exposure to the ground and or any handling contamination.
iv. Should be subject to control procedures for storage when not in use.
v. There should be a documented cleaning program for tools detailing the frequency of cleaning and sanitizing procedures.
vi. An anti-microbial solution (chlorinated or equivalent) should be used to sanitize the harvesting tools after cleaning has occurred.
vii. Records of cleaning and sanitation for tools should be kept.
viii. Harvesting tool dips solutions should be used and anti-microbial solution strength maintained. Records of the solutions checks should be maintained.

f. Where machinery is used in the harvesting process:
i. Food contact surfaces should be made of non-toxic, non-porous food grade materials (e.g. stainless steel) that are easy to clean. Food contact surfaces on equipment should be free of flaking paint corrosion, rust, etc., and maintained in good condition.
ii. The harvesting machinery should be subject to a documented cleaning program detailing the frequency of cleaning and sanitizing procedures.
iii. An anti-microbial solution (chlorinated or equivalent) should be used to sanitize the harvesting equipment after cleaning has occurred.
iv. Records of cleaning and sanitation for harvesting machinery should be kept.
v. The equipment should be designed and used properly to minimize product contamination (e.g. drip pans utilized, lights protected).
vi. Only food grade lubricants should be used on critical parts of the harvesting machinery that have the potential to contaminate product.
vii. Glass (e.g. lights) on harvesting machinery, in-field trucks and tractors should be protected There should be no evidence of cracked lenses.
viii. All platforms above product, packaging or food contact surfaces (e.g. belts) on the harvest machinery, in-field trucks should be fitted with protection to prevent product contamination.

g. Where water directly contacts edible portions of harvested crop (e.g. rehydration, core-in-field) there should be microbiological water samples collected and tested according to risk assessment and/or expected frequencies. Minimum requirements:
i. Samples should be taken prior to use then ideally monthly, or at frequency relative to the associated risks.
ii. There should be written procedures (SOPs) covering corrective measures for unsuitable or abnormal water test results.
iii. There should be documented corrective measures if there are unsuitable or abnormal results of a microbiological test.
iv. Anti-microbial parameters should be clearly documented and correct for the type anti- microbial being used.
v. Anti-microbial checks should be performed on a routine basis; corrective actions should be recorded when anti-microbial results are less than the stated minimum criteria.

h. Where the harvested product is "in-field processed" or "in-field semi-processed" (e.g. core in field, top & tail, florets, etc.), the process flow, machine layout, worker control, utensil control, etc. should ensure that processed products are not contaminated by unprocessed products.

i. All workers that come in contact with the product being harvested should wear clean protective outer garments (e.g. hairnets, plastic gloves, sleeves and aprons). Protective

outer garments should be removed and kept clean and in a secure area during breaks or when using the toilet facilities.

j. All plastic bins and/or liners should be closed and secured immediately after harvest to avoid contamination of the harvested product.
k. Where there is any post-harvest treatment performed to the product in the field, the following should be checked:
    i. There should be up to date records of all crop protection products applied in the field to the harvested product.
    ii. Grower should be aware of the crop protection products registered and/or authorized by a government agency for use in the target crops in the country of production and have the information available.
    iii. Crop protection applications should be restricted by the guidelines established by the product label, manufacturer recommendation, or by prevailing national/ local standards and guidelines.
    iv. Where the applications or treatments to harvested products are restricted by the guidelines established by product labels, manufacturer recommendations and/or by prevailing national/ local standards) the grower should adhere to these guidelines.
    v. In the situation that the country of production has no or a partial legislative framework covering plant protection products and the use of crop protection products that are registered for the target crop in another country (extrapolation) is not prohibited, the grower must have information for the plant protection products in the country(ies) of destination.
    vi. There should be evidence available that the grower is taking all the necessary measures to comply with the country(ies) of destination expectations regarding the crop protection products used.

2.14 Transportation & Tracking

a. Vehicles transporting fresh produce from field to facility should be limited to this function only and maintained in proper condition.
b. There should be a system in place to ensure product can be traced back to each exact growing location (e.g. grower identification, farm identification, block, etc.).
c. Product that is packed in the field after harvesting should be coded to identify date of harvest and production area information. This identification coding should be present in the primary packaging and if secondary packaging is used, the identification should be present in this also.

2.15 On-site Storage

a. On-site storage for items and/or equipment used in the harvest process (e.g. packing material, cartons, clamshells, re-usable containers, disinfectants, grading/packing tables, RPCs, etc.) should be stored to prevent cross contamination.
b. On-site storage areas should have a sanitation program in place and there should be records of the cleaning and sanitation activities performed.
c. There should be a pest control program implemented in the storage areas with the following characteristics:
    i. Pest control devices should be located away from items or equipment with food contact surfaces to prevent any physical or microbial contamination. Poisonous rodent bait traps should not be used inside any storage areas.

ii. Pest control devices should be maintained in working condition and replaced when damaged so they will accomplish their intended use. Date of inspections should be posted on the devices as well as kept on file.
iii. Pest control devices should be adequate in number and location.
iv. Pest control devices should be identified by a number or other code.
v. Pest control devices should be properly installed and secured.
vi. There should be a schematic drawing of the storage area showing numbered locations of all traps and bait stations, both inside and outside.
vii. There should be service reports created for pest control checks detailing inspection records, application records, and corrective actions if issues are noted.

GMP Option (from 2.16 to 2.31)

2.16 General GMP

a. There should be a person assigned responsibility for the facility food safety program.
b. Chemicals should be stored safely in a designated secured area and labeled correctly.
c. "Food grade" and "non-food grade" chemicals should be handled and stored in a controlled manner.
d. Visible and understood signs supporting appropriate Good Manufacturing Practices should be posted to remind workers of proper practices.
e. The necessary food defense controls should be implemented in the operation.

2.17 Pest Control

a. Products, ingredients and packaging supplies should be free of insects/rodents/birds/reptiles/mammals or any evidence of them.
b. Production and storage areas as well as the exterior of the facility should be free of pest activity.
c. The operation should have a pest control program in place with the following characteristics:
   i. Pest control devices should be located away from exposed food products and poisonous rodent bait traps should not be used within the facility.
   ii. Pest control devices should be maintained in a clean condition and marked as monitored on a regular basis.
   iii. Interior, exterior building perimeter and land perimeter pest control devices should be in the appropriate number and location depending on the facility needs like size, design, level of presence of pests, etc.
   iv. Pest control devices should be identified by a number or other code.
   v. Pest control devices should be properly installed and secured.

2.18 Storage Areas & Packaging Materials

a. Ingredients (including ice), products, and packaging should be stored appropriately to prevent cross contamination including:
   i. Off ground
   ii. Ice should be stored and used appropriately
   iii. Allergen control
   iv. In completely enclosed storage areas.
   v. Storage areas should be clean.
   vi. Non-food handling related items should not be stored in storage areas.

vii. Rejected and on-hold items should be clearly identified and stored separately from other materials.
viii. Storage should be at the appropriate temperatures for the specific products being stored.

b. Products, ingredients (including ice) and food contact packaging should be within accepted tolerances for spoilage or adulteration.
c. Materials, including commodities, packaging, ingredients, processing aids, work in progress, etc., should be properly marked with codes that enable traceability and rotation, which should be done using FIFO policy.

2.19 Operational Practices

a. Process flow, facility layout, worker control, utensil control, internal vehicle use, etc. should ensure that finished (processed) products are not contaminated by raw (unprocessed) products.
b. All exposed materials (product, packaging, etc.) should be protected from overhead contamination.
c. Packing and/or processing areas should be completely enclosed, clean and well maintained.
d. Re-work and re-packaging should be handled correctly to avoid mistaking with other products and maintaining traceability, as well for preventing contamination from environment or other products.
e. Raw ingredients should be examined before use and foreign material control methods (e.g. metal detectors, metal traps, visual inspection, etc.) should be used where appropriate and regularly tested.
f. Finished products should be lot coded in order to ensure an effective trace back and recall program and also for inventory control. Packaging labeling should include information about recommended storage conditions and usage.
g. The facility should have the appropriate test strips, test kits or test probes in operational condition, for verifying the concentrations of anti-microbial chemicals (product washing water, terminal sanitizers, dip stations, etc).
h. Hand washing stations should be provided in adequate number, in location and in good working order, have warm water and be properly stocked.
i. Toilet facilities should be provided in adequate number, in location and be adequately stocked.
j. Non-perfumed secondary hand sanitation stations and foot dip stations should be provided in the necessary locations of the facility and they should be properly maintained.
k. Single services containers should be used for their intended purpose only and re-usable containers should be clearly designated for the specific use.
l. Food safety measuring devices should be calibrated and in good working condition.

2.20 Worker Practices

a. Workers should follow appropriate Good Manufacturing Practices including:
   i. Workers should wash and sanitize their hands before starting work each day, after using the restroom, after breaks and whenever hands may be contaminated.
   ii. Workers' fingernails should be clean, short and if gloves are not used, free of nail polish.
   iii. Workers with boils, sores, open wounds or exhibiting signs of food borne illness should be excluded from operations involving direct and indirect food contact.
   iv. Workers should wear effective hair restraints.
   v. Jewelry should be confined to a plain wedding band.

vi. Workers should wear outer garments suitable for the operation; no items should be stored in top pockets and protective outer garments should be removed and stored in a designated area when on break and before using the toilets and when going home at the end of their shift. Where gloves are used, they should be latex-free.
vii. Workers' personal items should not be stored in the production and material storage areas.
viii. Smoking, eating, chewing and drinking should be confined to designated, non-production areas.
ix. First aid kit(s) should be provided in the facility, adequately supplied with the basic items for handling accidents and readily available for emergency access. Vinyl band aids should be waterproof and blue, that contain a metal strip for lines with metal detectors.

2.21 Equipment

a. Food contact and non-food contact surfaces on the equipment should be free of flaking paint, corrosion, rust and other unhygienic materials.
b. Equipment design and condition should facilitate effective cleaning and maintenance.
c. Monitoring thermometer(s) that are independent from the thermostat probe(s) should be present in all coolers and freezers. Thermometers should be non-glass and non-mercury.

2.22 Equipment Cleaning

a. Food contact and non-food contact surfaces should be clean.
b. Items that are used to hold or store product (barrels, bins, etc.) should be clean.
c. During cleaning foods and packaging should be protected from contamination.
d. Cooling units including coils in coolers and freezers should be clean and free of aged, dirty ice.
e. Fan guards dust-free with the ceiling in front of the fans free of excessive black deposits.
f. Stored equipment that is not used on a daily basis should be stored in a clean condition with food-contact surfaces protected and/or retained on cleaning schedule.
g. All utensils, hoses, and other items not being used should be stored clean and in a manner to prevent contamination.
h. Maintenance tools that are used in the production and storage areas of the facility should be clean, sanitary and corrosion free and stored appropriately to ensure they do not pose a risk of direct or indirect contamination when in production and storage areas.
i. Excess lubricants and grease should be removed from equipment.

2.23 General Cleaning

a. Waste and garbage should be frequently removed from packing and storage areas and spills should be cleaned up immediately.
b. Floor drains should flow in a manner that prevents contamination (e.g. from high to low risk areas, from high risk directly to drain system), covered, clean, free from odors and well maintained.
c. High level areas including overhead pipes, ducts, fans, etc. should be clean.
d. Plastic strip curtains should be maintained in a good condition, kept clean and mounted so that the tips are not touching the floor.
e. Safety equipment for the sanitation crew should be provided. It should be in good condition and stored to prevent cross contamination to ingredients, packaging or product.

f. Cleaning equipment should be available, stored properly and identified in order to prevent potential cross contamination issues. All items used for sanitation should be appropriate for their designated purpose.
g. Toilet facilities, hand wash stations, worker locker and lunchroom facilities should be clean.
h. The maintenance shop should be clean and well ordered.
i. Internal transport vehicles (e.g. forklifts, bobcats, pallet jacks, trolleys, floor cleaners, etc.), should be clean, should not emit toxic fumes and should be used in a sanitary manner.
j. Shipping trucks should be clean and in good condition.

2.24 Buildings and Grounds

a. All lights in the facility that could potentially contaminate raw materials, work in progress, ingredients, finish good, equipment or packaging, should be intact and protected against breakage.
b. Potential wood, metal, glass or plastic contamination issues should be controlled.
c. The facility should eliminate the use of wooden items or surfaces.
d. Lighting should be enough to perform activities in packing and storage areas.
e. The facility should have proper ventilation to remove dust, steam, and odors.
f. Floor surfaces should be in good condition, with no standing water, no debris trapping cracks and easy to clean.
g. Floor drains should be located where they are needed for drainage and cleanup.
h. Buildings should be well maintained to prevent pest entry:
    i. Doors to the outside should be pest proof.
    ii. Dock doors should be fitted with buffers to seal against trucks.
    iii. Dock load levelers and shelters should be maintained in a good condition, pest proof and debris free.
    iv. Exterior walls should be free of holes to exclude pests. All pipes, vents, air ducts should be designed and protected in order to prevent pest entry e.g. by using fine mesh.
    v. Interior walls and ceilings should be free of cracks and crevices to prevent pest harborage and allow proper sanitation.
    vi. False ceiling areas should have access to allow for inspection and cleaning.
    vii. An 18" internal wall perimeter should be maintained within the facility to allow inspection and cleaning.
i. Exterior areas should be well maintained:
    i. The exterior area immediately outside the facility should be free of litter, weeds and standing water.
    ii. Storage of pallets, equipment, tires, etc., should be controlled to prevent pest harborage.
    iii. Pallets should be inspected to separate and replace dirty or broken pallets.
    iv. The area around the dumpster/cull truck/trash area should be clean.
    v. Outside garbage receptacles and dumpsters should be kept covered or closed.
j. All water lines should be protected against back siphonage.
k. The on-site laboratory (where appropriate) should be completely enclosed and separated from production and storage areas.

2.25 Chemical Files

a. There should be copies of all Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file, clear indexed and fully accessible at all times.

b. There should be copies of specimen labels for chemicals used (where the full label is not immediately accessible e.g. rodent chemicals, product sanitizers).
c. There should be a chemical inventory and/or usage log.
d. There should be specific Standard Operating Procedures (SOPs) for the changing and testing of water and ice systems e.g. washing flumes, hydrovacuums, hydrocoolers, ice making machines, ice injectors, etc.

2.26 Pest Control Documentation

a. There should be a documented pest control program, including (where appropriate) a copy of the contract with the extermination company, Pest Control Operator license(s) and insurance documents.
b. There should be a schematic drawing of the facility showing numbered locations of all traps and bait stations, both inside and outside the plant.
c. Service reports should be maintained for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract).

2.27 Operation Monitoring Records

a. Inspection records of incoming goods and incoming trailers should be on file.
b. There should be records for all the process monitoring activities (e.g. pH, water temperature, metal detection, labeling, heating processes, etc.) including anti-microbial strength testing of wash water and ice solutions showing the monitoring frequencies, results and corrective actions if deviations are identified. Anti-microbial in wash water and ice solutions should be tested prior to start up and throughout the production runs.
c. Hand/foot/tool dip stations should be monitored and records of monitoring should be maintained.
d. Where knives or similar cutting hand tools are used, there should be a documented accountability program in place.
e. There should be a daily pre-operation inspection log.
f. The company should perform a documented risk assessment for the facility to identify and control any food safety hazards relevant to facility location and adjacent land use e.g. animal activity, industrial activity, waste water treatment sites (settling ponds, land applications, etc.) or any other potential sources of contamination. All national and local laws pertaining to land use and on-site water treatment systems should be followed. Where necessary, for waste water treatment areas, there should be applicable permits on file and evidence of regulatory and/or third party inspections evidence to ensure that any food safety hazards relevant to waste water treatments (e.g. settling ponds, land applications, etc.) are controlled.
g. There should be an annual certificate of inspection for the backflow prevention systems on water lines into the facility.
h. There should be records of internal audits performed to the operation, including all the details and corrective actions taken.

2.28 Maintenance and Sanitation Files

a. The facility should have a documented preventative maintenance program and schedule operation including production and ancillary equipment, facility structure and fittings.
b. There should be records of maintenance work or repairs ordered with signed work completion records showing that equipment is cleaned and sanitized after maintenance work has been completed.

c. There should be a documented sanitation program in place which includes:
   i. A written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often.
   ii. Written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment.
   iii. Sanitation records, showing cleaning was done, when and who carried out the cleaning.
   iv. Documented procedures and completion records for clean-in-place (CIP) activities, where applicable (e.g. cleaning re-circulating water systems such as washing flumes, ice injectors, etc.).
   v. A routine program and written procedure to validate sanitation effectiveness using rapid post sanitation checks, e.g., ATP measurements.
   vi. Records indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas).
   vii. Records showing cooling units are serviced and cleaned at least on an annual basis or more frequently as required.
d. There should be a documented glass management policy and procedures for handling glass items in the operation.

2.29 Worker Documentation

a. Records should be kept of worker training and worker policies and procedures, including:
   i. Records of new worker food safety (GMP) orientation training (with topics covered and attendees), and a document signed by all workers stating they will comply with the operations' personal hygiene and health policies
   ii. Ongoing worker food safety education training with topics covered and attendees.
   iii. Documented training program with training logs for the sanitation workers including best practices and chemical use details.
   iv. Written procedures in place that requires food handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced.
   v. Written sickness reporting and return to work procedures.
   vi. An worker non-compliance/disciplinary action procedure.
b. Visitors and contractors should be required to sign a log stating that they will comply with the operations' personal hygiene and health policies.

2.30 Testing/Analysis Records

a. There should be records of routine equipment and environmental microbiological testing.
b. There should be at least annual microbiological tests on water used in the facility (sampled from within the facility) and (at least) an annual microbiological test for in-house produced ice or a letter of guarantee from external suppliers of ice.
c. Routine tests should be performed on compressed air that is used directly on food and food contact surfaces.

2.31 Temperature Controlled Storage & Distribution

a. Appropriate temperature monitoring records should be available for:
   i. Final product temperature checks for temperature sensitive product.
   ii. Production and storage rooms (if refrigerated).

iii. Shipping truck temperature checks indicating that the truck was pre-cooled prior to loading and sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.).

2.32 Allergen Control

a. If the production process includes the handling of allergen containing materials, then the following requirements should be observed:
   i. An allergen management plan developed and implemented.
   ii. Adequate storage controls (separation, identification etc.) to ensure that allergens are not contaminating other materials.
   iii. A dedicated production line or adequate clean down and production procedures that prevent allergen cross contamination.
   iv. Utensils and work in progress storage containers identified in order to prevent allergen cross contamination.
   v. Re-work handling take into account the issues associated with allergen containing products.
   vi. Workers trained with respect to allergen risks and the facility allergen cross contamination controls, with the related training records kept.
   vii. Products manufactured on site, labeled correctly with respect to allergens.

3 HACCP

a. This module will not be applicable to field operations, i.e. for activities carried out only in the growing area at farm level.
b. This module will always be applicable to all facility operations.
c. For those facility operations where there are not Critical Control Points identified, some sections of the Module 3 may not be applicable. Applicability should be determined based on the outcome of the documented hazard analysis of all steps of each process.
d. In all cases the HACCP process and system must be in conformance with any applicable legal requirements.

3.1 Preliminary steps

a. There should be a documented list of the team carrying out the HACCP program in the operation, with one leader or coordinator assigned as responsible.
b. At least one member of the HACCP team should have a certificate of a formal HACCP training from a recognized organization, institution or trainer with a minimum duration of 2 days or 16 hours. The rest of the team should have at least an internal training to make sure they are knowledgeable of the principles.
c. There should be a documented product description for the products produced.
d. There should be a documented flow chart of the production process(es) in sufficient detail to completely describe the product handling/processing steps. The flow chart(s) should be verified.
e. A documented hazard analysis for the process should be conducted, showing the various types of hazard, their likelihood of occurrence and their associated severity

3.2 Development of the HACCP Plan

a. For those processes where CCPs have been identified, the criteria for managing and executing the necessary activities in the production line should be developed. For processes not having a CCP identified, it means that these steps are not applicable for the operation; therefore the requirements in the rest of the module are not applicable.

b. The CCP decisions should be made with documented justification and where CCPs are identified, they should be developed to control the hazards identified.
c. CCP critical control limits should be established with the support of relevant sources of information or by validation documentation.
d. Monitoring requirements and frequencies should be determined for the CCPs.
e. Documented procedures should be developed for the monitoring process of the CCPs, which should include how to carry out the monitoring activities.
f. Corrective Action procedures for the CCPs should be established, including a detailed action plan for operators to follow if the limits are not met and plans to adjust the process back into control.
g. Recording templates (recording forms) should be developed for monitoring the CCPs.
h. Specific responsibilities should be assigned for the monitoring, recording and corrective action management of each CCP.
i. Verification plans and schedules should be developed for each CCP.
j. Any changes in the process, equipment, ingredients etc., should cause timely reviews of HACCP systems, including hazard analysis, CCP decisions, CCP records and staff training.
k. There should be evidence recorded for HACCP training to all plant workers, including training for CCP operators.

3.3 Execution of the HACCP plan on the Plant Floor

a. All of the documents noted in the HACCP plan should be in place for real time monitoring of the CCPs.
b. The CCP monitoring activities and frequencies should be in compliance with the plan.
c. CCP operators should understand basic HACCP principles and their role in monitoring CCPs.
d. CCP monitoring records should be signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check.
e. Corrective actions should be detailed in writing when the failure of a CCP occurs or in case of a verification step shows a deviation against the HACCP Plan.
f. The CCP records should be reviewed and signed off daily by the quality control supervisor and/or management. The sign off should not be done by the same person who carried out the monitoring.
g. Any other CCP verification performed should be according to the HACCP Plan. Where verification activities have found that CCPs were not performing as required there should be records that show that this has prompted a review of the relevant part of the HACCP program.