

工程または食品安全制御システムのパフォーマンスを適切に検証できるような十分な数の結果が得られるようにすべき

**moving window** アプローチは実務的かつ費用のかけずに、継続的にプロセス、食品安全コントロールシステムの微生物的パフォーマンスをチェックする方法である。

**moving window** はコントロールが望まない方向にシフトしている場合には適切な介入が行えるように、パフォーマンスの許容性を判断する**moving window**の長さはタイミング良く改善措置がとれるような適切なものであること。

**moving window** アプローチはトレンド解析と混乱させてはならない

### Trend Analysis (トレンド解析)

- ・トレンド解析はある期間（通常は比較的長期間、多くは事前に決められていない）におよぶ観察パターンの変化を検出するための手順。
- ・ **microbiological criterion**に対する微生物検査の結果を含む多くのタイプの情報に適用することができる。
- ・トレンド解析は **moving window**アプローチによって検出できないかもしれない徐々にコントロールが失われる状態、また突然のコントロールが失われたことを検出できるかもしれない。
- ・トレンド解析は製造工程の望まない変化の結果をデータの変化またはパターンを示す。それにより食品事業者が食品安全コントロールシステムがコントロール下から逸脱する前に修正措置をとれる。トレンド（またはパターン）はビジュアルかできる（例：グラフに検査結果を図示する）

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION  
OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS**

(at Step 5/8)

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**1. INTRODUCTION**

1. Diseases caused by foodborne pathogens constitute a major burden to consumers, food business operators and national governments. Therefore, the prevention and control of these diseases are international public health goals. These goals have traditionally been pursued, in part, through the establishment of metrics such as the microbiological criterion, reflecting knowledge and experience of Good Hygienic Practice (GHP) and the impact of potential hazards on consumer health. Microbiological criteria have been used for many years and have contributed to improving food hygiene in general, even when established based on empirical observation of what is achieved under existing measures without any explicit linkage to specific levels of public health protection. Advances in microbiological risk assessment (MRA), and the use of the risk management framework are increasingly making a more quantifiable estimation of the public health risk and a determination of the effect of interventions possible. This has led to a series of additional food safety risk management metrics: Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC) (see Annex II of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)). Where MRA models are available or these metrics have been elaborated, they can allow the establishment of a more direct relationship between microbiological criteria and public health outcomes.

2. The establishment and application of microbiological criteria should comply with the principles outlined in this document and should be based on scientific information and analysis. When sufficient data are available, a risk assessment may be conducted on foodstuffs and their use.

3. The microbiological safety of foods is managed by the effective implementation of control measures that have been validated, where appropriate, throughout the food chain to minimise contamination and improve food safety. This preventative approach offers more advantages than sole reliance on microbiological testing through acceptance sampling of individual lots of the final product to be placed on the market. However, the establishment of microbiological criteria may be appropriate for verifying that food safety control systems are implemented correctly.

4. Criteria for monitoring of the food-processing environment are often considered important parts of the food safety control system. Since they cannot be defined as specifically as microbiological criteria for food they generally are not used in defining the acceptability of food, and therefore they are not in the scope of the document, despite their utility in managing food safety.

5. The required stringency of food safety control systems, including the microbiological criteria used, should be appropriate to protect the health of the consumer and ensure fair practices in food trade.

Microbiological criteria used should be capable of verifying that the appropriate level of control is achieved.

6. Codex Alimentarius has a role in recommending microbiological criteria at the international level. National governments may choose to adopt Codex microbiological criteria into their national systems or use them as a starting point for addressing their intended public health goals. National governments also may establish and apply their own microbiological criteria. Food business operators may establish and apply microbiological criteria within the context of their food safety control systems.

7. This document should be read in conjunction with the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007), the *General Guidelines on Sampling* (CAC/GL 50-2004) and the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).

## 2. SCOPE AND DEFINITIONS

### 2.1 Scope

8. These Principles and Guidelines are intended to provide a framework for national governments and food business operators on the establishment and application of microbiological criteria that can be applied for food safety and other aspects of food hygiene. Microbiological criteria established for the monitoring of the food processing environment are not in the scope of this document. Microbiological criteria can be applied, but are not limited to, to the following:

- Bacteria, viruses, moulds, yeasts, and algae;
- Protozoa and helminths;
- Their toxins/metabolites; and
- Their markers associated with pathogenicity (e. g. virulence-related genes or plasmids) or other traits (e. g. anti-microbial resistance genes) where/when linked to the presence of viable cells where appropriate.

### 2.2 Definitions

9. A **microbiological criterion** is a risk management metric which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain.

10. Other definitions relevant to these guidelines include:

- *Appropriate Level of Protection (ALOP)* <sup>1</sup>
- *Food Safety Objective (FSO)* <sup>2</sup>
- *Performance Objective (PO)* <sup>2</sup>
- *Performance Criterion (PC)* <sup>2</sup>
- *Lot* <sup>3</sup>
- *Sample* <sup>3</sup>
- *Food safety control system* <sup>4</sup>
- *Validation* <sup>4</sup>
- *Verification* <sup>4</sup>
- *Attributes sampling plans* <sup>3</sup>
- *Variables sampling plans* <sup>3</sup>

<sup>1</sup> *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)

<sup>2</sup> Codex Alimentarius Commission, *Procedural Manual*

<sup>3</sup> *General Guidelines on Sampling* (CAC/GL 50-2004)

<sup>4</sup> *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008)

### 3. GENERAL PRINCIPLES

- A microbiological criterion should be appropriate to protect the health of the consumer and where appropriate, also ensure fair practices in food trade.
- A microbiological criterion should be practical and feasible and established only when necessary.
- The purpose of establishing and applying a microbiological criterion should be clearly articulated.
- The establishment of microbiological criteria should be based on scientific information and analysis and follow a structured and transparent approach.
- Microbiological criteria should be established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain.
- The intended as well as the actual use of the final product by consumers needs to be considered when setting a microbiological criterion.
- The required stringency of a microbiological criterion used should be appropriate to its intended purpose.
- Periodic reviews of microbiological criteria should be conducted, as appropriate, in order to ensure that microbiological criteria continue to be relevant to the stated purpose under current conditions and practices.

### 4 . ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

#### 4.1 General considerations

1 1 . When considering the establishment of microbiological criteria, a variety of approaches can be used depending on the risk management objectives and the available level of knowledge and data. These approaches can range from developing microbiological criteria based on empirical knowledge related to GHPs, to using scientific knowledge of food safety control systems such as through HACCP, or by conducting a risk assessment. The choice of the approach should be aligned with the risk management objectives and decisions relating to food safety and suitability.

1 2 . Since the levels/prevalence of a microorganism can change over the course of manufacture, distribution, storage, marketing and preparation, a microbiological criterion is established at a specified point in the food chain.

1 3 . The need for a microbiological criterion should be demonstrated, e. g. by epidemiological evidence that the food under consideration may represent a significant public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment.

#### 4.2 Purpose

1 4 . There may be multiple reasons for establishing and applying microbiological criteria. The purposes of microbiological criteria include, but are not limited to, the following:

- i) Evaluating a specific lot of food to determine its acceptance or rejection, in particular if its history is unknown.
- ii) Verifying the performance of a food safety control system or its elements along the food chain, e. g. prerequisite programs and/or HACCP systems.
- iii) Verifying the microbiological status of foods in relation to acceptance criteria specified between food business operators.
- iv) Verifying that the selected control measures are meeting POs and/or FSOs.
- v) Providing information to food business operators on microbiological levels, which should be achieved when applying best practices.

1 5 . In addition, a microbiological criterion is a valuable risk management metric when applied to detect potential unforeseen problems in the design and/or operation of a food safety control system and for obtaining safety and suitability information that is not otherwise available.

#### 4.3 Relationship between Microbiological Criteria, other Microbiological Risk Management Metrics and ALOP

1 6 . Microbiological criteria may be used by competent authorities and food business operators to operationalize the ALOP either directly or through other microbiological risk management metrics (e. g. PO, FSO). This requires the use of quantitative risk assessment. The risk estimation should include a

combination of several factors such as the prevalence and concentration distribution of target microorganisms, as well as any changes in these after the step for which the microbiological criterion has been set. The risk assessment should include a characterization of the variability inherent to the food production system and express the uncertainty in the risk estimate. Ongoing efforts to reduce the complexity of risk assessment should help facilitate the development and use of risk-based microbiological criteria.

17. A microbiological criterion can be linked directly to the ALOP, without explicit articulation of an FSO or a PO. One approach involves testing the acceptability of individual lots and evaluating the relative risk to public health of the lot as compared to the ALOP. Another approach is to link a microbiological criterion directly to an ALOP, using a risk assessment model to estimate the reduction in public health risk as a result of applying corrective actions to lots or processes that do not conform to the microbiological criterion.

18. Statistical models can be used to translate a PO or FSO to a microbiological criterion. The link between the PO or the FSO and the ALOP should also be demonstrated. To establish such a microbiological criterion for a food, an assumption needs to be made regarding the distribution of the target microorganism in the food. A log-normal distribution is often assumed and a default value for the standard deviation applied.

Furthermore, the maximum frequency and/or concentration of the hazard needs to be defined in the FSO or PO. If a concentration is used as a limit, also the proportion (e. g. 95%, 99%) of the distribution of possible concentrations that satisfies this limit should be defined.

#### 4.4 Components and other considerations

19. A microbiological criterion consists of the following components:

- The purpose of the microbiological criterion;
- The food, process or food safety control system to which the microbiological criterion applies;
- The specified point in the food chain where the microbiological criterion applies;
- The microorganism(s) and the reason for its selection;
- The microbiological limits ( $m$ ,  $M$ ; see Section 4.6) or other limits ( e. g. a level of risk);
- A sampling plan defining the number of sample units to be taken ( $n$ ), the size of the analytical unit and where appropriate, the acceptance number ( $c$ );
- Depending on its purpose, an indication of the statistical performance of the sampling plan; and
- Analytical methods and their performance parameters.

20. Consideration should be given to the action to be taken when the microbiological criterion is not met and the action should be specified (see Section 4.11).

21. Other considerations could include, but are not limited to, the following:

- Type of sample (e. g. type of food matrix, raw materials, finished product);
- Sampling tools and techniques;
- Prevalence and concentration data for the organism of concern (e. g. baseline data)
- Frequency and timing of sampling;
- Type of sampling (randomized, stratified etc. );
- Methodology used and, when appropriate, suitable conditions for pooling of samples;
- Economic and administrative feasibility, in particular in the choice of sampling plan;
- Interpretation of results;
- Record keeping;
- The intended and actual use of the food;
- The microbiological status of the raw material(s);
- The effect of processing on the microbiological status of the food;
- The likelihood and consequences of microbial contamination and/or growth and inactivation during subsequent handling, packaging, storage, preparation and use; and
- The likelihood of detection.

22. In addition, for a microbiological criterion targeting a foodborne pathogen, consideration should be given to:

- The evidence of actual or potential risks to health; and

- The population at risk and consumption habits.

#### 4.5 Sampling plan

2.3. In the development and selection of sampling plans consideration should be given to the principles in the *General Guidelines on Sampling (CAC/GL 50-2004)*.

2.4. The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. Variables sampling plans for inspection evaluate quantitative data without grouping it into classes. Variables sampling plans require information about the distribution of microorganisms and typically assume that the inspected variables follow a normal or log-normal distribution.

Variables sampling plans are seldom used, in part because they are not applicable to presence/absence testing. For microbiological criteria based on quantitative levels, where information is available on within lot and between lot variability, variables sampling plans can be tailored for the specific condition of a particular production process, resulting in a more informative interpretation of results.

2.5. In practice, most microbiological sampling plans designed for lot acceptance are attributes sampling plans. For these, to assess the probability of acceptance as a function of the percentage of non-conforming units, no knowledge or assumption about the underlying distribution of the microorganism is required. For attributes sampling plans to be valid, all that is required is that some probability based sampling technique (e. g. simple random sampling or stratified random sampling) is used to collect the sample units from the entire lot. For these plans, to assess the probability of acceptance as a function of the level of the target microorganism, it is necessary to know or estimate the distribution of microorganisms.

2.6. The number and size of analytical units should be those stated in the sampling plan and should not be modified where the microbiological criterion has been established for regulatory compliance. In unusual circumstances (e. g. during a foodborne outbreak situation or when a food business operator wishes to increase the likelihood of detecting contaminated lots before placing them on the market) a sampling plan with increased stringency may become appropriate and it may become necessary to adopt an alternative microbiological criterion. The rules and procedures for switching from one sampling plan to another should be clearly stated in the sampling approach. Unless the sampling plan specifies otherwise, a lot should not be subjected to repeat testing.

#### 4.6 Microbiological and/or other limits

2.7. Microbiological limits separate conforming from non-conforming analytical units.

2.8. Where the microbiological limits  $m$  and  $M$  are part of an attributes sampling plan further defined through  $n$ ,  $c$ , and the size of the analytical unit, they are expressed as presence/absence or concentration of the microorganism in one analytical unit.

2.9. In the establishment of microbiological limits in the context of microbiological criteria, any changes (e. g. decrease or increase in numbers) in the levels of the target microorganism likely to occur after the point for which the microbiological criterion has been set should be taken into account, where appropriate. It should also be clearly stated in the microbiological criterion whether the limits apply to every analytical unit, to the average, or to another specific method of calculation.

3.0. In the case of a two-class attributes sampling plan, there is one upper microbiological limit on the acceptable concentration in the analytical unit, denoted by  $m$ , and the acceptance number  $c$  is the maximum tolerable number of analytical units above the limit.

3.1. For a three-class attributes sampling plan the microbiological limit  $m$  separates conforming from marginally acceptable, and a limit  $M$  defines non-conforming analytical units. In this case, the acceptance number  $c$  refers to the maximum allowable number of marginally acceptable analytical units.

3.2. Alternatives to microbiological limits  $m$  and  $M$  may be used in applying microbiological criteria to other risk management metrics or the ALOP.

#### 4.7 Analytical methods

3.3. Depending on the microbiological limit (e. g. presence/absence of a specific foodborne pathogen), an appropriate analytical method should be selected. The methods used should be fit for purpose, meaning the method has been validated for relevant performance characteristics (e. g. limit of detection, repeatability, reproducibility, inclusivity, exclusivity). The validation study should be based on internationally accepted protocols and include an interlaboratory study. If not available, a validation should be done by the laboratory applying the method, according to a standardised protocol.

3.4. The analytical methods specified should be reasonable with regard to complexity, availability of media, equipment, ease of interpretation, time required and costs.

35. The results of testing may be impacted by compositing (i. e. pooling) of sample units prior to analysis. Compositing will affect the final concentration in the tested sample and is not appropriate for enumeration methods of analysis or within three-class sampling plans. Compositing may be considered in the case of presence/absence testing within a two-class sampling plan, as long as it is ensured that the result of testing will not be affected when compared to testing of individual analytical units.

#### 4.8 Statistical performance

36. The statistical performance of a sampling plan is usually illustrated by its operating characteristic (OC) curve, which describes the probability of acceptance as a function of the actual proportion of non-conforming analytical units or concentration of the microorganisms in the food. An OC curve can be used to evaluate the influence of individual parameters of the sampling plan on the overall performance of the plan.

37. Web-based tools for evaluation of sampling plans developed by FAO and WHO through JEMRA or by others can be utilised to evaluate sampling plans under consideration.

#### 4.9 Moving Window

38. In a moving window approach a sufficient number of sample units ( $n$ ) is collected for a defined period of time (the “window”). The results of the latest  $n$  sample units are compared with the microbiological limit(s) ( $m$ ,  $M$ ) using the acceptance number  $c$ . Each time a new result from the sampling period is available, it is added to the window while the oldest result is removed, creating the “moving window”. This approach can also be applied to a set of results, e. g. results obtained during a week. The window, always consisting of  $n$  results, moves one result or set of results forward in time. In determining the size of the moving window consideration should be given to the combination of the production frequency and sample frequency necessary to obtain a sufficient number of results that enables appropriate verification of performance of a process or a food safety control system.

39. The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a process or a food safety control system. As in the traditional point-in-time approach commonly used in connection with microbiological criteria, the moving window determines the acceptability of the performance so that appropriate interventions can be made in case of unacceptable shifts in control.

40. The length of the moving window should be appropriate to enable corrective action to be taken in a timely manner. If more than  $c$  out of  $n$  results is above the limit  $m$ , or the limit  $M$  is exceeded, then corrective action is required.

41. The moving window approach should not be confused with trend analysis, which is described in the following section.

#### 4.10 Trend Analysis

42. Trend analysis is a procedure to detect a change in the patterns of observations over a period of time (usually over a relatively long period of time, often not predefined). It can be applied to many types of information including results of microbiological testing against a microbiological criterion. Trend analysis can detect a gradual loss of control that might not be detected by a moving window approach, as well as a more sudden loss of control.

43. Trend analysis may show changes or patterns in the data that are a result of unwanted changes in the manufacturing process enabling the food business operator to take corrective actions before the food safety control system is out of control. The trends (or patterns) can be visualized, e. g. by displaying the test results graphically.

#### 4.11 Action to be taken when the microbiological criterion is not met

44. In situations of non-conformance with the microbiological criterion (unsatisfactory results), actions to be applied should include corrective actions related to the purpose of the testing. These actions should be based on an assessment of the risk to the consumer where relevant; the point in the food chain, and the food specified and may consider history of conformance. Food business operators should re-evaluate their food safety control systems, including GHP and operational procedures, and/or further investigation to determine appropriate preventative actions to be taken.

45. In the event of a non-conformance with a microbiological criterion for a foodborne pathogen, actions should include appropriate product containment and disposition. This may include further processing, diversion to an alternate use, withdrawal and/or recall, rework, rejection or destruction of product, and/or

<http://www.mramodels.org/sampling/>

further investigation to determine appropriate actions to be taken. Other actions taken may include more frequent sampling, inspection and audits, fines or official suspension of operations.

#### 4.12 Documentation and Record Keeping

46. Documentation and records are essential to support the microbiological criterion, e. g. documentation on scientific evidence underpinning the microbiological criterion, records on application/performance of the microbiological criterion. Records such as test reports should give the information needed for complete identification of the sample, the sampling plan, the analytical method, the results and, if appropriate, their interpretation. Reporting against the microbiological criterion may be required by some national governments. See also Section 5.7 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 2.3.7 of the *General Guidelines on Sampling* (CAC/GL 50-2004).

47. Records should be maintained documenting all instances of non-conformance with the microbiological criterion, together with records of the corrective actions taken, both to manage food safety risks and to prevent further instances of non-conformance.

### 5. REVIEW OF MICROBIOLOGICAL CRITERIA FOR FOODS

48. As establishing and implementing microbiological criteria is a part of Microbiological Risk Management (MRM) activities, refer to the Section 8.2 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007). In addition, revision of microbiological criteria should be considered in response to revision of other MRM Metrics and also in response to emerging issues or changes in the following, but not limited to:

- Taxonomy, prevalence or distribution for selected microorganisms;
- The incidence of disease including attribution to specific foods;
- Traits of microorganisms (e. g. anti-microbial resistance, virulence);
- The suitability of an indicator organism;
- Available analytical methods/tests/appropriateness of test;
- Food/ingredients/technology/process of food production;
- Food safety control system;
- Population(s) at risk;
- Consumer behaviour or dietary intake pattern of the food concerned;
- Understanding/knowledge of risk;
- Trend analysis results; and
- Required level of assurance.

49. A review of the microbiological criterion may be initiated and carried out by national governments and/or food business operators. Codex members may propose review of microbiological criteria in Codex texts.

50. A review will result in retention, adjustment or revocation of a microbiological criterion, as appropriate.

51. The risk management framework should be used to continuously improve, refine and adjust the relevant components of the microbiological criterion in relation to their effectiveness, to improved scientific knowledge and the increasing knowledge of public health risk and related food safety risk management metrics (FSO, PO and PC). The goal should ultimately be to achieve a more quantifiable estimation of the linkages between microbiological criteria, other metrics and public health outcomes.

52. When microbiological criteria have been developed to address specific risk outcomes they should be reviewed against those outcomes and, if shown not to be effective, they should be adjusted or revoked.



表 1 構成对照表

<p>PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS (<i>CAC/GL 21 – 1997</i>)</p>	<p>PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS (Step5/8)</p>
<p>Introduction..</p> <p>1. DEFINITION OF MICROBIOLOGICAL CRITERION</p> <p>2. COMPONENTS OF MICROBIOLOGICAL CRITERIA FOR FOODS</p> <p>3. PURPOSES AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS...</p> <p><i>3.1.1 Application by regulatory authorities.</i></p> <p><i>3.1.2 Application by a food business operator...</i></p> <p>4. GENERAL CONSIDERATIONS CONCERNING PRINCIPLES FOR ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA</p> <p>5. MICROBIOLOGICAL ASPECTS OF CRITERIA</p> <p><i>5.1 Microorganisms, parasites and their toxins/metabolites of importance in a particular food ..</i></p> <p><i>5.2 Microbiological methods .</i></p> <p><i>5.3 Microbiological limits....</i></p> <p>6. SAMPLING PLANS, METHODS AND HANDLING .</p> <p>7. REPORTING.....</p>	<p>1. Introduction</p> <p>2. Scope and Definitions</p> <p>2.1 Scope</p> <p>2.2 Definitions</p> <p>3. <u>General Principles</u></p> <p>4. Establishment and Application of Microbiological Criteria</p> <p>4.1 General considerations</p> <p>4.2 Purpose</p> <p>4.3 Relationship between Microbiological Criteria, other Microbiological Risk Management Metrics and ALOP</p> <p>4.4 Components and other considerations</p> <p>4.5 Sampling Plan</p> <p>4.6 Microbiological and/or other limits</p> <p>4.7 Analytical Methods</p> <p>4.8 Statistical Performance</p> <p>4.9 <u>Moving Window</u></p> <p>4.10 <u>Trend Analysis</u></p> <p>4.11 Actions to be taken when the Microbiological Criterion is not met</p> <p>4.12 Documentation and Record Keeping</p> <p>5. Review of Microbiological Criteria for Foods</p>

主な内容の対比

なお、このMC本文書は1997年版と次のような変更点がある。

	新	旧(CAC/GL 21 - 1997)
定義	<p><b>A microbiological criterion</b> はリスク管理の数的指標 (metric) で、フードチェーンのなかの特定のポイントにおける、微生物、毒素、代謝産物または病原性に関連したマーカー等の検査結果に基づき、食品、工程または食品安全コントロールシステムの出来 (performance) の許容性を示唆するもの</p>	<p>食品のための microbiological criterion は、単位体積、面積、重量またはロット当たりの微生物 (寄生虫または毒素/代謝産物を含む) の存在・不在または菌数に基づき、製品、またはある食品のロットの許容性を判断するもの</p>
スコープ	<p>これらの原則及びガイドラインは国の政府及び食品事業者に対し、食品安全及びその他の食品衛生に適用されるMCを設定し、適用するための枠組みを提供するためのもの</p> <p>・MC食品加工環境のモニタリングのために設定されるMCは本文書のスコープではない。</p> <p>MCは以下 (ただし限定されない) に適用される:</p> <ul style="list-style-type: none"> <li>●細菌, ウイルス, かび, 酵母, 及び藻類;</li> <li>●原虫及び蠕虫;</li> <li>●毒素/代謝産物;</li> <li>●病原性に関連したマーカー (例: 毒性に関連した遺伝子またはプラスミド) またはその他の形質(例: 抗菌剤耐性遺伝子) いくっている細胞との関連性が適切な場合に限る</li> </ul>	<p>この文書の目的のため、微生物には次が含まれる:</p> <ul style="list-style-type: none"> <li>- 細菌, ウイルス, かび, 酵母, 及び藻類;</li> <li>- 寄生原虫及び蠕虫;</li> <li>- 毒素/代謝産物.</li> </ul>
一般原則	<p>MCは消費者の健康を守るため、場合によっては食品貿易における公正な取引を保障するため、適切であること。</p> <ul style="list-style-type: none"> <li>●MCは必要なときにのみ設定し、実務的で実行可能であること</li> <li>●MCを設定し、適用する目的を明確に文書に記述すること。</li> <li>●MCの設定は科学的な情報及び解析に基づくべきであり、構造建てた、透明なアプローチで実施すること。</li> <li>●MCは微生物、それらの発生及びフードチェーンにおける挙動に関する情報に基づき設定すること。</li> <li>●MCを設定するときには最終製品の意図される、また消費者による実際の使用を検討する必要がある</li> </ul>	<p>ない</p>

	<ul style="list-style-type: none"> <li>• 使用するMCの必要とされる厳しさ (stringency) は意図する目的に対して適切なものであること。</li> <li>• 現在の条件及び取り扱いにおいても、MC が記述した目的に対し、継続的に適切であることを確認するため、MC は定期的なレビューを行うこと。</li> </ul>	
<p>目的</p>	<p>MCを設定し、適用する複数の理由がある。MCの目的には次のようなものがある：</p> <ul style="list-style-type: none"> <li>i) 特定のロットの食品を受入るか、受入拒否するかを評価するため、特にその食品の履歴が不明なとき。</li> <li>ii) 食品安全コントロールシステムまたはそのフードチェーン上の要素 (elements) の performanceを検証するため 例：prerequisite programs and/or HACCP システム。</li> <li>iii) 食品事業者間で取りきめられる受入れ規格に関連して、食品の微生物的 status を 検証するため</li> <li>iv) 選択した制御措置 (control measures) がPOs and/or FSOsを満たしているか、検証するため</li> <li>v) ベストな衛生管理を行ったときに達成すべき微生物レベルに関する情報を食品事業者に伝えるため。</li> </ul> <p>さらに MCは、食品安全コントロールシステムをデザインまたは適用する際に予見できない、潜在的な問題を検出することができ、また、他で入手できない食品安全およびsuitabilityに関する情報が得られる、価値のあるリスク管理上の数的指標である</p>	<p>MC はデザインの要件を策定したり、適切なフードチェーン上のいかなるステージにおける生の原材料、原料および最終製品に関する、必要とされる微生物学的状態を示すのに使用できる。</p> <p>食品（生の原材料及び原料を含む）で、出荷先が不明または不確実な場合、またはHACCPに基づくシステムおよび優良衛生規範の効果を検証する他の手立てがない場合に、食品（生の原材料及び原料を含む）の検査にも適切となりうる。</p> <p>一般的に、MCは規制当局または食品事業者によって、生の原材料、原料、製品、ロットが許容できるか否かを判断するのに適用されうる。</p> <p>MCは、工程が食品衛生の一般原則 (CAC/RCP 1-1969)に従っているかを決めるために用いられることもある。</p>

Main		Annex I		Annex II		Annex III		Annex IV		Annex V						
INTRODUCTION	DESCRIPTION	INTRODUCTION	DESCRIPTION	INTRODUCTION	DESCRIPTION	INTRODUCTION	DESCRIPTION	INTRODUCTION	DESCRIPTION	INTRODUCTION	DESCRIPTION					
	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 health benefits 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 fruit and vegetables over the past two decades. However, the recent increase in reports of food borne illnesses associated with fresh fruits and vegetables has raised concerns from public health agencies and consumers about the safety of these products.	The health benefits associated with fresh fruits and vegetables combined with the on-going consumer 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 home, the preparation of these products has moved from the point of consumption to the food processor or retailer. The processing of fresh produce under 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 <i>Salmonella</i> spp., <i>Shigella</i> spp., pathogenic strains of <i>Escherichia coli</i> , <i>Listeria monocytogenes</i> , <i>Novosphrangium</i> like virus and hepatitis A virus and parasites such as <i>Cryptosporidium</i> . Some of these pathogens are also associated with fresh produce. The scientific literature proposes microbiological decontamination of seeds treatment which can achieve different levels of pathogen reduction. There is currently no treatment available that can guarantee pathogen free seeds. Research is in progress to find efficient microbiological decontamination treatments which would provide sufficient pathogen reduction on seeds especially if pathogens are resistant.	1	OBJECTIVE This code addresses Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) 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 practiced. 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.	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 (GMP) 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.	1	OBJECTIVE This annex recommends control measures to occur in two areas: during seed production and during sprout production. During seed production, conditioning and storage, the application of Good Agricultural Practices (GAP) and Good Hygienic Practices (GHP) are aimed at preventing microbial pathogens contamination of seeds. During sprout production, the microbiological decontamination of seeds step is aimed at reducing potential contaminants and the good hygienic practices at preventing the introduction of microbial pathogens and minimizing their potential growth. The degree of control in these two areas has a significant impact on the safety of sprouts.	1	OBJECTIVE The objective of this Annex is to provide specific guidance to reduce the microbial food safety risks associated with fresh leafy vegetables that are intended to be consumed without cooking during their production, harvesting, packing, processing, storage, distribution, marketing and consumer use. This includes fresh, pre-cut, pre-washed or ready-to-eat products such as pre-packaged salads. Because of the diversity of leafy vegetables and practices and conditions used throughout the supply chain, recommendations to minimize microbial contamination will be most effective when adapted to specific operations.	1	OBJECTIVE Hygienic recommendations for the primary production of fresh fruits are covered in general under the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003). The primary purpose of this Annex is to provide specific guidance on how to minimize microbiological hazards during primary production through packing and transport of fresh melons, including fresh melons processed for the pre-cut market and consumer use.	1	OBJECTIVE Hygienic recommendations for the primary production of fresh fruits are covered in general under the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003). The primary purpose of this Annex is to provide specific guidance to minimize microbiological hazards during primary production through packing and distribution of fresh melons, as well as fresh berries that are processed without a microbiological step (e.g. frozen berries eaten raw and ready-to-eat berries) and consumer use.	1	OBJECTIVE Berries are geographically diverse and represent a wide range of phenotypically unique fruits. Not only are they diverse in the size, shape and colour of their fruits, they are also diverse horticulturally, from low growing berries (e.g. strawberry), to small bushes (e.g. blackberries, blueberries, raspberries) and tall shrubs (e.g. blackcurrant and gooseberry). All are perennial and some are cultivated as annuals (e.g. strawberry) must be cultivated while others are collected from the wild (e.g. wild blueberry). These fruits are relevant to international trade due to increasing consumption of fresh produce and globalization as a result of changes and/or optimization in production and distribution. There is increasing awareness on the risk factors associated with berry consumption on the part of public health officials. Berries have been associated with several foodborne illness outbreaks caused by a broad range of etiological agents, from viruses (Hepatitis A, Norovirus), to bacteria (e.g. <i>Coli</i> O157:H7 2, 3 and protozoa ( <i>Cryptosporidium parvum</i> , <i>Cryptosporidium parvum</i> ). Most berries are conventionally marketed as ready to eat fruits. The handling of berries during production and harvesting and the broad range of etiological agents that have been associated with berry consumption suggest that the safety of these fruits that are consumed raw is highly dependent on maintaining good hygienic practices along the food chain, including up to the point of consumption.
	SCOPE, USE AND DEFINITIONS		SCOPE, USE AND DEFINITIONS		SCOPE, USE AND DEFINITIONS		SCOPE, USE AND DEFINITIONS		SCOPE, USE AND DEFINITIONS		SCOPE, USE AND DEFINITIONS					
2.1	Scope		Scope		Scope		Scope		Scope		Scope					
2.2	Use		Use		Use		Use		Use		Use					
2.3	Definitions		DEFINITIONS		DEFINITIONS		DEFINITIONS		DEFINITIONS		DEFINITIONS					
3	PRIMARY PRODUCTION		PRIMARY PRODUCTION		PRIMARY PRODUCTION		PRIMARY PRODUCTION		PRIMARY PRODUCTION		PRIMARY PRODUCTION					
3.1	Environmental hygiene				ENVIRONMENTAL HYGIENE		ENVIRONMENTAL HYGIENE		ENVIRONMENTAL HYGIENE		ENVIRONMENTAL HYGIENE					



3.2.1.2	Manure, biosolids and other natural fertilizers	<p>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:</p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>Minimize direct or indirect contact between manure, biosolids and other natural fertilizers, and fresh fruits and vegetables, especially close to harvest.</li> <li>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 control) should be implemented to minimize the risk.</li> <li>Avoid loading 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.</li> </ul>	3.2.1.2	Manure and biosolids	<p>When seeds are destined for the production of sprouts for human consumption, wild or domestic animals should not be allowed to graze in the fields where seeds are grown (e.g. employing sheep for spring clip back of alfalfa). It is particularly important to prevent microbial contamination during the production of seeds which will be used to produce sprouts for human consumption because of the potential for pathogens to grow during the sprouting process. Consequently, manure, biosolids and other natural fertilizers should only be used when they have undergone treatments which achieve a high level of pathogen reduction.</p>	3.2.1.2	Manure, biosolids and other natural fertilizers	<p>Manure, biosolids and other natural fertilizers may contain human or animal waste, animal parts or products, or be composed primarily of plant materials. Because of this, natural fertilizers and other soil amendments may contain human pathogens that may persist for weeks or even months, particularly if treatment of these materials is inadequate.</p> <p>Proper treatment of biosolids, manure and by-products (e.g. physical, chemical, or biological treatment) will reduce the risk of potential human pathogen survival. The persistence of human pathogens in soil depends on many factors (soil type, relative humidity, temperature, Ultraviolet Index 1 and pathogen type among other known factors). Composting, if done properly, can be a practical and efficient method to inactivate human pathogens in manure. When using aerobic composting methods, compost heaps should be regularly and thoroughly turned so that all of the material will be exposed to elevated temperatures because pathogens can survive for months on the heap surface. Anaerobic methods can also effectively inactivate pathogens; however, special consideration should be given to determine the length of time needed to inactivate pathogens that may be present. In general, only fully decomposed animal waste or plant materials should be applied to fresh leafy vegetables.</p> <p>Fresh leafy vegetables may be contaminated through direct contact with contaminated soil amendments. Therefore untreated and/or partially treated manure, biosolids, and other natural fertilizers should not be applied to leafy vegetables after plant emergence unless it can be demonstrated that product contamination will not occur. Field soil contaminated with human pathogens may also provide a means of fresh leafy vegetables contamination via rain splash or plant uptake. Therefore, establishing suitably conservative pre-plant fertilizer intervals appropriate for specific regional and field conditions is an effective step towards minimizing risk. Competent authorities should provide guidance on appropriate intervals.</p>	3.2.1.2	Manure, biosolids and other natural fertilizers	<p>Manure, biosolids and other natural fertilizers may contain human or animal waste, animal parts or products, or be composed primarily of plant materials. Because of this, foodborne pathogens may be present and may persist for weeks or even months, particularly if treatment of these materials is inadequate.</p> <p>Growers should consider the following when using any of these materials:</p> <ul style="list-style-type: none"> <li>Use proper treatment by physical, chemical or biological methods to reduce the risk of potential human pathogen survival.</li> <li>Composting, if done properly, can be a practical and efficient method to inactivate foodborne pathogens in manure. In general, only fully decomposed animal waste or plant material should be applied to melon fields.</li> <li>When using aerobic composting methods, regularly and thoroughly turn compost heaps to ensure that all of the material will be exposed to elevated temperatures because pathogens can survive for months on the heap surface.</li> <li>When using anaerobic methods, special consideration should be given to determine the length of time needed to inactivate pathogens that may be present.</li> <li>Use of untreated and/or partially treated manure, biosolids, and other natural fertilizers should not be used after plant emergence or after a transplant is put into the soil, unless it can be demonstrated that product contamination will not occur.</li> </ul>	3.2.1.2	Manure, biosolids and other natural fertilizers	<p>The use of untreated manure and liquid manure should be avoided to the extent possible. Foodborne pathogens can persist in soil for long periods of time and as some berries have a short production cycle, they could become contaminated by pathogens in the manure.</p> <p>Growers who are purchasing manure, biosolids and other natural fertilizers that have been treated to reduce microbial or chemical contaminants should obtain documentation from the supplier that identifies the origin, treatment used, tests performed and the results thereof. Growers may also evaluate the information provided by the supplier on testing for contamination of natural fertilizer samples or auditing the composting process.</p>				
3.2.1.3	Soil	<p>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.</p>																
3.2.1.4	Agricultural chemicals	<ul style="list-style-type: none"> <li>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.</li> <li>In order to minimize and contain the emergence of microbial resistance: <ul style="list-style-type: none"> <li>the use of antimicrobial agents significant to human and animal therapy should be avoided.</li> <li>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.</li> </ul> </li> <li>Agricultural workers who apply agricultural chemicals should be trained in proper application procedures.</li> <li>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 application and harvesting is appropriate.</li> <li>Agricultural chemical sprayers should be calibrated, as necessary, to control the accuracy of the rate of application.</li> <li>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.</li> <li>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.</li> <li>Agricultural chemicals should be kept in their original containers, labelled 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.</li> <li>Empty containers should be disposed of as indicated by the manufacturer. They should not be used for other food-related purposes.</li> </ul>	3.2.1.4	Agricultural chemicals	<p>Seed producers should only use chemicals (e.g. pesticides, desiccants) which are acceptable for seeds intended for the production of sprouts for human consumption.</p>													
3.2.1.5	Biological control	<p>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.</p> <p>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.</p>																
3.2.2.2	Indoor facilities associated with growing and harvesting	<p>For operations where fresh fruits and vegetables are grown indoors (greenhouses, hydroponic culture, etc.) suitable premises should be used.</p>																
3.2.2.2	Indoor facilities associated with growing and harvesting																	
3.2.2.1	Location, design and layout	<ul style="list-style-type: none"> <li>Premises and structures should be located, designed and constructed to avoid contaminating fresh fruits and vegetables and harbouring pests such as insects, rodents and birds.</li> <li>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.</li> </ul>																
3.2.2.1	Location, design and layout																	

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.							3.2.2.2	Protective agricultural structures	Some protective agricultural structures are located in the field (hoop houses, high tunnels, etc.) Factors that influence the magnitude and frequency of the transfer of pathogenic microorganisms in the field, such as the climate, weather, topology, hydrology and other geographic characteristics in or nearby the field may pose a similar risk for certain protective structures. The methods for adequate maintenance of the environment around the structures include, but are not limited to: - Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests. • Adequately draining areas that may contribute contamination to food by providing a breeding place for pests • Runoff, leakage, or polluted water flowing into food growing areas. • Transfer of contaminants via equipment or foot traffic. • The land nearby certain protective structures (high tunnel, hoop house, etc.) should not be a significant source of contamination. Appropriate measures should be taken to minimize any relative risks from surrounding land use or environment. These measures may include berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards.						
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.							3.2.2.3	Water supply	Refer to 3.2.1.1 (Water for Irrigation) and 3.2.1.3 (Hydroponic Water)						
									3.2.2.4	Drainage and waste disposal	The following should be considered: • Good drainage should be maintained around the structure to eliminate standing water. • Waste disposal systems and facilities should be provided. All refuse should be disposed of in containers with lids and stored away from the facility to prevent harborage of pests. • Refuse containers should be emptied regularly.						
									3.2.2.5	Cleaning, maintenance and sanitation	• Workers and visitors should take effective measures (e.g., wash hands) before entering greenhouses. • Plant debris and cull piles should be removed promptly from inside the structure. There should be no plant refuse around the outside of the structure or nearby to attract or harbour pests.						
3.2.5	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.							3.2.5	Personnel health, hygiene and sanitary facilities	The following should be considered: • Each business operating primary production should have written Standard Operating Procedures (SOPs) that relate to health, hygiene and sanitary facilities. The SOPs should address worker training, facilities and supplies to enable workers to practice proper hygiene, and company policies relating to expectations for worker hygiene as well as illness reporting. • All workers should properly wash their hands using soap and clean, running water before handling leafy vegetables, particularly during harvesting and post harvest handling. Workers should be trained in proper techniques for hand washing and drying. • If gloves are used, a procedure for glove use in the field should be documented and followed. If the gloves are reusable, they should be made of materials that are readily cleaned and sanitized, should be cleaned as needed and stored appropriately. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated. • Non-essential persons and casual visitors, particularly children, should not be allowed in the harvest area as they may present an increased risk of contamination.	3.2.5	Personnel health, hygiene and sanitary facilities	The following should be considered: • Where appropriate, each business operating primary production operations should have written Standard Operating Procedures (SOPs) that relate to health, hygiene and sanitary facilities. The SOPs should address worker training, facilities and supplies to enable agricultural workers to practice proper hygiene, and company policies relating to expectations for worker hygiene as well as illness reporting. • All agricultural workers should properly wash their hands using soap and clean running water before handling melons, particularly during harvesting and post harvest handling. Agricultural workers should be trained in proper techniques for hand washing and drying. • If gloves are used, a procedure for glove use in the field should be documented and followed. If the gloves are reusable, they should be made of materials that are easily cleaned and disinfected, and they should be cleaned regularly and stored in a clean area. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated. • Non-essential persons, casual visitors and, to the extent possible, children, should not be allowed in the harvest area as they may present an increased risk of contamination.	3.2.5	Personnel health, hygiene and sanitary facilities	Personal hygiene is critical with manual harvesting due to the amount of human handling that could lead to contamination of berries. Wherever possible, harvesting, packing and inspection processes should be designed to reduce fruit handling. All agricultural workers should properly wash their hands using soap and clean running water and dry their hands before handling berries, particularly during harvesting and postharvest handling. If gloves are used, a procedure for glove use in the field should be documented and followed. If the gloves are reusable, they should be made of materials that are easily cleaned and disinfected, and they should be cleaned regularly and stored in a clean area. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated. Glove use alone is not a suitable substitute for good hand washing practices. Where appropriate, each business operating primary production should have written Standard Operating Procedures (SOPs) that relate to health, hygiene and sanitary facilities. The SOPs should address worker training, facilities and supplies to enable agricultural workers to practice proper hygiene, and company policies relating to expectations for worker hygiene as well as illness reporting. Non-essential persons, casual visitors and, to the extent possible, children, should not be allowed in the harvest area as they may present an increased risk of contamination.
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.							3.2.3.1	Personnel hygiene and sanitary facilities	The following should be considered: • Growers should provide areas away from the field and packing lines for workers to take breaks and eat. For worker convenience, these areas should contain toilet and hand washing facilities so workers can practice proper hygiene. • All workers should be trained in proper use of hygienic facilities. Training should include toilet use, paper disposal of toilet paper or equivalent, and proper hand washing and drying procedures. As far as possible, such facilities should be located close to the field and readily accessible to the work area. • Sanitary facilities should be located in a manner to encourage their use and reduce the likelihood that workers will relieve themselves in the field. Facilities should be present in sufficient number to accommodate personnel (e.g. 1 per 10 people) and be appropriate for both genders if workers consist of males and females. • Portable facilities should not be located or cleaned in cultivation areas or near irrigation water sources or conveyance systems. Growers should have a standard plan that identifies the areas where it is safe to put portable facilities and to prevent traffic in case of a spill. • Facilities should include clean running water, soap, toilet paper or equivalent, and single use paper towels or equivalent.	3.2.3.1	Personnel hygiene and sanitary facilities	Growers should consider providing areas away from the field and packing lines for agricultural workers to take breaks and eat. For worker convenience, these areas should provide access to toilet and hand washing facilities so that agricultural workers can practice proper hygiene. As far as possible, sanitary facilities should be located close to the field and readily accessible to the work area. • Sanitary facilities should be located in a manner to encourage their use and reduce the likelihood that agricultural workers will relieve themselves in the field. Facilities should be present in sufficient number to accommodate all personnel. • Portable facilities should not be located or cleaned in cultivation areas or near irrigation water sources or conveyance systems. Growers should identify the areas where it is safe to put portable facilities. • Facilities should include clean running water, soap, toilet paper or equivalent, and single use paper towels or equivalent. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed. • If clean running water is not available, an acceptable alternative hand washing method should be recommended by the relevant competent authority.	3.2.3.1	Personnel hygiene and sanitary facilities	Growers should consider providing areas away from the field and packing lines for agricultural workers to take breaks and eat. For worker convenience, these areas should provide access to toilet and hand-washing facilities so that agricultural workers can practice proper hygiene. As far as possible, sanitary facilities should be located close to the field and readily accessible to the work area. • Sanitary facilities should be located in a manner to encourage their use and reduce the likelihood that agricultural workers will relieve themselves in the field. Facilities should be present in sufficient number to accommodate all personnel. • Portable facilities should not be located or cleaned in cultivation areas or near irrigation water sources or conveyance systems. Growers should identify the areas where it is safe to put portable facilities. • Facilities should include clean running water, soap, toilet paper or equivalent, and single use paper towels or equivalent. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed. • If clean running water is not available, an acceptable alternative hand washing method should be recommended by the relevant competent authority.
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.							3.2.3.2	Health status	The following should be considered: • Farm and packinghouse managers should be encouraged to observe symptoms of diarrhoeal or food transmissible communicable diseases and reassign workers as appropriate. • Employees should be encouraged to notice and report symptoms of diarrhoeal or food transmissible communicable diseases. • Medical examination of food handlers should be carried out if clinically or epidemiologically indicated.	3.2.3.2	Health status	The following should be considered: • Growers should be encouraged to note symptoms of diarrhoeal or food-transmissible, communicable diseases, and reassign agricultural workers as appropriate. • Agricultural workers should be encouraged and, where feasible, be motivated with appropriate incentives to report symptoms of diarrhoeal or food-transmissible, communicable diseases. • Medical examination of agricultural workers should be carried out if clinically or epidemiologically indicated.	3.2.3.2	Health status	The following should be considered: • Growers should be encouraged to recognize symptoms of diarrhoeal or food-transmissible communicable diseases, and reassign agricultural workers as appropriate. • Agricultural workers should be encouraged and, where feasible, be motivated with appropriate incentives to report symptoms of diarrhoeal or food-transmissible communicable diseases. • Medical examination of agricultural workers should be carried out if clinically or epidemiologically indicated.
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.							3.2.3.3	Personal cleanliness	When personnel are permitted to continue working with cuts and wounds covered by water proof dressings, they should wear gloves to cover the bandages thereby providing a secondary barrier between them and the fresh leafy vegetables they handle. • Workers should wear clean clothes and bathe daily.	3.2.3.3	Personal cleanliness	When personnel are permitted to continue working with cuts and wounds covered by water proof dressings, they should wear gloves to cover the bandages thereby providing a secondary barrier between them and the melons they handle.	3.2.3.3	Personal cleanliness	When personnel are permitted to continue working with cuts and wounds covered by waterproof dressings, they should wear gloves to cover the bandages thereby providing a secondary barrier between them and the berries they handle or, otherwise they should be reassigned to another working area where they do not handle berries directly.
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.							3.2.3.4	Personal behaviour	• Personal items (e.g., purses, backpacks, clothes, etc.) should be stored away from production areas.						
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 uses 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, byproducts and insoluble 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.	5.2.4	Equipment associated with growing and harvesting	Prior to harvest, harvesting equipment should be adjusted to minimize soil intake and seed damage and should be cleaned from any debris or earth. Diseased or damaged seeds, which could be susceptible to microbial contamination, should not be used for the production of sprouts for human consumption.	3.2.4	Equipment associated with growing and harvesting	Growers and harvesters should adopt the following sanitary practices: • Employees should be trained to follow SOPs for the maintenance requirements of equipment used for growing and harvesting. • All safety guards should be used and maintained according to manufacturers' instructions. Such equipment should be maintained in good order. • Equipment used to harvest leafy vegetables by cutting or mowing should be thoroughly cleaned and sanitized before use and cutting edges should be kept smooth and sharp.	3.2.4	Equipment associated with growing and harvesting	Standard operating practices should be developed for the maintenance, cleaning and disinfecting operations of growing and harvesting equipment. In addition: • Agricultural workers should be trained to follow the SOPs. • Cutting equipment used to harvest melons should be thoroughly cleaned and disinfected before use and cutting edges should be kept smooth and sharp.	3.2.4	Equipment associated with growing and harvesting	Standard operating practices should be developed for the maintenance, cleaning and disinfecting operations of growing and harvesting equipment, which include the following: • Containers used repeatedly during harvest should be cleaned after each load. • Containers (including liners of containers made from biodegradable material) that are no longer cleanable should be disposed of since they may increase the risk of microbial contamination of berries. • Harvesting containers should not be placed directly on the ground. • If the containers are stored outside, they should be cleaned and disinfected before being used to transport berries.			







5.2.2.2	Chemical treatments	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul>	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.	5.2.2.2	Initial rinse	<ul style="list-style-type: none"> <li>The seeds should be rinsed thoroughly before the microbiological decontamination treatment to remove dirt and increase the efficiency of this treatment.</li> <li>Seeds should be rinsed and thoroughly agitated in large volumes of clean water, in such a way to maximize surface contact. The process should be repeated until most of the dirt is removed and rinse water remains clear.</li> </ul>	5.2.2.2	Post-harvest water use	<ul style="list-style-type: none"> <li>The following should be considered: <ul style="list-style-type: none"> <li>Water quality management will vary throughout all operations. Packers should follow GMP to prevent or minimize the potential for the introduction or spread of pathogens in processing water. The quality of water 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.</li> <li>Clean or preferably potable water should be used when water is applied under pressure or vacuum during washing as these processes may alter the leaf structure and force pathogens into plant cells.</li> <li>Where appropriate, the pH, hardness, temperature of the post-harvest water should be controlled and monitored, e.g. where these impact the efficacy of the antimicrobial treatments.</li> <li>Water recirculated for reuse in the establishment should be treated and maintained in conditions that do not constitute a risk to the safety of fresh leafy vegetables. For example the following may be used to maintain the suitability of the water: primary screening, secondary filtration, and antimicrobial treatment process.</li> </ul> </li> </ul>	5.2.2.2	Chemical treatments	<ul style="list-style-type: none"> <li>Fungicides may be applied to melons by use of an aqueous spray or immersion to extend the post-harvest life of the fruit. The following are recommended: <ul style="list-style-type: none"> <li>Clean or preferably potable water should be used in water-based chemical treatments to ensure that the water used is of sufficient microbial quality for the intended use and does not contaminate the melons with foodborne pathogens.</li> <li>If hot water treatments are used as an alternative to post-harvest chemical fungicide treatments, it is recommended that the water temperature and time be evaluated and monitored to ensure that the water temperature and time is maintained and that antimicrobial agents are present in the water at sufficient levels for the temperature used.</li> </ul> </li> </ul>
5.2.2.3	Cooling of fresh fruits and vegetables	<ul style="list-style-type: none"> <li>Condensate and deionized 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.</li> <li>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.</li> <li>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.</li> </ul>	5.2.2.3	Washing and microbial decontamination	Refer to section 5.2.2.1 of the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition: <ul style="list-style-type: none"> <li>Water used for final rinses should be of potable quality, particularly for these products as they are not likely to be washed before consumption.</li> </ul>	5.2.2.3	Microbiological decontamination of seeds	<ul style="list-style-type: none"> <li>Due to the difficulty of obtaining seeds which can be guaranteed as pathogen free, it is recommended that seeds be treated prior to the sprouting process. Although there are other options like the use of lactic acid bacteria, liquid microbiological decontamination treatment is generally used. During this treatment sprout producers should adhere to the following: <ul style="list-style-type: none"> <li>All containers used for microbiological decontamination of seeds should be cleaned and disinfected prior to use.</li> <li>Seeds should be well agitated in large volumes of antimicrobial agent to maximize surface contact.</li> <li>The duration of treatment and the concentration of antimicrobial agent used should be accurately measured and recorded.</li> <li>Strict measures should be in place to prevent re-contamination of seeds after the microbiological decontamination treatment.</li> <li>Antimicrobial agent should be used according to manufacturer's instructions for their intended use.</li> </ul> </li> </ul>	5.2.2.3	Chemical treatments	<ul style="list-style-type: none"> <li>Certain post harvest treatments, i.e. paraffin and fungicides, should not be used for fresh leafy green vegetables.</li> </ul>	5.2.2.3	Cooling melons	<ul style="list-style-type: none"> <li>Forced air cooling operations can avoid the risk of melon infiltration with cooling water, but also may spread product contamination if forced-air cooling equipment is not cleaned and disinfected regularly.</li> <li>Water that is used in hydrocoolers should be potable. Water that is used only once and not recirculated is preferable.</li> <li>If water is used for cooling and is recirculated, it should be evaluated and monitored to ensure that disinfectant levels are sufficient to reduce the potential risk of cross-contaminating melons.</li> <li>Cooling and exit storing melons as soon as possible after harvest is recommended to prevent multiplication of foodborne pathogens, if present, on or from the rind surface of melons.</li> <li>Cooling equipment should be cleaned and disinfected on a regular basis according to written procedures to ensure that the potential for cross-contamination is minimized.</li> </ul>
5.2.2.4	Cold storage	<ul style="list-style-type: none"> <li>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.</li> <li>Condensate and deionized 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.</li> </ul>	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.	5.2.2.4	Rinse after seed treatment	<ul style="list-style-type: none"> <li>As appropriate, seeds should be thoroughly rinsed after the microbiological decontamination treatment with potable water or at least clean water. Rinsing should be repeated sufficiently to eliminate antimicrobial agent.</li> </ul>	5.2.2.4	Cooling of fresh leafy vegetables	<ul style="list-style-type: none"> <li>The following should be considered: <ul style="list-style-type: none"> <li>Fresh leafy vegetables can be cooled immediately after harvest by either, using ice (partially), forced air cooling, vacuum cooling (iceberg lettuce), hydrocooling, or spray vacuum hydrocooling. Water used in post-harvest operations may contaminate fresh leafy vegetables if there is direct contact of water containing human pathogens with edible portions of the plant.</li> <li>For fresh leafy vegetables and the control of inputs such as water used for cooling, particular attention should be paid to: <ul style="list-style-type: none"> <li>Water used to cool fresh leafy vegetables should be free from human pathogens.</li> <li>Water that is used in hydrocoolers should be clean or preferably potable. Water that is used only once and is not recirculated is preferable. If recirculated water is used, water disinfectant at sufficient levels to reduce the potential risk of cross-contamination should be used and monitored.</li> <li>Cooling equipment should be cleaned and sanitized on a regular basis according to written procedures to ensure that the potential for cross-contamination is minimized.</li> </ul> </li> </ul> </li> </ul>			
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.	5.2.2.5	Pre-germination on soak	<ul style="list-style-type: none"> <li>Soaking is often necessary to improve germination. When soaking, the sprout producer should adhere to the following: <ul style="list-style-type: none"> <li>All containers used for soaking should be cleaned and disinfected prior to use.</li> <li>Seeds should be soaked in cleaned water for the shortest possible time to minimize microbial growth.</li> <li>This step may also employ antimicrobial agents.</li> <li>After soaking, seeds should be rinsed thoroughly with potable water or at least clean water.</li> </ul> </li> </ul>	5.2.2.5	Germination	<ul style="list-style-type: none"> <li>During germination, keep the environment and equipment clean to avoid potential contamination. All equipment should be cleaned and disinfected before each new batch.</li> <li>Only potable water should be used.</li> <li>Where necessary and when used, soils or other matrices should be treated (e.g., pasteurized) to achieve a high degree of microbial reduction.</li> </ul>	5.2.2.5	Cutting, slicing, shredding and similar pre-cut processes	<ul style="list-style-type: none"> <li>The following should be considered: <ul style="list-style-type: none"> <li>Maintain sharpness and condition of knives and cutting edges to maintain product quality and safety.</li> <li>Cutting equipment should be cleaned and sanitized on a regular basis according to written procedures to ensure that the potential for cross-contamination is minimized.</li> </ul> </li> </ul>	5.2.2.5	Cutting, slicing and peeling melons	<ul style="list-style-type: none"> <li>Melons should be washed with potable water before cutting or peeling.</li> <li>Before cutting or other processing, a further reduction in microbial contamination may be achieved by scrubbing in the presence of a sanitizer or application of an alternative surface decontamination process such as hot water, steam or other treatments.</li> <li>Cutting or peeling knife blades should be cleaned and disinfected on a regular basis according to written procedures to reduce the potential for cross-contaminating melons during the cutting or peeling process.</li> <li>Knife blade disinfecting solutions should be monitored to ensure that the disinfectant is present at sufficient levels to achieve its intended purpose and does not promote the potential for cross-contamination.</li> <li>It is recommended that pre-cut melons should be wrapped/packaged and refrigerated as soon as possible and distributed under refrigeration temperatures (e.g., 4 °C or less).</li> </ul>
5.2.2.6	Washing after cutting, slicing, shredding and similar pre-cut processes	<ul style="list-style-type: none"> <li>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: <ul style="list-style-type: none"> <li>Water should be replaced at sufficient frequency to prevent the build-up of organic material and prevent cross-contamination.</li> <li>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.</li> <li>Drying or draining to remove water after washing is important to minimize microbiological growth.</li> </ul> </li> </ul>	5.2.2.6	Germination	<ul style="list-style-type: none"> <li>During germination, keep the environment and equipment clean to avoid potential contamination. All equipment should be cleaned and disinfected before each new batch.</li> <li>Only potable water should be used.</li> <li>Where necessary and when used, soils or other matrices should be treated (e.g., pasteurized) to achieve a high degree of microbial reduction.</li> </ul>	5.2.2.6	Cutting, slicing, shredding and similar pre-cut processes	<ul style="list-style-type: none"> <li>The following should be considered: <ul style="list-style-type: none"> <li>Maintain sharpness and condition of knives and cutting edges to maintain product quality and safety.</li> <li>Cutting equipment should be cleaned and sanitized on a regular basis according to written procedures to ensure that the potential for cross-contamination is minimized.</li> </ul> </li> </ul>						
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: <ul style="list-style-type: none"> <li>Pre-cut fresh fruits and vegetables should be maintained at low temperatures at all stages, from cutting through distribution to minimize microbiological growth.</li> </ul>	5.2.2.7	Harvesting	<ul style="list-style-type: none"> <li>All equipment should be cleaned and disinfected before each new batch.</li> <li>Harvesting should be done with cleaned and disinfected tools dedicated for this use.</li> </ul>									
5.2.2.8	Final rinse and cooling	<ul style="list-style-type: none"> <li>A final water rinse will remove hulls, cool product, and may reduce microbial contamination on sprouts. The following should be adopted: <ul style="list-style-type: none"> <li>As appropriate, sprouts should be rinsed in cold potable water to lower sprout temperature and slow down microbial growth.</li> <li>Water should be changed, as needed (e.g., between batches), to prevent cross-contamination.</li> <li>Sprouts should be drained using appropriate equipment (e.g. food grade centrifugal dryer) that is clean and disinfected prior to use.</li> <li>If additional cooling time is necessary, steps should be taken to facilitate rapid cooling (e.g., placed in smaller containers with adequate air flow between containers).</li> </ul> </li> </ul>												
5.2.2.9	Storage of finished product	<ul style="list-style-type: none"> <li>Where appropriate, sprouts should be kept under cold temperature (e.g. 50C) that will minimize microbial growth for the intended shelf life of the product.</li> <li>Regular and effective monitoring of temperature of storage areas and transport vehicles should be carried out.</li> </ul>												
5.2.3	Microbiological and other specifications	Refer to the General Principles of Food Hygiene.	5.2.3	Microbiological and other specifications	<ul style="list-style-type: none"> <li>It is recommended that seed and sprouts or spent irrigation water be tested for the presence of pathogens.</li> </ul>	5.2.3	Microbiological and other specifications	<ul style="list-style-type: none"> <li>The following should be considered: <ul style="list-style-type: none"> <li>Microbiological testing can be a useful tool to evaluate and verify the effectiveness of safety and sanitation practices, provide information about an environment, a process, and even a specific product lot, when sampling plans and methodology are properly designed and performed. The intended use of information obtained (e.g. evaluating the effectiveness of a sanitation practice, evaluating the risk posed by a particular hazard, etc.) can aid in determining what microorganisms are most appropriate to test for. Test methods should be selected that are validated for the intended use. Consideration should be given to ensure proper design of a microbiological testing program. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems.</li> </ul> </li> </ul>	5.2.3	Microbiological and other specifications	<ul style="list-style-type: none"> <li>Microbiological testing can be a useful tool to evaluate and verify the effectiveness of safety and sanitation practices, provide information about an environment, a process, and even a specific product lot, when sampling plans and methodology are properly designed and performed. The intended use of information obtained (e.g. evaluating the effectiveness of a sanitation practice, evaluating the risk posed by a particular hazard, etc.) can aid in determining what microorganisms are most appropriate to test for. Test methods should be selected that are validated for the intended use. Consideration should be given to ensure proper design of a microbiological testing program. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems.</li> </ul>	5.2.3	Microbiological and other specifications	<ul style="list-style-type: none"> <li>Microbiological testing can be a useful tool to evaluate and verify safety and the effectiveness of cleaning practices and to provide information about an environment, a process, and even a specific product lot, when sampling plans and methodology are properly designed and performed. The intended use of information obtained (e.g. evaluating the effectiveness of a sanitation practice, evaluating the risk posed by a particular hazard, etc.) can aid in determining what microorganisms are most appropriate to test for. Test methods should be selected that are validated for the intended use. Consideration should be given to ensure proper design of a microbiological testing program. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems.</li> </ul>
5.2.3.1	Testing of seed lots before entering production	<ul style="list-style-type: none"> <li>It is recommended that each new lot of seeds received at the sprouting facility is tested before entering production (i.e. before the microbiological decontamination of seeds).</li> <li>The seed sample selected for testing should be sprouted prior to analysis to increase the potential to detect pathogens if present. Analysis may be performed on the sprouted seeds or the water used to sprout the sample.</li> <li>Seed samples for microbial analysis should not be subject to any microbiological decontamination treatment at the sprouting facility.</li> </ul>												
5.2.3.2	Testing of sprouts and/or spent irrigation water	<ul style="list-style-type: none"> <li>Current seed treatments cannot guarantee total elimination of pathogens. Further, if even a few pathogens survive the microbiological decontamination treatment, they can grow to high numbers during sprouting. Therefore, producers should have in place a sampling/testing plan to regularly monitor for pathogens at one or more stages after the start of germination.</li> <li>Analyses can be performed during the germination process (e.g. spent irrigation water or sprouts) and/or finished product may be analysed after harvest.</li> <li>Testing spent irrigation water is a good indicator of microbial conditions of sprouts. It is homogeneous and is simpler to analyse. Further, sampling spent irrigation water (or sprouts) during germination allows earlier results compared to testing finished product.</li> <li>Because of the sporadic nature of seed contamination, it is recommended that producers test every production lot.</li> </ul>												

5.2.4	Microbial cross-contamination	Refer to the General Principles of Food Hygiene.			5.2.4	Microbiological cross-contamination	Sprout producers should adhere to the following: • The traffic pattern of employees should prevent cross-contamination of sprouts. • For example: the employees should avoid going back and forth to various areas of production. The employees should not go from a potentially contaminated area to the germination and/or packaging area unless they have washed their hands and changed to clean protective clothing.			5.2.4	Microbiological cross-contamination	• Where dry dump stations are used for unloading field containers (e.g. bins, gondolas, trailers or wagons), melon contact surfaces (including padding materials to protect melons from physical damage) should be constructed of material that can be cleaned and disinfected. • Where wet dump stations are used for unloading field containers, the containers should not be directly immersed into dump tanks, where they have been in direct contact with the soil, to reduce the potential for product cross-contamination with field or road debris.	5.2.4	Microbiological cross-contamination	Berries that have undergone cleaning and/or chemical treatment should be effectively separated, either physically or by time, from raw material and environmental contaminants. Prevent cross-contamination between raw and washed berries, which will be frozen. From sources such as wash water, rinse water, equipment, utensils and vehicles. Only workers who have been trained on hygienic handling should be assigned to pack berries.	
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.			5.3	INCOMING MATERIAL REQUIREMENTS				5.3	Incoming material requirements	• Avoid using whole melons that have visible signs of decay or damaged rinds (e.g. mechanical damage or cracking) due to the increased risk for microbial contamination in melons. • Damaged or decayed melons should be discarded in a manner that does not serve to attract pests.	5.3	Incoming material requirements	The following are recommended: • For berries that are intended to be consumed raw as well as to be frozen, sorting and selection should be implemented to avoid using fruits that have visible signs of decay or damage due to the increased risk of microbial contamination. • Berries should be cooled and stored as soon as possible under temperature controls within the process.	
					5.3.1	Specifications for incoming seeds	• Sprout producers should recommend that seed producers adopt good agricultural practices and provide evidence that the product was grown according to section 3 of this Annex and the Code of Hygienic Practice for Fresh Fruits and Vegetables. • Seed and sprout producers should obtain assurance from seed producers or distributors that chemical residues of each incoming lot are within the limits established by the Codex Alimentarius Commission and, where appropriate, they should obtain certificates of analysis for microbial pathogens of concern.									
					5.3.2	Control of incoming seeds	Seed containers should be examined at their arrival to minimize the potential for introducing obvious contaminants in the establishment. • Seed containers should be examined for physical damage (e.g. holes from rodents) and signs of contamination (e.g. stains, rodent, insects, faeces, urine, foreign material, etc.). If found to be damaged, contaminated or potentially contaminated, its contents should not be used for the production of sprouts for human consumption. • If seed lots are analysed for the presence of microbial pathogens of concern, these should not be used until results of analysis are available.									
					5.3.3	Seed storage	Seeds should be handled and stored in a manner that will prevent damage and contamination. • Seeds should be stored off the floor, away from walls and in proper storage conditions to prevent mould and bacterial growth and facilitate pest control inspection. • Open containers should be stored in such a way that they are protected from pests and other sources of contamination.									
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.	5.7	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 fresh pre-cut fruits and vegetables. Records should be kept long enough to facilitate recalls and foodborne 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	5.7	DOCUMENTATION AND RECORDS	Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition: Written records that accurately reflect product information and operational controls should be available to demonstrate the adequacy of the production activities. • Upon receipt of seeds, records should be maintained of the seed supplier, the lot number and the country of origin to facilitate recall procedures. • Records should be legible, permanent and accurate. Records should include written procedures, controls, limits, monitoring results and subsequent follow-up documents. Records must include: seed sources and lot numbers, water analysis results, sanitation checks, pest control monitoring, sprout lot codes, analysis results, production volumes, storage temperature monitoring, product distribution and consumer complaints. • Records should be kept long enough to facilitate recalls and food borne illness investigation, if required. This period will likely be much longer than the shelf life of the product.	5.7	Documentation and records	Where practicable, a written food safety control plan that includes a written description of each of the hazards identified in assessing environmental hygiene and the steps that will be implemented to address each hazard should be prepared by the businesses operating primary production. The description should include, but is not limited to, the following: an evaluation of the production site, water and distribution system, manure use and composting procedures, personnel illness reporting policy, sanitation procedures, and training programs. The following are examples of the types of records that should be retained: • Microbiological testing results and trend analyses • Water testing results • Employee training records • Pest control records • Cleaning and sanitation reports • Equipment monitoring and maintenance records • Inspection/audit records	5.7	Documentation and records	Where practicable, a written food safety control plan that includes a written description of each of the hazards identified in assessing environmental hygiene, as well as the steps that will be implemented to address each hazard, should be prepared by the business operating the primary production. The description should include, but is not limited to, the following: an evaluation of the production site, water and distribution system, manure use and composting procedures, personnel illness reporting policy, sanitation procedures and training programs. The following are examples of the types of records that should be retained: • Microbiological test results and trend analyses • Water monitoring and test results • Employee training records • Pest control records • Cleaning and disinfection reports • Equipment monitoring and maintenance records • Inspection/audit records		
5.8	Recall procedures	Refer to the General Principles of Food Hygiene. In addition, where appropriate: • Growers and packers should have programmes to ensure effective lot identification. These programmes 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 are 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.	5.8	RECALL PROCEDURES	Refer to the General Principles of Food Hygiene.	5.8	TRACEABILITY/PRODUCT RECORDS	The following should be considered: The traceability/product tracing system should be designed and implemented according to the Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CAC/GL 60-2006), especially to enable the withdrawal of the products, where necessary. • Detailed records should be kept that link each supplier of the product with the immediate subsequent recipient of the food throughout the supply chain. The information should include, if available, the packer name, address, and phone, date packed, date released, type of food including brand name and specific variety (e.g. sometimes better rather than just lettuce), lot identification, and number of items. • The following are examples of the types of records that should be retained to facilitate traceability: - Shipping documents - Invoices - Other records maintained by the firm that identifies the supplier and the buyer - Operators such as growers and producers and, in cases where contract harvesters are used, harvesters should keep current all relevant information on agricultural activities such as information concerning such as, date harvested, grower contact information, harvest practices, if water used in harvesting, water quality • In fresh cut, pre-cut or ready to eat salad operation, multiple ingredients from different sources may be combined in a single package. This practice can complicate efforts to trace leafy vegetables to their source. The processors should consider establishing and maintaining records to identify the source of each ingredient in the product.	5.8	Recall procedures	In the event of a foodborne illness outbreak associated with melons, maintaining appropriate records of production, processing, packaging and distribution may help to identify the source of contamination in the berry food chain and facilitate product recalls. Growers/packers/processors/distributors should consider developing and maintaining a traceability/product tracing system. The traceability/product tracing system should be designed and implemented according to the principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CAC/GL 60-2006), especially to enable the withdrawal of the products, where necessary. Detailed records should be kept that link each supplier of the product with the immediate subsequent recipient of the berries throughout the food chain. The information needed to link each supplier should include, if available, the packer name, address, and phone number, date packed, date released, type of berry (e.g. strawberry, blueberry, etc.) including brand name, lot identification and number of lots, and transporter.	5.8	Recall procedures	In the event of a foodborne illness outbreak associated with berries, maintaining appropriate records of production, processing, packaging and distribution may help to identify the source of contamination in the berry food chain and facilitate product recalls. Growers/packers/processors/distributors should consider developing and maintaining a traceability/product tracing system. The traceability/product tracing system should be designed and implemented according to the principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CAC/GL 60-2006), especially to enable the withdrawal of the products, where necessary. Detailed records should be kept that link each supplier of the product with the immediate subsequent recipient of the berries throughout the food chain. The information needed to link each supplier should include, if available, the packer name, address, and phone number, date packed, date released, type of berry (e.g. strawberry, blueberry, etc.) including brand name, lot identification and number of lots, and transporter.		
6	PACKING ESTABLISHMENT MAINTENANCE AND SANITATION	Refer to the General Principles of Food Hygiene.	6	ESTABLISHMENT MAINTENANCE AND SANITATION	Refer to the General Principles of Food Hygiene.	6	ESTABLISHMENT MAINTENANCE AND SANITATION	Refer to the General Principles of Food Hygiene.		6	ESTABLISHMENT MAINTENANCE AND SANITATION	Refer to the General Principles of Food Hygiene.		6	ESTABLISHMENT MAINTENANCE AND SANITATION	Refer to the General Principles of Food Hygiene.
										6.1	Maintenance and Cleaning		6.1	Maintenance and Cleaning		
										6.1.1	General	Food contact surfaces should be cleaned and disinfected before the start of the season and throughout the melon season to ensure microbial pathogens do not become established in the facility or on the equipment.	6.1.1	General	Food contact surfaces should be cleaned and disinfected before the start and throughout the season of the specific fruit to ensure microbial pathogens do not become established in the facility or on the equipment.	
										6.1.2	Cleaning procedures and methods	Written SOPs should be developed and implemented for the cleaning and disinfection of equipment used for post-harvest treatment.	6.1.2	Cleaning procedures and methods	Written SOPs should be developed and implemented for the cleaning and disinfection of equipment used for post-harvest treatment.	
										6.3	Pest control systems	Melons have a very high sugar content and are extremely attractive to flies and other insects that may cross-contaminate melons. It is recommended that an aggressive melon cull and waste removal program be implemented to reduce the potential for insect to melon contamination.	6.3	Pest control systems	Melons have a very high sugar content and are extremely attractive to flies and other insects that may cross-contaminate melons. It is recommended that an aggressive melon cull and waste removal program be implemented to reduce the potential for insect to melon contamination.	
7	PACKING ESTABLISHMENT PERSONAL HYGIENE	Refer to the General Principles of Food Hygiene.	7	ESTABLISHMENT PERSONAL HYGIENE	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 to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food.	8	TRANSPORTATION	Refer to the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables.	8	TRANSPORTATION	Refer to the General Principles of Food Hygiene.		8	TRANSPORTATION	Refer to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food (CAC/RCP 47-2001).		8	TRANSPORTATION	Refer to the Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables (CAC/RCP 44-1995).
9	PRODUCT INFORMATION AND CONSUMER AWARENESS	Refer to the General Principles of Food Hygiene.	9	PRODUCT INFORMATION AND CONSUMER AWARENESS	Refer to the General Principles of Food Hygiene.	9	PRODUCT INFORMATION AND CONSUMER AWARENESS	Refer to the General Principles of Food Hygiene.		9	PRODUCT INFORMATION AND CONSUMER AWARENESS	Refer to the Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables (CAC/RCP 44-1995).		9	PRODUCT INFORMATION AND CONSUMER AWARENESS	Refer to the Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables (CAC/RCP 44-1995).
										9.3	LABELLING	Refer to the General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) and In addition, the following should be considered: Consumer's handling information should provide specific directions for product storage and use, including regarding the 'use-by' date or other shelf-life indicators when provided. Consumers need clear guidance on keeping washed RTE bagged fresh leafy vegetables refrigerated until used.	9.3	LABELLING	Refer to the General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) and In addition, the following should be considered: Consumer's handling information should provide specific directions for product storage and use, including regarding the 'use-by' date or other shelf-life indicators when provided. Consumers need clear guidance on keeping washed RTE bagged fresh leafy vegetables refrigerated until used.	

