ANNEXURE- II (a)

AGREEMENT ON THE APPLICATION OF

SANITARY AND PHYTOSANITARY MEASURES

("SPS Agreement")

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all

Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and

recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX (b) 1;

Hereby agree as follows:

Article 1: General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.

2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.

3. The annexes are an integral part of this Agreement.

4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement

Article 2: Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3: Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human,

animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.2 Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4: Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other

Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative

approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose them.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.3

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the

potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6: Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, ***inter alia*****,** the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7: Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8: Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9: Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, ***inter alia*****,** in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfill the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10: Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11: Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

Article 12: Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can

enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in therelevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, ***inter alia*****,** to the experience gained in its implementation.

Article 13: Implementation

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by

other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or nongovernmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14: Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

ANNEX A: DEFINITIONS[4]

1. ***Sanitary or phytosanitary measure*** - Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, ***inter alia*****,** end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. ***Harmonization*** - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. *International standards, guidelines and recommendations*

(a) For food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) For animal health and zoo noses, the standards, guidelines and recommendations developed under the auspices of the International Office of

Epizootics;

(c) For plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) For matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. ***Risk assessment*** - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. ***Pest- or disease-free area*** - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area – whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

ANNEX B: TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations5 which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

(a) Any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) Any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

(c) Risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) The membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements

within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals 6 of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) Publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) Notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) Provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) Without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) Immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) Provides, upon request, copies of the regulation to other Members;

(c) Allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

(a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

ANNEX C: CONTROL, INSPECTION AND APPROVAL PROCEDURES

1. Members shall ensure, with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that:

(a) Such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

(b) The standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

(c) Information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

(d) The confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favorable than for domestic products and in such a manner that legitimate commercial interests are protected;

(e) Any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

(f) Any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;

(g) The same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;

(h) Whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

(i) A procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

ANNEXURE- II (b)

CODE OF HYGIENIC PRACTICES FOR FRESH FRUITS AND VEGETABLES (CODEX)

Introduction

Scientific research over the last decades has shown that a diet rich in fruits and vegetables is protective against many cancers and lowers the occurrence of coronary heart disease. This recognition of the importance of routine consumption of fresh fruits and vegetables, together with a marked increase in the year-round availability of fresh fruits and vegetables from a global market, has contributed to the substantial increase in consumption of fresh fruits and vegetables over the past two decades. However, the recent increase in reports of food borne illness associated with fresh fruits and vegetables has raised concerns from public health agencies and consumers about the safety of these products.

1. Objectives of the code

This code addresses Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) that will help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing. Particular attention is given to minimizing microbial hazards. The code provides a general framework of recommendations to allow uniform adoption by this sector rather than providing detailed recommendations for specific agricultural practices, operations or commodities. The fresh fruit and vegetable industry is very complex. Fresh fruits and vegetables are produced and packed under diverse environmental conditions. It is recognized that some of the provisions in this code may be difficult to implement in areas where primary production is conducted in small holdings, in both developed and developing countries and also in areas where traditional farming is practised. Therefore, the code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination for different groups of commodities.

2. Scope, use and definitions

2.1 Scope

This code of practice covers general hygienic practices for the primary production and packing of fresh fruits and vegetables cultivated for human consumption in order to produce a safe and wholesome product: particularly for those intended to be consumed raw. Specifically, this code is applicable to fresh fruits and vegetables grown in the field (with or without cover) or in protected facilities (hydroponics systems, greenhouses). It concentrates on microbial hazards and addresses physical and chemical hazards only in so far as these relate to GAPs and GMPs.

The Annex for Ready –to-eat Fresh Pre-cut Fruits and Vegetables (Annex I) and the Annex for Sprout Production (Annex II) are supplements to this code and include additional recommendations to cover, respectively, the hygienic practices for the processing of ready-to-eat fresh pre-cut fruits and vegetables, and the hygienic practices that are specific for the primary production of seeds for sprouting and the production of sprouts for human consumption. The code does not provide recommendations for handling practices to maintain the safety of fresh fruits and vegetables at wholesale, retail, food services or in the home. It excludes food products for which there is a specific Codex Alimentarius Code of Hygienic Practices.

2.2 Use

This code follows the format of the Codex Recommended International Code of Practice – General Principles of Food Hygiene- CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with it. This code focuses upon hygienic issues that are specific to the primary production and packing of fresh fruits and vegetables. The major issues are covered in Section 3. In other sections, the General Principles of Food Hygiene have been expanded where there are issues specific to primary production and packing. The Annex for Ready-to-Eat Fresh Pre-Cut Fruits and Vegetables provides additional recommendations specific for the processing of ready-to-eat fresh pre-cut fruits and vegetables and the Annex for Sprout Production provides additional recommendations

specific for the primary production of seeds for sprouting and the production of sprouts for human consumption.

2.3 Definitions

Definitions of general expressions are included in the General Principles of Food Hygiene. For the purpose of this code, the following terms have the definition stated:

Agricultural inputs - any incoming material (e.g. seeds, fertilizers, water, agricultural chemicals, plant support, etc.) used for the primary production of fresh fruits and vegetables.

Agricultural worker - any person that undertakes one or more of the following: cultivation, harvesting and packing of fresh fruits and vegetables.

Antimicrobial agents - any substance of natural, synthetic or semi-synthetic origin which at low concentrations kills or inhibits the growth of microorganisms but causes little or no host damage.

Biological control - the use of competing biological (such as insects, microorganisms and/or microbial metabolites) for the control of mites, pests, plant pathogens and spoilage organisms.

Biosolids - Sludge and other residue deposits obtained from sewage treatment plants and from treatment applied to urban and industrial wastes (food industries or other types of industry).

Composting - a managed process in which organic materials are digested aerobically or anaerobically by microbial action.

Cultivation- any agricultural action or practice used by growers to allow and improve the growing conditions of fresh fruits or vegetables grown in the field (with of without cover) or in protected facilities (hydroponics systems, greenhouses).

Farm - any premise or establishment in which fresh fruits and/or vegetables are grown and harvested and the surroundings under the control of the same management.

Grower - the person responsible for the management of the primary production of fresh fruits and vegetables.

Harvester - the person responsible for the management of the harvesting of fresh fruits and vegetables.

Hazard – a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazardous material - any compound which, at specific levels, has the potential to cause adverse health effects. Hydroponics - a general term for the production of plants without soil in a water medium.

Manure - Animal excrement which may be mixed with litter or other material, and which may be fermented or otherwise treated.

Micro organisms -include yeasts, moulds, bacteria, viruses and parasites. When used as an adjective, the term "microbial" is used.

Packer - the person responsible for the management of post-harvest processing and packing of fresh fruits and vegetables.

Packing -the action of putting fresh fruits and vegetables in a package. This may take place in a field or in an establishment.

Packing establishment - any indoor establishment in which fresh fruits and vegetables receive post harvest treatment and are packaged.

Primary production - those steps involved in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc.

Types of Water

Clean water - water that does not compromise food safety in the circumstances of its use.

Potable water - water which meets the quality standards of drinking water such as described in the WHO Guidelines for Drinking Water Quality.

3. Primary production

Fresh fruits and vegetables are grown and harvested under a wide range of climatic and diverse geographical conditions, using various agricultural inputs and technologies, and on farms of varying sizes. Biological, chemical and physical hazards may therefore vary significantly from one type of production to another. In each primary production area, it is necessary to consider the particular agricultural practices that promote the production of safe fresh fruits and vegetables, taking into account the conditions specific to the primary production area, type of products, and methods used. Procedures associated with primary production should be conducted under good hygienic conditions and should minimize potential hazards to health due to the contamination of fresh fruits and vegetables.

3.1. Environmental hygiene

Where possible, potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in or on fresh fruits and vegetables after harvest. Where possible, growers should evaluate the previous uses of the sites (indoor and outdoor) as well as adjoining sites in order to identify potential microbial, chemical and physical hazards. The potential for other types of contamination (e.g., from agricultural chemicals, hazardous wastes, etc.) should also be considered. The evaluation process should include the following:

• Previous and present usage of the primary production area and the adjoining sites (e.g. crop grown, feed lot, animal production, hazardous waste site, sewage treatment site, mining extraction site) to identify potential microbial hazards including faecal contamination and contamination by organic waste and potential environmental hazards that could be carried to the growing site.

• The access of farm and wild animals to the site and to water sources used in primary production to identify potential faecal contamination of the soils and water and the likelihood of contaminating crop. Existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with crops. Considering this potential source of contamination, efforts should be made to protect fresh produce growing areas from animals. As far as possible, domestic and wild animal should be excluded from the area.

• Potential for contaminating produce fields from leaking, leaching or overflowing manure storage sites and flooding from polluted surface waters.

If previous uses cannot be identified, or the examination of the growing or adjoining sites leads to the conclusion that potential hazards exist, the sites should be analysed for contaminants of concern. If the contaminants are at excessive levels and corrective or preventative actions have not been taken to minimize potential hazards, the sites should not be used until correction/control measures are applied.

3.2 Hygienic primary production of fresh fruits and vegetables

3.2.1 Agricultural input requirements

Agricultural inputs should not contain microbial or chemical contaminants (as defined under the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3 (1997) at levels that may adversely affect the safety of fresh fruits and vegetables and taking into consideration the WHO guidelines on the safe use of wastewater and excreta in agriculture and aquaculture as appropriate.

3.2.1.1 Water for primary production

• Growers should identify the sources of water used on the farm (municipality, re-used irrigation water, well, open canal, reservoir, rivers, lakes, farm ponds etc.). They should assess its microbial and chemical quality, and its suitability for intended use, and identify corrective actions to prevent or minimize contamination (e.g. from livestock, sewage treatment, human habitation).

• Where necessary, growers should have the water they use tested for microbial and chemical contaminants. The frequency of testing will depend on the water source and the risks of environmental contamination including intermittent or temporary contamination (e.g. heavy rain, flooding, etc.). If the water source is found to be contaminated corrective actions should be taken to ensure that the water is suitable for its intended use.

3.2.1.1.1 Water for irrigation and harvesting

Water used for agricultural purposes should be of suitable quality for its intended use. Special attention to water quality should be considered for the following situations:
• Irrigation by water delivery techniques that expose the edible portion of fresh fruits and vegetables directly to water (e.g. sprayers) especially close to harvest time.
• Irrigation of fruits and vegetables that have physical characteristics such as leaves and rough surfaces which can trap water.
• Irrigation of fruits and vegetables that will receive little or no post-harvest wash treatments prior to packing, such as field-packed produce.

3.2.1.1.2 Water for fertilizers, pest control and other agricultural chemicals

Water used for the application of water-soluble fertilizers and agricultural chemicals in the field and indoors should not contain microbial contaminants at levels that may adversely affect the safety of fresh fruits and vegetables. Special attention to the water quality should be considered when using fertilizer and agricultural chemical delivery techniques (e.g. sprayers) that expose the edible portion of fresh fruits and vegetables directly to water especially close to harvest time.

3.2.1.1.3 Hydroponics water Plants grown in hydroponics systems absorb nutrients and water at varying rates, constantly changing the composition of the re-circulated nutrient solution. Because of this:

• Water used in hydroponics culture should be changed frequently, or if recycled, should be treated to minimize microbial and chemical contamination.

• Water delivery systems should be maintained and cleaned, as appropriate, to prevent microbial contamination of water.

3.2.1.2 Manure, biosolids and other natural fertilizers

The use of manure, biosolids and other natural fertilizers in the production of fresh fruits and vegetables should be managed to limit the potential for microbial, chemical and physical contamination. Manure, biosolids and other natural fertilizers contaminated with heavy metals or other chemicals at levels that may affect the safety of fresh fruits and vegetables should not be used. Where necessary, in order to minimize microbial contamination the following practices should be considered:

• Adopt proper treatment procedures (e.g. composting, pasteurization, heat drying, UV irradiation, alkali digestion, sun drying or combinations of these) that are designed to reduce or eliminate pathogens in manure, biosolids and other natural fertilizers. The level of pathogen reduction achieved by different treatments should be taken into account when considering suitability for different applications.

• Manure, biosolids and other natural fertilizers which are untreated or partially treated may be used only if appropriate corrective actions are being adopted to reduce microbial contaminants such as maximizing the time between application and harvest of fresh fruits and vegetables.

• Growers who are purchasing manure, biosolids and other natural fertilizers that have been treated to reduce microbial or chemical contaminants, should, where possible, obtain documentation from the supplier that identifies the origin, treatment used, tests performed and the results thereof.

• Minimize direct or indirect contact between manure, biosolids and other natural fertilizers, and fresh fruits and vegetables, especially close to harvest.

• Minimize contamination by manure, biosolids and other natural fertilizers from adjoining fields. If the potential for contamination from the adjoining fields is identified, preventative actions (e.g. care during application and run-off controls) should be implemented to minimize the risk.
• Avoid locating treatment or storage sites in proximity to fresh fruit and vegetable production areas. Prevent cross-contamination from runoff or leaching by securing areas where manure, biosolids and other natural fertilizers are treated and stored.

3.2.1.3 Soil

Soils should be evaluated for hazards. If the evaluation concludes that such hazards are at levels that may compromise the safety of crops, control measures should be implemented to reduce hazards to acceptable levels. If this cannot be achieved by available control measures, growers should not use these soils for primary production.

3.2.1.4 Agricultural chemicals

• Growers should use only agricultural chemicals which are authorized for the cultivation of the specific fruit or vegetable and should use them according to the manufacturer's instructions for the intended purpose. Residues should not exceed levels as established by the Codex Alimentarius Commission.
• In order to minimize and contain the emergence of microbial resistance the use of antimicrobial agents significant to human and animal therapy should be avoided.
• Antimicrobial agents not significant to human and animal therapy should be used only when unavoidable and in accordance with good agricultural practices and in a manner that achieves this objective.
• Agricultural workers who apply agricultural chemicals should be trained in proper application procedures.
• Growers should keep records of agricultural chemical applications. Records should include information on the date of application, the chemical used, the crop sprayed, the pest or disease against which it was used, the concentration, method and frequency of application, and records on harvesting to verify that the time between applications and harvesting is appropriate.

• Agricultural chemical sprayers should be calibrated, as necessary, to control the accuracy of the rate of application.
• The mixing of agricultural chemicals should be carried out in such a way as to avoid contamination of water and land in the surrounding areas and to protect employees involved in this activity from potential hazards.
• Sprayers and mixing containers should be thoroughly washed after use, especially when used with different agricultural chemicals on different crops, to avoid contaminating fruits and vegetables.
• Agricultural chemicals should be kept in their original containers, labeled with the name of the chemical and the instructions for application. Agricultural chemicals should be stored in a safe, well ventilated place, away from production areas, living areas and harvested fruits or vegetables, and disposed of in a manner that does not pose a risk of contaminating crops, the inhabitants of the area, or the environment of the primary production.
• Empty containers should be disposed of as indicated by the manufacturer. They should not be used for other food-related purposes.

3.2.1.5 Biological control

Environmental and consumer safety should be considered when using competing biological organisms and/or their metabolites applied for the control of pests, mites, plant pathogens and spoilage organisms in fresh fruits and vegetables. Growers should use only biological controls which are authorized for the cultivation of the specific fruit or vegetable and should use them according to the manufacturer's instructions for the intended purpose.

3.2.2 Indoor facilities associated with growing and harvesting

For operations where fresh fruits and vegetables are grown indoors (greenhouses, hydroponics culture, etc.) suitable premises should be used.

3.2.2.1 Location, design and layout

• Premises and structures should be located, designed and constructed to avoid contaminating fresh fruits and vegetables and harboring pests such as insects, rodents and birds.
• Where appropriate, the internal design and layout should permit compliance with good hygienic practices for the primary production of fresh fruits and vegetables indoors, including protection against cross-contamination between and during operations. Each establishment should be evaluated individually in order to identify specific hygienic requirements for each product.

3.2.2.2 Water supply

Where appropriate an adequate supply of potable or clean water with appropriate facilities for its storage and distribution should be available in indoor primary production facilities. Non-potable water should have a separate system. Non-potable water systems should be identified and should not connect with, or allow reflux into, potable water systems.
• Avoid contaminating potable and clean water supplies by exposure to agricultural inputs used for growing fresh produce.
• Clean and disinfect potable and clean water storage facilities on a regular basis.
• Control the quality of the water supply.

3.2.2.3 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. These systems should be designed and constructed so that the potential for contamination of fresh fruits and vegetables, agricultural inputs or the potable water supply is avoided.

3.2.3 Personnel health, hygiene and sanitary facilities

Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with fresh fruits and vegetables during or after harvesting are not likely to contaminate them.
Visitors should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

3.2.3.1 Personnel hygiene and sanitary facilities

Hygienic and sanitary facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained. As far as possible, such facilities should:
• Be located in close proximity to the fields and indoor premises, and in sufficient number to accommodate personnel.
• Be of appropriate design to ensure hygienic removal of wastes and avoid contamination of growing sites, fresh fruits and vegetables or agricultural inputs.
• Have adequate means of hygienically washing and drying hands.
• Be maintained under sanitary conditions and good repair.

3.2.3.2 Health status

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through fresh fruits and vegetables, should not be allowed to enter any food handling area if there is a likelihood of their contaminating fresh fruits and vegetables. Any person so affected should immediately report illness or symptoms of illness to the management.

3.2.3.3 Personal cleanliness

Agricultural workers who have direct contact with fresh fruits and vegetables should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing and footwear.
Cuts and wounds should be covered by suitable waterproof dressings when personnel are permitted to continue working. Personnel should wash their hands when handling

fresh fruits and vegetables or other material that comes in contact with them. Personnel should wash their hands before starting work involving the handling of fruits and vegetables, each time they return to handling areas after a break, immediately after using the toilet or after handling any contaminated material where this could result in contamination of fresh fruits and vegetables.

3.2.3.4 Personal behaviour

Agricultural workers should refrain from behaviour which could result in the contamination of food, for example: smoking, spitting, chewing gum or eating, or sneezing or coughing over unprotected fresh fruits and vegetables. Personal effects such as jewellery, watches, or other items should not be worn or brought into fresh fruit and vegetable production areas if they pose a threat to the safety and suitability of the food.

3.2.4 Equipment associated with growing and harvesting

As required, growers and harvesters should follow the technical specifications recommended by the equipment manufacturers for their proper usage and maintenance. Growers and harvesters should adopt the following sanitary practices:

• Equipment and containers coming into contact with fresh fruits and vegetables should be made of materials that are non-toxic. They should be designed and constructed to ensure that, when necessary, they can be cleaned, disinfected and maintained to avoid the contamination of fresh fruit and vegetables. Specific hygienic and maintenance requirements should be identified for each piece of equipment that is used and the type of fruit or vegetable associated with it.

• Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Where appropriate, such containers should be lockable to prevent malicious or accidental contamination of fresh fruits and vegetables or agricultural inputs. Such containers should be segregated or otherwise identified to prevent their use as harvesting containers.

• Containers that can no longer be kept in a hygienic condition should be discarded.

• Equipment and tools should function according to the use for which they are designed without damaging the produce. Such equipment should be maintained in good order.

3.3 Handling, storage and transport

3.3.1 Prevention of cross-contamination

During the primary production and post-harvest activities, effective measures should be taken to prevent cross-contamination of fresh fruits and vegetables from agricultural inputs or personnel who come directly or indirectly into contact with fresh fruits and vegetables. To prevent the potential of cross contaminating fresh fruits and vegetables, growers, harvesters and their employees should adhere to the recommendations presented elsewhere in section 3 of this code and the following:

• At the time of harvest, consideration should be given to the need for additional management action where any local factor, for example adverse weather conditions, may increase the opportunity for contamination of the crop.

• Fresh fruits and vegetables unfit for human consumption should be segregated during harvesting. Those which cannot be made safe by further processing should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.

• Agricultural workers should not use harvesting containers for carrying materials (e.g. lunches, tools, fuel, etc.) other than harvested fruits and vegetables.

• Equipment and containers previously used for potentially hazardous materials (e.g. garbage, manure, etc.) should not be used for holding fresh fruits or vegetables or have contact with packaging material that is used for fresh fruits and vegetables without adequate cleaning and disinfecting.

• Care must be taken when packing fresh fruits and vegetables in the field to avoid contaminating containers or bins by exposure to, manure or animal/human faeces.

3.3.2 Storage and transport from the field to the packing facility

Fresh fruits and vegetables should be stored and transported under conditions which will minimize the potential for microbial, chemical or physical contamination. The following practices should be adopted:

• Storage facilities and vehicles for transporting the harvested crops should be built in a manner to minimize damage to fresh fruits and vegetables and to avoid access by pests. They should be made of non-toxic materials that permit easy and thorough cleaning. They should be constructed in a manner to reduce the opportunity for potential contamination from physical objects such as glass, wood, plastic, etc.
• Fresh fruits and vegetables unfit for human consumption should be segregated before storage or transport. Those which cannot be made safe by further processing should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.
• Agricultural workers should remove as much soil as possible from fresh fruits and vegetables before they are stored or transported. Care should be taken to minimize physical damage to crop during this process.
• Transport vehicles should not be used for the transport of hazardous substances unless they are adequately cleaned, and where necessary disinfected, to avoid cross-contamination.

3.4 Cleaning, maintenance and sanitation

Premises and harvesting equipment should be kept in an appropriate state of repair and condition to facilitate cleaning and disinfection. Equipment should function as intended to prevent contamination of fresh fruits and vegetables. Cleaning materials and hazardous substances such as agricultural chemicals should be specifically identifiable and kept or stored separately in secure storage facilities. Cleaning materials and agricultural chemicals should be used according to manufacturer's instructions for their intended purpose.

3.4.1 Cleaning programs

Cleaning and disinfection programs should be in place to ensure that any necessary cleaning and maintenance is carried out effectively and appropriately. Cleaning and disinfection systems should be monitored for effectiveness and should be regularly reviewed and adapted to reflect changing circumstances. Specific recommendations are as follows:

• Harvesting equipment and re-usable containers that come in contact with fresh fruits and vegetables should be cleaned, and, where appropriate, disinfected on a regular basis.
• Harvesting equipment and re-usable containers used for fresh fruits and vegetables that are not washed prior to packing should be cleaned and disinfected as necessary.

3.4.2 Cleaning procedures and methods

The appropriate cleaning methods and materials will depend on the type of equipment and the nature of the fruit or vegetable. The following procedure should be adopted:
• Cleaning procedures should include the removal of debris from equipment surfaces, application of a detergent solution, rinsing with water, and, where appropriate, disinfection.

3.4.3 Pest control systems

When primary production is carried out in indoor establishments (e.g. greenhouses), the recommendations of the General Principles of Food Hygiene, section 6.3 should be followed with respect to pest control.

3.4.4 Waste management

Suitable provision must be made for the storage and removal of waste. Waste must not be allowed to accumulate in fresh fruit and vegetable handling and storage areas or the adjoining environment. Storage areas for waste should be kept clean.

4. Packing establishment: design and facilities

Refer to the General Principles of Food Hygiene.

5. Control of operation

5.1 Control of food hazards

Refer to the General Principles of Food Hygiene.

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

Refer to the General Principles of Food Hygiene.

5.2.2 Specific process steps

5.2.2.1 Post-harvest water use

Water quality management will vary throughout all operations. Packers should follow GMPs to prevent or minimize the potential for the introduction or spread of pathogens in processing water. The quality of water used should be dependent on the stage of the operation. For example, clean water could be used for initial washing stages, whereas water used for final rinses should be of potable quality.

• Post-harvest systems that use water should be designed in a manner to minimize places where product lodges and dirt builds up.

• Antimicrobial agents should only be used where absolutely necessary to minimize cross contamination during post-harvest and where their use is in line with good hygienic practices. The antimicrobial agent's levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of antimicrobial agents, followed by a wash as necessary, should be done to ensure that chemical residues do not exceed levels as recommended by the Codex Alimentarius Commission.

• Where appropriate, the temperature of the post-harvest water should be controlled and monitored.

• Recycled water should be treated and maintained in conditions that do not constitute a risk to the safety of fresh fruits and vegetables. The treatment process should be effectively monitored and controlled.

• Recycled water may be used with no further treatment provided its use does not constitute a risk to the safety of fresh fruits and vegetables (e.g. use of water recovered from the final wash for the first wash).

• Ice should be made from potable water. Ice should be produced, handled and stored to protect it from contamination.

5.2.2.2 Chemical treatments

• Packers should only use chemicals for post-harvest treatments (e.g. waxes, fungicides) in accordance with the General Standards on Food Additives or with the Codex Pesticide Guidelines. These treatments should be carried out in accordance with the manufacturer's instructions for the intended purpose.
• Sprayers for post-harvest treatments should be calibrated regularly to control the accuracy of the rate of application. They should be thoroughly washed in safe areas when used with different chemicals and on different fruits or vegetables to avoid contaminating the produce.

5.2.2.3 Cooling of fresh fruits and vegetables

• Condensate and defrost water from evaporator type cooling systems (e.g. vacuum cooling, cold rooms) should not drip onto fresh fruits and vegetables. The inside of the cooling systems should be maintained clean.
• Potable water should be used in cooling systems where water or ice is in direct contact with fresh fruits and vegetables (e.g. hydro cooling, ice cooling). The water quality in these systems should be controlled and maintained.
• Forced-air cooling is the use of rapid movement of refrigerated air over fresh fruits and vegetables in cold rooms. Air cooling systems should be appropriately designed and maintained to avoid contaminating fresh produce.

5.2.2.4 Cold storage

• When appropriate, fresh fruits and vegetables should be maintained at low temperatures after cooling to minimize microbial growth. The temperature of the cold storage should be controlled and monitored.
• Condensate and defrost water from the cooling system in cold storage areas should not drip on to fresh fruits and vegetables. The inside of the cooling systems should be maintained in a clean and sanitary condition.

5.2.3 Microbiological and other specifications

Refer to the General Principles of Food Hygiene.*

5.2.4 Microbial cross-contamination

Refer to the General Principles of Food Hygiene. *

5.2.5 Physical and chemical contamination

Refer to the General Principles of Food Hygiene. *

5.3 Incoming material requirements

Refer to the General Principles of Food Hygiene. *

5.4 Packing

Refer to the General Principles of Food Hygiene. *

5.5. Water used in the packing establishment

Refer to the General Principles of Food Hygiene. *

5.6 Management and supervision

Refer to the General Principles of Food Hygiene. *

5.7 Documentation and records

Where appropriate, records of processing, production and distribution should be kept long enough to facilitate a recall and food borne illness investigation, if required. This period could be much longer than the shelf life of fresh fruits and vegetables. Documentation can enhance the credibility and effectiveness of the food safety control system.

• Growers should keep current all relevant information on agricultural activities such as the site of production, suppliers' information on agricultural inputs, lot numbers of agricultural inputs, irrigation practices, use of agricultural chemicals, water quality data, pest control and cleaning schedules for indoor establishments, premises, facilities, equipment and containers.

• Packers should keep current all information concerning each lot such as information on incoming materials (e.g. information from growers, lot numbers), data on the quality of processing water, pest control programmes, cooling and storage temperatures, chemicals used in post-harvest treatments, and cleaning schedules for premises, facilities, equipment and containers, etc.

5.8 Recall procedures

Refer to the General Principles of Food Hygiene.
In addition, where appropriate:
• Growers and packers should have programs to ensure effective lot identification. These programs should be able to trace the sites and agricultural inputs involved in primary production and the origin of incoming material at the packing establishment in case of suspected contamination.
• Growers' information should be linked with packers' information so that the system can trace products from the distributor to the field. Information that should be included is the date of harvest, farm identification, and, where possible, the persons who handled the fresh fruits or vegetables from the primary production site to the packing establishment.

6. Packing establishment: maintenance and sanitation

Refer to the General principles of Food Hygiene. *

7. Packing establishment: personal hygiene

Refer to the General Principles of Food Hygiene. *

8. Transportation

Refer to the General Principles of Food Hygiene* and to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food.

9. Product information and consumer awareness

Refer to the General Principles of Food Hygiene. *

10. Training

Refer to the General Principles of Food Hygiene except for section 10.1 and 10.2. *

10.1 Awareness and responsibilities

Personnel associated with growing and harvesting should be aware of GAPs, good hygienic practices and their role and responsibility in protecting fresh fruits and vegetables from contamination or deterioration. Agricultural workers should have the necessary knowledge and skills to enable them to carry out agricultural activities and to handle fresh fruits and vegetables and agricultural inputs hygienically. Personnel associated with packing should be aware of GMPs, good hygienic practices and their role and responsibility in protecting fresh fruits and vegetables from contamination or deterioration. Packers should have the necessary knowledge and skills to enable them to perform packing operations and to handle fresh fruits and vegetables in a way that minimizes the potential for microbial, chemical, or physical contamination. All personnel who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques. They should be aware of their role and responsibility in protecting fresh fruit and vegetables from contamination during cleaning and maintenance.

10.2 Training programmes

Factors to take into account in assessing the level of training required in growing, harvesting and packing activities include:

• The nature of the fruit or vegetable, in particular its ability to sustain growth of pathogenic microorganisms.

• The agricultural techniques and the agricultural inputs used in the primary production including the probability of microbial, chemical and physical contamination.

• The task the employee is likely to perform and the hazards and controls associated with those tasks.

• The manner in which fresh fruits and vegetables are processed and packaged including the probability of contamination or microbial growth.

• The conditions under which fresh fruits and vegetables will be stored.

• The extent and nature of processing or further preparation by the consumer before final consumption.

Topics to be considered for training programmes include, but are not limited to, the following:

• The importance of good health and hygiene for personal health and food safety.

• The importance of hand washing for food safety and the importance of proper hand washing techniques.

• The importance of using sanitary facilities to reduce the potential for contaminating fields, produce, other workers, and water supplies.

• Techniques for hygienic handling and storage of fresh fruits and vegetables by transporters, distributors, storage handlers and consumer.

ANNEX FOR READY-TO-EAT FRESH PRE-CUT FRUITS AND VEGETABLES

Introduction

The health benefits associated with fresh fruits and vegetables combined with the on–going consume interest in the availability of a variety of ready-to-eat foods have contributed to a substantial increase in the popularity of pre-cut fruits and vegetables. Because of the increased convenience and consumption of pre-cut fruits and vegetables in and away from the home, the preparation of these products has moved from the point of consumption to the food processor or retailer. The processing of fresh produce without proper sanitation procedures in place in the manufacturing environment may enhance the potential for contamination by microbiological pathogens. The potential for pathogens to survive or grow may be enhanced by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process to eliminate them, and the potential for temperature abuse during processing, storage, transport, and retail display. Some of the microbiological pathogens associated with fresh fruits and vegetables include Salmonella spp., Shigella spp., pathogenic strains of Escherichia coli, Listeria mono cytogenes, Norwalk-like virus and hepatitis A virus and parasites such as Cyclospora. Some of these pathogens are associated with the agricultural environment, whereas others are associated with infected workers or contaminated water. Because of the ability for pathogens to survive and grow on fresh

produce, it is important for the pre-cut industry to follow good hygienic practices to ensure the microbiological safety of its products.

1. Objective

Hygienic recommendations for the primary production of fresh fruits and vegetables are covered under the Code of Practice for Fresh Fruits and Vegetables. This Annex recommends the application of Good Manufacturing Practices (GMPs) for all stages involved in the production of ready-to-eat fresh pre-cut fruits and vegetables, from receipt of raw materials to distribution of finished products.

The primary objective of this Annex is to identify GMPs that will help control microbiological,

Physical and chemical hazards associated with the processing of fresh pre-cut fruits and vegetables. Particular attention is given to minimizing microbiological hazards. This Annex provides elements that should be taken into account in the production, processing and distribution of these foods.

2. Scope, use and definitions

2.1 Scope

This Annex specifically applies to ready-to-eat fresh fruit and vegetables that have been peeled, cut or otherwise physically altered from their original form but remain in the fresh state and particularly those that are intended to be consumed raw. This Annex applies irrespective of where the operations take place (e.g. in the field, at the farm, at the retailer, at the wholesaler, at the processing establishment, etc.). For some establishments that process fresh pre-cut fruit and vegetables, this Annex will cover all operations from receipt of raw material to the distribution of the final product. For other establishments, (e.g. those that use ready-to-eat pre-cut fresh fruit and vegetables in combination with other products, such as sauces, meat, cheese, etc.) only the specific sections that relate to the processing of the fresh precut fruit and vegetable components will apply.

This Annex does not directly apply to fresh fruit and vegetables that have been trimmed leaving the food intact. Nor does it apply to other fresh fruit and vegetables that are pre-cut but are destined for further processing that would be expected to eliminate any pathogen that may be present (e.g. cooking, juice processing, fermentation) nor to fresh fruit or vegetable juices. However, some of the basic principles of the Annex could still be applicable to such products.

Packaging includes single serving containers (e.g., sealed pouches or plastic trays), larger consumer or institutional size packages and bulk containers. This Annex concentrates on microbial hazards and addresses physical and chemical hazards only in so far as these relate to GMPs.

2.2 Use

This document follows the format of the Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables.

2.3 Definitions

Processor - the person responsible for the management of the activities associated with the production of ready-to-eat fresh pre-cut fruits and vegetables.

3. Primary production

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. *

4. Establishment: design and facilities

Refer to the General Principles of Food Hygiene*. In addition:

4.4 Facilities

4.4.2 Drainage and Waste Disposal

The processing of products covered by this Annex generates a large quantity of waste that can serve as food and shelter for pests. It is therefore very important to plan an

effective waste disposal system. This system should always be maintained in good condition so it does not become a source of product contamination.

5. Control of operations

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition:

5.1 Control of food hazards

For the products covered by this Annex it should be recognised that while processing may reduce the level of contamination initially present on the raw materials, it will not be able to guarantee elimination of such contamination. Consequently, the processor should ensure that steps are taken by their suppliers (growers, harvesters, packers and distributors) to minimise contamination of the raw materials during primary production. It is recommended that processors ensure that their suppliers have adopted the principles outlined in the Code of Hygienic Practice for Fresh Fruits and Vegetables.

There are certain pathogens, Listeria monocytogenes and Clostridium botulinum, which present specific concern in relation to ready to eat fresh pre-cut vegetables packaged in a modified atmosphere. Processors should ensure that they have addressed all relevant safety issues relating to the use of such packaging.

5.2 key aspects of control systems

5.2.2 Specific Process Steps

5.2.2.1 Receipt and inspection of raw materials

During unloading of raw material, verify the cleanliness of the food transportation unit and raw materials for evidence of contamination and deterioration

5.2.2.2 Preparation of raw material before processing

Physical hazards (such as the presence of animal and plant debris, metal, and other foreign material) should be removed through manual sorting or the use of detectors, such as metal detectors. Raw materials should be trimmed to remove any damaged, rotten or mouldy material.

5.2.2.3 Washing and microbiological decontamination

Refer to section 5.2.2.1 of the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition:

• Water used for final rinses should be of potable quality, particularly for these products as they are not likely to be washed before consumption.

5.2.2.4 Pre-cooling Fresh Fruits and Vegetables

Refer to section 5.2.2.3 of the Code of Hygienic Practice for Fresh Fruits and Vegetables.

5.2.2.5 Cutting, slicing, shredding, and similar pre-cut processes

Procedures should be in place to minimize contamination with physical (e.g. metal) and microbiological contaminants during cutting, slicing, shredding or similar pre-cut processes.

5.2.2.6 Washing after cutting, slicing, shredding, and similar pre-cut processes

Washing cut produce with potable water may reduce microbiological contamination. In addition, it removes some of the cellular fluids that were released during the cutting process thereby reducing the level of available nutrients for microbiological growth. The following should be considered:

• Water should be replaced at sufficient frequency to prevent the build-up of organic material and prevent cross-contamination.

• Antimicrobial agents should be used, where necessary, to minimize cross-contamination during washing and where their use is in line with good hygienic practices. The antimicrobial agents levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of antimicrobial agents, followed by a wash as necessary, should be done to ensure that chemical residues do not exceed levels as recommended by the Codex Alimentarius Commission.

• Drying or draining to remove water after washing is important to minimize microbiological growth

5.2.2.7 Cold Storage

Refer to section 5.2.2.4 of the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition:

• Pre-cut fresh fruits and vegetables should be maintained at low temperatures at all stages, from cutting through distribution to minimise microbiological growth.

5.7 Documentation and records

Where appropriate, records should be maintained to adequately reflect product information, such as product formulations or specifications and operational controls. Maintaining adequate documentation and records of processing operations is important in the event of recall of with fresh pre-cut fruits and vegetables. Records should be kept long enough to facilitate recalls and food borne illness investigations, if required. This period will likely be much longer than the shelf life of the product. Some examples of records to keep are the following:

• Fresh fruit and vegetable supplier records
• Water quality and supply records
• Equipment monitoring and maintenance records
• Equipment calibration records
• Sanitation records
• Product processing records
• Pest control records
• Distribution records

5.8 Recall procedures

Refer to the General Principles of Food Hygiene. *

6. Establishment: maintenance and sanitation

Refer to the General Principles of Food Hygiene. *

7. Establishment: personal hygiene

Refer to the General Principles of Food Hygiene. *

8. Transportation

Refer to the General Principles of Food Hygiene* and the Code of Hygienic Practice for Fresh Fruits and Vegetables.

9. Product information and consumer awareness

Refer to the General Principles of Food Hygiene. *

10. Training

Refer to the General Principles of Food Hygiene* and the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition:

10.2 Training programs

To evaluate the level of training required of persons responsible for the production of fresh pre-cut fruits and vegetables, the additional following factors should be taken into account:

• The packaging systems used for fresh pre-cut fruits and vegetables, including the risks of contamination or microbiological growth involved in this method;

• The importance of temperature control and GMPs.

ANNEXURE- II (c)

GLOBALG.A.P. (EUREPGAP) General Regulations (Integrated Farm Assurance)

1 GLOBALGAP (EUREPGAP) NORMATIVE DOCUMENTS

This document explains the structure of certification to GLOBALGAP (EUREPGAP) Integrated Farm Assurance, and the procedures that should be followed in order to obtain and maintain certification. It details the duties and rights of the GLOBALGAP (EUREPGAP) secretariat, certifiers, and producers seeking certification.

The **scope** of the Integrated Farm Assurance is separated into a modular structure and covers the production destined for human consumption of Crops, Livestock and Aquaculture. It also covers the safe production of Flowers and Ornamentals (as a sub-scope under the Crops scope). See 4.9.1 for definitions of scope and sub-scope.

GLOBALGAP (EUREPGAP) is a set of normative documents, which covers the General Regulations (this document), the GLOBALGAP (EUREPGAP) Control Points and Compliance Criteria and GLOBALGAP (EUREPGAP) Checklists.

The version, GLOBALGAP (EUREPGAP) General Regulations Integrated Farm Assurance V3-March07 becomes valid from the 1st of March 2007 (see point 4.1 for transition period information).

1.1 The General Regulations

The General Regulations document describes the basic steps and considerations involved for the applicant producer to obtain and maintain GLOBALGAP (EUREPGAP) certification, as well as the role and relationship of producers, GLOBALGAP (EUREPGAP) and the CBs.
The document is divided into five different parts:

PART I: GENERAL INFORMATION
PART II: CERTIFICATION BODY RULES
PART III: PRODUCER GROUP (OPTION 2) CERTIFICATION
PART IV: BENCHMARKING (OPTIONS 3 & 4)
PART V: TRAINING REGULATIONS

Part I, General Information, the base document, contains information important to **all GLOBALGAP (EUREPGAP) interested parties**, as it explains what GLOBALGAP (EUREPGAP) is, describes the certification process, the rules of certification, training etc. It is recommended that **producers** familiarize themselves with this part.

Part II, Certification Body Rules, contains important information for **Certification Bodies** (CB) (including a guideline on how to inspect a producer group) and **Accreditation Bodies** (AB).

Part III, Producer Group Certification, explains what a Producer Group is and how it must function. It is therefore important information for all **producer groups, CBs and ABs.**

Part IV, Benchmarking, explains GLOBALGAP (EUREPGAP) certification for those schemes that have been found to be technically equivalent to GLOBALGAP (EUREPGAP). All parties interested in
Bench marking and producers of a **Benchmarked Scheme**, as well as all **CBs and ABs** must be familiar with this part.

Part V, Training Regulations, is important to all members interested in becoming **GLOBALGAP (EUREPGAP) Approved Trainers**, or already approved trainers as it describes the requirements, application, and approval of trainers.

For definitions of terms used in the General Regulations and Control Points and Compliance, please refer to Annex I.1

1.2 Control Points and Compliance Criteria

Contains all the Control Points and Compliance Criteria (CPCC) that must be followed by the Producer/group and which is audited to verify compliance. This document is divided into modules, listing for each scope and sub-scopes the control points, compliance criteria and the level of compliance required for each point. The levels can be Major Must, Minor Must or Recommendation.

1.3 Checklists

Checklists replicate the Control Points in the CPCC, and are therefore also composed of modular sections (called “modules”). There are three checklist types in GLOBALGAP (EUREPGAP):

a) The checklist used for inspection of producers, which contains all the control points and must be used during inspection by the CB. The checklist can also be used by the producer/group when performing the self-assessments.

b) The QMS Checklist used for auditing producer group Quality Management Systems, which contains all the requirements detailed in Part III – Group Certification, must be used during audits by the CB. The producer group when performing internal Quality Management Systems audits can also use this checklist.

c) The Benchmarking Cross-Reference Checklist (BMCL) or the Approved Modified Checklist (AMC) used by applicant scheme owners applying for benchmarking against GLOBALGAP (EUREPGAP) to show equivalence (See GLOBALGAP (EUREPGAP) General Regulations

PART IV Benchmarking (Options 3 & 4)

1.4 Other

In **addition to these normative documents**, guidelines for dealing with general interpretation and application of control points and guidelines dealing with specific geographic and cultural differences may be approved and issued by the relevant Sector Committee (SC), with support from the recognized GLOBALGAP (EUREPGAP) National Technical Working Groups (see 4.7). Transition and implementation rules will be set within the guidelines, and application is mandatory for all CBs and producers

operating within the defined application scope of the guideline. Where necessary, the SCs will combine interpretations common to national interpretation guidelines to develop a global guideline.

All normative documents, as well as additional guiding documents are available, free of charge, on the GLOBALGAP (EUREPGAP) website (www.globalgap.org).

2. GLOBALGAP (EUREPGAP) TERMS OF REFERENCE

"The Global Partnership for Safe and Sustainable Agriculture"

To respond to consumer concerns on food safety, environmental protection, worker health, safety and welfare and animal welfare by:

(i) Encouraging adoption of commercially viable farm assurance schemes, which promote the minimization of agrochemical and medicinal inputs, within Europe and worldwide.

(ii) Developing a Good Agricultural Practice (G.A.P.) framework for benchmarking existing assurance schemes and standards including traceability.

(iii) Providing guidance for continuous improvement and the development and understanding of best practice.

(iv) Establish a single, recognized framework for independent verification.

(v) Communication and consulting openly with consumers and key partners, including producers, exporters and importers.

3. INTRODUCTION

3.1 What is GLOBALGAP (EUREPGAP)?

(i) GLOBALGAP (EUREPGAP) is a private sector body that sets out voluntary standards for the certification of agricultural (including Aquaculture) products around the globe.

(ii) GLOBALGAP (EUREPGAP) is a global scheme and a reference for Good Agricultural Practice (G.A.P.), which is managed by the GLOBALGAP (EUREPGAP) Secretariat.

(iii) Food PLUS GmbH, a non-profit industry owned and governed organisation, legally represents the GLOBALGAP (EUREPGAP) Secretariat,
(iv) GLOBALGAP (EUREPGAP) is an equal partnership of agricultural producers and retailers that want to establish certification standards and procedures for Good Agricultural Practices (G.A.P.).
(v) GLOBALGAP (EUREPGAP) provides the standards and framework for independent, recognised third party certification of farm production processes based on EN45011 or ISO/IEC Guide 65. (Certification of the production process – cropping, growing, rearing, or producing – of certified products ensures that only those that reach a certain level of compliance with established GAP set out in the GLOBALGAP (EUREPGAP) normative documents are certified.)
(vi) GLOBALGAP (EUREPGAP) Integrated Farm Assurance standard is a pre-farm gate standard that covers the whole agricultural production process of the certified product from before the plant is in the ground (origin and propagation material control points) or from when the animal enters the production process to non-processed end product (no processing, manufacturing or slaughtering is covered). The objective of GLOBALGAP (EUREPGAP) certification is to form part of the verification of Good Practices along the whole production chain.
(vii) GLOBALGAP (EUREPGAP) is a business-to-business tool and is therefore not directly visible to the final consumer.
(viii) The GLOBALGAP (EUREPGAP) logo and Trademark have restricted use. See Appendix I.1 for rules on the use of the GLOBALGAP (EUREPGAP) Trademark and Logo. Participation is voluntary and based on objective criteria. GLOBALGAP (EUREPGAP) is not discriminatory to Certification Bodies and/or farmers.

Membership

GLOBALGAP (EUREPGAP) membership is voluntary and independent from certification (for producers) or approval as a GLOBALGAP (EUREPGAP) approved certifier. GLOBALGAP (EUREPGAP) is an open system, where any producer can apply and receive certification when complying with the objective criteria set out. Members show additional commitment to shape and improve GLOBALGAP (EUREPGAP) as active partners. Members also enjoy additional benefits.

3.2.1 Member Benefits

• Right to participate in and contribute to the various Committees and National Technical Working Groups
• Discounts for GLOBALGAP (EUREPGAP) seminars, workshop and brochures
• Display of member organization logos and names in GLOBALGAP (EUREPGAP) publications
• Internet link from the GLOBALGAP web page to the organization websites
• Invitation to special GLOBALGAP (EUREPGAP) meetings
• Input into the continued technical improvement of the GLOBALGAP (EUREPGAP) standards First-hand information on the developments in the sector.
• Producer groups can apply for a discount equal in amount to the Option 2 producer registration fees paid in the previous calendar year by the producer group, up to the total annual membership fee.

3.2.2 Available Membership

- **Retailer Membership**

  Retailers and Food service organizations interested in supporting and developing GLOBALGAP (EUREPGAP) standards. Members can be nominated and elected to the Board or the Sector Committees.

- **Supplier Membership**

  Supplier (for the scopes of Crops, Livestock and/or Aquaculture) that are interested in showing more commitment to GLOBALGAP (EUREPGAP) than receiving certification. Members can be nominated and elected to the Board or the Sector Committees.

- **Associate Membership**

  Certification Bodies, Consulting companies, Plant protection or Fertilizer Industries, Universities, etc. and their associations. Members can be nominated and elected to the Certification Body Committee.

NOTE: Applicable fees and application forms are available at www.globalgap.org

3.2.3 Governance

Governance (see Figure 3.2.3) is by the GLOBALGAP Board, elected by the retailer and supplier members and is chaired by an independent chairman. The Board agrees on the vision and short- and long/term activity plan of the organisation.

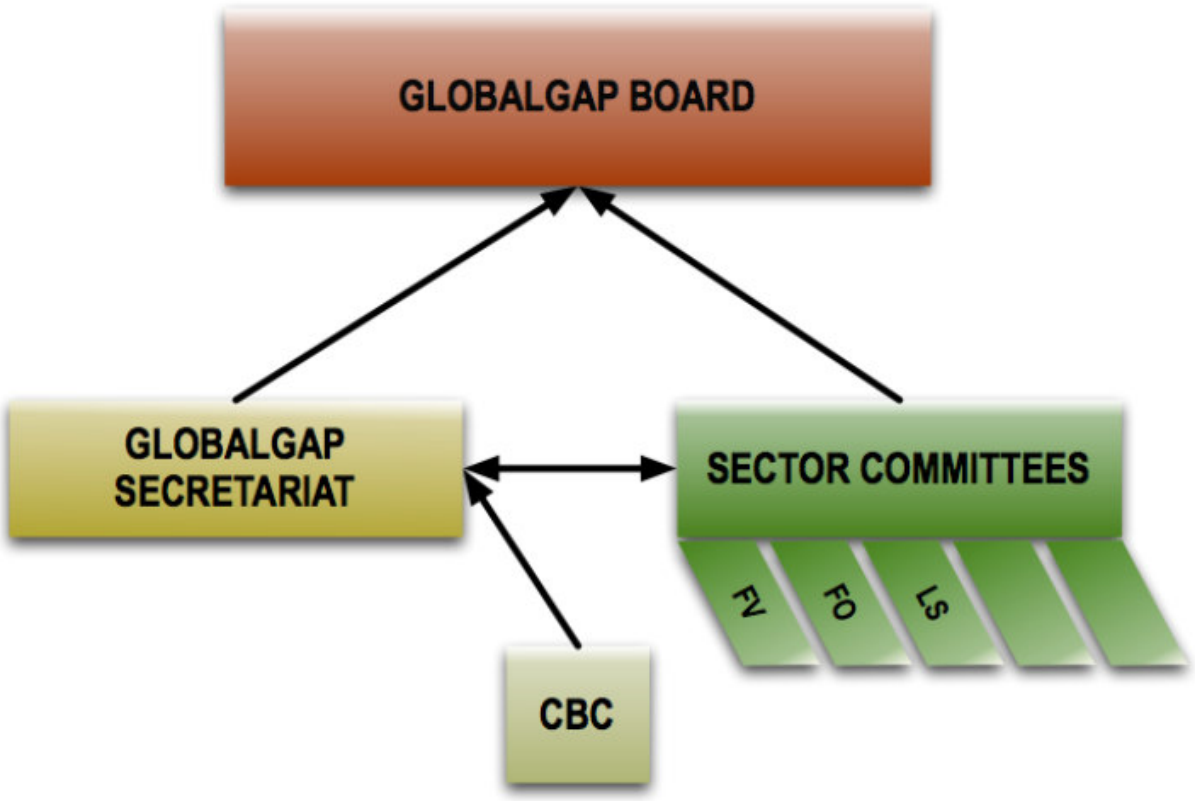


Figure 3.2.3 GLOBALGAP Governance

The Sector Committees (SC), also elected by the retailer and supplier members, is established for the different sub-scopes of the Integrated Farm Assurance standard. These sector committees work mainly on the technical side of the standard, and together with input from the Certification Body Committee, develop and maintain the Control Points and Compliance Criteria

The Certification Body Committee (CBC) members are elected by their peers (Certification Bodies who are GLOBALGAP (EUREPGAP) members). The main function of the CBC is to harmonize the interpretation of the compliance criteria set by the SC.

(All committees are elected for a period of three years and the Terms of Reference document for each committee is available on the GLOBALGAP website.)

The Executive Management of the GLOBALGAP Secretariat, its Managing Director, represents GLOBALGAP (EUREPGAP) before the Board.

4. GENERAL RULES

4.1 Introduction of New Version

This normative document (GLOBALGAP (EUREPGAP) General Regulations Integrated Farm Assurance V3.0-March07 Parts I to V) and the GLOBALGAP (EUREPGAP) Control Points and Compliance Criteria Integrated Farm Assurance V3.0-March07 and the GLOBALGAP (EUREPGAP) Checklist Integrated Farm Assurance V3.0-March07 and any other documents released by GLOBALGAP (EUREPGAP) as normative and related to this version, **comes into force on the 1st of March 2007**.Certificates can still be issued against the normative documents (General Regulations and relevant Control Points and Compliance Criteria) mentioned below **until 31 December 2007**, with last possible validity date 30th December 2008.

During the transition period of the name change from EUREPGAP to GLOBALGAP until 31st December 2008, all Logo and Trademark users (Producers, CB´s, and Members) shall only use the trade name GLOBALGAP in connection with the trade name EUREPGAP, but may continue to use the trade name EUREPGAP exclusively. Example for connected use: GLOBALGAP (EUREPGAP). Any changes to this rule will be published well before they come into effect.

(i) GLOBALGAP (EUREPGAP) Fruit and Vegetables Normative Documents V2.1-Oct04

(ii) GLOBALGAP (EUREPGAP) Coffee Normative Documents V1.0-Sept04

(iii) GLOBALGAP (EUREPGAP) Tea Normative Documents V1.0-March06

(iv) GLOBALGAP (EUREPGAP) Flower and Ornamentals Normative Documents V1.1-Jan04

(v) GLOBALGAP (EUREPGAP) Integrated Farm Assurance Normative Documents V2.0-March05

(vi) GLOBALGAP (EUREPGAP) Integrated Aquaculture Assurance Normative Documents V2.1- June05

NOTE 1: A service contract signed between a producer and a Certification Body, with validity beyond December 2007 does not exempt a producer from being inspected against the new version (V3.0-Mar07) from 1 January 2008.

NOTE 2: Even though certificates for Cattle and Sheep may be extended to 18 months, the last date of validity for certificates issued under V2.0-March05 is 30th December 2008.

4.2 Other Languages

The English language edition of this and other GLOBALGAP (EUREPGAP) documents are the original editions. GLOBALGAP (EUREPGAP) documents will be translated into other languages and published on the GLOBALGAP (EUREPGAP) website. Once published, these official GLOBALGAP (EUREPGAP) documents will be the only ones that may be used for GLOBALGAP (EUREPGAP) certification in that language. Translated documents will be identified as having normative status after a thorough translation review. Until the translations reach the normative status, the sentence "please refer to the English version in case of doubt" will be written on each sheet of the translated documents, in the respective language. Accreditation may be sought and obtained by CBs in other languages only against documents with normative status recognized in this way.

4.3 Official Communication Updates

From time to time, when necessary, GLOBALGAP (EUREPGAP) will issue edition updates to this General Regulations document or its annexes. All modifications shall be indicated in the "Editions Update Register" at the back of the modified document. The version name shall indicate the date of publication and the "Edition Update Register" shall indicate the date when the new document comes into force.

- For detailed information of the modifications please contact the GLOBALGAP (EUREPGAP) Secretariat for the history document.

- When the changes do not affect the accreditation of the standard, the version will remain “3.0” and edition update shall be indicated with “3.-x” (e.g."3.0-1").
- When the changes do affect the accreditation of the standard, the version name will change to “3.x”. (e.g."3.1")

The updates will be sent to all GLOBALGAP (EUREPGAP) approved CBs as official communications, and will form part of the normative document and must therefore be followed. It is the responsibility of the CBs to inform their clients of such updates.

4.4 Applicants

Any **producer*** of primary agricultural products, which the Integrated Farm Assurance standard covers may apply for GLOBALGAP (EUREPGAP) certification through a GLOBALGAP (EUREPGAP) approved Certification Body.

* *In this document, the term “producer” refers to individual producers as well as producer groups.*

For GLOBALGAP (EUREPGAP) certification, the term “producers” is defined as follows:

A person (individual) or business (individual or producer group) representing the production of the products, relevant to the scope (Crops, Livestock or Aquaculture), who has the legal responsibility for the products sold by that farming business.

4.4.1 Rights of Producers

(i) The CB and applicant will agree on Service of Notice terms, which must include a commitment by the CB to confirm the receipt of formal application for registration within 14 calendar days after the CB received the unique GLOBALGAP (EUREPGAP) Client Number (GGN) from the GLOBALGAP (EUREPGAP) Database (refer to point 4.8), and to confirm certification within 14 calendar days after closure of any outstanding non conformances.

(ii) The service contract between the CB and producer may have an initial duration of up to 3 years, with subsequent renewal or extension for periods up to 3 years.

(iii) Any complaints or appeals against CBs will follow the CB's own complaints and appeals procedure which each CB must have and communicate to its clients. In case the CB does not respond adequately, the complaint can be addressed to the GLOBALGAP (EUREPGAP) secretariat using the GLOBALGAP (EUREPGAP) Complaints Extranet, available on the GLOBALGAP (EUREPGAP) website (www.globalgap.org)

(iv) A producer may apply to different certification options *(See 5. for explanation of Options)* within the same sub-scope, but **may not** apply to different options for the same product (see Annex I.2 for list of products within the GLOBALGAP (EUREPGAP) context).

e.g. Possible: Register Apples under Option 1 and Cherries under Option 2.

Possible: Register Cattle under Option 1 and Sheep under Option 4.

Possible: Register Bananas under Option 2 and Cattle under Option 1.

Possible: Register Melons under one Option 2 and peaches under another Option 2

Possible: Register Apples under Option 2 and Cucumbers under Option 3.

Possible: Register Apples under Option 1 and Cucumbers under Option 1

Impossible: Register Salmon under both Options 1 and 3.

Impossible: Register Lemons under both Options 1 and 4.

(v) A producer may change from one CB to another CB, (unless a sanction is pending by a CB, see point 6.2) either voluntarily or if a situation arises where a CB that has previously been approved by GLOBALGAP (EUREPGAP) should become not approved (through sanction enforcement, bankruptcy, or other reasons).

(vi) A producer is able to ask for annulment of the contract held with a CB at any time (unless a sanction is pending by a CB, see point 6.2), and is obliged to do so when changing CBs. This will not allow the producer to avoid paying the registration and other applicable fees owed to the "outgoing" CB.

(vii) A producer may apply to one CB for certification of one product, and to another CB for another product, under the following circumstances:

a) If the producer seeks certification for more than one product under more than one option (as explained in point (iv) above) or

b) If the producer participates in more than one certified producer group; (e.g. cattle under one producer group and poultry under another with another CB) or

c) If the producer seeks certification across scopes and/or sub-scopes (e.g. across scopes - Crops scope (bananas) and Livestock scope (cattle) or within sub-scope – Fruit and Vegetables (apples and cucumbers) or within Crops scope - Fruit and Vegetables and Combinable Crops).See 4.4.2.vi for producer obligations in this case.

viii) A producer/producer group is able to ask voluntarily from the respective CB(s) for a suspension of one, several or all of the products covered by the certificate (unless a sanction is pending by a CB, see point 6.2). This can happen if the producer experiences difficulty with compliance to the standard and needs time to close any non-compliance out. This suspension will not delay the renewal date, nor will it allow the producer to avoid paying registration and other applicable fees. The producer's status shall change to "self declared partial suspension" on product level.

(ix) Confidentiality: GLOBALGAP (EUREPGAP) and GLOBALGAP (EUREPGAP) approved CB s will treat any information relating to the producer, including details of products and processes, evaluation reports and associated documentation as confidential (unless otherwise required by law). No information is released to third parties without the prior written consent of the producer, except where stated otherwise in this General Regulations document.

4.4.2 Obligations of Producers

(i) The certificate holder (individual producer in Option 1 or producer group in Option 2) is responsible for compliance of the certified products to the GLOBALGAP (EUREPGAP) Control Points and Compliance Criteria and General Regulations within the declared extent of the certificate scopes.

(ii) Producers must register with an approved CB (or Trustee, see 4.6) as the first step towards obtaining a GLOBALGAP (EUREPGAP) certificate. The registration process must be finalised before the first CB inspection/audit.

(iii) Producers who are sanctioned by a responsible CB cannot change that CB until that CB (the "outgoing" CB) closes out the corresponding non-conformance, or until the sanction penalty period is over.

(iv) Producers can change the CB they are working with only after “annulment” has been granted by the “outgoing” CB.

(v) A registered producer that changes CB, or applies to a new CB for certification of a different product, must communicate the unique GLOBALGAP (EUREPGAP) client number (GGN) assigned by GLOBALGAP (EUREPGAP), to the CB applied to.

(vi) When a producer makes use of the service of different CBs as explained in 4.4.1.

vii) The producer **must**

a) Apply during registration to the GLOBALGAP Secretariat for approval through the CB. This will be treated as an exception and the GLOBALGAP (EUREPGAP) Secretariat shall permit it based on a valid justification.

b) Agree in writing to inform the relevant CBs if one of the CBs issued a sanction (and all detail of the sanction, i.e. non-conformance, time limit for corrective action, etc.) and also to allow open communication between the CBs regarding the scope and details of actions to be taken across CBs (if any).

c)Agree in writing to allow GLOBALGAP (EUREPGAP) to share information on non conformances and sanctions between the relevant CBs.

d) Assign one CB to be responsible for collection of the registration fee or for granting this role to a chosen trustee (see 4.6). The CB must accept this responsibility in the database.

(vii) Registered producers are responsible for communicating data updates to CB s according to the internal procedures of each CB, such as farm or product area changes and inclusion/de-listing of members within a producers group.

(viii) Producers must commit themselves to follow the requirements established in this General Regulations document, including payment of the registration fee established by GLOBALGAP (EUREPGAP), and declare this in a signed document held by the CB.

(ix) Producers applying for GLOBALGAP (EUREPGAP) must specify, at registration, **all** locations and areas where the product that they are seeking certification for, is grown/produced or transported from under their ownership.

4.5 Certification Bodies

4.5.1 Approved Certification Bodies

GLOBALGAP (EUREPGAP) approved CBs are accredited through an Accreditation Body (AB) for EN 45011 or ISO/IEC Guide 65 to the relevant scope(s) or the relevant benchmarked scheme scope(s). Approved CBs must follow GLOBALGAP (EUREPGAP) rules and have signed a Certification and License Agreement with GLOBALGAP.

Information on CB status (approved or provisionally approved) is available on the GLOBALGAP website and producers are urged to verify that the chosen CB appears on the website.
Each CB sets up its own fee structure and will explain it to its prospective clients.

For detailed information on approved CB requirements as well as auditor and inspector qualifications, please see General Regulations Part II: Certification Body Rules.

More information for CBs interested in approval to inspect benchmarked schemes is available in General Regulations Part IV Benchmarking (Options 3 &4).

4.6 Trustees

4.6.1 Approved Trustees

GLOBALGAP approved Trustees are organizations (e.g CB, producer group organizations, standard owners, consultants, etc.) that have signed a Licence agreement with GLOBALGAP and acquired the right from producers to upload and/or register these producer activities in the GLOBALGAP (EUREPGAP) database.

The service includes first registration and any modifications as well as settings of links in the database. The approved Trustee must be granted these rights in writing from the producer or other legal entity in the GLOBALGAP (EUREPGAP) system.

4.6.2 Trustee Roles

GLOBALGAP (EUREPGAP) approved Trustees are per default the CB for an individual producer, or the group organization for a producer in the producer group.

Any other organization may apply to the GLOBALGAP Secretariat and sign an agreement to perform the role of Trustee and can receive trustee rights and role transferred from the CB where the producer is already registered with the CB and agrees in writing with the transfer.

The Trustee is also responsible to GLOBALGAP for timeliness of registration data updates of assigned producers and collecting the GLOBALGAP (EUREPGAP) registration fees of these producers.

4.7 National Technical Working Groups

GLOBALGAP (EUREPGAP) seeks to gain qualified input from national experts in their own language with respect to interpretation as well as specific legal and structural conditions within the different areas covered by GLOBALGAP (EUREPGAP). The establishment of GLOBALGAP (EUREPGAP) National Technical Work Groups (NTWG) is one important step towards this goal. Any interpretation guidelines developed by an NTWG shall go through Sector Committee approval before becoming normative in the specific country.

The groups work in close cooperation with the GLOBALGAP Secretariat and the GLOBALGAP (EUREPGAP) Committees and support as well as facilitate the GLOBALGAP (EUREPGAP) implementation and continuous improvement based on the specific interest area needs.

The GLOBALGAP (EUREPGAP) NTWG is the platform to harmonize certification activities within the region and scope. For the GLOBALGAP Secretariat the Group will be the direct link in the country and the first contact point.

The Terms of Reference is published on the GLOBALGAP website for more information on the operation and roles of these groups.

4.8 Registration

All relevant information concerning producers applying for GLOBALGAP (EUREPGAP) certification must be recorded for the producer to become GLOBALGAP (EUREPGAP) registered for Option 1, 2, 3 and/or 4. This information will be used by GLOBALGAP (EUREPGAP) to supply the registered party with a unique GLOBALGAP (EUREPGAP) client number (GGN), which will be used as a unique identifier for all GLOBALGAP (EUREPGAP) activities. The registration information includes:

4.8.1 General Information

(i) Name of Company
(ii) Name of Contact person
(iii) Full updated address (physical and postal)
(iv) Other ID (VAT Number, ILN, UAID, etc.) - whatever is mandatory and available in the country of production.
(v) Contact data (telephone number and e-mail and/or fax number)

4.8.2 Producer Registration information

The information required is consistent with the information required by the Sub-license and Certification Agreement signed between the producer and the CB. The following information is required for each product wishing to be registered:

(i) Product
(ii) Annual Area under production (crops) / Quantity of production (livestock, aquaculture)
(iii) Covered or non-covered crop (if crop)
(iv) First harvest or further harvest (if crop)
(v) Option
(vi) Scheme name (if a benchmarked scheme)

(vii) GLOBALGAP (EUREPGAP) Number (GGN) and previous GLOBALGAP (EUREPGAP)- related registration number (where applicable)

(viii) Certification Body(ies) to be used as set out 4.4.2.

(ix) For Fruit and Vegetables: Exclusion of produce handling when not applicable (for each product certified)

(x) For Fruit and Vegetables: The GLOBALGAP (EUREPGAP) client number(s) (GGN) of the producer(s) who do(es) produce handling if it is included when done off-farm (see Produce Handling Exclusion scope 4.9.6.3)

(xi) For Fruit and Vegetables: If produce handling is included, the producer must declare whether products are also packed for other GLOBALGAP (EUREPGAP) certified producers (in which case all Minor Must control points in the CPCC section FV.5 must also be inspected as Major Musts)

(xii) For Coffee and Tea: The GLOBALGAP (EUREPGAP) client number (GGN) of the processing unit(s) as indicated in the Chain of Custody certification must be entered into the GLOBALGAP (EUREPGAP) database as soon as the producer knows it, and it must be communicated to the CB and updated whenever there are changes.

(xiii) For Livestock: The GLOBALGAP (EUREPGAP) client number (GGN) of the transporter(s) must be entered into the GLOBALGAP (EUREPGAP) database as soon as the producer knows it, communicated to the CB and updated whenever there are changes.

(xiv) For Aquaculture: The GLOBALGAP (EUREPGAP) client number (GGN) of the transporter(s) (maritime and terrestrial) must be entered into the GLOBALGAP (EUREPGAP) database as soon as the producer knows it, and it must be communicated to the CB and updated whenever there are changes.

(xv) For Aquaculture: The GLOBALGAP (EUREPGAP) client number (GGN) of the processing unit(s) as indicated in the Chain of Custody certification must be entered into the GLOBALGAP (EUREPGAP) database as soon as the producer knows it, and it must be communicated to the CB and updated whenever there are changes.

4.8.3 Registration Acceptance

For the registration to be accepted, the producer will have:
(i) Signed the Sub-license and Certification Agreement between the CB and the producer,
(ii) Been assigned a GLOBALGAP (EUREPGAP) Client number (GGN), as well as any registration number the CB may assign,
(iii) Agreed to pay the GLOBALGAP (EUREPGAP) registration fee as explained in the current GLOBALGAP (EUREPGAP) Fee Table (available on the GLOBALGAP website).
***NOTE**: The registration process **must** be finalized, **before** certification can take place.*

More information on the registration data detail is available in Annex I.3 – GLOBALGAP (EUREPGAP) Registration Data Requirements.

4.9 Certification process

4.9.1 The Control Points and Compliance Criteria (CPCC) document

The GLOBALGAP (EUREPGAP) IFA CPCC document is separated into different modules, each one covering different areas or levels of activity on a production site. These sections are grouped into:
1. “Scopes” covering more generic production issues, classified more broadly (All Farm Base, Crops Base, Livestock Base and Aquaculture Base).
2. “Sub-scopes” covering specific production details, classified per product type (Fruit and Vegetables, Combinable Crops, Coffee (green), Tea, Flowers and Ornamentals, Cattle & Sheep, Pigs, Dairy, Poultry, Salmon and Trout and any sub-scopes that might be added during the validity period of this document).
The sub-scope modules applicable depend on the certificate scope applied for.

It is not possible to certify the respective sub-scope without also verifying compliance to the applicable scope. The inspection of compliance criteria of the scope must be interpreted according to the sub-scope applied for. Any certification applied for that

introduces additional sub-scopes into an existing certificate must have the scope inspected taking into account the additional sub-scopes concerned.

The scopes are automatically coupled to the sub-scopes according to the choice of sub-scopes applied for.

e.g. 1: the certification of Pigs automatically involves the certification audit of the All Farm Base and the Livestock Base.

e.g. 2: the certification of Tea automatically involves the certification audit of the All Farm Base and the Crops Base.

e.g. 3: the certification of Salmon automatically involves the certification audit of the All Farm Base and the Aquaculture Base.

NOTE: Where the sub-scope applied for is Dairy, the sub-scope Cattle & Sheep must also be inspected.

It is possible for some sections as a whole to be not applicable; such as the control points on Outdoor Poultry Production (PY.6) if no Outdoor Poultry production occurs, or Final Produce Packing at Point of Harvest (FV.4.2) in Fruit and Vegetable production if there is no final packing in the field.

For more information on the structure and modular approach, please read the introduction at the beginning of the CPCC document.

4.9.2 Inspection timing

The inspection of a producer is linked to the registration (no inspection can take place until the CB has accepted the producer's registration or re-registration, which must be done on an annual basis - for more information on registration see Annex I.3), but has a different timing according to whether it is a first or subsequent inspection, and depending on the product to be inspected. This is explained below.

4.9.2.1 Crop Certification

(i) First inspections

All records to be externally inspected in the first year are only valid going back up to three months before the date of first harvest after registration is completed, or to the date of the producer's first registration with GLOBALGAP (EUREPGAP), whichever is longer. Harvest and Produce handling must take place after registration with GLOBALGAP (EUREPGAP). Records that relate to harvest or produce handling before the producer registered with GLOBALGAP (EUREPGAP) are not valid.

a) First Inspection Timing at Harvest

The ideal timing for inspecting all control points and when sufficient records/evidence is available is during harvest time, especially to facilitate verification of the control points related to harvest (i.e. MRLs, hygiene during harvest, etc.).

b) First Inspection Alternative Timing

Alternative timing options may be followed where inspection during harvest time is not possible. The 1st inspection therefore takes place before or after harvest (though always after registration of the farmer). In these cases, justification for this alternative timing must be given by the CB, and noted in the audit report. Examples of justification may be logistics and timing constraints of farmer and/or inspector, variation in harvest dates, perennial crop not yet producing a crop, etc. Additionally the following constraints need to be followed by the CB:

1. Practically, inspection of records and visual evidence requires that the inspection must take place as close to harvest as possible, for the inspector to verify as many control points as possible.
2. Some control points will not be able to be inspected if the inspection is made before harvest of the registered crop, and as a result either a follow-up visit will be required, or proof can be sent by fax, photos or other acceptable means (to be discussed and agreed between farmer and CB). No certificate will be issued until all control points have been verified and closed out. If once the farmer is registered, harvest has already taken place at the moment of inspection, the farmer must retain evidence for compliance of control points related to that harvest, otherwise some

control points may not be able to be checked and certification is not possible until the following harvest.

3. The CB must make sure that in the sampling for unannounced visits, those farmers that did not receive a 1st inspection during harvest have a greater chance of getting an unannounced inspection during the next harvest (this needs to be conveyed to the farmer when discussing inspection timing). Additionally, the CB must make every effort to carry out the subsequent inspection during harvest.

c) First Inspection Timing and Multiple Crop Certifications:

The farmer may be seeking certification for more than one crop, and the crops may not all have the same seasonal timing, i.e. harvest of one crop does not necessarily coincide with the harvest of other crops.

Here there are two scenarios:

1. Where the crops to be included in the certification scope are concurrent, i.e. cropped at the same time, then the first year's inspection will be timed so that the principal crop can be viewed at or as close to harvest as possible, making an assumption that the other crops will be compliant to the same degree ("principal crop" will be defined by the CB in their inspection procedures, taking into account area, food risk, market for export, or any other relevant criteria). Where the CB considers it necessary, evidence of compliance can be demanded closer to harvest of the "non-principal" crops, and a re-visit may be scheduled when any outstanding control points may be verified.

2. Where the crops to be included in the certification scope are consecutive, i.e. the production of one crop finalizes before the production of the next one commences, then in the first year a full inspection of the first crop must be made during harvesting. Subsequent crops grown in that same first year can be added to the certificate only once compliance has been verified for each crop, either through a site inspection at harvest of each crop or through application of guidelines set out in point 4.9.2.1.i.b.3 above.

(ii) Subsequent inspections

There must be at least one product of the registered sub-scope present (present meaning in the field, in the storage, or crops that are not yet ready for harvest) to give the CB confidence that any other registered crops (if any) not present at that time, are handled in compliance with GLOBALGAP (EUREPGAP).

a) Extension of certificate validity:

There may arise situations where there is no crop or produce present at the time when the annual inspection is due (i.e. only one crop is registered and harvest has already taken place and there is no storage on farm). In such cases, providing the farmer has re-registered at the end of the period of validity of the previous certificate, and the CB concerned had also issued the previous certificate of the farmer, the CB can opt to extend the validity of the previous certificate by up to 3 months longer than the 12 month period (15 months in total), in order to be able to reach a point in time when the farm may be inspected with presence of crop/produce. An extension can only be granted if the producer re-registered before the expiry date.

Therefore, the subsequent inspection can be done at any time during an "inspection window" that ranges for 9 months: **from 6 months before** the original expiry date of the certificate, and (only if the CB extends the certificate validity in the GLOBALGAP (EUREPGAP) database) **up to 3 months after** the original expiry date of the certificate**.**

e.g. 1st certification date: 14 February 2007 (expiry date: 13 February 2008)

2nd inspection can be any time from 14 August 2007 to 13 May 2008, if the certificate validity is extended.

The **validity date** for subsequent certificates issued shall however always **revert** to

the date linked to the original certification date (13 February 2009, 13 February 2010, etc.)

NOTE: Registered *producers and/or producers with certified products* ***must*** *re-register annually before the expiry date; otherwise the product status will change from "Certified" to "Certificate not renewed or not reregistered". A valid justification (see 4.9.2.1.ii.a) must be given before the CB can extend the certificate validity in the database.*

4.9.2.2 Livestock and Aquaculture Certification

(i) The registered livestock or aquaculture species must be present on the farm at the time of the inspection.

(ii) The subsequent inspection can be done any time during an "inspection window" that ranges for 9 months: from 6 months before the original expiry date of the certificate, and (only if the CB extends the certificate validity in the GLOBALGAP (EUREPGAP) database) up to 3 months after the original expiry date of the certificate except for Cattle and Sheep and Dairy; see point (iii).e.g. 1st certification date: 14 February 2007 (expiry date: 13 February 2008)

2nd inspection can be any time from 14 August 2007 to 13 May 2008, if The certificate validity is extended.

The **validity** date for subsequent certificates issued shall however always **revert** to the date linked to the original certification date (13 February 2009, 13 February 2010, etc.; except for Cattle and Sheep and Dairy, see point (iii).

(iii) Where a producer has registered for the Cattle & Sheep and Dairy sub-scopes **only** (including the applicable base scopes), the subsequent inspection can take place **up to 18 months after the first inspection, providing the registration and license fee is paid annually** and the certificate validity has been extended by 6 months in the database**.** The "inspection window" ranges for 12 months: from 6 months before the original expiry date of the certificate, up to the end of the extension period. If, however, the producer or producer group has also registered for other sub-scopes, the inspection frequency must be once in every 12 months in order to match the base scope inspections of those other sub-scopes registered for.

e.g. for Cattle and Sheep and Dairy only:

1st certification date: 14 February 2007 (expiry date: 13 February 2008, after re-registration and payment of the registration and license fee can it be extended to 13 August 2008) the 2nd inspection can be any time from 14 August 2007 to 13 August

2008, if the certificate validity is extended before the expiry date of 13February 2008.

The validity date for subsequent certificates issued for producers who extended the validity to 6 months after the annual registration shall always revert to the date linked to the original certification date plus 18 months (13 February 2010, 13 August 2011, etc.).

***NOTE**: Extension can only be done after the producer has re-registered (before The expiry date) and paid the annual registration and license fee.*

(iv) For Livestock: Decision-making on inspection timing in every 24-month period must take winter/summer conditions into consideration – indoor and outdoor production must be verified once during this period where it exists.

(v) All products certified, must be subjected to an inspection prior to issuing the certificate.

***NOTE*:** Registered producers and/or producers with certified products must re-register annually before the expiry date; *otherwise the product status will change from "Certified" to "Certificate not renewed or re registered".*

4.9.3 Compliance levels

Compliance with GLOBALGAP (EUREPGAP) IFA consists of three types of control points (set out in the Control Points and Compliance Criteria documents) that the producer is required to comply with in order to obtain GLOBALGAP (EUREPGAP) certification. These are Major musts, minor Musts and Recommendations, which must be fulfilled with as follows:

4.9.3.1 Major Musts

100% compliance of all applicable Major Must control points is compulsory.

Reference evidence must be recorded as comments next to each Major Must in the checklist.

4.9.3.2 Minor Musts

For all scopes 95% compliance of all applicable Minor Must control points is compulsory for the sum of the control points in the applicable modules. For the sake of calculation, the following formula will apply for each combination of modules:

$$\{ \textit{(Total number of Minor Must control points/module)} - \textit{(Not Applicable Minor Musts control points scored)} \} \times 5\% = \textit{(Total Minor Must control point Non-compliance allowable)}$$

e.g. A producer seeks certification for Fruit and Vegetables: The producer needs to comply with 95% of the applicable Minor Musts of the All Farm (AF), Crops Base (CB) and Fruit and Vegetables (FV) modules combined.

e.g. A producer seeks certification for Combinable Crops and Dairy: The producer needs to comply with 95% of the applicable Minor Musts of the All Farm (AF),Crops Base (CB) and Combinable Crops (CC) modules combined and with 95% of the applicable Minor Musts of the All Farm (AF), Livestock Base (LB), Cattle and Sheep (CS) and Dairy (DY) modules combined.

e.g. (Total number of Minor Must control points/module – NA Minor Must) x 5% (122 – 52) x 0.05 = 70 x 0.05 = 3.5.

This means that the total number of Minor Must control point non-compliance allowable is 3.5, which must be rounded down. Therefore this producer can only have 3 Minor Must control points that are non-compliant. 70 applicable Minor Must control points – 3 non-compliant Minor Must control points = 67. This gives a compliance level of 95.7%, whereas if 3.5 were rounded up to 4 it would give a compliance level of 94.2% that is **not compliant with the certification rule.**

*NOTE: A score for example of 94.8% **cannot** be rounded to 95% (the pass Percentage)*

4.9.3.3 Recommendations

No minimum percentage of compliance is set.

All Recommendation control points in the CPCC must be inspected during the self assessments (Option 1), internal inspections (Option 2) and external announced inspections by CBs.

4.9.4 Compliance Verification and Comments

Compliance is indicated with a “Yes” (for compliant), “No” (for not compliant), and “N/A”. Control points that are indicated as “No N/A” in the compliance criteria field, unless specifically indicated in the respective compliance criteria text, must be inspected and may not be justified as being “not applicable”. In cases of exception where the control point is not applicable, the answer must be given as “yes” with a clear justification.

Evidence (comments) should be provided for each control point – these shall enable the audit trail to be reviewed after the event, and will include details of references taken during the inspection. It is, however, obligatory to give evidence (comments) for **all** the Major Musts control points inspected/audited in all external inspections, self-assessments, and internal inspections.

***NOTE**: Comments **must** be entered in the checklist for all control points that are found to be **non-compliant** during external inspections and self-assessments/internal inspections and audits.*

4.9.4.1 Non-compliance vs Non-conformance

Non-compliance: A GLOBALGAP (EUREPGAP) control point in the checklist is not fulfilled according to the compliance criteria. **e.**g. The producer does not comply with the Minor Must AF.2.2.2

Non-conformance: A GLOBALGAP (EUREPGAP) rule that is necessary for obtaining the certificate (see 4.9.3.1 and 4.9.3.2) is infringed. e**.**g. The producer does not comply with a Major Must (e.g. AF.1.2) or complies only with 93% of the applicable Minor Musts of the scope applied for instead of the required 95%.

4.9.5 Validity of GLOBALGAP (EUREPGAP) certificate

Certificate granting is conditional on compliance by the producer with all the applicable requirements set out in this General Regulations document.

4.9.5.1 Time period

The validity of the certificate will be 12 months subject to any sanctions and extensions in accordance with the scope described. A certificate cannot be issued with a validity period of less than 12 months.

NOTE: Only when the producer reconfirmed registration before the expiry period, can the validity period be extended to 15 months (See 4.9.2.1.ii and 4.9.2.2.ii), or for Cattle and Sheep and Dairy only to 18 months (see 4.9.2.2.iii).

The initial **date of validity** that appears on a paper certificate will be the date when the CB made the **certification decision** after all non-conformances were closed out.

4.9.5.2 Paper certificate requirements

The certificate issued by a CB must conform completely to the templates for Option 1, 2, 3 and 4 available on the GLOBALGAP (EUREPGAP) website. The paper certificate will be replaced by an electronic certificate when available and will be supported by the GLOBALGAP (EUREPGAP) Database. From that moment on, the CB will only issue certificates using the information available at that time in the GLOBALGAP (EUREPGAP) Database.

4.9.5.3 E-certificate

The electronic certificate (abbreviation: e-certificate) will be issued by the GLOBALGAP (EUREPGAP) approved CB by making use of the current data in the GLOBALGAP (EUREPGAP) database and will be the online way to verify certification at any time. The e-certificate will carry a date and time stamp to indicate verification and download date.

NOTE 1: GLOBALGAP (EUREPGAP) Approved CBs may issue a letter of Non-Conformance where GLOBALGAP (EUREPGAP) has given its approval on a case-by-case basis. This letter ***must*** *follow the template available on the CB Extranet. It cannot show the GLOBALGAP (EUREPGAP) logo and is* ***not equivalent*** *to a GLOBALGAP (EUREPGAP) certificate. It will state that the producer has been inspected, but that the producer cannot be certified because it is not possible (due to reasons beyond the producer) to comply with a specific Major Must.*

NOTE 2: GLOBALGAP (EUREPGAP) CBs or their subcontracted parties **shall not** issue any other communication to or about a producer to demonstrate any other status than those described in Annex I.4.

4.9.6 Granting Scopes

These scopes are cumulative, not alternative, and must be considered together when registering, certifying and applying any sanctions. This means that product scope is linked to the location where that product is produced. ***Product produced in a non-registered location cannot be certified*****, and** ***likewise products other than those in the registered scope that are grown on a registered location cannot be certified*****.** Sanctions will apply across products and location if a complete sanction is imposed.
Only producers may apply for GLOBALGAP (EUREPGAP) certification of their products.

4.9.6.1 Product scope

(i) Certificate and sub-Licence is issued to the registered producer, on the farms where the products are produced and for the products declared.
(ii) A producer who is included in the annex of a certificate of a producer group for a registered list of product(s) may only sell product outside of the group IF the product is not sold as GLOBALGAP (EUREPGAP) certified. Products sold outside of the group cannot make reference to the GLOBALGAP (EUREPGAP) certificate and all

sales volumes must be reported to the group and the mass balance will indicate these sales.

(iii) The legal entity that places the certified product on the market must be the legal certificate holder.

4.9.6.2 Location scope

(i) The entire production process of the declared and registered products must comply with GLOBALGAP (EUREPGAP) requirements. Certified locations cannot be separated into growing areas or production facilities that are certified and other growing areas or production facilities of the same product that are excluded from Certification. e.g. If a producer registered “apples” or “pigs” to be certified, the entire production process of all the apples or pigs produced under the ownership of the producer must be declared, registered and certified.

4.9.6.3 Produce handling exclusion

For Fruit and Vegetables sub-scope certification (see Figure 4.9.6.3):

(i) When a producer does produce handling (see definition in AnnexI.1), control points FV.5 are obligatory for the respective product. If the produce handling facility already has BRC/IFS/SQF 2000 certification, the GLOBALGAP (EUREPGAP) inspector needs not inspect the whole section FV.5, but must anyway inspect FV.5.8.1-14.

(ii) When no produce handling takes place on farm, this must be declared during registration and will be indicated on the certificate.

(iii) If a producer does not do produce handling on farm, but at another producer that does have GLOBALGAP (EUREPGAP) certification (including produce handling), produce handling can be included on the growing producer’s certificate, AS LONG AS

a) The produce still belongs to the growing producer when packed

b) The produce handling facility is on farm of the packing producer and produce handling is included in the packing producer’s certificate

c) If the products specified on the certificate as being packed are the same for both producers

d) The produce handling facility has clear traceability to individual producers

e) All Minor Must CPCs under FV.5 are being inspected as Major Musts for the packing producer.

f) The produce handling facility does not pack nor handle and store non-GLOBALGAP (EUREPGAP) produces of the product (s) scope specified on the certificate.

All other cases must be presented to the GLOBALGAP Secretariat on a case-by-case basis.

4.9.6.4 Harvesting exclusion –exceptional

For Fruit and Vegetables sub-scope certification;

(i) If produce is sold in the field before harvest and the buyer, who is also responsible for produce handling, harvests the produce, the Harvesting section (FV.4) can be excluded from the producer's certificate. This exception applies where the produce does not belong to the producer anymore at point before harvest and the producer has no control over the harvesting process, i.e. no knowledge or influence on the exact time of harvest. It is also not an activity that is subcontracted by the producer.

(ii) The producer must apply for exclusion per product during registration with detailed justification. The GLOBALGAP Secretariat will give approval of exclusion on a case-by-case basis **before** the registration is approved. If harvesting is excluded for the producer or producer group, produce handling shall also be excluded for that producer or producer group.

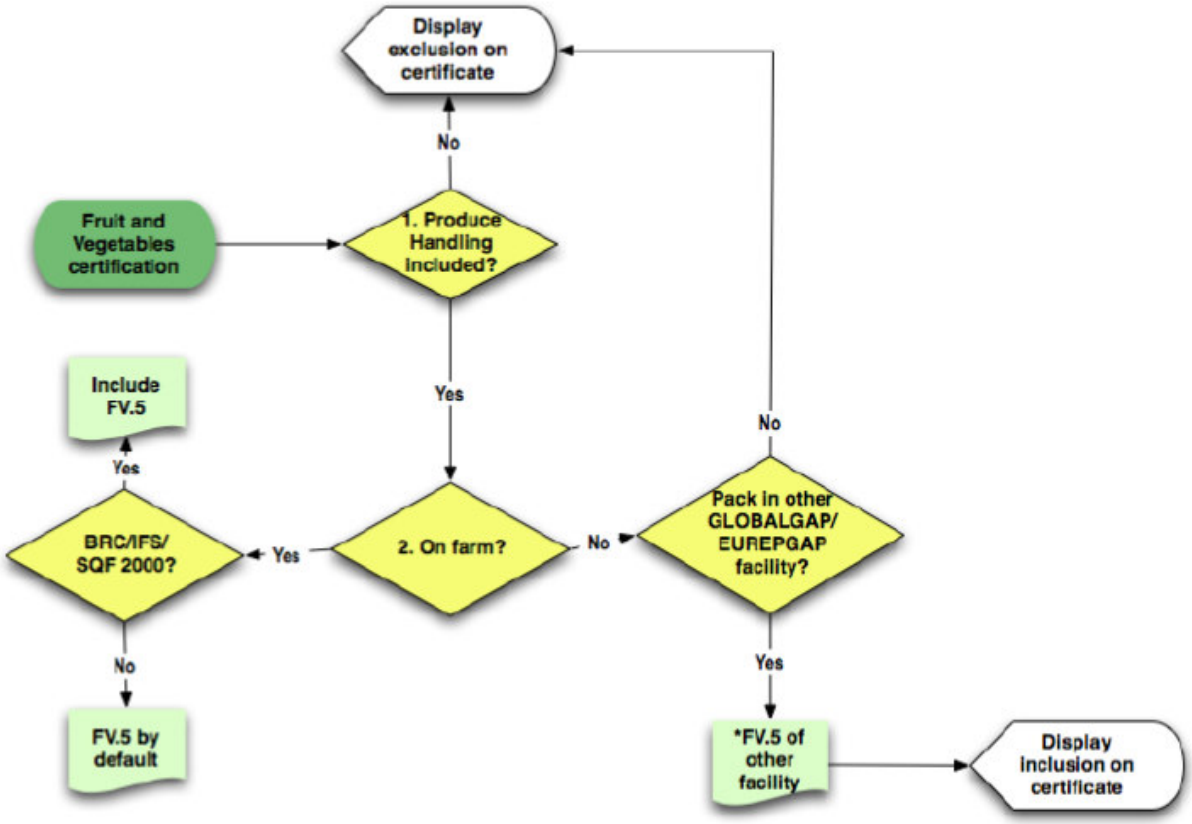


Figure 4.9.6.3 Exclusion or Inclusion of Produce Handling

*See requirements under 4.9.6.3(iii).

4.9.6.5 Chain of Custody

(i) The Chain of Custody (CoC) scope covers all activities once products are sold off the farm and its legal ownership over the product is taken over by a different party (trading, storing, collecting, transport, and processing to the point of final customer selling to the end-consumer) and consists of a management system with an appropriate combination of segregation and identification to ensure that certified and uncertified materials are not mixed. This is used in the certification of the Aquaculture scope and the Green Coffee and Tea sub-scopes certification.

(ii) Product processing remains outside GLOBALGAP (EUREPGAP) scope, where not explicitly included. In addition, GLOBALGAP (EUREPGAP) links up with among others, BRC and IFS, to cover the supply chain.

4.10 Maintenance of GLOBALGAP (EUREPGAP) certification

(i) The registration of the producer and the proposed products for the relevant scopes must be reconfirmed with the CB annually **before** the expiry date.

(ii) The full checklist and verification process must be completed by the inspector annually for the process of certification to be carried out (except for Cattle and Sheep that may have 18-month inspection intervals, see 4.9.2.2 (iii).

5. CERTIFICATION OPTIONS

Producers can achieve GLOBALGAP (EUREPGAP) certification under any one of the four options described below.

5.1 Option 1

Individual producer applies for GLOBALGAP (EUREPGAP) certification. The individual producer will be the certificate holder, once certified.

5.1.1 Internal Self-assessment

5.1.1.1 Frequency

The internal self-assessment must be carried out at least once a year. This self assessment will be carried out under the responsibility of the producer.

5.1.1.2 Scope

The self-assessment shall be against the complete checklist (Major and Minor Musts and Recommendations) of the applicable scope(s) and sub-scope(s). The completed checklist must be available on site for review by the inspector during the external inspection.

5.1.2 External Inspection by GLOBALGAP (EUREPGAP) approved CB

5.1.2.1 Frequency

One announced external inspection carried out by the GLOBALGAP (EUREPGAP) approved CB per annum of the registered producer.

5.1.2.2 Scope

The CB will inspect the complete checklist (Major and Minor Musts and Recommendations) of the applicable scope(s) and sub-scope(s).

5.1.3 Unannounced Surveillance Inspections

5.1.3.1 Frequency

The granting CB (or its subcontracted agent) will carry out an additional minimum of 10% unannounced surveillance inspections per annum among all certified producers it has registered under Option 1. A GLOBALGAP (EUREPGAP) auditor or inspector can carry out the inspections.

5.1.3.2 Scope

The CB will inspect the Major and Minor Musts of the applicable scope(s) and sub scope(s). Any non-compliance will be handled in the same way as those found during an announced inspection

5.1.3.3 Notification

The CB will inform the producer within 48 hours in advance of the intended visit. In the exceptional case where the proposed date is impossible to be accepted by the producer (due to medical or other justifiable reasons), the producer will have one more chance to be informed of an unannounced surveillance inspection. The producer shall receive a written warning if the first, or where applicable, second proposed date has not been accepted. The producer will receive another 48-hour notification of a visit. If the visit cannot take place because of non-justifiable reasons, a complete suspension will be issued.

5.2 Option 2

A producer group (see requirements in PART III – Producer Group Certification) applies for GLOBALGAP (EUREPGAP) group certification. The producer group, as legal entity, will be the certificate holder once certified.

5.2.1 Internal Quality Management System (QMS) Audit

5.2.1.1 Frequency

The QMS, developed according to requirements set out in the General Regulations PART III – Producer Group Certification, must be audited internally, at least annually by the internal producer group auditor (see internal auditor requirements in PART III. (Appendix 2).

5.2.1.2 Scope

The audit must be carried out by using the QMS Checklist, which is based on the General Regulations PART II – Certification Body Rules, Appendix 3 and Part III – Producer Group Certification.

5.2.2 Producer Group Internal Producer Inspections

5.2.2.1 Frequency

A minimum of one internal inspection per annum of each registered producer within the producer group must be carried out by qualified internal producer group inspectors (see requirements in PART III Appendix 1) within the producer group, or subcontracted to an external verification body, different from the certification body responsible for the external certification inspections of the group.

NOTE: Self-assessments by each member of the group is only required if it is an internal requirement by the group, but it is not a GLOBALGAP (EUREPGAP) requirement

5.2.2.2 Scope

The internal inspection shall be based on the complete GLOBALGAP (EUREPGAP) checklist (Major and Minor Musts and Recommendations) of the applicable scope(s) and sub-scope(s).

5.2.3 External Quality Management System (QMS) Audit by GLOBALGAP (EUREPGAP) approved Certification Body

5.2.3.1 Frequency

One announced external audit carried out annually by the GLOBALGAP (EUREPGAP) approved CB of the registered producer group.

5.2.3.2 Scope

The CB will audit the QMS by using the QMS Checklist based on the General Regulations PART II – Certification Body Rules, Appendix 3 and Part III – Producer Group Certification.

5.2.4 External Producer Inspection by GLOBALGAP (EUREPGAP) approved Certification Body

5.2.4.1 Frequency

External farm inspections are annual.

5.2.4.2 Sampling

Selection of producers is made by taking a random sample that, as a minimum, is the square root (or next whole number rounded upwards if there are any decimals) of the total number of GLOBALGAP (EUREPGAP) registered producers within the producer group (see criteria to determine sample size in General Regulations Appendix II.3, 6.1.2

(v) . For the first inspection by a newly chosen CB or against a new version, the square root (as a minimum) of the producers in a producer group must be inspected in full by the CB.

Example: Producer Group X has 25 registered members, and the CB, **after the QMS audit,** sets the square root as the sample. Therefore, 5 producers (v25) must be inspected at this first inspection.

During the validity period (12 months) of a certificate, the CB will carry out an unannounced inspection on a number of producers in the producer group equivalent to 50% of the inspection sample size inspected in the previous announced inspection. Only if the producers inspected externally have no non-conformities raised in that unannounced surveillance inspection, the following regular announced inspection by the CB will be reduced to 50% of the original farmer sample size (providing the findings from the Quality Management System audit carried out at the following regular announced inspection are also favorable to this reduction)

Example: Six months after the certificate was issued to Group X (full compliance with QMS audit and 5 farm inspections), the CB inspects 3 (50% of 5 = 3) producers unannounced. If the 3 producers have no non-conformities during this unannounced surveillance inspection, the CB will only check 2 producers during the following regular announced inspection IF the QMS audit during the regular announced inspection does not show any non-conformances. If any non-conformance is raised during the “unannounced” surveillance inspection, Group X will be sanctioned accordingly, and no reduction of sample size will result in the next regular announced inspection.

If there are non-conformities raised in the unannounced inspections, in the following regular announced inspection, justification must be given for inspecting only the minimum (square root) sample size, and not an increased sample size.

5.2.4.3 Scope

The CB will inspect the complete checklist (Major and Minor Musts and Recommendations) of the applicable scope(s) and sub-scope(s)

5.2.5 Unannounced Surveillance Audits

5.2.5.1 Frequency

The granting CB (or its subcontracted agent) will annually carry out additional unannounced surveillance audits on a minimum of 10% of all certified producer groups it has registered under Option 2. These additional unannounced surveillance audits will cover only the Producer Group Quality Management (QMS) system. If the CB has 10 or fewer producer groups registered under Option 2, 1 producer group must be chosen. The 10% must not only take into account total numbers, but must be calculated considering factors such as geography, legislation (where several jurisdictions are covered by the CB), crop type, compliance history, etc.

5.2.5.2 Scope

The CB will audit the QMS of the group. Any non-conformances will lead to a sanction applied to the whole group.

5.2.5.3 Prior Notification

The CB will inform the producer group within 48 hours in advance of the intended visit. In the exceptional case where the proposed date is impossible to be accepted by the producer group (due to medical or other justifiable reasons), the producer group will have one more chance to be informed of an unannounced surveillance inspection. The producer group shall receive a written warning if the first, or where applicable, second proposed date has not been accepted. The producer group will receive another 48-hour notification of a visit. If the visit cannot take place because of non-justifiable reasons, a complete suspension will be issued.

5.3 Options 3 and 4

Benchmarking: The scheme applying for benchmarking is assessed for equivalence by comparing content and performance criteria against GLOBALGAP (EUREPGAP). Refer to the GLOBALGAP (EUREPGAP)

Benchmarking Procedure in its latest version and see the General Regulations PART
IV – Benchmarking (Options 3 & 4) for more information.

Scheme Rules: All registered producers/sites/farms Licensed/certified are operating under the Applicant Scheme rules.

GLOBALGAP (EUREPGAP) Approved CBs: All certification carried out within a full Benchmarked Standard must be done by GLOBALGAP (EUREPGAP) approved CBs that must be accredited to EN 45011 or ISO 65 to the scope of the benchmarked standard and for the case of Approved Modified Checklist (AMC) category to GLOBALGAP (EUREPGAP).

5.3.1 External Inspection by GLOBALGAP (EUREPGAP) approved CB

5.3.1.1 Frequency

The applicant scheme must ensure verification of producers according to rules for option 1 and of producer groups according to rules for Option 2

6. NON-CONFORMANCES AND SANCTIONS

6.1 Types of Non-Conformances

Three types of non-conformances exist within GLOBALGAP (EUREPGAP); Major Must, Minor Must and Contractual. They cover control point compliance and contractual issues, as detailed below:

6.1.1 Major Must Non-Conformances

6.1.1.1 Sub-scope Level

This type of non-conformance is when the producer does not comply with 100% of the Major Musts in one of the sub-scope modules.
e.g. The producer seeks certification for green beans, and a non-conformance with one of the Major Musts in the Fruit and Vegetables sub-scope is detected. The green beans **cannot** be certified and a suspension is applied.

e.g. The producer seeks certification for green beans and coffee. A non-conformance of a Major Must is detected in the Coffee sub-scope. The Coffee cannot be certified, and a warning is applied to that sub-scope. The green beans can **only** be certified **IF** the responsible CB justifies that there is no concern to the integrity of the producer and production as a whole resulting from the Major Must non-conformance in the Coffee sub-scope

6.1.1.2 Scope Base Level

A non-conformance on scope base level is when there is not 100% compliance with the Major Musts in any of the Base scopes.

e.g. The producer seeks certification for pigs. A non-conformance with one of the Major Musts in the Livestock Base scope is detected. The pigs **cannot** be certified.

e.g. The producer seeks certification for pigs and vegetables. A non-conformance with one of the Major Musts in the All Farm Base is detected; **neither** the pigs, **nor** the vegetables can be certified.

e.g. A producer seeks certification for pigs and vegetables. A non-conformance with one of the Major Musts in the Crops Base is detected, and a suspension is applied to all products covered by the Crops Scope and respective sub-scopes. The pigs can only be certified if the responsible CB justifies that there is no concern to the integrity of the producer or production as a whole resulting from the non-conformance in the Crops.

6.1.2 Minor Must Non-Conformances

When a producer complies with less than 95% of the Minor Musts of the applicable control points, a Minor Must non-conformance is issued.

e.g. 1: A producer seeks certification for cattle and complies with 100% of the Major Musts, but only 90% of the applicable Minor Musts, corrective action is needed before certification can take place.

e.g. 2: A producer seeks certification for cattle and pigs. The producer complies with 100% of the Major Musts and 95% of the applicable Minor Musts for cattle, but only with 92% of the applicable Minor Musts for pigs.

The certificate can only include pigs when corrective actions on the non-compliances have been closed out. See 6.2.2.iv

6.1.3 Contractual Non-Conformances

6.1.3.1 Major Contractual Non-Conformance

Non-compliance of any of the agreements signed in the contract between the CB and the producer that **objectively shows mismanagement** on GLOBALGAP (EUREPGAP) related procedures at producer level.

6.1.3.2 Minor Contractual Non-Conformance

Non-compliances of minor issues agreed in the contract between the CB and the producer.

6.1.3.3 Technical Contractual Non-Conformance

Non-compliance of any of the agreements signed in the contract between the CB and the producer or any issue found during the inspection that leads to technical doubts about the producer's **way of proceeding.**

6.2 Types of Sanctions

All CBs and producer groups must have in place a penalty procedure addressing non-conformances identified as described in 6.1.

Three types of sanction exist within GLOBALGAP (EUREPGAP); Warning, Suspension and Cancellation. These apply to non-conformances that result from non-compliances with control points and contractual issues. Additionally, the producer may voluntarily impose Suspensions (via the CB). Sanctions are applied to the producer as well as to the product, and can extend from before the certificate is issued (i.e. if a non-conformance is detected in a first inspection) to after it has expired (i.e. when a cancellation is applied). Producers will be prevented from changing CB until the non-conformance that led to the respective sanction is satisfactorily closed out.

6.2.1 Warning

(i) For all types of non-conformance detected, a Warning is issued.

(ii) A time period allowed for correction will be agreed upon **between the CB and producer**, up to a maximum corrective action submission period of 28 calendar days from the date of the Warning.

NOTE 1) If the non-compliance is against a **Major Must** that is not complied with, time given for compliance before suspension is applied, which is up to a maximum delay of **28 days**, will depend on the criticality of the non-compliance, in terms of safety of people, environment and consumers, evaluated by the inspector/auditor carrying out the inspection/audit decision on the period for implementing corrective actions. The CB shall make the decision on the period that is given (within the 28-day limit) to the producer for closing out the Major Must non-conformance. No time is given for compliance where a serious threat to the safety of people, environment and consumer is present. **QMS** points can be closed out through a plan for closing out the non-compliance. The period must be set according to criticality of non-compliances and circumstances, detailing the specific number of days for the producer to close out the non-compliance, up to a maximum of 28 days. The producer MUST close out Major Must non-conformances before obtaining/regaining certified status.

(iii) If the cause of the sanction is not resolved within the time period set (maximum of 28 days), a Suspension is imposed.

6.2.2 Suspension

(i) A Suspension is issued when a producer cannot show sufficient corrective action after a Warning has been issued. A suspension may also be issued to the producer who voluntarily asks for it, for some (partial) or all (complete) of his products.

(ii) After the Suspension is applied, a time period allowed for correction will be set **by the CB**, and will have a maximum validity of 6 months. If the suspension is voluntary, the period and corrective actions for compliance are

set by the farmer himself, which must be agreed upon with the respective CB(s), but must be closed out before re-registration.

(iii) During this time (period of suspension), the producer will be prevented from using the GLOBALGAP (EUREPGAP) logo/trademark, License/certificate or any other type of document that has any relation to GLOBALGAP (EUREPGAP).

(iv) Two types of Suspension exist:

a) **Partial**: only certain part(s) of the certified product scope is/are suspended.

e.g. If apples and cherries are certified, a Partial Suspension can be issued for the entire cherry production if there is not sufficient corrective action after the warning has been issued. This is only possible if the non-conformance that resulted in the warning was only detected in the cherries.

e.g. If a Warning for the following situation has not been closed out, a Partial Suspension is issued to the group whereby the one producer is suspended and not the whole group: A non-conformance is detected at one producer in a producer group, and after the CB investigated by increasing the sample size to determine the seriousness of the non-compliance within the producer group, decided that the QMS is compliant and that the one producer is non-compliant.

b) **Complete:** all certified product scopes are suspended for a period of time set by the CB. If the reason for the suspension relates to a non-conformance against the All Farm scope or Base scopes (Crops Base, Livestock Base or Aquaculture Base) that covers all the sub-scopes of the certified products, a complete suspension must be issued.

e.g. A Warning was issued based on a Major Must non-conformance in the All Farm module.

e.g. If only apples are registered and certified (in other words only one sub scope and only one product), a complete suspension must be issued.

(v) Suspension will be lifted when there is sufficient evidence of corrective action (either through a follow-up visit with additional cost to the producer, or

other written or visual evidence) within the allocated time for correction (6 months or shorter).

(vi) If the cause of the Suspension is not resolved within the time period set, the certificate and the producer will be sanctioned with a Cancellation.

6.2.3 Cancellation

(i) A Cancellation of the contract will be issued when

a) A producer cannot show sufficient corrective action after a Partial or Complete Suspension has been issued and six months have elapsed, or

b) A non-conformance in one scope leads to doubt about the integrity of the produce, or

c) When major contractual non-conformances are detected (see 6.1.3.3).

(ii) A Cancellation of the contract will result in the total prohibition of the use of the GLOBALGAP (EUREPGAP) logo/trademark, License/certificate, or any device or document that could relate to GLOBALGAP (EUREPGAP).

(iii) A producer that has had a Cancellation sanction applied may not re-submit for GLOBALGAP (EUREPGAP) certification until 12 months after the date of Cancellation.

6.3 Notification and Appeals

6.3.1 Decisions on Sanction

(i) All sanctions (Warnings, Suspensions, and Cancellations) will be decided by the CB Certification Committee (or equivalent decision making department of the CB).

(ii) Upon finding that a producer no longer conforms to the GLOBALGAP (EUREPGAP) standard, the inspector/auditor will report this to his CB and to the certified producer, detailing the non-compliances identified during the inspection.

(iii) The GLOBALGAP (EUREPGAP) Sector Committees reserve the right to impose certain sanctions for certain non-compliances. These will be detailed in an Annex and CBs and their clients will be made aware of these.

6.3.2 Producer Resolutions

(i) The producer must either resolve the non-conformances communicated or appeal to the CB in writing against the non-conformances, explaining the reasons for the appeal.

(ii) If the non-conformances are not resolved within the permitted time scale, the sanction will be escalated as explained in 6.2.

6.3.3 Lifting of Sanctions

(i) If a producer notifies the CB that the non-conformance is resolved before the set period, the respective sanction will be lifted, subject to satisfactory evidence and closing out.

6.3.4 Sanctioning of Certification Bodies

(i) GLOBALGAP reserves the right to sanction CBs based on evidence of not following procedures or clauses of the Certification and License Agreement signed between GLOBALGAP and the CB (refer to General Regulations Part II, 3.2 for Types of sanctions).

7. TRAINING

7.1 Train-the-Trainer workshops

GLOBALGAP recognizes the global need for qualified GLOBALGAP (EUREPGAP) training, which can be cost efficient and customized for growers. There is no official requirement for producers to show proof that a staff member or external adviser has attended a GLOBALGAP (EUREPGAP) training course.

GLOBALGAP will conduct Train-the-Trainer (TT) Workshops including an examination for final approval, to provide a limited but sufficient number of qualified trainers and register them on the GLOBALGAP website. Once qualified, the trainer can conduct classroom-training courses (train-the public)

For more information on training offered by GLOBALGAP and how to become an approved Train-the- Public trainer, refer to General Regulations Part V.

8. ABBREVIATIONS

8.1 Abbreviations

AB	Accreditation Body	CB	Certification Body
CC	Compliance Criteria	CoC	Chain of Custody

CP	Control Point	CPCC	Control Points and Compliance Criteria
IFA	Integrated Farm Assurance	HACCP	Hazard Analysis, Critical Control Points
NTWG	National Technical Working Group	SC	Sector Committee
CBC	Certification Body Committee	IAF	International Accreditation Forum
MLA	Multilateral Agreement	EA	European co-operation for Accreditation
CL	Checklist	QMS	Quality Management System
BMCL	Benchmarking Checklist		

9 APPENDIX I.1 RULES FOR USE OF EUREPGAP AND GLOBALGAP TRADEMARK AND LOGO

The EUREPGAP trademark and logo as defined in this document is the fully registered trademark and may never appear on the product, consumer packaging of the product, or at the point of sale. The EUREPGAP trademark will be replaced by the trademark GLOBALGAP with further notice. The EUREPGAP trademark shall be used until further notice alone or in conjunction with GLOBALGAP.

The Certification Body is expected to check up on the correct use of the EUREPGAP trademark and logo on farms at all times. Infringement of these rules by suppliers could lead to sanctions.

9.1 EUREPGAP Trademark

The EUREPGAP Trademark is the word "EUREPGAP" in any shape or form.

(i) Producers may only use the trademark sign to maximum height of 100 millimetres on pallets that only contain certified EUREPGAP products and that will NOT appear at the point of sale.

(ii) EUREPGAP certified producers may use the trademark in business-to-business communication, and for traceability/segregation/identification purposes on site at the production location.

(iii) EUREPGAP Retailer, Associate and Supplier members can use the trademark in promotional material (not directly linked to certified product) and in business-to-business communication.

9.2 EUREPGAP Logo

9.2.1 Specifications

The EUREPGAP logo and the GLOBALGAP logo must always be obtained from the GLOBALGAP Secretariat. This will ensure that it contains the exact corporate colour and format, as below:

EUREPGAP®

GLOBALG.A.P.

9.2.2 Use of EUREPGAP and GLOBALGAP Logo

The GLOBALGAP Secretariat makes use of the EUREPGAP and the GLOBALGAP logo, and Licences its restricted use to the following organisations:

(i) GLOBALGAP (EUREPGAP) Retailer, Associate and Supplier members may use it ONLY in relation to membership claims and business-to-business communication. Business-to-business communication includes the use of signs, letterheads, visiting cards, and advertisement publicity. Supplier members can only use the logo in this way when there is a valid GLOBALGAP (EUREPGAP) certificate linked to that member.

(ii) Accredited GLOBALGAP (EUREPGAP) approved Certification Bodies, for promotion of their accredited GLOBALGAP (EUREPGAP) certification activities in business-to-business communication, and on accredited GLOBALGAP (EUREPGAP) certificates by them.

NOTE: Certification Bodies that are NOT yet accredited, ***cannot*** *use the GLOBALGAP (EUREPGAP) logo on non-accredited certificates they issue.*

(iii) Any other organisation, based on individual agreements, such as GLOBALGAP approved Trainers, publications, benchmarked schemes, etc.

9.3 GLOBALGAP (EUREPGAP) Client Number

(i) The GLOBALGAP (EUREPGAP) Client Number (GGN) is a alpha-numerical number, not including the trade mark "EUREPGAP" or "GLOBALGAP", is issued by GLOBALGAP and is unique to each and every producer and any other legal entity in the GLOBALGAP (EUREPGAP) system.

(ii) On the product and/or final packaging at the point of sale, the GGN **can only** be used in connection with a GLOBALGAP (EUREPGAP) approved traceability system.

(iii) GLOBALGAP (EUREPGAP) grants approval to a traceability system based on individual assessment and a signed agreement with the traceability system owner.

9.4 Registration Number

(i) The registration number is a number that may be issued by the Certification Body to identify the producer. This number serves as alias identification to the GGN (see 9.3).

(ii) The number is made up of the Certification Body name (in its short form as agreed between the CB and the GLOBALGAP Secretariat: "CB Short name") followed by a space, followed by the number of the producer or group, as issued by the Certification Body. The trade name "GLOBALGAP (EUREPGAP)" **shall not** appear in this number.

e.g. CBXYZ 12345

NOTE: The registration number can be used, on request of a customer, with prior permission of the issuing Certification Body on the product or final packaging at the point of sale. GLOBALGAP (EUREPGAP) does not claim any responsibility with respect to traceability and authenticity of products labeled with this registration number.

10 EDITION UPDATES REGISTER

General Regulation Version	Replaces	Replaced document obsolete	New document comes into force	Description of Modification
3.0-1_2July07	3.0-Mar07	2 July 2007	2 July 2007	Modification of references in 4.4.1(i), 4.4.1(x), 4.4.2(vi), 4.8.2(viii), 4.8.2.(x), 4.9.4.1, 4.10(ii) Clarification of wording in 3.2.3, 4.4.2(ii), 4.4.2(vi)a, 4.8.2(vii), 4.9.2.1(ii); 4.9.2.1(ii)a Note, 4.9.2.2.v Note, 4.9.3.2, 4.9.5.1, 4.9.6, 4.9.6.3(ii), 6.1.1.1, 6.2, 6.2.2(v), 6.3.1(ii)
3.0-2_Sep07	3.0-1_2July07	30 Sep 2007	30 Sep 2007	Modification GLOBALGAP (EUREPGAP), see new paragraph in 4.1 and Appendix I.1; Clarification of wording: 6.1.1.1

1. For detailed information of the modifications please contact GLOBALGAP Secretariat for the History document.
2. When the changes do not affect the accreditation of the standard, the version will remain "3.0" and edition update shall be indicated with "-x".
3. When the changes do affect the accreditation of the standard, the version name will change to "3.x".

ANNEXURE- II (d)

GLOBALG.A.P (EUREPGAP) Control Points and Compliance Criteria

Integrated Farm Assurance

FRUIT AND VEGETABLES

Nº	Control Point	Compliance Criteria	Level
FV	**FRUITS AND VEGETABLES**		
FV . 1	**PROPAGATION MATERIAL**		
FV . 1 . 1	**Choice of Variety or Rootstock**		
FV . 1 . 1 . 1	Is the producer aware of the importance of effective crop husbandry in relation to the "mother crops" (i.e. the seed producing crop) of the registered product crop?	Cropping techniques and measures are adopted in the "mother crops" which can minimise inputs such as plant protection products and fertilizers in the registered product crops.	Recom.
FV . 2	**SOIL AND SUBSTRATE MANAGEMENT**		
FV . 2 . 1	**Soil Fumigation (N/A if no soil fumigation)**		
FV . 2 . 1 . 1 .	Is there a written justification for the use of soil fumigants?	There is written evidence and justification for the use of soil fumigants including location, date, active ingredient, doses, method of application and operator. The use of Methyl Bromide as soil fumigant is not permitted.	Minor Must
FV . 2 . 1 . 2	Is any pre-planting interval complied with?	Pre-planting interval must be recorded.	Minor Must
FV . 2 . 2	Substrates (N/A if no substrates are used)		

FV . 2 . 2 . 1	Does the producer participate in substrate recycling programmes for substrates where available?	The producer keeps records with quantities recycled and dates. Invoices/loading dockets are acceptable. If there is no participation in a recycling program available, it should be justified.	Recom.
FV . 2 . 2 . 2	If chemicals are used to sterilize substrates for reuse, have the location, the date of sterilization, type of chemical, method of sterilization, name of the operator and pre-planting interval been recorded?	When the substrates are sterilized on the farm, the name or reference of the field, orchard or greenhouse is recorded. If sterilized of off farm then f the name and location of the company which sterilizes the substrate are recorded. The following are all correctly recorded: the dates of sterilization (day/month/year); the name and active ingredient; the machinery (e.g. 1000 l-tank etc); the method (e.g. drenching, fogging); the operator operator's name (the person who actually applied the chemicals and did the sterilization); and the pre-planting interval.	Major Must
№	**Control Point**	**Compliance Criteria**	**Level**
FV . 2 . 2 . 3	For substrate of natural origin, can it be demonstrated that it does not come from designated conservation areas? .	There are records that prove the origin of the substrates of natural origin being used. These records demonstrate that the substrates do not come from designated conservation areas.	Recom
FV . 3	**IRRIGATION/FERTIGATION**		
FV . 3 . 1	**Quality of Irrigation Water**		
FV . 3 . 1 . 1	According to the risk analysis (CB.6.3.2), does the analysis consider the microbial contaminants ?	According to the risk analysis (if there is a risk of microbial contaminants), there is a documented record of the relevant microbial contaminants through a laboratory analysis.	Minor Must

FV . 3 . 1 . 2	If the risk analysis so requires, have adverse results been acted upon?	Records are available of corrective actions or decisions taken.	Minor must
FV . 4	**HARVESTING**		
FV . 4 . 1	**General**		
FV .4. 1 . 1	Has a hygiene risk analysis been performed for the harvest and pre-farm gate transport process?	There is a documented and up to date (reviewed annually) risk analysis covering physical, chemical and microbiological contaminants and human transmissible diseases, customized to the products. It must also include FV FV.4.1.2 to FV .4.1.2 FV.4.1.9. .4.1.9. The risk analysis shall be tailored to the scale of the farm, the crop, and the technical level of the business. No N/A.	Major Must
FV .4 . 1 . 2	Are documented hygiene procedures for the harvesting process implemented ?	The farm manager or other nominated person is responsible for implementation of the hygiene procedures. No N/A	Major Must
FV .4 . 1 . 3	Have workers received basic instructions in hygiene before handling produce?	There must be evidence that the workers received training regarding personal cleanliness and clothing, e.g. hand washing, wearing of jewellery jewellery, fingernail length or cleaning, etc.; personal behaviour , behaviour, e.g. No , smoking, spitting, etc (reference AF AF.3.1.1). .3.1.1).	Major Must
FV . 4 . 1 . 4	Are hygiene instructions and procedures for handling produce to avoid contamination of the product implemented?	There is evidence that the workers are complying with the hygiene instructions and procedures. Packers must be trained, using written (in appropriate languages) and/or pictorial instructions, to prevent physical (such as snails, stones, insects, knives, fruit residues, watches, mobile phones etc.),	Major Must

		microbiological and chemical contamination of the product during packing.	
Nº	**Control Point**	**Compliance Criteria**	**Level**
FV . 4 . 1 . 5	Are the containers and tools used for harvesting cleaned, maintained and protected from contamination?	Reusable harvesting containers, harvesting tools (i.e., scissors, knifes, pruning shears, etc.) and harvesting equipment (machinery) are cleaned and maintained, and a cleaning and disinfection schedule is in place (at least once a year) to prevent produce contamination?	Major Must
FV . 4 . 1 . 6	Are vehicles used for transport of harvested produce cleaned and maintained?	Farm vehicles used for transport of harvested produce that are also used for any purpose other than transport of harvested produce, are cleaned and maintained, and a cleaning schedule to prevent produce contamination is in place (i.e. soil, dirt, organic fertilizer fertilizer, spills, etc.).	Major Must
FV . 4 . 1 . 7	Do harvest workers that come into direct contact with the crops have access to clean hand washing equipment?	Fixed or mobile hand washing equipment to clean and disinfect hands is accessible to harvest workers. No N/A.	Major Must
FV . 4 . 1 . 8	Do harvest workers have access to clean toilets in the vicinity of their work?	Fixed or mobile toilets (including pit latrines) constructed of materials that are easy to clean and with catch basins designed to prevent contamination in the field are accessible to harvest workers within 500m and they are in a good state of hygiene. Where an employee is working independently independently, the 500m distance can be modified to allow the presence , of toilets at an increased	Minor Must

		distance, providing that there is reasonable and adequate transport available to the worker worker.	
FV . 4 . 1 . 9	Are produce containers used exclusively for produce?	Produce containers are only used to contain harvested product (i.e. No agricultural chemicals, lubricants, oil, cleaning chemicals, plant or other debris, lunch bags, tools, etc.). If multi-purpose trailers, carts, etc. are used as produce containers, they must be cleaned prior to use.	Major Must
FV . 4 . 2	Final Produce Packing at point of harvest (Applicable when during harvest, final packing and last human contact with product takes place in-field)		
FV . 4 . 2 . 1	Does the harvesting process hygiene procedure consider handling of harvested produce and produce packed and handled directly in the field, orchard or greenhouse?	All produce packed and handled directly in the field, orchard or greenhouse must be removed from the fieldovernight, in accordance with the harvest hygiene risk assessment results. All field packed producemust be covered to prevent contamination once packed.	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
FV . 4 . 2 . 2	Is a documented inspection process in place to ensure compliance with defined quality criteria?	An inspection process is in place to ensure products are packed according to documented quality criteria	Minor Must
FV . 4 . 2 . 3	Are packed produce protected from contamination?	All field packed produce must be protected from contamination.	Major Must
FV . 4 . 2 . 4	Is any collection/ storage /distribution point of field packed produce maintained in clean and hygienic conditions?	If packed produce is stored on farm, storage areas must be cleaned.	Major Must
FV . 4 . 2 . 5	Is packing material used for in-field packing, stored to protect against	Packing material must be stored to protect it against contamination	Major Must

	contamination?		
FV . 4 . 2 . 6	Are bits of packaging material and other non-produce waste removed from the field?	Bits of packaging material and non-produce waste must be removed from the field	Minor Must
FV . 4 . 2 . 7	If packed produce are stored on farm, are temperature and humidity controls (where applicable) maintained and documented?	Temperature and humidity controls (where applicable) must be maintained and documented, in accordance with the hygiene risk assessment results and quality requirements when packed produce are stored on farm.	Major Must
FV . 4 . 2 . 8	f ice or water is used in produce handling at point of harvest, is it made with potable water and handled under sanitary conditions to prevent produce contamination?	Any ice or water used at point of harvest should be made with potable water and handled under sanitary conditions to prevent produce contamination.	Minor Must
FV . 5	**PRODUCE HANDLING** (N/A if Produce Handling in a packing facility on farm is excluded from certification; see General Regulations Part I, 4.9.6.3)		
FV . 5 . 1	**Principles of Hygiene**		
FV . 5 . 1 . 1	Has a hygiene risk analysis and risk assessment been performed for the harvested crop handling process that covers the hygiene aspects of the produce handling operation?	There is a documented and up to date (reviewed annually) risk analysis of the possible risks, and an assessment of the likelihood and severity of the risks covering physical, chemical and microbiological contaminants and humantransmissable diseases, customised to the products and operation of the packhouse.	Major Must
FV . 5 . 1 . 2	Are documented hygiene procedures implemented for the process of harvested crop handling?	The farm manager or other nominated person is responsible for implementation of the hygiene procedures as a direct result of the produce handling hygiene risk	Minor Must

		analysis.	
Nº	**Control Point**	**Compliance Criteria**	**Level**
FV . 5 . 2	**Personal Hygiene**		
FV . 5 . 2 . 1	Have workers received basic instructions in hygiene before handling produce?	There must be evidence that the workers received training regarding transmission of communicable diseases, personal cleanliness and clothing, i.e. hand washing, wearing of jewellery and fingernail length and cleaning, etc.; personal behaviour behaviour, i.e. no smoking, spitting, eating, , chewing, perfumes, etc.	Major Must
FV . 5 . 2 . 2	Do the workers implement the hygiene instructions for handling produce?	There is evidence that the workers are complying with the hygiene instructions. Unless exclusion from Produce Handling declaration exists **f**or each registered product, no N/A.	Minor Must
FV . 5 . 2 . 3	Are all workers wearing outer garments that are clean and fit for purpose for the operation and able to protect products from contamination?	All workers wear outer garments (e.g. smocks, aprons, sleeves, gloves) that are clean and fit for purpose for the operation according to the risk analysis. This will depend on the product and operation.	Recom.
FV . 5 . 2 . 4	Are smoking, eating, chewing and drinking confined to designated areas segregated from products?	Smoking, eating, chewing and drinking are confined to designated areas and are never allowed in the produce handling or storage areas. (Drinking water is the exception).	Minor Must
FV . 5 . 2 . 5	Are signs clearly displayed in the packing facilities with the main hygiene instructions for workers and visitors?	Signs with the main hygiene instructions must be visibly displayed in the packing facility facility.	Minor Must
FV . 5 . 3	**Sanitary Facilities**		
FV . 5 . 3 . 1 .	Do workers in the packing facility have access to clean toilets and hand washing facilities in the vicinity of their	Toilets in a good state of hygiene must not open directly onto the produce Toilets handling area,	Major Must

	work?	unless the door is self-closing. Hand washing facilities, containing non-perfumed soap, water to clean and disinfect hands, and hand dry facilities must be accessible and near to the toilets (as near as possible without the potential for cross-contamination)	
FV . 5 . 3 . 2	Are signs clearly displayed instructing workers to wash their hands before returning to work?	Signs must be visible with clear instructions that hands must be washed before handling products, especially after using toilets, eating, etc.	Major Must
FV . 5 . 3 . 3	Are there suitable changing facilities for the workers?	The changing facilities should be used to change clothing and protective outer garments as required.	Recom.
FV . 5 . 3 . 4	Are there lockable storage facilities for the workers?	Secure storage facilities should be provided at the changing facility to protect the workers' personal belongings.	Recom.
FV . 5 . 4	**Packing and Storage areas**		
Nº	**Control Point**	**Compliance Criteria**	**Level**
FV . 5 . 4 . 1	Are produce handling and storage facilities and equipment cleaned and maintained so as to prevent contamination?	To prevent contamination, produce handling and storage facilities and o equipment (i.e. process lines and machinery machinery, walls, floors, storage areas, pallets, etc.) must be cleaned and/or maintained according to the cleaning and maintenance schedule, with defined minimum frequency Documented records of cleaning and maintenance must be kept.	Minor Must
FV . 5 . 4 . 2	Are cleaning agents, lubricants, etc. stored to prevent chemical contamination of produce?	Cleaning agents, lubricants etc. are kept in a designated area, away from where produce is packed, to avoid chemical contamination of produce.	Minor Must

FV . 5 . 4 . 3	Are cleaning agents, lubricants etc. that may come into contact with produce, approved for application in the food industry? Are dose rates followed correctly?	Documentary evidence exists (i.e. specific label mention or technical data sheet) authorising use for the food industry of cleaning agents, lubricants etc. which may come into contact with produce.	Minor Must
FV . 5 . 4 . 4	Are all forklifts and other driven transport trolleys clean and well maintained and of suitable type to avoid contamination through emissions?	Internal transport should be maintained to avoid product contamination, with special attention to fume emissions. Forklifts and other driven transport trolleys should be electric or gas-driven.	Recom.
FV . 5 . 4 . 5	Is rejected produce and waste material in the packing environment stored in designated areas, which are routinely cleaned and/or disinfected?	Rejected produce and waste materials are stored in clearly designated and segregated areas designed to avoid contamination of products. These areas are routinely cleaned and/or disinfected according to the cleaning schedule.	Minor Must
FV . 5 . 4 . 6	Are breakage safe lamps or lamps with a protective cap used above the sorting, weighing and storage area?	Light bulbs and fixtures suspended above produce or material used for produce handling are of a safety type or are protected/shielded so as to prevent contamination of food in case of breakage.	Major Must
FV . 5 . 4 . 7	Are there written glass and clear hard plastic handling procedures in place?	Written procedures exist for handling glass or clear hard plastic Written breakages in produce handling, preparation and storage areas.	Minor Must
FV . 5 . 4 . 8	Are packing materials clean and stored in clean and hygienic conditions?	Packing materials (including re-useable crates) are stored in a clean and hygienic area, to prevent product contamination until used.	Minor Must
FV . 5 . 4 . 9	Is access of animals to the facilities restricted?	Measures are in place to prevent access by animals.	Minor Must
№	**Control Point**	**Compliance Criteria**	**Level**
FV . 5 . 5	**Quality Control**		

FV . 5 . 5 . 1	Is a documented inspection process in place to ensure compliance with a defined quality standard?	An inspection process is in place to ensure products are packed according to documented quality standards	Minor Must
FV . 5 . 5 . 2	Are temperature and humidity (where applicable) controls maintained and documented where produce are packed and/or stored on farm?	If packed produce are stored on farm, temperature and humidity controls (where applicable and also for controlled atmosphere storage) must be maintained and documented in accordance with the hygiene risk assessment results.	Major Must
FV . 5 . 5 . 3	For products that are sensitive to light (e.g. potatoes), is daylight ingress controlled in longer term storage facilities?	Check for no daylight ingress.	Major Must
FV . 5 . 5 . 4	Is stock rotation being managed?	Stock rotation must be managed to ensure maximum product quality and safety	Recom.
FV . 5 . 5 . 5	Is there a process for verifying measuring and temperature control equipment?	Equipment used for weighing and temperature control, must be routinely verified to see if equipment is calibrated	Minor Must
FV . 5 . 6	**Rodent and Bird Control**		
FV . 5 . 6 . 1	Are all entry points to buildings or equipment that may come into contact with them suitably protected to prevent, whenever practically possible, the ingress of rodents and birds?	Visual assessment. No N/A isual	Minor Must
FV . 5 . 6 . 2	Are there site plans with bait points and/or traps?	Site plan showing bait points must exist. No N/A.	Minor Must
FV . 5 . 6 . 3	Are baits placed in such a manner that non-target species do not have access?	Visual observation. Non-targeted species must not have access to the usual bait. No N/A.	Minor Must
FV . 5 . 6 . 4	Are detailed records of pest control inspections and necessary actions taken, kept?	Records of pest control inspections and follow up action plan(s). The producer can have his own records.	Minor Must

		Inspections must take place whenever there is evidence of presence of pests. In case of vermin, the producer must have a contact number of the pest controller or evidence of in-house capability to control pests.	
FV . 5 . 7	**Post-Harvest Washing** (N/A when no post-harvest washing)		
№	**Control Point**	**Compliance Criteria**	**Level**
FV . 5 . 7 . 1	Is the source of water used for final product washing potable or declared suitable by the competent authorities?	The water has been 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 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.	Major Must
FV . 5 . 7 . 2	If water is re-circulated for final product washing, has this water been filtered and are pH, concentration and exposure levels to disinfectant routinely monitored?	Where water is re-circulated for final produce washing, it is filtered and disinfected, and pH, concentration and exposure levels to disinfectant are routinely monitored, with documented records maintained. Filtering must be done with an effective system for solids and suspensions that have an effective documented routine cleaning schedule according to the usage and water volume.	Major Must
FV . 5 . 7 . 3	Is the laboratory carrying out the water analysis a suitable one?	The water analysis for the product washing is undertaken by a laboratory currently accredited to ISO 17025 or its national equivalent or that can demonstrate via	Recom.

		documentation that it is in the process of gaining accreditation.	
FV . 5 . 8	**Post-Harvest Treatments** (N/A when no post-harvest treatments)		
FV . 5 . 8 . 1	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, which demonstrate that the label instructions for chemicals applied are compliant.	Major Must
FV . 5 . 8 . 2	Are all the biocides, waxes and plant protection products used for post harvest Protection of the harvested crop of harvest officially registered in the country officially of use?	All the post harvest biocides, waxes and plant protection products used on harvested crop are of officially registered or permitted by the appropriate officially 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 it is applied as indicated on the biocides, waxes and crop protection products' labels. Where no of official registration of ficial scheme exists, refer to the GLOBALGAP (EUREPGAP) guideline (CB Annex 2 PPP) on this subject and F FAO International Code of Conduct on AO the Distribution and Use of Pesticides	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
FV . 5 . 8 . 3	Are only any biocides, waxes and plant protection products used on harvested crop destined for sale in the European Union that are not banned in the European Union?	The documented post harvest biocide, wax and crop protection product application records confirm that no biocides, waxes and crop protection products that have been used within the last 12 months on the harvested crop grown under	Major Must

		GLOBALGAP (EUREPGAP) destined for sale within the E.U., have been prohibited by the E.U. (under EC Prohibition Directive List - 79/1 117/EC.) 17/	
FV . 5 . 8 . 4	Is an up-to-date list maintained of post-harvest plant protection products that are used, and approved for use, on crops being grown?	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 protection being, or which have been, grown on the farm under GLOBALGAP (EUREPGAP) within the last 12 months. No N/A.	Minor Must
FV . 5 . 8 . 5	Is the technically responsible person for the harvested crop handling process 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 self sufficient level of technical competence via nationally recognised certificates or formal training.	Major Must
FV . 5 . 8 . 6	Have the post-harvest biocides, waxes and plant protection product applications, including the harvested crops' identity (i.e. lot or batch of produce), been recorded?	The lot or batch of harvested crop treated is documented in all post-harvest biocide, wax and plant protection product application records. harvest	Major Must
FV . 5 . 8 . 7	Has the location of the post-harvest biocides, waxes and plant protection products applications been recorded?	The geographical area, the name or reference of the farm or harvested crop handling site where the treatment was undertaken is documented in all post-harvest biocide, wax and plant protection product application records.	Major Must
FV . 5 . 8 . 8	Have the application dates of the	The exact dates (day/month/year) of	Major

	post-harvest biocide, wax and plant protection product been recorded?	the applications are documented in all post-harvest biocide, wax and plant protection product application records.	Must
FV . 5 . 8 . 9	Has the type of treatment been recorded for the post-harvest biocide, wax and plant protection product applications?	The type of treatment used for product application (i.e. Spraying, drenching, gassing etc.) is documented in all post-harvest biocide, wax and plant protection product application records.	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
FV . 5 . 8 . 10	Has the product trade name of the post-harvest biocide, wax and plant protection product applications been recorded?	The trade name of the products applied is documented in all post-post harvest biocide, wax and plant protection product application records.	Major Must
FV . 5 . 8 . 11	Has the product quantity applied of the post-harvest biocide, waxes and plant protection product applications been recorded?	The amount of product applied in weight or volume per litre of water or other carrier medium is recorded in all post-harvest biocide, wax and plant protection product applications records.	Major Must
FV . 5 . 8 . 12	Has the name of the operator of the post-harvest biocide, wax and plant protection product applications been recorded?	The name of the operator who has applied the plant protection product to the harvested crop is documented in all post-harvest biocide, wax and plant protection product application records.	Minor Must
FV . 5 . 8 . 13	Has the justification for application for the post-harvest biocide, wax and plant protection product applications been recorded?	The common name of the pest, disease to be treated is documented in all post-harvest biocide, wax and plant protection product application records.	Minor Must
FV . 5 . 8 . 14	Are all of the post-harvest plant protection product applications also considered under points CB.8.6 of this document?	There is documentary evidence to demonstrate that the producer considers all post-harvest biocides and plant protection products applications under Control Points	Major Must

		CB.8.6, and acts accordingly accordingly	

EDITION UPDATE REGISTER

Control Points and Compliance Criteria Version	Replaces	Replaced document obsolete	New document comes into force	Description of Modifications
3.0-1_2July07	3.0-Mar07	2 July .2007	2 July .2007	Clarification of wording for Control Point: 5.8.3 Clarification of wording for Compliance Criterion: 5.3.1; 5.3.3; 5.3.4
3.0-2_Sep07	3.0-1_July07	30-Sep-07	30-Sep-07	Modification GLOBALGAP (EUREPGAP): Clarification of wording for Compliance Criteria: 5.3.4

1. For detailed information of the modifications please contact GLOBALGAP Secretariat for the History document.

2. When the changes do not affect the accreditation of the standard, the version will remain "3.0" and edition update shall be indicated with "-x".

3. When the changes do affect the accreditation of the standard, the version name will change to "3.x"

ANNEXURE- II (e)

GLOBALG.A.P (EUREPGAP) Control Points and Compliance Criteria

Integrated Farm Assurance

COMBINABLE CROPS

Nº	Control Point	Compliance Criteria	Level
CC	**COMBINABLE CROPS**		
CC . 1	**PROPAGATION MATERIAL**		
CC . 1 . 1	**Choice of Variety**		
CC . 1 . 1 . 1	Is the choice of variety based on acceptable agronomic performance in the local conditions?	The producer must be able to demonstrate the varieties grown meet these requirements either through official trials (variety lists), seed supplier information or customer requirements.	Minor Must
CC . 1 . 2	**Seed/Rootstock Quality and Origin**		
CC . 1 . 2 . 1	Are purchased seeds accompanied by records of variety name, batch number, supplier, seed certification details and are seed treatment records retained?	Producer must provide records of variety name, batch number, supplier, seed certification details and seed treatments applied.	Minor Must
CC . 1 . 2 . 2	Do home-saved seed have available records of the identity, source, treatments applied (e.g. cleaning and seed treatments)?	Producer must keep records and have them available on the farm.	Minor Must
CC . 2	**IRRIGATION/FERTIGATION**		
CC . 2 . 1	**Quality of Irrigation Water**		
CC . 2 . 1 . 1	According to the risk analysis (CB.6.3.2), does the analysis consider the microbial, physical and chemical contaminants?	According to the risk analysis, there is a documented record of the relevant microbial, chemical or heavy metal contaminants	Minor Must

CC . 2 . 1 . 2	If the risk analysis so requires, have adverse results been acted upon?	Records are available of corrective actions or decisions taken.	Minor Must
CC . 3	**MACHINERY AND EQUIPMENT**		
CC 3 . 1	**Hygiene**		
CC . 3 . 1 . 1	Are lorries/trucks and trailers carrying crops or stock feed clean and fit for the purpose of carrying raw materials entering into the food chain, with particular care given to the cleanliness of dual purpose trailers to prevent contamination?	Workers to demonstrate awareness at interview and visual assessment of transport vehicles. Type of cleaning must be appropriate to clean what was being previously transported. No N/A unless no supplement feeding of livestock on farm.	Major Must
CC . 3 . 1 . 2	Are all bulk loaders used for loading crops or stock feed cleaned prior to use, with particular care given to the cleanliness of dual purpose loaders, to prevent contamination?	Visual assessment that bulk loaders are kept in a clean, dry and fit state to avoid harm to the goods being carried inside	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
CC . 3 . 1 .3	Is crop or forage conditioning equipment serviced and cleaned in accordance with manufacturers' instructions and are records maintained?	Records must be available, together with manufacturers' instructions. N/A if no relevant equipment.	Minor Must
CC . 4	**CROP PROTECTION**		
CC . 4 . 1	**Choice of Chemicals**		
CC . 4 . 1 . 1	Are restrictions imposed by national or local legislation on plant protection product application methodology complied with?	Where national or local legislation imposes restrictions on methods of plant protection product application (for example: distance to water ways while spraying etc.) producer must show knowledge at interview and demonstrate compliance.	Major Must
CC . 5	**HARVESTING**		
CC . 5 . 1	**Hygiene**		

CC . 5 . 1 . 1	Do workers receive basic instructions in hygiene before handling crops destined for food or feed?	There must be evidence that the workers received training, regarding hygiene basic instructions (i.e. use of jewelery contamination with foreign, bodies, etc.).	Minor Must
CC . 5 . 1 . 2	Do harvest workers have access to clean toilets in the vicinity of their work?	Fixed or mobile toilets (including pit latrines) constructed of materials that are easy to clean and with catch basins designed to prevent contamination in the field are accessible to harvest workers within 500m and they are in a good state of hygiene. Where an employee is working independently independently, the 500m distance can be modified to allow the presence, of toilets at an increased distance, providing that there is reasonable and adequate transport available to the worker worker.	Minor Must
CC . 6	**HARVESTED CROP HANDLING**		
CC . 6 . 1	**Hygiene**		
CC . 6 . 1 . 1 .	Have workers received basic instructions in hygiene before handling product?	There must be evidence that the workers received training, regarding transmission of communicable diseases, personal cleanliness and clothing, i.e. hand washing, wearing of jewellery and fingernail length and cleaning, etc.; personal behaviour behaviour, i.e. No smoking, spitting, eating, , chewing, perfumes, etc.	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
CC . 6 . 1 . 2	Do the workers implement the hygiene instructions for handling produce?	There is evidence that the workers are complying with the hygiene instructions. No N/A.	Minor Must

CC . 6 . 1 . 3	Are smoking, eating, chewing and drinking confined to designated areas segregated from products?	Smoking, eating, chewing and drinking are confined to designated areas and are never allowed in the produce handling or storage areas. (Drinking water is the exception).	Minor Must
CC . 6 . 1 . 4	Are all product store walls, floors and horizontal surfaces of any storage, holding or reception facilities cleaned and where appropriate, washed and insecticide treated prior to use? Are residues of previous crops cleaned from all areas including ventilated floors and beneath conveyors?	Farmer to demonstrate compliance at interview and through visual inspection. Applicable to all farms that store harvested crop. Insecticides used must comply with all label instructions (registrations, consumer intervals, etc.) as in CB.8.1 and treatments must be recorded according to CB.8.2.	Major Must
CC . 6 . 1 . 5	Where livestock buildings are intended for use as product storage or temporary holding facilities, are they thoroughly cleaned and power washed at least 5 weeks prior to storage?	Farmer to demonstrate compliance at interview and through visual inspection. Applicable to all farms that store harvested crop.	Major Must
CC . 6 . 1 . 6	Are pre-harvest insect trapping in product storage areas carried out to demonstrate that cleaning operations have been successful?	Compliance to be demonstrated by the production of receipts for traps and records detailing monitoring. Baits containing nuts should not be used.	Recom.
CC . 6 . 1 . 7	Are signs clearly displayed in the handling area with the main hygiene instructions for workers and visitors?	Signs with the main hygiene instructions must be visibly displayed in the handling area.	Minor Must
CC . 6 . 2	**Quality Control**		
CC . 6 . 2 . 1	Is a documented inspection process in place to ensure compliance to a defined quality standard?	An inspection process is in place to ensure products are packed according to documented quality standards	Minor Must
CC . 6 . 2 . 2	Are temperature and humidity (where applicable) controls maintained and documented where packed produce are stored on farm?	If packed products are stored on farm temperature and humidity controls (where applicable) must be maintained and documented, in	Major Must

		accordance with the hygiene risk assessment results.	
CC . 6 . 2 . 3	Is stock rotation being managed?	Stock rotation must be managed to ensure maximum product quality and safety	Recom.
CC . 6 . 2 . 4	Is there a process for verifying measuring and temperature control equipment?	Equipment used for weighing and temperature control, must be routinely verified according to a risk analysis.	Minor Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
CC . 6 . 3	**Rodent and Bird Control**		
CC . 6 . 3 . 1	Are all entry points to buildings or equipment that may come in contact with rodents or birds suitably protected to prevent, whenever practically possible, the ingress of rodents and birds?	Visual assessment of all buildings or equipment that comes in contact with harvested product. No N/A.	Minor Must
CC . 6 . 3 . 2	Are there site plans with bait points and/or traps?	Site plan showing bait points must exist.	Minor Must
CC . 6 . 3 . 3	Are baits placed in such a manner that non-target species do not have access?	Visual observation. Non-targeted species must not have access to the bait. No N/A.	Minor Must
CC . 6 . 3 . 4	Are detailed records of pest control inspections and necessary actions taken, kept?	Records of pest control inspections and follow up action plan(s). The producer can have his own records. Inspections must take place whenever evidence of pests present. In case of vermin, the producer must have a contact number of the pest controller or evidence of in-house capability to control pests.	Minor Must
CC . 6 . 4	**Post-Harvest Treatments** (N/A if no post-harvest treatment)		
CC . 6 . 4 . 1	Are all labeling instructions observed?	There are clear procedures and documentation available, i.e. post-postharvest biocides and plant	Major Must

		protection products application records and harvest packaging/delivery dates of treated products, which demonstrate that the label instructions for chemicals applied to the harvested crop have been observed.	
CC . 6 . 4 . 2	Are only biocides and plant protection products used that are of officially registered in the country of use, and for use post-harvest on the harvested crop being protected?	All the post harvest biocides and plant protection products used on harvested crop are of officially registered or permitted by the appropriate governmental organization in the country of application and are approved for use in the country of application and are approved for use on the harvested crop to which it is applied as indicated on the biocides and plant protection products' labels. Where no of official registration scheme exists, refer to the GLOBALGAP (EUREPGAP) guideline on this subject and FAO International Code of Conduct on the Distribution and Use of FAO Pesticides.	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
CC . 6 . 4 . 3	Are only biocides and plant protection products used on harvested crop destined for sale in the European Union that are not banned in the European Union?	The documented post harvest biocide and plant protection product application records confirm that no biocides and plant protection products have been used within the last 12 months on the harvested crop grown under GLOBALGAP (EUREPGAP) destined for sale within the E.U.,having been prohibited by the E.U. (under EC Prohibition Directive List - 79/117/EC.)	Major Must

CC . 6 . 4 . 4	Is an up-to-date list maintained of post-harvest plant protection products that are used, and approved for use, on crops being grown?	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 protection being, or which have been, grown on the farm under GLOBALGAP (EUREPGAP) within the last 12 months. No N/A.	Minor Must
CC . 6 . 4 . 5	Is the technically responsible person for the harvested crop handling process able to demonstrate competence and knowledge with regard to the application of biocides and plant protection products?	The technically responsible person for the post harvest biocides and plant protection products applications can demonstrate sufficient level of technical competence via nationally recognised certificates or formal training.	Major Must
CC . 6 . 4 . 6	Have the post-harvest biocides and plant protection product applications, including the harvested crops' identity (i.e. lot or batch of produce), been recorded?	The lot or batch of harvested crop treated is documented in all post harvest biocide and plant protection product application records.	Major Must
CC . 6 . 4 . 7	Has the application of the post-harvest biocides and plant protection product applications been recorded?	The geographical area, the name or reference of the farm or harvested crop handling site where the treatment was undertaken is documented in all post-harvest biocide and plant protection product application records.	Major Must
CC . 6 . 4 . 8	Have the application dates of the post-harvest biocide and plant protection product been recorded?	The exact dates (day/month/year) of the applications are documented in all post-harvest biocide and plant protection product application records	Major Must
CC . 6 . 4 . 9	Has the type of treatment been	The type of treatment used for	Major

	recorded for the post-harvest biocide and plant protection product applications?	product application (i.e. Spraying, drenching, gassing etc.) is documented in all post-harvest biocide and plant protection product application records.	Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
CC . 6 . 4 . 10	Has the product trade name of the post-harvest biocide and plant protection product applications been recorded?	The trade name and active ingredient of the products applied are documented in all post-harvest biocide and plant protection product application records.	Major Must
CC . 6 . 4 . 11	Has the product quantity applied of the post-harvest biocide and plant protection product applications been recorded?	The amount of product applied in weight or volume per litre of water or other carrier medium is recorded in all post-harvest biocide and plant protection product applications records	Major Must
CC . 6 . 4 . 12	Has the name of the operator of the post-harvest biocide and plant protection product applications been recorded?	The name of the operator who has applied the plant protection product to the harvested crop is documented in all post-harvest biocide and plant protection product application records.	Major Must
CC . 6 . 4 . 13	Has the justification for application for the post-harvest biocide and plant protection product applications been recorded?	The common name of the pest, disease to be treated is documented in all post-harvest biocide and plant protection product application records.	Major Must
CC . 6 . 4 . 14	Are all of the post-harvest plant protection product applications also considered under points CB.8.6 of this document?	There is documentary evidence to demonstrate that the producer considers all post-harvest fungicide or insecticide applications under Control Points CB.8.6 of this document, and acts accordingly.	Major Must
CC . 6 . 5	**Storage of Harvested Crop**		

CC . 6 . 5 . 1	Is the risk of contamination by glass or any other physical contaminants prevented?	Light bulbs and fixtures suspended above harvested crop or material used for harvested crop handling are of a safety type or are protected/shielded so as to prevent contamination of food in case of breakage. The risk for contamination with any other physical contaminants must also be prevented. This applies to temporary holdings, long-term stores and all product movement areas.	Major Must
CC . 6 . 5 . 2	Is access of domestic animals and birds to the facilities restricted?	Domestic animal and bird access to facilities is managed, to prevent harvested crop contamination	Major Must
Nº	**Control Point**	**Compliance Criteria**	**Level**
CC . 6 . 5 . 3	Is a specific storage strategy required for longer term product storage?	Where longer term storage takes place, producer to demonstrate compliance by means of records detailing the regular checking and follow up actions, such as: regular monitoring of temperature and condition of product, including investigation of any changes. Bird and rodent activity, Water ingress, and hot spots within the heap must have been acted upon and remedied The frequency of inspection may be reduced once the condition of the crop has stabilized. No N/A unless no longer term storage.	Major Must
CC . 6 . 5 . 4	Is storage adapted to type of product and conditions, is implementation of best practice encouraged minimizing risk of contamination?	Storage may be inside or outside. The storage conditions are adapted to the type of product and conditions (weatherproof, solid floors, suitable walls and doors, etc.).	Major Must
CC . 6 . 5 . 5	Do harvested crops, susceptible to deterioration and, which are stored for	Damage caused by heating must be avoided. Product conditioning	Major Must

	more than a few days in conditions that may lead to their deterioration, have conditioning? Does long term stored product have a moisture content and temperature suitable for storage?	equipment must be available where applicable and producer todemonstrate compliance at interview. No N/A unless no storage for more than a few days	
CC . 6 . 5 . 6	Does the responsible person have easy access to product storage monitoring devices if they store harvested crops?	The responsible person must demonstrate compliance by showing evidence of the monitoring devices or policy.	Major Must
CC . 6 . 5 . 7	Is product drying equipment regularly maintained in line with manufacturers' instructions and are the dates recorded?	Maintenance records and manufacturer's instructions should be available	Recom
CC . 6 . 5 . 8	In the case of flat product stores, are hard outside loading areas maintained in a clean and well drained condition?	Loading areas should be clean with no dips and areas where standing water can gather.	Recom.
CC . 6 . 6 . 1	Is ex-farm transport carried out by the producer covered once loaded and during transit?	Farmer/operatives must demonstrate compliance on interview.	Minor must

EDITION UPDATE REGISTER

Control Points and Compliance Criteria Version	Replaces	Replaced document obsolete	New document comes into force	Description of Modifications
3.0-1_2July07	3.0-Mar07	2 July .2007	2 July .2007	Clarification of wording for Control Point: 6.4.3
3.0-2_Sep07	3.0-1_July07	30-Sep-07	30-Sep-07	Modification GLOBALGAP (EUREPGAP)

1. For detailed information of the modifications please contact GLOBALGAP Secretariat for the History document.

2. When the changes do not affect the accreditation of the standard, the version will remain "3.0" and edition update shall be indicated with "-x".

3. When the changes do affect the accreditation of the standard, the version name wil

ANNEXURE- II (f)

THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM (HACCP)

1. Introduction

HACCP (Hazard Analysis and Critical Control Point) is a systematic approach in identifying, evaluating and controlling food safety hazards. Food safety hazards are biological, chemical or physical agents that are reasonably likely to cause illness or injury int he absence of their control. A HACCP system is a preventive system of hazard control rather than a reactive one. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent hazards attributable to a product or a process, determining the necessary steps that will control the identified hazards, and implementing active managerial control practices to ensure that the hazards are eliminated or minimized.

Essentially, HACCP is a system that identifies and monitors specific foodborne hazards - biological, chemical, or physical properties - that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential hazards are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan.

HACCP represents an important food protection tool supported by Standard Operating Procedures, employee training and other prerequisite programs that small independent businesses as well as national companies can implement to achieve active managerial control of hazards associated with foods. Employee training is key to successful implementation. Employees must learn which control points are critical in an operation

and what the critical limits are at these points, for each preparation step they perform. Establishment management must also follow through by routinely monitoring the food operation to verify that employees are keeping the process under control by complying with the critical limits.

Local jurisdictions can effectively promote the industry's use of HACCP and apply the concepts during inspections. The implementation of HACCP continues to evolve as hazards and their control measures are more clearly defined. To meet the challenges presented by advances in food research, product development, and their impact at retail, regulatory personnel must keep themselves informed. Food protection publications issued by the food industry, professional organizations, and other groups and continuing education programs can be particularly helpful in providing an understanding of food operations and how the application of HACCP can bring a focus to food safety that traditional inspection methods have lacked.

FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. The document entitled, "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level" is discussed in Annex 2, 3. And can be found at the web site http://vm.cfsan.fda.gov/~dms/hret-toc.html. This Guide recognizes that there are differences between using a HACCP plan in food manufacturing plants. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system. The Agency recognizes that this document has areas that need to be further clarified, developed with broader input, and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

FDA has also issued the guidance document, "FDA's Recommended National Retail Food Regulatory Program Standards" as discussed in Annex 2, 3. Program Standard 3 addresses the regulatory program's use of HACCP principles at retail.

(A) Definitions

Many terms are used in discussion of HACCP that must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

1. ***Acceptable level*** means the presence of a hazard which does not pose the likelihood of causing an unacceptable health risk.
2. ***Control point*** means any point in a specific food system at which loss of control does not lead to an unacceptable health risk.
3. ***Critical control point***, as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.
4. ***Critical limit****,* as defined in the Food Code, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.
5. ***Deviation*** **means** failure to meet a required critical limit for a critical control point.
6. ***HACCP plan****,* as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.
7. ***Hazard****,* as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.
8. ***Monitoring*** **means** a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.
9. ***Preventive measure*** means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.
10. ***Risk*** means an estimate of the likely occurrence of a hazard.
11. ***Sensitive ingredient*** means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code.

12. ***Verification*** means methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

(B) History

The application of HACCP to food production was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautic and Space Administration (NASA), Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group. Application of the system in the early 1960's created food for the United State's space program that approached 100% assurance against contamination by bacterial and viral pathogens, toxins, and chemical or physical hazards that could cause illness or injury to astronauts. HACCP replaced end-product testing to provide food safety assurance and provided a preventive system for producing safe food that had universal application.

In the succeeding years, the HACCP system has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing and is widely accepted in the United States and internationally.

(C) Advantages of HACCP

FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility is to establish and maintain records that document adherence to the critical limits that relate to the identified critical control points, thus

resulting in continuous self-inspection. Secondly, a HACCP system allows the regulatory agency to more comprehensively determine an establishment's level of compliance. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a HACCP approach, both current and past conditions can be determined. When regulatory agencies review HACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better ensure that processes are under control.

Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for ensuring food safety. Regulatory agencies are challenged to find new approaches to food safety that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of HACCP-based inspections are becoming increasingly acknowledged by the regulatory community.

Examples of the successful implementation of HACCP by food establishments may be found throughout the food industry. During the past several years, FDA and a number of state and local jurisdictions have worked with two national voluntary pilot projects for retail food stores and restaurants. These projects involved more than 20 food establishments and demonstrated that HACCP is a viable and practical option to improve food safety. FDA believes that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry-wide basis.

2. HACCP principles

(A) Background of NACMCF

Established in 1988, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of

Agriculture (USDA) and comprised of participants from the USDA (Food Safety and Inspection Service), Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and state employees. NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

(B) Development of HACCP Principles

In November 1992, NACMCF defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HCCP Working Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. From this committee, HACCP was defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.
Principle 2: Determine the critical control points (CCPs).
Principle 3: Establish critical limits.
Principle 4: Establish monitoring procedures.
Principle 5: Establish corrective actions.
Principle 6: Establish verification procedures.
Principle 7: Establish record-keeping and documentation procedures.

PRINCIPLE #1: HAZARD ANALYSIS

(a) Purposes

The hazard analysis process accomplishes three purposes:

a. Hazards of significance are identified;
b. The hazard analysis provides a risk basis for selecting likely hazards;
c. Identified hazards can be used to develop preventive measures for a process or product to ensure or improve food safety.

Before beginning to develop a HACCP plan, a team should be assembled that is familiar with the overall food operation and the specific production processes to be included in the plan. The team's goal and each member's responsibilities in reaching that goal must be clearly defined.

The first step in the development of a HACCP plan for a food operation is identification of hazards associated with the product. A hazard may be a biological, chemical, or physical property that can cause a food to be unsafe. The analysis of hazards requires the assessment of two factors with respect to any identified hazard, i.e., the likelihood that the hazard will occur and the severity if it does occur. Hazard analysis also involves establishment of preventive measures for control. Hazards that involve low risk and that are not likely to occur need not be considered for the purposes of HACCP.

To be effectively addressed, hazards must be such that their prevention, elimination, or reduction to acceptable levels is attained.

Numerous issues have to be considered during hazard analysis. These relate to factors such as ingredients, processing, distribution, and the intended use of the product. These issues include whether a food contains sensitive ingredients that can create microbiological, chemical, or physical hazards; or whether sanitation practices that are used can introduce these hazards to the food that is being prepared or processed. An example is whether the finished food will be heated by the consumer, if it is consumed off the premises. Even factors beyond the immediate control of the food establishment,

such as how the food will be treated if taken out by the consumer and how it will be consumed, must be considered because these factors could influence how food should be prepared or processed in the establishment.

(b) Flow Diagram

Consequently, a flow diagram that delineates the steps in the process from receipt to sale or service forms the foundation for applying the seven principles. The significant hazards associated with each step in the flow diagram should be listed along with preventative measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a **HACCP** team that has knowledge and expertise on the product, process, and the likely hazards. Each step in a process should be identified and observed to accurately construct the flow diagram. Some examples of flow diagrams are found at the end of this Annex.

(c) Biological Hazards

Food borne biological hazards include bacterial, viral, and parasitic organisms. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these pathogens occur naturally in the environment where foods are grown. Most are killed or inactivated by adequate cooking and numbers are kept to a minimum by adequate cooling during distribution and storage.

Bacterial pathogens comprise the majority of reported food borne disease outbreaks and cases. A certain level of the pathogens can be expected with some raw foods. Temperature abuse, such as improper hot or cold holding temperatures, can significantly magnify this number. Cooked food which has been subject to cross-contamination with pathogens often provides a fertile medium for their rapid and progressive growth.

Enteric viruses can be food borne, waterborne, or transmitted from a person or from animals. Unlike bacteria, a virus cannot multiply outside of a living cell. Hepatitis A and Norwalk viruses are examples of viral hazards associated with ready-to-eat foods.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross contamination of ready-to-eat food. Fish borne parasites in products that are intended to be eaten raw, marinated, or partially cooked can be killed by effective freezing techniques.

The following table provides an assessment of severity of the biological hazards which may be associated with food being prepared, served, or sold in food establishments.

1. Hazardous Microorganisms and Parasites

Grouped on the Basis of Risk Severity[a]

Severe Hazards:

Clostridium botulinum types A, B, E, and F
Shigella dysenteriae
Salmonella Typhi; paratyphi A, B
Hepatitis A and E
Brucella abortus; *B. suis*
Vibrio cholerae 01
Vibrio vulnificus
Taenia solium
Trichinella spiralis

Moderate Hazards: Potentially Extensive Spread[b]

Listeria monocytogenes
Salmonella spp.
Shigella spp.
Enterovirulent *Escherichia coli* (EEC)
Streptococcus pyogenes
Rotavirus
Norwalk virus group

Entamoeba histolytica
Diphyllobothrium latum
Ascaris lumbricoides
Cryptosporidium parvum

Moderate Hazards: Limited Spread

Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Staphylococcus aureus
Vibrio cholerae, non-01
Vibrio parahaemolyticus
Yersinia enterocolitica
Giardia lamblia
Taenia saginata

(d) *Chemical Hazards*

Chemical hazards in foods should be considered during a hazard analysis. Chemical contaminants may be naturally occurring or may be added during the processing of food. Harmful chemicals at very high levels have been associated with acute cases of food borne illnesses and can be responsible for chronic illness at lower levels.

The following table provides some examples of chemical hazards found within the naturally occurring and added chemical categories. The Code of Federal Regulations, Title 21, provides guidance on naturally occurring toxic substances and allowable limits for many of the chemicals added during processing (food additives). The FDA Compliance Policy Guidelines also provide information on other naturally occurring chemicals.

2. Types of Chemical Hazards and Examples[a]

Naturally Occurring Chemicals

Mycotoxins (e.g., aflatoxin) from mold
Scombrotoxin (histamine) from protein decomposition
Ciguatoxin from marine dinoflagellates
Toxic mushroom species
Shellfish toxins (from marine dinoflagellates)
Paralytic shellfish poisoning (PSP)
Diarrhetic shellfish poisoning (DSP)
Neurotoxic shellfish poisoning (NSP)
Amnesic shellfish poisoning (ASP)
Plant toxins
Pyrrolizidine alkaloids
Phytohemagglutinin

Added Chemicals

Agricultural chemicals:
Pesticides, fungicides, fertilizers, insecticides, antibiotics and growth hormones
Polychlorinated biphenyls (PCBs)
Industrial chemicals
Prohibited substances

Direct
Indirect
Toxic elements and compounds:
Lead, zinc, arsenic, mercury, and cyanide

Food additives:

Direct - allowable limits under GMPs
Preservatives (nitrite and sulfating agents)

Flavor enhancers (monosodium glutamate)
Nutritional additives (niacin)
Color additives
Secondary direct and indirect
Chemicals used in establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, coatings, and paints)
Poisonous or toxic chemicals intentionally added (sabotage)

(e) Food Allergens

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially involving the production of allergen-specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label.

To combat this problem, the agency issued a letter titled "Notice to Manufacturers," dated June 10, 1996, which addressed labeling issues and Good Manufacturing Practices (GMPs). This letter is available on FDA's web site, www.cfsan.fda.gov/~lrd/allerg7.html.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.

- Peanuts
- Soybeans
- Milk
- Eggs
- Fish
- Crustacean
- Tree

- Wheat

Current FDA policy, as reflected in FDA Compliance Policy Guide (CPG) 555.250 with regard to direct addition as ingredients or sub-ingredients, is:

Products which contain an allergenic ingredient by design must comply with 21 U.S.C. 343(i)(2). Where substances that are, bear, or contain allergens are added as ingredients or sub-ingredients (including rework), the Federal Food, Drug, and Cosmetic Act (the Act) requires a complete listing of the food ingredients (section 403(i) (2); 21 U.S.C. 343(i) (2); 21 C.F.R.101.4 (689 KB)) unless a labeling exemption applies.

FDA's Regulations (21 CFR 101.100(a)(3) (689 KB)), provide that incidental additives, such as processing aids, which are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food are exempt from ingredient declaration. Some manufacturers have asserted to FDA that some allergens used as processing aids qualify for this exemption. FDA, however, does not consider food allergens eligible for this exemption. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts; therefore, the presence of an allergen must be declared in accordance with 21 CFR 101.4 (689 KB).

Allergens may be unintentionally added to food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances can be unsanitary conditions that may render the food injurious to health and adulterate the product under section 402(a) (4) of the Act [21 U.S.C. 342(a) (4)].

(f) Physical Hazards

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment.

As establishments develop their HACCP programs, the following table can be used to further identify sources of potential physical risks to the food being prepared, served, or sold.

Table 1. Main Materials of Concern as Physical Hazards and Common Sources[a,b]

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, fields, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

[a] Adapted from Corlett (1991).

[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

(f) Determining Level of Risk

The potential significance or risk of each hazard should be assessed by considering its likelihood of occurrence and severity. The estimate of risk for a hazard occurring is based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if it were to become an actuality.

Hazard identification in conjunction with risk estimation provides a rational basis for determining which hazards are significant and must be addressed in the HACCP plan. To determine risk during the hazard analysis, safety concerns must be differentiated from quality concerns. A food safety hazard is a biological, chemical, or physical property that may cause a food to be unsafe. There may be differences of opinion, even among experts, as to the risk of a hazard. The food establishment must rely upon the expert opinion published in peer reviewed literature or experts who actively assist in the development of the HACCP plan.

The hazards must at least include those that are commonly associated with a specific product. If a hazard that is commonly associated is dismissed from the plan, the basis for rejecting it must be clearly stated in the hazard analysis so that it is understood and agreed to by the regulatory authority reviewing the HACCP plan.

(g) Hazard Analysis Process

This point in hazard analysis consists of asking a series of questions which are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

i. Ingredients

Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g., ***Salmonella***, ***Staphylococcus aureus***), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

ii. Intrinsic factors of food

Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrate, water activity, preservatives) of the food during and after preparation can cause or prevent a hazard.

Which intrinsic factors of the food must be controlled in order to ensure food safety?

Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?

Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

Are there other similar products in the market place? What has been the safety record for these products?

iii. Procedures used for preparation/processing

Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores

Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

iv. Microbial Content of the Food

Is the food commercially sterile (i.e., low acid canned food)?

Is it likely that the food will contain viable spore forming or non sporeforming pathogens?

What is the normal microbial content of the food stored under proper conditions?

Does the microbial population change during the time the food is stored before consumption?

Does that change in microbial population alter the safety of the food?

v. Facility design

Does the layout of the facility provide an adequate separation of raw materials from

ready-to- eat foods?

Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

vi. Equipment design

Will the equipment provide the time/temperature control that is necessary for safe food?

Is the equipment properly sized for the volume of food that will be prepared?

Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

Is the equipment reliable or is it prone to frequent breakdowns?

Is the equipment designed so that it can be cleaned and sanitized?

Is there a chance for product contamination with hazardous substances, e.g., glass?

What product safety devices such as time/temperature integrators are used to enhance consumer safety?

vii. Packaging

Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

Is the package clearly labeled "Keep Refrigerated" if this is required for safety?

Does the package include instructions for the safe handling and preparation of the food by the consumer?

Are tamper-evident packaging features used?

Is each package legibly and accurately coded to indicate production lot?

Does each package contain the proper label?

viii. Sanitation

Can the sanitation practices that are employed impact upon the safety of the food

that is being prepared?

Can the facility be cleaned and sanitized to permit the safe handling of food?

Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

ix. Employee health, hygiene, and education

Can employee health or personal hygiene practices impact the safety of the food being prepared?

Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

Will the employees inform management of a problem which could impact food safety?

x. Conditions of storage between packaging and the consumer

What is the likelihood that the food will be improperly stored at the wrong temperature?

Would storage at improper temperatures lead to a microbiologically unsafe food?

xi. Intended use

Will the food be heated by the consumer?

Will there likely be leftovers?

xii. Intended consumer

Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill.?

Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immuno compromised individuals)?

(h) ***Developing Preventive Measures***

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards the food establishment must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

For example, if a HACCP team were to conduct a hazard analysis for the preparation of hamburgers from frozen beef patties, enteric pathogens on the incoming raw meat would be identified as a potential hazard. Cooking is a preventive measure which can be used to eliminate this hazard. Thus, cooking, the preventive measure would be listed along with the hazard (i.e., enteric pathogens) as follows:

Step	**Identified Hazard**	**Preventive Measures**
Cooking	Enteric pathogens	Cooking sufficiently to kill enteric pathogens

PRINCIPLE #2: IDENTIFY THE CRITICAL CONTROL POINTS (CCP) IN FOOD PREPARATION

A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in food preparation that may be CCPs include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene. For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens are a critical control point. Likewise, refrigeration or the adjustment of a

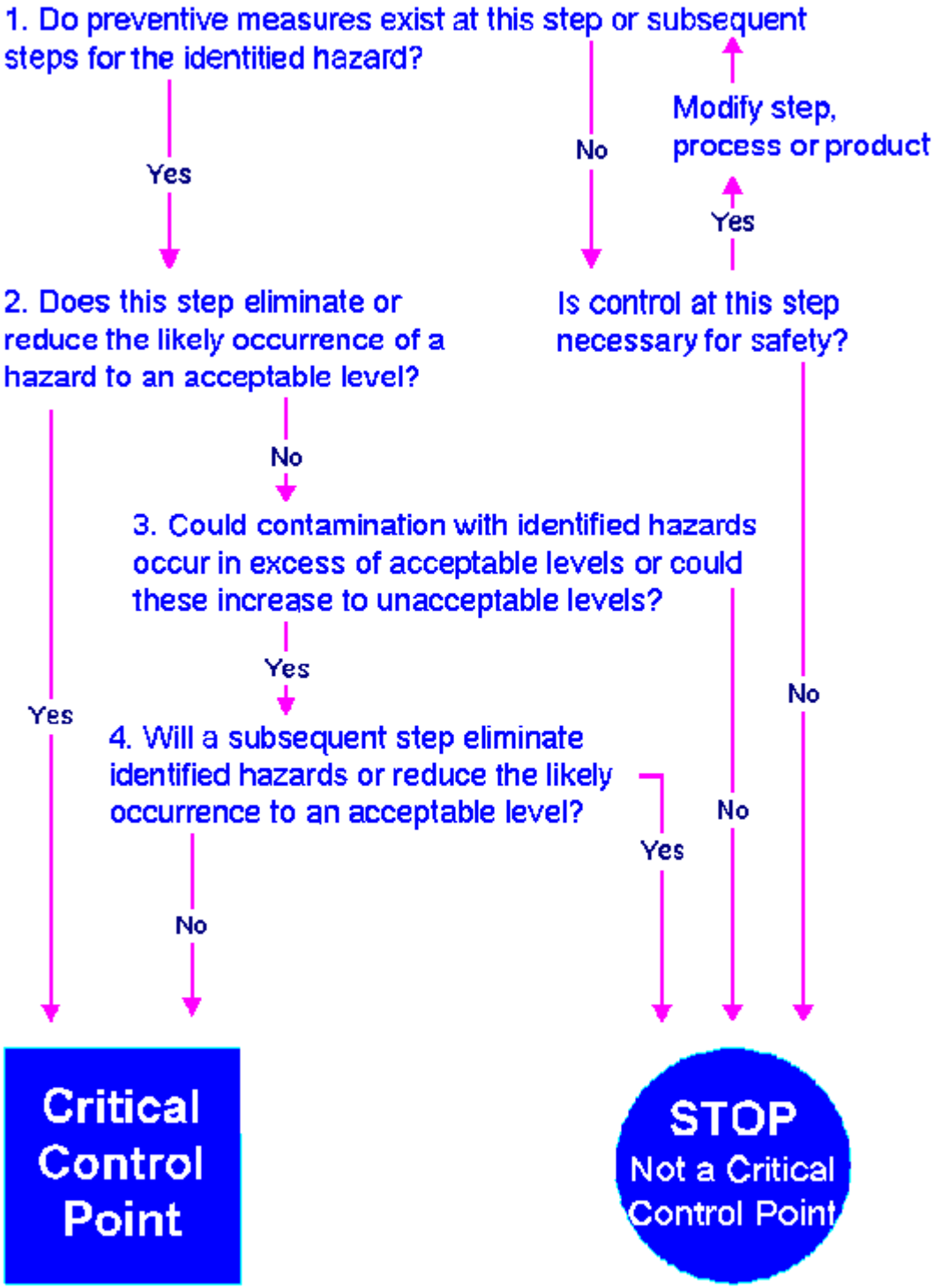
food's pH to a level required to prevent hazardous microorganisms from multiplying or toxins from forming are also CCPs.

Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control points; however, since these control points do not relate to food safety, they are not included in the HACCP plan.

Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCPs. This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is used. Generic HACCP plans can serve as useful guides; however, it is essential that the unique conditions within each facility be considered during the development of a HACCP plan.

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. The following decision tree is helpful in verifying which of the food preparation steps should be designated as CCPs.

CCP Decision Tree Table



Decision Tree adapted from NACMCF.

PRINCIPLE #3: ESTABLISH CRITICAL LIMITS FOR PREVENTIVE MEASURES

Associated with Each Identified Critical Control Point

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, a_w, pH, and available chlorine. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

Criteria Most Frequently Used for Critical Limits

- Time
- Temperature
- Humidity
- a_w
- pH
- Titratable acidity
- Preservatives
- Salt concentration
- Available chlorine
- Viscosity

(a) Critical Limit

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to ensure prevention, elimination, or reduction of hazards to acceptable levels. The food establishment is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

(b) Target Level

In some cases, variables involved in food preparation may require certain target levels to ensure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal product temperature of 71°C (160°F) during one stage of a process. The oven temperature, however, may be 71 ±3°C (160±°F); thus an oven target temperature would have to be greater than 74°C (165°F) so that no product receives a cook of less than 71°C (160°F).

(c) Application Example

An example for Principle 3 is the cooking of beef patties. The process should be designed to eliminate the most heat-resistant vegetative pathogen which could reasonably be expected to be in the product. Criteria may be required for factors such as temperature, time, and meat patty thickness. Technical development of the appropriate critical limits requires accurate information on the probable maximum numbers of these microorganisms in the meat and their heat resistance. The relationship between the CCP and its critical limits for the meat patty example is shown below:

Process Step	**CCP**	**Critical Limits**
Cooking	YES	Minimum internal temperature of patty: 68°C / 155°F Broiler temperature: _____°C / _____°F Time; rate of heating/cooling (e.g., conveyer belt speed in): cm/min: _____ ft/min _____ Patty thickness: _____ cm / ____in Patty composition: e.g., % Fat, % Filler Oven humidity: _____% RH

PRINCIPLE #4: ESTABLISH PROCEDURES TO MONITOR CCPs

(a) Observations and Measurements

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

i. It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;
ii. It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and
iii. It provides written documentation for use in verification of the HACCP plan.

Examples of Measurements for Monitoring

- Visual observations
- Temperature
- Time
- pH
- a_w

(b) *Continuous Monitoring*

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical defect, monitoring procedures must be effective.

Continuous monitoring is always preferred when feasible and continuous monitoring is possible with many types of physical and chemical methods. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts. If the temperature falls below the

scheduled temperature or the time is insufficient, as recorded on the chart, the batch must be recorded as a process deviation and reprocessed or discarded.

Instrumentation used by the food establishment for measuring critical limits must be carefully calibrated for accuracy. Records of calibrations must be maintained as a part of the HACCP plan documentation.

(c) *Monitoring Procedures*

When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control. Statistically designed data collection or sampling systems lend themselves to this purpose. When statistical process control is used, it is important to recognize that violations of critical limits must not occur. For example, when a temperature of 68°C (155°F) or higher is required for product safety, the minimum temperature of the product may be set at a target that is above this temperature to compensate for variation.

Most monitoring procedures for CCPs will need to be done rapidly because the time frame between food preparation and consumption does not allow for lengthy analytical testing. Microbiological testing is seldom effective for monitoring CCPs because of its time-consuming nature. Therefore, physical and chemical measurements are preferred because they may be done rapidly and can indicate whether microbiological control is occurring.

Assignment of responsibility for monitoring is an important consideration for each CCP within the operation. Specific assignments will depend on the number of CCPs, preventive measures, and the complexity of monitoring. The most appropriate employees for such assignments are often directly associated with the operation, such as the person in charge of the food establishment, chefs, and departmental supervisors.

Individuals monitoring CCPs must be trained in the monitoring technique, completely understand the purpose and importance of monitoring, and be unbiased in monitoring and reporting so that monitoring is accurately recorded. The designated individuals

must have ready access to the CCP being monitored and to the calibrated instrumentation designated in the HACCP plan.

The person responsible for monitoring must also record a food operation or product that does not meet critical limits and ensure that immediate corrective action can be taken. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Random checks may be useful in supplementing the monitoring of certain CCPs. They may be used to check incoming ingredients, serve as a check for compliance where ingredients are recertified as meeting certain standards, and assess factors such as equipment. Random checks are also advisable for monitoring environmental factors such as airborne contamination, and cleaning and sanitizing gloves.

With some foods containing microbiologically sensitive ingredients, there may not be an alternative to microbiological testing. However, it is important to recognize that a sampling frequency which is adequate for reliable detection of low levels of pathogens is seldom possible because of the large number of samples needed. For this reason, microbiological testing has limitations in a HACCP system, but is valuable as a means of establishing and verifying the effectiveness of control at CCPs (such as through challenge tests, random testing, or testing that focuses on isolating the source of a problem).

PRINCIPLE #5: ESTABLISH THE CORRECTIVE ACTION TO BE TAKEN WHEN MONITORING SHOWS THAT A CRITICAL LIMIT HAD BEEN EXCEEDED

(a) Purpose of Corrective Action Plan

Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

i. Determine the disposition of any food that was produced when a deviation was occurring;

ii. Correct the cause of the deviation and ensure that the critical control point is under control; and

iii. Maintain records of corrective actions.

(b) Aspects of Corrective Action Plan

Because of the variations in CCPs for different food operations and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Individuals who have a thorough understanding of the operation, product, and HACCP plan must be assigned responsibility for taking corrective action. Corrective action procedures must be documented in the HACCP plan.

Food establishments covered by the Food Code will usually be concerned with food which has a limited shelf-life and distribution. Primary focus for the application of this HACCP principle will be on the correction of the procedure or condition which led to the noncompliance. More frequent monitoring may be temporarily required to ensure that the deviation from the established critical limit is not continuing when the operation is resumed.

If a deviation should occur in food operations that are traditionally considered food processing operations, such as cook-chill, curing and smoking, or reduced oxygen packaging, the food establishment must place the product on hold pending completion of appropriate corrective actions and analyses. As appropriate, scientific experts and regulatory agencies must be consulted regarding additional testing or disposition of the product. Identification of deviant lots and corrective actions taken to ensure safety of these lots must be noted in the HACCP record. This record must remain on file for a reasonable period after the expiration date or expected shelf life of the product.

PRINCIPLE #6: ESTABLISH PROCEDURES TO VERIFY THAT *THE HACCP SYSTEM IS WORKING*

(a) Establishing Verification Procedures

i. The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory. This can be complex and may require intensive involvement of highly skilled professionals from a variety of disciplines capable of doing focused studies and analyses. A review of the critical limits is necessary to verify that the limits are adequate to control the hazards that are likely to occur.

ii. The second phase of verification ensures that the facility's HACCP plan is functioning effectively. A functioning HACCP system requires little end-product sampling, since appropriate safeguards are built in early in the food preparation. Therefore, rather than relying on end-product sampling, food establishments must rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate risk management decisions and product dispositions are made when preparation deviations occur.

iii. The third phase consists of documented periodic revalidations, independent of audits or other verification procedures that must be performed to ensure the accuracy of the HACCP plan. Revalidations are performed by a HACCP team on a regular basis and/or whenever significant product, preparation, or packaging changes require modification of the HACCP plan. The revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan. The HACCP team modifies the HACCP plan as necessary.

iv. The fourth phase of verification deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily.

(b) The following are some examples of HACCP plan verification activities which should be used as a part of a HACCP program:

i. Verification procedures may include:

- Establishment of appropriate verification inspection schedules;
- Review of the HACCP plan;
- Review of CCP records;
- Review of deviations and their resolution, including the disposition of food;

- Visual inspections of operations to observe if CCPs are under control;
- Random sample collection and analysis;
- Review of critical limits to verify that they are adequate to control hazards;
- Review of written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken;
- Validation of HACCP plan, including on-site review and verification of flow diagrams and CCPs; and
- Review of modifications of the HACCP plan.

ii. Verification inspections should be conducted:

- Routinely or on an unannounced basis, to ensure that selected CCPs are under control;
  When it is determined that intensive coverage of a specific food is needed because of new information concerning food safety;
- When foods prepared at the establishment have been implicated as a vehicle of food borne disease;
- When requested on a consultative basis and resources allow accommodating the request
- When established criteria have not been met; and
- To verify that changes have been implemented correctly after a HACCP plan has been modified.

iii. Verification reports should include information about:

Existence of a HACCP plan and the person(s) responsible for administering and updating the HACCP plan;

The status of records associated with CCP monitoring;
Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;
Deviations and corrective actions;
any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or organoleptic methods;
Modifications to the HACCP plan; and
Training and knowledge of individuals responsible for monitoring CCPs.

(c) Training and Knowledge

i. Focus and Objective

Training and knowledge are very important in making HACCP successful in any food establishment. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra.

The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times. The training plan should be specific to the establishment's operation rather than attempt to develop HACCP expertise for broad application.

The food employee's training should provide an overview of HACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper hand washing and use of utensils or gloves for working with ready-to-eat food should be stressed. The use of recipes or Standard Operating

Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks which the HACCP plan requires them to perform. This includes the development of a level of competency in their decision making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

ii. Reinforcement

Training reinforcement is also needed for continued motivation of the food establishment employees. Some examples might include:

A HACCP video training program such as the Pennsylvania Department of Environmental Regulation's Food borne Illness: It's Your Business;

Changing reminders about HACCP critical limits such as "HANDWASHING PAYS BIG DIVIDENDS" printed on employee's time cards or checks; and
Work station reminders such as pictorials on how and when to take food temperatures.

Every time there is a change in a product or food operation within the establishment, the HACCP training needs should be evaluated. For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. The employees should be made sensitive to how the changes will affect food safety

The HACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous food safety improvement cycle because the old statement is very true, "The customer's health is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the food provided by their establishment.

HACCP PRINCIPLE #7: ESTABLISH EFFECTIVE RECORD KEEPING SYSTEMS THAT DOCUMENT THE HACCP SYSTEM

(a) Written HACCP Plan

This principle requires the preparation and maintenance of a written HACCP plan by the food establishment. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's HACCP plan. HACCP plan implementation strategy should be provided as a part of the food establishment's documentation.

(b) Record Keeping

The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with HACCP procedures ultimately makes the system work. One conclusion of a study of HACCP performed by the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation. A sous vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

(c) Contents of the Plan and Records

The approved HACCP plan and associated records must be on file at the food establishment. Generally, the following are examples of documents that can be included in the total HACCP system:

i. Listing of the HACCP team and assigned responsibilities;
ii. Description of the product and its intended use;
iii. Flow diagram food preparation indicating CCPs;

iv. Hazards associated with each CCP and preventive measures;

v. Critical limits;

vi. Monitoring system;

vii. Corrective action plans for deviations from critical limits;

viii. Record keeping procedures; and
ix. Procedures for verification of HACCP system.

(d) Format for HACCP Information

In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP plan can be tabulated as follows:

Process Step	CCP	Chemical Physical Biological Hazards	Critical Limit	Monitoring Procedures Frequency Person(s) Responsible	Corrective Action(s) Person(s) Responsible	HACCP Records	Verification Procedures/ Person(s) Responsible

The following chart is an example of a HACCP plan documentation for a product cooling step in a retail level food establishment.

PROCESS STEP	**COOLING**
CCP	**Critical Control Point #8**
Criteria or Critical Limit	Cool Foods Rapidly in Small Quantities to 5℃ (41℉)
Establish Monitoring	Department Personnel Break Down Food into Small Quantities and Monitor The Cooling Process
Corrective/Preventive Action	Modify Cooling Procedures/ Discard
HACCP Records	Deli Cooking/Cooling Log