Bord Bia

Prepared Fruit and Vegetables Standard

Revision 03
September 2008

Contents:

1.1 Bord Bia

Bord Bia is the State agency with overall responsibility for the development of the Irish food industry including horticulture. The Board runs a series of quality assurance programmes to assist the production, marketing and consumption of horticultural produce and honey and this Standard is a key element of those programmes.

1.2 Quality Assurance Programmes

Consumers are concerned about food safety and traceability within the food chain. Food safety is therefore an essential element of all Bord Bia Quality assurance programmes. Quality has also become a critical issue in food production in recent times. Consumers and retailers alike now demand produce that has been grown, handled, packaged and transported to the highest standards of quality and hygiene, in a clean and environmentally friendly manner.

1.3 Objectives of the Prepared Fruit and Vegetables Standard

The primary objectives are:

- To set out the requirements for best practice in Prepared Fruit and Vegetable production;
- To provide a uniform mechanism for recording and monitoring quality assurance criteria with a view to achieving continuous improvement in production standards;
- To underpin the successful marketing of quality assured Prepared Fruit and Vegetables.

1.4 Scope:

The Bord Bia Quality Scheme for the Prepared Fruit and Vegetable industry describes the requirements for those involved in the preparation, packaging and delivery of pre-cut fruit and vegetables for human consumption.

1.5 General:

The requirements of this Standard are based on established best practice as determined by technical, industry and other experts. They are also based on current legislation, relevant industry guidelines and international standards.

Other codes of practice / schemes that embody the specific provisions of this Standard may be acceptable, subject to formal approval by Bord Bia.

This Prepared Fruit and Vegetable Standard was developed by an expert group representing the following bodies / organisations:

- Bord Bia;
- The Food Safety Authority of Ireland;
- The Prepared Fruit and Vegetable industry;
- The Department of Agriculture, Fisheries and Food.

1.6 Terms, Requirements Categories and Application of Non-Compliances

In Section 3, Requirements, all the each statement that are shown in the text indented and with an identifying letter constitute the requirements of the standard. An example is as follows:

a) The Participant must ….
b) All documents must …

Mandatory Requirements are indicated in the text with the term "must". Non-mandatory requirements are indicated in the text with the term "should".

The requirements and their meaning and significance (and compliance with these requirements as determined by audit or other means) are detailed here:

Critical: where a breach of the requirements may constitute a grave and immediate food safety risk. These requirements are indicated in the text in **bold underlined** typeface and the word "Critical" appears in bold underlined text in parentheses at the end of the sentence or paragraph as follows **(Critical)**.

Category 1: where the requirements deal with core best practices. These requirements are indicated in the text in **bold** typeface and the word "Category 1" appears in bold text in parentheses at the end of the sentence or paragraph as follows **(Category 1)**.

Category 2: all the mandatory requirements not Critical or Category 1 are Category 2 and appear in the text in normal typeface.

Category 3: These are recommendations for best practice and are indicated in the text in *italic* typeface. While not mandatory, they are expected to be adopted unless evidence exists that the requirement(s) need not be adopted. This evidence will be examined on a case-by case basis during audits.

1.7 Application of Non-Compliances (as determined by independent audits)

1.7.1 First Time Participants

Critical or Category 1 Non-Compliances:
Failure to comply with a Critical or Category 1 requirement as determined by audit automatically excludes first time Participant from certification under the Scheme.

Category 2 Non-Compliances:
Where there are more than 15 category 2 non-compliances the Participant will be deemed to have a Category 1 non-compliance (see above) and will be automatically excluded from certification under the Scheme. Where there are 15 or less Category 2 non-compliances, the Participant must then give a signed commitment to the Auditor to have the necessary corrective/preventive action put in place within the time-scale specified (maximum period 3 months).
Written evidence that the corrective/preventive action has been/is being put in place must be available before certification is granted.

Depending on the nature of the non-compliance and the corresponding response, an on-site verification of the corrective/preventive action may be required.

Category 3 Non-Compliances:
Failure to comply with applicable recommendations as determined by audit will be noted in the audit report and corrective/preventive actions must be implemented before the next full audit.

1.7.2 Existing Members

Critical Non-Compliance:
Failure to comply with a critical requirement, as determined by audit, obliges the Processor to immediately cease to market produce as 'Quality Assured' under the Scheme. The auditor will immediately advise the Certification body (or Bord Bia) of the situation. The Participant's Membership will be automatically "Suspended" pending a review of the situation and a formal decision regarding membership.

Category 1 Non-Compliance:
Failure to comply with a Category 1 requirement, as determined by audit, obliges the Participant to initiate immediate corrective/preventive action. The Auditor will specify the nature of the non-compliance and the corresponding time-scale for completion (up to a maximum of one month). Membership status will be "Under Review" during this one-month period.

The Processor must give a signed commitment to the Auditor to have the problem resolved within the time-scale specified (maximum one month from date of audit).

Depending on the nature of the non-compliance and the corresponding response, an on-site verification of the corrective/preventive action may be required. On confirmation that effective corrective/preventive action has been put in place, certification will be renewed.

Failure to provide satisfactory evidence within the specified time-scale will result in cancellation of membership, removal from the Bord Bia register/database and withdrawal of the certificate.

Category 2 Non-Compliances:

Where there are more than 15 category 2 non-compliances the Participant will be deemed to have a Category 1 non-compliance (see above).

Where there are 15 or less Category 2 non-compliances, the Participant must then give a signed commitment to the Auditor to have the necessary corrective/preventive action put in place within the time-scale specified (maximum period 3 months). Written evidence that the corrective/ preventative action has been/is being put in place must be provided before certification can be renewed.

Depending on the nature of the non-compliance and the corresponding response, an on-site verification of the corrective/preventive action may be required.

Failure to provide satisfactory evidence within the specified time-scale will result in cancellation of membership, removal from the Bord Bia register/database and withdrawal of the certificate.

Category 3 Non-Compliances:

Failure to comply with applicable recommendations as determined by audit will be noted in the audit report and corrective/preventive actions must be implemented before the next full audit.

1.8 Definitions and Abbreviations

Abbreviations:
DAFF: the Department of Agriculture, Fisheries and Food.
FSAI: The Food Safety Authority of Ireland
QAS: the Quality Assurance Scheme.

Definitions:
Certification Committee: the Committee to which Bord Bia has devolved responsibility for all certification decisions with regard to Membership of the Schemes.
Standard: the Prepared Fruit and Vegetable Standard consists of the requirements as set out in the Introduction, Rules, Requirements and the Appendices.
Scheme: the Prepared Fruit and Vegetable Quality Assurance Scheme consists of three elements:

- The system, as administered by Bord Bia, for ensuring that the requirements as set out in the Standard are met through auditing, certification, etc. (see Rules);
- The Standard;
- The participating Prepared Fruit and Vegetable Scheme Members.

Participant: a food business operator involved in the Prepared Fruit and Vegetable sector that is in the process of achieving certification under the Prepared Fruit and Vegetable Quality Assurance Scheme.
Member: a participant that is certified under the Prepared Fruit and Vegetable Quality Assurance Scheme.
Certificate Validity Period: this will be 18 months from the date of issue of the Certificate or until the next audit whichever is first.
Membership Types (as determined by the Certification Committee):

- **Full Membership:** the status (as indicated on the Bord Bia database) which is given where there is full compliance (as defined in Section 2 Rules);
- **Under Review**: the status (as indicated in the Bord Bia database) of the Participant where non-compliances as determined by audit exist or where an appeal exists (as defined in Section 2 Rules, see Appeals);
- **Suspended**: the status (as indicated on the Bord Bia Database) of the membership of the Prepared Fruit and Vegetable Participant where a critical non-compliance has been identified during audit. In this situation, the Participant cannot market product under the Scheme pending re-inspection and confirmation that the critical non-compliance has been addressed.

Formal Training: certified training received from a national or public body or from a Bord Bia approved organisation / individual.

Technical Advisory Committee: The committee that advises Bord Bia with regard to the requirements and rules of the Scheme. This committee is composed of Members from :

- Bord Bia;
- The Food Safety Authority of Ireland;
- The Prepared Fruit and Vegetable Industry;
- The Department of Agriculture and Food.

Certified Producer / Packer: a horticultural producer / packer that has a Quality Award certificate under the Bord Bia schemes.

1.9 Participation

The Prepared Fruit and Vegetable Quality Assurance Scheme is voluntary and application for membership is open to all Prepared Fruit and Vegetable food business operators operating in the Prepared Fruit and Vegetable sector who wish to participate. Certification to the standard, however, will only be granted to participants who meet the relevant requirements (see Section 2 Rules) and demonstrate on-going compliance with the requirements of the scheme in subsequent audits.

1.10 Random Testing

Bord Bia reserves the right to carry out random product related testing to ensure that the participants as a whole are compliant with the requirements of scheme.

1.11 Reference Basis of the Standard

This Standard has been derived bearing in mind the requirements of the following legislation and standards:

- Recognised international Quality Management Systems such as ISO 9001:2000 and ISO 22000:2005;
- Hazard Analysis and Critical Control Point (HACCP), such as outlined by Codex Alimentarius (1997) and as contained in Regulation (EC) 852 / 2004;
- Relevant National and EU derived legislative requirements;
- EN 45011 (1998) General Requirements for Bodies Operating Product Certification Systems.

1.12 Cautionary Notes

Although every effort has been made to ensure the accuracy of this Standard, Bord Bia cannot accept any responsibility for errors or omissions.

It is not a requirement that the participant be registered to any part of the ISO (9001 or 22000) Standards nor is it implied that meeting the requirements of this Standard will automatically mean full compliance with those standards.

Bord Bia is not liable for any potential or estimated loss of earnings (by applicants, or Participants) resulting from compliance with any requirement of this scheme or in regard to the consequences of being found to be in breach of any requirements.

The full onus of responsibility for ensuring compliance with the requirements of this standard is on the participants wishing to participate in the Scheme and not on Bord Bia, or the scheme Auditors or any other third party.

The requirements detailed in this Standard do not and are not intended to replace any statutory obligations of the industry.

2 Prepared Fruit and Vegetable Standard: Scheme Rules

2.1 Membership

Membership of the Scheme is voluntary and open to all food business operators in the Prepared Fruit and Vegetable sector that have been notified to / registered with the relevant competent authority (HSE, or DAFF).
Participants seeking membership must apply initially in writing to Bord Bia on the application form provided (see sample in Appendix 2) and will then receive a copy of the Prepared Fruit and Vegetable Standard.
Following application, an on-site independent confidential audit of the Participant's facility will be carried out (and follow-up inspections if required) to evaluate the capability of the applicant to meet all the requirements of the Standard.

The Participant, having complied with the requirements of the Standard, will then be certified under the Scheme. If the Participant wishes to use the Bord Bia Quality Symbol (for horticultural products) to promote the enterprise, the Participant will be required to:

- Formally apply for permission to use the relevant Bord Bia Quality Symbol;
- Formally undertake to only use this Quality Symbol in a manner agreed with Bord Bia and in full accordance with the current procedures regarding the use of its Quality Symbol. The conditions of use are available separately from Bord Bia.

2.2 Scheme Operation

2.2.1 Control

Overall control of the Scheme will be exercised by Bord Bia in collaboration with the Technical Advisory Committee for the Scheme, which is responsible for drafting the Standard and formulating required amendments.

The decision of Bord Bia on any matter relating to the control or operation of the Scheme is final.

2.2.2 Monitoring and Surveillance

Monitoring of Prepared Fruit and Vegetable Participant compliance with the requirements of the Prepared Fruit and Vegetables Standard will be carried out by Bord Bia or its appointed agents.

Each Prepared Fruit and Vegetable Participant will initially be independently audited twice annually and then annually thereafter. The frequency of audits may be varied at the discretion of Bord Bia. Members will be advised in this event. Costs associated with additional interim audits may be recouped by Bord Bia.

Independent auditors with relevant sectoral experience will carry out these audits and a full report will be issued to the Prepared Fruit and Vegetable Participant.

Bord Bia reserves the right to carry out audits or spot checks on an unannounced basis for the purposes of verifying compliance with the requirements of the Standard or to determine that corrective / preventive actions specified during audit are in place.

Auditors are entitled to seek access to regulatory information in the possession of the participant during audits to verify legal compliance.

Auditors are entitled to seek access to other external information (such as audit reports) as may be necessary to verify compliance with previous corrective actions required.

2.2.3 Certification Decisions

Decisions on whether to grant or renew, extend, refuse or withdraw certification will be made by the relevant Bord Bia Certification Committee. This decision will be made on the basis of the audit findings, the auditor recommendation and any other information that is relevant to food safety and legality (e.g. conviction for a breach of food law).
These certification decisions can be appealed.
The certificate issued to a Participant is the property of Bord Bia and must be returned in the event that the member resigns or is expelled from the Scheme.

2.3 Complaints and Appeals

2.3.1 Complaints

A Member, Participant or Applicant has a right to complain to Bord Bia with regard to the operation of any aspect of the Scheme such as:

- The Auditing process;
- Documentation (notifications, certificates, etc);
- Promptness of communications;
- Operation of the Scheme;
- Other issues.

All such complaints must be made in writing. All complaints will be formally recorded by Bord Bia and acknowledged in writing enclosing a copy of the complaints procedure. Bord Bia will decide the appropriate corrective action and inform the complainant.
The decision on the outcome can be appealed.

2.3.2 Appeals:

A Participant has a right to appeal any decision taken by Bord Bia that affects the status of Membership. All such appeals must be made in writing within two weeks of being informed of the decision regarding Membership status. Bord Bia will formally record all appeals and acknowledge them enclosing a copy of the appeals procedure. The status of membership of the Participant will be Under Review during the appeal period (see definitions, Section 1: Introduction).

2.4 Revision Updates

Users should note that only this Revision 03 now applies. When future changes occur, updates will be issued in whole or in part and the previous revisions must be destroyed.

2.5 Notification of Change

In the event that the ownership, structure or management of the food business changes, or in the event that the Management Representative changes, Bord Bia must be immediately informed.

3. Prepared Fruit and Vegetable Participant Requirements

Requirements: Quality System Core Elements

3.1. Quality Policy Statement

a) Participants must have a written Quality Policy, which must include a commitment to the objectives of the Bord Bia Prepared Fruit and Vegetable Quality Assurance Scheme and to compliance with all current food law and customer requirements.
b) The Quality Policy must be approved by senior management and prominently displayed on the premises.
c) All employees must be aware of the location of the Quality Policy.
d) The Quality Policy should include a commitment to Continual Improvement and providing appropriate information, training and resources for all employees.
e) The Quality Policy should be communicated, understood and implemented by all employees.
f) *The Quality Policy should be regularly reviewed for suitability and effectiveness*.

3.2. Management Responsibility

a) An organisation chart must be available showing the company structure.
b) The commitment of senior management to the effective implementation of the requirements of this standard must be clearly demonstrated and communicated.
c) The responsibilities of key personnel must be documented.
d) Management must be able to demonstrate an adequate level of technical support with appropriate qualifications / competence and other resources for the effective implementation of the Standard.
e) **In the event that a critical non-compliance is identified during internal audits or routine checks, the Participant must immediately notify Bord Bia and implement the relevant procedures (including recall) (Critical)**.
f) Management must define the person(s) who ideally is independent of the production function and who has responsibility for:
    i. Ensuring compliance with regulatory requirements (see also Appendix 1: Reference Information) and compliance with the requirements of this Standard;
    ii. Non-conforming product management;
    iii. Corrective and preventive action management.
g) Management must define the person(s) who is responsible for ensuring compliance with the food safety and hygiene requirements and must establish an acceptable system to demonstrate that the requirements are being met.

3.3. Management Representative

a) The Participant must identify to Bord Bia the Management Representative who, irrespective of other responsibilities, has responsibility for ensuring that the requirements of this Standard are met.

3.4. Management Review

a) Management, which must include senior Management, must meet at least annually with a clearly defined agenda to:
   i. Review the complete Quality System for improvement opportunities;
   ii. Ensure that all aspects of the Quality System as specified in these requirements remain suitable and effective and that preventive or corrective actions are assigned, documented and implemented;
   iii. Review all Quality System data to establish and assign responsibility for improvements including Audit Reports, Customer Complaints, Customer Satisfaction data, Process and Non-conformance Data;
   iv. Set out Quality Improvement Objectives for the next year.
b) Minutes of this meeting must be retained.

3.5. Quality Documentation

a) Participants must document their own Quality System so that all the requirements of this Standard are addressed.
b) The Participants Quality System documentation must include or reference all the procedures, records and plans specified in this Standard.
c) The Quality System documentation must be accessible so that all employees clearly understand their roles and responsibilities in the operation of the process.

3.6. Quality Control Plan

a) Participants must document how the process is controlled at each process stage so as to ensure the quality of the product.

Note: See also the requirements for non-conforming product management detailed in Requirement 3.22

3.7. Document and Data Control

Background information:
It is recommended that the requirements for document and data control as outlined in ISO9001 should be adopted.

a) All documents and data (including this Standard, Customer and Regulatory documentation and other relevant external documentation) that relate to the requirements of this Standard must be managed and controlled as part of the Quality Management System (see Appendix 1 for References).
b) At a minimum, the Participant must ensure that:
   i. Only current issues of all documents are available for use;
   ii. All documents are authorised and identified with the current revision status;
   iii. A procedure for issue of new documents, or amending existing documents, or removal of obsolete documents is in place and is effective;
   iv. Data is reviewed and signed off by an authorised person;
   v. A master list of current documents and procedures exists;
   vi. Applicable documents of external origin are identified and effectively controlled.

3.8. Records

a) All records must be controlled (e.g. by signing and dating), maintained at a secure location and retrievable for a minimum period of three years unless an alternative period is required by regulations.
b) Records relating to traceability must be immediately available for 6 months after placing on the market (Category 1).

3.9. Improvement Plans

a) Participants should carry out an analysis of current and future market requirements (e.g. including those of a regulatory nature, audit reports, customer complaints and incidences of non-conformance). This can be included in the Management Review.
b) Management and key operational staff should have received an appreciation of the tools and techniques of Total Quality Management / Continuous Improvement.

3.10. Reference Information

a) Participants should maintain up-to-date information on all developments relevant to the operation of the Scheme.

3.11. Training

a) The Participant must ensure that the person with overall responsibility for training is identified.
b) An annual review of the training needs of all staff must be conducted to verify the effectiveness of the training given and to create a plan for training requirements.
c) **All operational staff, including maintenance staff must receive induction and on-going food hygiene and appropriate HACCP training; records of this must be maintained (Category 1).**
d) Training records must be maintained for all personnel performing key tasks.

3.12. Product and Process Design and Development

a) Participants must be able to demonstrate that all proposed products and processes are designed to fully meet all relevant regulatory and customer requirements.
b) <u>Shelf-life of all ready-to-eat products must be established and validated; a system for establishing it must be documented and records must be maintained (Critical).</u> (see also Annex 2 Regulation EC 2073:2005 and FSAI Guidance Notes 18 on Determination of Shelf Life)
c) A schedule for the verification of the shelf life must be in place.

3.13. Customer List and Specifications

a) The Customer list and contracts must be reviewed at least once each year.
b) For each product supplied, the Participant must maintain a documented product specification.

c) Participants must maintain a list of all the customers to which each product is being supplied under the Scheme (names, address, nature of products supplied, dates of supply) (refer also to section 3.20 Traceability and Recall).

3.14. HACCP and Pre-requisite Plans

Background Information:
FSAI has published comprehensive guidance notes that are directly relevant to the industry (Code of Practice 4, Guidance Note 11, Rev 01). Participants could use these or other guidelines in the development of their HACCP systems (see Appendix 1, Reference Information). All Participants must comply with Regulation (EC) 852/2004 which specifies, among other things, that Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles Article 5 (1). Participants will be aware that water is an important vehicle for the introduction hazards (e.g. pathogenic bacteria, viruses, cryptosporidium and other parasitic organisms) and risks associated with these hazards need to be considered and addressed in the HACCP plan.

a) Documentation must be available that demonstrates that the essential "Pre-requisite" requirements of Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP) have been adequately addressed at all appropriate steps, including procurement (Category 1).

b) The HACCP system must comply with the following:
   i. **The Participant must have a Hazard Analysis Critical Control Point (HACCP) Plan which shows how product / process safety is ensured through control and prevention of hazards (Critical);**
   ii. This plan must be supported by senior Management;
   iii. It should be put in place by a multi-disciplinary team;
   iv. *At least one member of this team should have received formal training in the application of HACCP Principles.*

c) At a minimum the Hazard Control Plan must include (all Category 1):
   i. A detailed description of the products and process steps (e.g. a flow diagram showing all the steps of each process);
   ii. A detailed description of the hazards (chemical, microbiological and physical / foreign bodies) that could arise at each process step and the risks that these represent;
   iii. The identification of the Critical Control Points (CCP) in the plan;
   iv. The limits that must be met to ensure control of each CCP;
   v. The monitoring required to ensure that control of each CCP is maintained;
   vi. The corrective action to be taken if a non-conformance occurs at a CCP;
   vii. The responsibilities, procedures and records that are applicable at each CCP.

d) The HACCP plan must be verified / tested annually at a minimum to ensure that it is effective (Category 1).

e) As part of this verification / testing process, microbiological criteria (as set out in the regulation EC 2073/2005) must be used in accordance with Appendix 3 (Critical)

f) The Participant must establish a schedule for this testing where the frequency is based on the established risks and the microbiological history of the product (Category 1).

g) The data must be monitored and trends analysed so that appropriate actions or corrective actions can be taken and documented.

h) The HACCP plan must be supported by the GMP and GHP Plans (3.27 – 3.58).

3.15. Purchasing, Supplier and Materials Controls

General

a) The Participant must maintain a list of suppliers (with contact details) that they have approved to supply materials or services that could affect product quality and / or food safety.
b) All approved supplier lists must be reviewed at defined intervals to maintain accuracy of the information (and this should include a risk assessment review).
c) There must be specifications for all raw materials that could affect product quality and food safety.
d) The Participant must maintain a list of the products supplied with details that include the following: name, address, nature of products supplied, date of supply for each product.
e) All incoming materials must be inspected against the specifications in accordance with an inspection schedule prior to release to the process and a record of these checks and approvals must be maintained.
f) An effective stock rotation of all raw materials must be in place.
g) The storage of all materials that could affect product quality or safety must be managed in a way that ensures continuing fitness for purpose.
h) Documentation must be maintained to demonstrate that the traceability of all such materials that could come into contact with food is fully established at all stages (purchasing, intake, use).

Packaging

i) All packaging materials that come in contact with the product must be purchased from suppliers that comply with the relevant packaging regulations (see Appendix 1).
j) All packaging in contact with food must be identified with the appropriate food grade symbol(s).
k) A certificate of suitability / conformance must be available for all packaging materials that come into contact with the product.
l) Documentation must be maintained to demonstrate that the traceability of all such materials that could come into contact with food is fully established at all stages (purchasing, intake, use).

Detergents, Lubricants and Sanitisers.

m) Current certificates of suitability for use with fruit and vegetables must be maintained for detergents (including soaps), lubricants, and sanitisers.
n) All such materials and chemicals must be stored in a manner that permits control over their use.

3.16. Sourcing of Fruit and Vegetables

a) Where a product with the Bord Bia scheme logo is being placed on the market, it must have been made using fruit and vegetables that have been sourced from a Bord Bia certified Producer.
b) Fruit and Vegetable raw material suppliers should ideally all be Bord Bia certified.

3.17. Preparation and Processing

a) Participants must have a documented procedure that covers all stages of the preparation and processing of all fruit and vegetables (Category 1).

b) The procedure must be supported by documentation that defines how each stage of the operation is to be conducted (e.g. peeling, shredding, dicing) and the equipment to be used at each stage.

c) Participants must ensure that only water suitable for human consumption is used in the final washing of ready-to-eat fruit and vegetables (Critical).
(See also Requirement 3.59 regarding potable water).

d) Participants must ensure that only water suitable for human consumption is used in the washing of other fruit and vegetables (Category 1).

e) Participants must have records that validate the effectiveness of the wash water sanitiser product at the selected solution strength and must have established operational limits based on the available literature (e.g. FSAI Code of Practice 4) (Category 1).

f) Participants must have documented the monitoring required to ensure that the washing solution remains active and must have identified the person responsible for carrying out the tests (Category 1).

g) Participants must have a documented procedure for washing fruit and vegetables that specifies how washing is to be conducted (the equipment settings / times, the strength of solutions that must be maintained, etc.) (Category 1).

h) Participants must have a documented procedure specifying how excess water is removed from the fruit and vegetables after washing and before processing / packaging.

i) The temperature at which the fruit and vegetables must be maintained during all stages of preparation and processing must be documented and a record maintained of the actual temperatures (see also Requirement 3.21: Processing Storage, Dispatch and Transport below).

Note: FSAI Code of Practice 4 (see Appendix 1, Reference Information) gives detailed recommendations with regard to temperature controls during processing. These could be used in the development of the plan.

3.18. Final Product Release

Positive Release

a) All products must be inspected and positively released for dispatch by qualified personnel according to a documented inspection procedure that includes tests that establish the effectiveness of any modified atmosphere packaging where used (Category 1).

b) The personnel with responsibility and authority for final product approval and release must be identified in the documentation.

c) This inspection must also ensure that all product:
Is free from visible contamination before dispatch;
Meets internal and customer requirements for quality.

Metal Detection

d) Where required by the HACCP Plan or through customer requirements, all products must be passed through a metal detector.

e) Detectors must be set for optimum sensitivity for the product consistent with customer requirements and incorporate an alarm to signify the presence of metal (ferrous and non-ferrous) and non-conforming product must be treated as in Requirement 3.22.
f) A schedule of testing of the effectiveness of the metal detection system must be in place.
g) A corrective action procedure must be documented to deal with failures of the metal detection equipment.

3.19. Identification[1] and Labelling

a) <u>Product must be clearly marked with Identification and traceability codes (Critical).</u>
b) The use of the Quality Symbol for the Scheme (if applicable) must be in accordance with the Bord Bia conditions which govern its use (Available separately from Bord Bia) (Category 1).
c) Product must also conform to legal requirements for Prepared Fruit and Vegetable labelling. These include requirements such as:
   i. Product Name;
   ii. Net Quantity;
   iii. Shelf life as indicated by a "Use By or Expiry" date;
   iv. List of ingredients in descending order (including allergen specific information and Quantitative Ingredient Declaration (QUID));
   v. Recommended storage conditions;
   vi. Participant / Packer name;
   vii. Origin of the product;
   viii. Batch number, or other traceability code;
   ix. A declaration that "this product is packed in a modified atmosphere" where modified atmosphere packaging is used.

Note 1: Items i - iii above must appear in the same field of vision on all labels for product sold directly to the customer.

Note 2: Item iii can also be achieved by an indication of position of Use By date (e.g. "see bottom of pack for Use By date").

Note 3: Where a packaged foodstuff is sold to another business for further processing (i.e. not for selling on in its original packaging), only the name of the food, the use-by date and the name and address of the packer, processor or seller in Europe need be on the label affixed to the packaging (i.e. i, iii and vi above). All other compulsory labelling items must be included, but can be placed on the documentation where it can be guaranteed that the documentation accompanies the foodstuff.

[1] Regulation EC 178/2002 requires one step forward (i.e. customer), one step back (i.e. supplier) traceability of all materials that are or could be incorporated into food

Note 4: Information specific to allergens is available on the FSAI website (see reference information, Appendix 1).

3.20. Traceability and Recall

a) **Participants must have in place a traceability procedure that permits full traceability to its suppliers (i.e. of ingredients raw materials and packaging) and its customers[2] (i.e. one step forward and one step back) (Critical).**
(See also FSAI Guidance Note 10 on Traceability and Recall).

Note 1: specific documentation specified regarding the source (Requirement 3.15.d) and destination (Requirement 3.13.c) for all products is required in support of this requirement.
Note 2: record retention period is specified in Requirement (3.8.b).

b) **Participants must have a traceability procedure that permits full traceability at all stages of the process (intake, process, delivery) (Category 1).**
c) **Participants must establish an effective product recall procedure and this recall procedure must also include a provision to inform the regulatory authorities (FSAI, HSE or DAFF as appropriate) in advance of activating the recall (Category 1).**
d) Documentation must be maintained to demonstrate that the recall procedure was tested annually for effectiveness.

3.21. Processing, Storage, Dispatch and Transport

Processing and Storage (in-process or finished product) Temperature Requirements Summary:

Area / Product	Temperature Requirement
Production Rooms	Ambient Temperature not exceeding 12ºC
Chilled Storage:	0 – 5ºC
Frozen Storage:	- 12ºC or Colder
Transit Temperatures: Chilled	0 – 5ºC
Transit Temperatures: Frozen	- 12ºC or colder as stipulated by customer contract

a) All temperature controlled areas must be constantly monitored (and ideally alarmed) and a permanent record available of the temperatures.
b) There must be a procedure for defining and documenting the Corrective Action to be taken to address temperature non-conformances observed in these systems.

[2] Customer traceability is not required where the customer is the final consumer

Product Storage

c) Product must be stored in a manner in which it is easily identifiable.
d) All stored product must be labelled or identified to ensure compliance on traceability (see also Requirement 3.19 above).
e) All personnel involved with product storage and dispatch areas must have documented training relevant to this task (see also Requirement 3.11, Training and elsewhere where specific training requirements are identified).
f) All product (including packaged product) must be stored so as to ensure it is protected from damage or contamination.
g) All product in the processing areas must be stored in clean plastic or stainless steel containers.
h) All product must be stored off the ground to avoid any possibility of contamination especially microbial.
i) Wooden pallets, cardboard boxes must be stored outside processing areas to avoid contamination.

Dispatch and Transport

Background Information:
Participants will be well aware of the need for food to be adequately protected during transport. The type of containers required depends on the nature of the food and the conditions under which it has to be transported. Food may become contaminated or may reach its destination in an unsuitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain. Under Regulation (EC) 852 / 2004, it is the responsibility of the Participant and the transporter to ensure that the cold chain is maintained. This applies to the loading and transport or product in a manner that is appropriate to the product.

j) Transport containers must be designed and managed so that they:
   i. Do not contaminate foods or packaging;
   ii. Can be effectively cleaned and where necessary disinfected;
   iii. Permit effective separation of different foods, or from non food items where necessary, during transport;
   iv. Provide effective protection from contamination including dust and fumes;
   v. Can effectively maintain the temperature, humidity, and other conditions, necessary to protect food from harmful or undesirable bacteria;
   vi. Allow any necessary temperature conditions to be recorded;
   vii. Are subject to effective cleaning and where necessary disinfection between loads (where the same container is used for transporting other food types).

k) A record of the following checks must be maintained (All Category 1):
   i. Inspections of all transport vehicles prior to loading (to ensure they are clean, waterproof and undamaged, that door seals and air circulation ducts are intact and that the refrigeration unit is working properly);
   ii. Checks of all containers to ensure that they are pre-cooled prior to loading;
   iii. Product temperatures prior to loading.

l) Records must be maintained to demonstrate the effectiveness of temperature control appropriate to the product during transit.
m) A contingency plan must be in place to deal with refrigerated delivery breakdown.

3.22. Control of Non-Conforming Product (Including returns)

a) There must be a documented procedure to ensure that product / material at any stage that does not conform to requirements, is prevented from unintended use or release (Category 1).

b) The procedure must provide for clear identification, adequate segregation and final disposition of the non-conforming material and records of such disposition must be maintained.
c) The disposition must only be conducted in a manner that permits full traceability and must only be authorised by the personnel specified in Requirement 3.2 above and disposition can include:
    i. Reworking to meet requirements;
    ii. Acceptance with or without reworking by agreed concession from the customer;
    iii. Re-grading, including where necessary re-labelling, for alternative use to which it fully conforms;
    iv. Rejection and destruction.

3.23. Internal Audits

a) Participants must establish documented procedures for the scheduling, planning and the implementation of internal audits to verify internal compliance with the requirements of the Standard and to demonstrate the effectiveness of the Quality System, records and procedures.
(See also the responsibility for reporting critical non-compliances in Management Responsibility, Requirement 3.2 above).
b) All corrective and preventive actions defined in these audits must be assigned and tracked until completed by the target completion dates.
c) The records of such audits must be available for inspection.
d) Internal auditors must have received training in the requirements of the Standard.
e) Internal auditors should be independent of the activity being audited and should also have received formal training in auditing skills.

3.24. Inspection and Testing

a) Participants must document the procedures used for all inspection and testing (for raw materials, in-process materials and finished product) and maintain appropriate records to demonstrate ongoing compliance with all controls.
b) Where relevant, the competence of the Participant's laboratory staff must be demonstrated (e.g. through training records, certifications etc.).
c) The suitability, effectiveness and accuracy of the test methods must be demonstrated (e.g. by reference to industry norms or other standard test methodologies and by laboratory test validation).
d) Where testing is outsourced, the Participant should only use laboratories independently accredited to ISO 17025 for that test.
e) All measurement systems must be capable of complying with regulatory requirements for accuracy.

3.25. Control of Inspection, Measuring and Test Equipment

Participants need to document the procedures used to control, calibrate and maintain inspection, measuring and test equipment used to demonstrate compliance with the requirements of the Standard. At a minimum, the following requirements apply:

a) A register of all such equipment must be maintained which includes:
    i. Identity / location;
    ii. Operating range;
    iii. Tolerance and accuracy required;
    iv. Calibration frequency and responsibility;

v. Calibration method or reference;
vi. Operational checking (e.g. start-up checks) to ensure continuing accuracy.

b) Records of all calibrations with traceability to National Standards must be maintained.
c) When a device was found to be out of calibration, an assessment must be made of the validity of previous inspection results and the likely impact of inaccurate results; the appropriate corrective and preventive actions must be determined and recorded.

26. Improvement

Corrective and Preventive Action

a) There must be documented and effective procedures for Corrective and Preventive action management.
b) Corrective and Preventive actions must be tracked and their priorities appropriately identified (e.g. by means of defined time scales for completion).

Customer Complaints

c) Participants must establish an effective procedure for handling of customer complaints, including any of regulatory origin.
d) The procedures must clearly outline responsibilities for logging, tracking and closing off complaints in conjunction with the complainant.
e) The complaint log and related correspondence must be maintained and be available for inspection.

Requirements: General Hygiene and GMP

Background Information:
Hygienic practices and effective food temperature control is key to the prevention of the food borne illness or food spoilage. Participants therefore will have a Good Manufacturing Practices (GMP) plan which complies with the Hygiene and GMP Requirements as set out below and which supports the HACCP plan. Compliance with these requirements does not in any way lessen the responsibility on Participants to conform to existing statutory requirements. Management will therefore be aware of the need to ensure that that the premises and plant are designed, constructed and maintained to prevent and control the risk of contamination and comply with all relevant legislation pertaining to food safety.
The requirements listed below elaborate the essential management procedures necessary to implement hygiene / GMP.

3.27. Site Security and Visitors

a) Participants must ensure the site security is maintained to minimise possible product contamination.
b) Management must define how visitors are managed so as to minimise risk to product.

3.28. Premises

Background Information:
Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measure that might be taken to protect food. Participants will be aware of the need to ensure that the internal design and layout

of the premises would permit good food hygiene practices, including protection against cross-contamination between and during operations where foodstuffs are involved.

Location

a) The premises should be located away from:
i) Environmentally polluted areas and industrial activities which pose a threat of food contamination;
ii) Areas subject to flooding unless sufficient safeguards are provided;
iii) Areas prone to infestation of pests;
iv) Areas where wastes, either solid or liquid, are collected.

Design & Layout

b) The area for delivery of raw materials should ideally be located at the opposite end of the premises to that of dispatch to further minimise cross-contamination occurring.

Premises and Plant

c) Process flow and traffic should be arranged to prevent product contamination.
d) Laboratories on-site should be located and operated to prevent product contamination (such as by contact between raw and processed fruit and vegetables).

3.29. Cleaning and Sanitation

Background Information:
Participants will be aware of the need to ensure that the cleaning programme is effective. Methods such as microbial swabbing or rapid hygiene tests can be used to demonstrate this.

a) Participants must document and implement a comprehensive cleaning and sanitation programme for plant, facilities and equipment (Category 1).
b) The cleaning and sanitation programme must cover all food contact surfaces and interior of the plant including at a minimum: walls, floors, windows, drains, machines, equipment (e.g. knives, trays), food surfaces (e.g. conveyors), facilities, and ancillary structures including ventilation ducts and stores.
c) The cleaning and sanitation programme must also include appropriate measures regarding the exterior of the plant.
d) Participants must adopt a "clean as you go approach" throughout the operation and must document, monitor and record the cleaning activities.
e) The Participant must define the frequency and method of cleaning (including safety hazards) required to ensure that the appropriate surfaces are cleaned and then sanitised.
f) A designated person must verify the effectiveness of cleaning prior to allowing production to re-commence (Category 1).

g) Where cleaning is done by a subcontractor, a contract with full specification must be in place (Category 1).

3.30. Microbiological Cross Contamination

a) Raw unprocessed food must be effectively separated from ready-to-eat foods and Participants must ensure that there is effective cleaning and, where appropriate, disinfection between these foods where processed consecutively on the same equipment.
b) Where ready-to-eat foods are being produced, environmental sampling for *L. monocytogenes* must be carried out[3] (Critical).
c) Access to processing areas must be restricted or controlled.
d) Where risks are particularly high, access to processing must be only via a changing facility and designated zoned area. (See also requirements relating to entry to production, Requirement 3.35).
e) Surfaces, utensils, equipment, fixtures and fittings must be thoroughly cleaned and disinfected after use in the preparation of raw food.
f) Where there is a need to control microbial levels, the use of low temperature disinfectants must only be used after risk assessment analysis has been completed.
g) The level of disinfectant solution being used must be monitored daily to maintain limited dosing to prevent residues.
h) The average contact time must be validated and product rinsed with potable water immediately where recommended on the chemical data sheet from the supplier.
i) Drying or draining of some products is an important step in the manufacturing process that can affect product quality, and procedures for these process steps must be documented.

3.31. Pest Control

a) Participants must implement a documented pest control programme and all baiting materials must be certified by the manufacturer as being appropriate for the particular use (Category 1).
b) An annual review of the pest control programme must be conducted to establish its suitability and effectiveness.
c) Buildings must be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Openings must be sealed, or protected with fine wire mesh screens and animals (such as birds, pets, wildlife, etc.) must be excluded from the premises and other at-risk areas.
d) Where baiting supplies are stored on site, the store must be kept locked.
e) All bait stations and electronic fly killers, must be secured, numbered and clearly indicated on a map.

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[3] See FSAI report from the scientific committee on the Control and Management of *Listeria monocytogenes* in Food (see Appendix 1)

f) Inspections for pest control must be made and recorded (minimum 8 visits per year) by an independent contractor.
g) There should be a multi level baiting system such as:
   i. First line of defence: Perimeter with bait points at 6-8m intervals along the entire perimeter;
   ii. Second line of defence: along factory building wall;
   iii. Third line of defence: internally where there is a risk of rodent ingress.
h) Bait containers should be secured to the ground or wall and protected from birds and species other than pests.

3.32. Maintenance

a) A preventive maintenance programme for essential plant and equipment affecting product quality / safety must be in place.
b) Maintenance schedules and procedures must be documented.
c) All internal maintenance staff must receive training in hygiene.
d) All external maintenance personnel must be made aware of the company hygiene regulations prior to commencing work.
e) Maintenance procedures must indicate the precautions taken to ensure that the product is not contaminated in any way by the maintenance activity, whether carried out by internal or contracted staff.
f) A record of maintenance activities must be maintained.
g) There must be a procedure to approve equipment for re-use after maintenance is complete.
h) A system for accountability for tools used and equipment parts removed during maintenance should be developed and implemented.

Requirements: Environmental Hygiene

3.33. General Requirements and Breakables

Background Information:
Participants will understand that the structure and fabrication of the premises and the supply of services must be such as to minimise contamination. The following specific requirements apply:

a) Wooden structures, pallets or fittings are not permitted in any food production area.
b) A glass / hard plastics policy and written procedures for handling breakages in all process and storage areas must be in place. This must cover all plastics that are likely to give rise to sharp fragments.
c) Where glass / hard plastics are present a glass / hard plastics register must be maintained.

3.34. Exterior, Structure and Grounds

a) The grounds and all areas of the premises must be well presented and maintained so as to minimise sources of contamination.
b) A perimeter fence, wall, or other suitable physical demarcation must protect access to the grounds.

c) Equipment, pallets, and other materials stored in the factory grounds must be stored neatly and in clean and clearly defined areas.
d) Any unused buildings, service buildings etc. must be maintained in good repair and free from debris.
e) There must be a clearance of one metre wide around the factory to avoid rodent infestation.
f) Exterior finish of the premises must be maintained in sound condition (i.e. no flaking paint or broken plaster).
g) The grounds must be kept free of debris and there must be no stagnant water, potholes or open drains.
h) Roofs, valleys, and gutters must be maintained in good repair and free from debris and weeds.
i) Areas directly outside premises must be free of weeds, grass, rubbish, or any item that may harbour pest and/or disease.

3.35. Entry to production

a) A procedure must be in place to ensure good hygiene practices at entry and exit from all production areas (i.e. hygiene barriers, protective clothing and footwear changing).
b) The entry point must contain a hygiene barrier (e.g. seat) for staff entry and exit from the production area.
c) Wash-hand basins and footwear cleaning facilities must be provided at all entry points to production areas.
d) Taps must be knee, foot, arm or electronically operated.
e) Paper towel dispensers and receptacles must be in place.
f) Hand sanitising solutions or sanitising liquid odourless soap must be provided at each hand washing point and clearly identified.
g) Hand-washing instructions (ideally following the recommendations of Health Protection Surveillance Centre (HPSC) see Appendix 1) must be posted adjacent to the wash stations.
h) Where Foot Baths are provided, these must be located outside production areas and be designed to ensure adequate contact with footwear and allow footwear to drain after use.
i) A procedure should be in place to ensure that the disinfecting solution remains at a working strength at all times.

Note: See also protective clothing requirements (Requirement 3.54)

3.36. Interiors: General

Background Information
Participants will appreciate that structures within food premises need to be soundly built, constructed of durable materials, and easy to maintain, clean and disinfect. This can achieved with a number of building materials including stainless steel sheeting, PVC sheeting, tiles, smooth finish plaster treated with non-toxic / non peel food grade paint, or other equivalent materials.

a) All pipes, pipe work, lagging, electrical cables etc. must be clean, secure and properly constructed.
b) A schedule of internal washing and sanitation must be in operation (see also Requirement 3.29).
c) Working surfaces that come in contact with food must be in sound condition, impermeable to water, durable and easy to clean, maintain and disinfect.

d) Work surfaces must be made of smooth, non–absorbent materials and inert to food, detergent and disinfectant under normal working conditions.
e) All equipment must be placed or installed in a manner that permits cleaning all around.
f) All electrical fittings and cables must be to an approved standard and retained within the premises structure.
g) To protect internal walls and prevent damage, a solid barrier should be constructed large enough to limit impact (e.g. forklifts).
h) Pallet racking must be of sound structure, free of peeling paint, corrosion free and be secured to the ground.
i) Coving should be used in areas where walls join ceilings.
j) All metallic equipment used in the process area should ideally be stainless steel.
k) Aprons, where used, should be subjected to frequent cleaning (e.g. in wash cabinets designed to minimise the risk of cross contamination).
l) Hoses (which would ideally be completely constructed of corrosion free materials) must be maintained in a clean and tidy condition and must always be kept off the floor when not in use.

3.37. Interior Walls

a) Wall surfaces must be designed and constructed to be durable, smooth, light coloured, easily cleaned and impermeable to liquids.
b) They must be maintained in a clean condition, free from cobwebs and moulds, etc.
c) Junctions and joints must be smooth and impervious.
d) Wall-to-floor junctions must be sealed and constructed so as to be easily cleanable.
e) Ledges and sills must be sloped and kept free from dust, dirt or other miscellaneous items.
f) Walls must be well maintained, e.g. no flaking paint or broken plaster, no damaged or missing tiles, all tile cracks sealed or grouted.

3.38. Ceilings and Overheads

a) Ceilings must be designed and constructed to be of sufficient height, smooth, light coloured, prevent the shedding of particles and easily cleaned.
b) All joints must be sealed and impermeable.
c) Ceilings must be maintained in good repair, clean and be free of condensation.
d) False or cavity ceilings must have access to the void above to enable cleaning and inspection.
e) Girders and overhead pipe-work and structures must be clean, free from rust, dust, mould growth, flaking paint and other extraneous material.
f) Skylights are undesirable, but where present they must be clean and be fitted with fly screens where they can be opened.

3.39. Floors

a) Floors must be constructed of durable, non-slip, water resistant material and be maintained in good condition (i.e. no holes or cracks).
b) Floors must be kept clean and free from the accumulation of water or debris especially in corners or in areas hidden by machinery.
c) Rubber mats or plastic meshes, where used, must be easily removed and easily cleaned.
d) Concrete floors must be treated with a floor sealant to prevent dust in the premises.

3.40. Drainage

a) Drainage must be such as to prevent risk of contamination.
b) Stagnant pools of liquid on floors must be prevented by adequate sloping towards the drainage channels or by other management techniques.
c) Drainage channels crossing personnel working areas and passage-ways, must be protected with removable covers to facilitate cleaning.
d) Fat and debris traps must be fitted to all drains.
e) Drainage from on-site laboratories should be designed to exit the building before joining up with other waste systems.
f) Where manholes are present inside a premises they must be doubly sealed and secured to prevent overflow and odour.
g) Drains must be constructed in a manner that will prevent odours or vermin entry to the premises (such as by using swan neck waste pipes and gridded drain covers).
h) A cleaning schedule for drains must be in place with spot-checks to ensure on-going cleanliness.
i) Direction of drainage flow should be opposite to that of product flow.

3.41. Doors

a) Doors and door frames must be constructed of durable impermeable material; these must be tight fitting and of smooth easy-to-clean finish.
b) Glass must not be used in doors opening into storage or production areas; oher clear shatterproof material must used instead.
c) All external doors and internal doors (excluding emergency doors) leading from non-process into process areas must be self-closing or otherwise screened to prevent pest ingress.
d) All chill and freezer doors must be capable of being opened from both sides.

3.42. Windows

a) Windows opening to the exterior in production areas must be at least two meters above ground, have sloping ledges and if opening, fitted with suitable and effective fly-screens.
b) They must be constructed of shatterproof material or, if glass / hard plastic, laminated to prevent shattering.
c) Windows, window frames etc. must be tight fitting, maintained in good condition, free from cracks, moulds, flaking paint etc. and must be clean.

3.43. Lighting

a) Lighting in production areas, must be designed to be permanently fixed, easily cleaned and must be protected by shatterproof covering.
b) Lighting must be adequate at all times for the particular operation and must be of a type that does not distort colour where process decisions are taken on the basis of colour.

3.44. Water, and Water Treatment

a) All water, steam and ice used in production in contract with the final product must be of potable quality (S.I. 278:2007 as listed in Appendix 1).
b) Water tanks must be kept covered.

Note: See also the requirements regarding water (Requirement 3.59) below.

3.45. Extraction and Ventilation

a) All processes that emit steam or vapours must be effectively hooded and fitted with suitable extraction equipment to prevent condensation.
b) Suitable ventilation must be available in all process areas where steam or water vapour arises to prevent condensation.
c) Vents from drains, sewers and rainwater drainpipes must not be located within the plant.
d) Ventilation systems must be designed and constructed so that air does not flow from contaminated areas to clean areas.
e) All ventilation equipment must be serviced and maintained clean as per the recommendations of the manufacturer(s).

3.46. Cleaning Materials and Storage

a) All cleaning equipment and materials, chemicals and other substances likely to contaminate product must be stored in a lockable, secure place (ideally with appropriate bunding) away from production.
b) A safety data sheet must be available for each chemical.
c) Adequate safety and protective clothing, footwear and apparatus should be available when handling such substances.

3.47. Effluent Treatment

a) Effluent treatment facilities must be operated in accordance with the relevant licences.
b) Where an effluent treatment plant exists on site it should be placed as far away as possible from the plant air intake points.

3.48. Food Trays

a) Facilities with adequate ventilation must be provided for the washing and sanitising of food trays.
b) At a minimum there must be separate areas for the storage of soiled trays, the washing of soiled trays and the storage of clean trays.
c) In all cases, cross-contamination between clean and dirty trays must be prevented.

Note requirements relating to materials in contact with foods (see Requirement 3.15).

3.49. Electronic Fly Killers.

a) There must be a programme and records for the inspection of electronic fly killers and for replacement of the light tubes.
b) Electronic fly killers must be located away from food processing areas and from packaging equipment or packaging operations.
c) Electronic fly killers must not be located close to or above exposed unpacked prepared product.

Note: Consideration should be given to locating the electronic fly killers to ensure effective operation and to minimise their potential to contaminate food.

3.50. Waste Management General

Background Information:
Containers for use internally (i.e. within the plant) and skips are also important elements in the management of waste.

a) **There must be a documented programme for the management of all organic and inorganic waste material (Category 1).**
b) Waste materials must be controlled in the production area and must be stored in containers pending collection / disposal.
c) Participants must have procedures to prevent waste material coming in contact with fresh or processed fruit and vegetables.
d) The plant cleaning schedule must include all waste areas.

Containers and Skips

Background Information
Containers for use internally (i.e. within the plant) and skips are also important elements in the management of waste.

e) Waste containers must be clearly identified so that they cannot be mistaken for food use containers.
f) Waste containers must be clearly designated and identified according the type of waste (separate waste containers for food and non-food materials) to be disposed in them.
g) Waste containers must be available at appropriate locations.
h) Skips must be covered at all times except when being filled and be located as far as practicable from the "Clean" area.
i) Skips must be sited on a concrete surface that ensures that any leakage is contained and disposed of safely.
j) Skips must be emptied according to a documented schedule, and spillages cleaned up immediately.

Other Waste Material

k) Discarded wrapping, packaging and other refuse must be placed in designated bins or skips so that it does not compromise the hygiene of the premises and does not provide a habitat for pests and vermin.

Requirements: Personnel Hygiene

Background Information;
It is the responsibility of management to ensure that all aspects of personnel hygiene are addressed. Several documents are published which give guidance in this area and some are listed in Appendix 1, Reference Information). However, at a minimum Participants are required to demonstrate compliance with the following specific requirements.

3.51. Personnel Hygiene: General

a) **A documented staff training programme covering all relevant aspects of Hygiene and GMP must be in place (Category 1).**
b) Training records must be available to demonstrate that all operatives have been trained accordingly.

3.52. Personal Hygiene

a) Fingernails must be kept short, clean and unvarnished.
b) No loose jewellery, except plain wedding rings may be worn by personnel working in the production area.
c) All head hair, including facial hair must be contained (e.g. by means of a snood, mop cap or other covering) to prevent contamination of product.
d) Cuts, sores and grazes must be covered after treatment with a distinctively coloured waterproof dressing incorporating a metal detectable strip and which is supplied by the company.
e) All production operatives should be encouraged to minimise the use of perfumed personal care products.

3.53. Medical Records

Background Information:
Management and employees will be aware of the need to control infectious diseases and to have adequate on-going medical screening of employees.

a) **Participants must have a procedure in place to ensure that no person that is likely to be a carrier of or suffering from a disease likely to be transmitted through food or that has infected wounds, skin infections, sores or diarrhoea is be permitted to handle food or enter any food-handling area in any capacity (Category 1)**.
b) The procedure must ensure that any person so affected who is likely to come into contact with food immediately reports the illness or symptoms, and if possible their causes, to the food business operator.
c) Participants must ensure that:
   i. Food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
   ii. Those responsible for the development and maintenance of the HACCP system have received adequate training in the application of the HACCP principles.
d) Personnel must be made aware of their responsibility to notify management of any infectious disease or condition they may be suffering from or have been in contact with that could adversely affect the safety of the product.

3.54. Personnel Clothing and Locker Room Facilities

Protective Clothing

a) All personnel (food operatives) working within the plant must be provided with protective clothing, suitable headgear and footwear that is designated by area.
b) Clean protective clothing must be issued daily or more frequently where required.
c) Amenity facilities (including individual lockers) must be provided that ensure the separation of street (civilian) and in-plant protective clothing.
d) Specific arrangements must be in place that provide for the hygienic handling of used or contaminated clothing.
e) A scheduled laundering of all protective clothing must be in place.
f) Where work clothing is laundered on site, the wash cycle must exceed 80^{o}C operating temperature.

3.55. Personnel Facilities including Canteens

a) Smoking, eating and drinking must only be permitted in designated areas and there must be clear signs to this effect.
b) All personnel facilities (canteens, locker-rooms, toilets) must be included in the plant sanitation programme and maintained in a clean condition.

3.56. Toilet Facilities

a) All toilets, including office toilets, must be clean and adequately ventilated and all toilets must not lead directly into the processing area.
b) There should be at least one toilet and one hand-basin per 15 male and per 10 female employees.
c) Odourless liquid soaps and sanitising liquids must be provided and dispensed from wall-mounted units.
d) Paper towel dispensers and a bin for used paper towels must be provided in every wash area.
e) Hygiene notices must be clearly displayed in all toilet areas indicating that hands must be washed after the use of the facilities.

3.57. Washing Facilities in Production

a) In all process areas, all operatives must have direct access to hand-washing facilities at their work areas (see also Requirement 3.35).
b) Paper towel dispensers and a bin for used paper towels must be provided in every wash area.
c) Air driers are prohibited in production areas.

3.58. First Aid

a) At least one member of staff must be trained in First Aid procedures and fully stocked first aid kits must be available to treat minor injuries.

Requirements: Plant and Facilities

3.59. Water

Background Information:
Regulation (EC) 852 / 2004 states that there is to be an adequate supply of potable water which is to be used in the process whenever necessary to ensure that foodstuffs are not contaminated. The term “Potable water” refers to water for human consumption as defined in SI 278: 2007

a) The potable process water must be tested at a minimum annually from multiple sample points (as in 3.59.h below) by trained personnel and analysed for *E.coli* and Enterococci; the results must be retained; in the event that the source of the water is changed at any time, the water must be tested for *E.coli* and Enterococci before use (Category 1).

b) If there is a failure (detection of either organisms), an alternative compliant supply must be used immediately; corrective measures must be taken and the original supply may only be reused when it has been demonstrated to be compliant.
c) Microbiological analysis of the process water supply must comply with the following:
    i. *E.coli* 0 / 100 ml (ISO method 9308-1);
    ii. Enterococci 0 / 100 ml (ISO method 7899-2).
(Note: Sampling should meet n=3, c=0 for each parameter; equivalent test methods can be used)
d) Where chlorination is installed, the dosing system must incorporate an alarm device and must be designed so that the chlorination process is effective (as determined by test) and non-tainting; there must be measurement at least twice daily of residual chlorine in treated water and records must be retained.
(Note: details and recommendations regarding chlorination are contained in the FSAI COP 4 guideline. See Appendix 1)
e) Where an alternative disinfection system(s) is used (e.g. Ozonation, membrane filtration, etc.) the effectiveness of the system must be validated; the system must be designed so that operators can easily determine that it is operating effectively (as determined by test) and non-tainting; there must be measurement at least twice daily of active constituent (where relevant) in the treated water and records must be retained.
f) A programme must be in place to prevent organic matter build up in tanks.
g) Non-potable water is not permitted in the plant except where dedicated pipes are used and the non-potable water pipes are clearly distinguished from Potable pipes to prevent inadvertent use.
h) There must be a water distribution system map or drawing showing, the source of the water, the storage facilities (tanks etc.), the Hot and Cold distribution systems in the plant and the locations of the sampling points which must be located in food processing areas.
i) Storage Tanks must conform to the following specification:
    i. Manufactured from inert material;
    ii. Covered and fitted with an inspection hatch;
    iii. Water inlet at the top of the tank (to prevent sediment disturbance);
    iv. Water outlet at the bottom of the tank;
    v. Fitted with screened vent pipes.
j) Where the water supply is derived from well(s), the well-head(s) must be sealed and the area around the well-head(s) maintained to prevent water contamination.

3.60. Noise

Background Information:
A guide to compliance on noise is published by the Health and Safety Authority (see Reference Information, Appendix 1).

a) Where noise is generated, Participants should comply with the Noise regulations.

Reference Information

Published by Codex Alimentarius (www.codexalimentarius.net):

- Hazard Analysis and Critical Control Point system (HACCP) and Guidelines for its Application, (2003)

Legislation / Regulations:

- S.I. 747 of 2007 European Communities (General Food Law) Regulations 2007
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of January 28th 2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- S.I. 278 of 2007, European Communities (Drinking Water) regulations, 2007
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs (as amended)
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (as amended).
- S.I. 483 of 2002, Labelling, presentation and advertising of foodstuffs regulations 2002 (as amended).
- Regulation (EC) No 2073 / 2005 (as amended) on microbiological criteria for foodstuffs

Other:

- Health Protection Surveillance Centre (HPSC), Report, 2004
- FSAI Allergens leaflet and other FSAI Information
- FSAI The Control and Management of *Listeria monocytogenes* Contamination of Food

Published by the National Standards Authority of Ireland (www.nsai.ie):

- I.S. 3219:1990, Code Of Practice For Hygiene In The Food And Drink Manufacturing Industry
- I.S. 341: 2007, Hygiene in Food Retail and Wholesaling
- I.S. 340: 2007, Hygiene in the Catering Sector
- I.S. 342:1997, Guide to good hygiene practice for the food processing industry in accordance with Council Directive 94/43/EEC on Hygiene in Foodstuffs
- ISO 9001:2000, Quality Management Systems - Requirements

Published by the Food Safety Authority of Ireland (www.fsai.ie):

- Code of Practice No. 4: Code Of Practice For Food Safety In The Fresh Produce Supply Chain In Ireland.
- Code of Practice No. 10: Code of practice for hygiene in the fresh food supply chain
- Guidance Note 10: Product Recall and Traceability
- Guidance Note 11: Assessment of HACCP Compliance (as amended)
- Guidance Note 18: Determination of Product Shelf Life 2005

- Guides to Food Safety Training,
  - Level 1 – Induction Skills; Food Service, Retail and Manufacturing Sectors
  - Level 2 – Additional Skills; Food Service, Retail and Manufacturing Sectors
  - Level 3 – Food Safety Skills for Management

Published by Bord Bia (for horticulture):

- Bord Bia Guideline Documents :
  - No. 1: Water Quality
  - No. 2: Guidelines to Risk Assessment
  - No. 3: Introduction to HACCP
  - No. 4: Waste Management
- Bord Bia Quality Manuals for:
  - Fruit
  - Potatoes
  - Protected Crops
  - Mushrooms
  - Field Vegetables
- Bord Bia Codes of Practice for crop production incorporating Integrated Crop Management for:
  - Mushrooms
  - Fruit
  - Protected Crops
  - Field Vegetables
  - Potatoes

Health and Safety Authority: (www.hsa.ie)

- The Safety, Health and Welfare at Work Act, 2005.
- Guide to the Safety, Health and Welfare at Work (General Application) Regulations 2007 Chapter 1 of Part 5: Control of Noise at Work

Other Websites:

Government Publications Website:

- Irish Statute Book website: www.irishstatutebook.ie
- Department of Agriculture, Fisheries and Food website: www.agriculture.gov.ie

European Legislation Website:

- Eur-Lex: http://eur-lex.europa.eu

Bord Bia Prepared Fruit and Vegetables Quality Assurance Scheme

Bord Bia
Irish Food Board

Bord Bia Horticultural Quality Assurance Scheme
Application Form – Prepared Fruit & Veg

BLOCK CAPITALS ONLY PLEASE

Company Name To appear on certificate if applicable	Reference: For office use only
Contact	Prepared Fruit and Vegetables
Position	Dept. Reg No. Optional

Address/es: List all facility addresses – indicate if these are separate operations – Use reverse of sheet if necessary

Facility 1	
Postal	
Postal	
Tel	
Fax	
Mobile	
Email	

Directions from Nearest Town		
I/We agree to allow right of access for the inspector to carry out inspections	Yes	No
I/We agree to allow my company name to be included in Bord Bia public website and relevant publications	Yes	No
If you are a new applicant please tick	Yes	No
I understand the requirements of the scheme and believe that the operation can achieve the standard required.	Yes	No
I have received a copy of the standard.	Yes	No

Please tick appropriately ✓

SIGNATURE:_____ DATE:_____

Application Fee Enclosed: Yes/No

Prepared Fruit & Veg €729 (600+ VAT)
Project Code: 5R0834

Note:

1. All details furnished are confidential to Bord Bia and .
2. Applications should be accompanied with a cheque for the appropriate application fee, made payable to **"Bord Bia".**
3. Return application forms plus application fee to this address: **Bord Bia, Clanwilliam Court, Lwr Mount Street, Dublin 2.**

Micro Criteria for Pre-Cut Fruit and Vegetables

Food safety criteria for i) *Salmonella* spp. in pre-cut fruit & vegetables (ready-to-eat) and ii) *L. monocytogenes* in ready-to-eat foods as specified in Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs

Organism	Food category	Sampling plan [1]		Limit [2]		Analytical reference method [3]	Stage where the criterion applies
		n	C	M	M		
***Salmonella* spp.**	Pre-cut fruit & vegetables (ready-to-eat)	5	0	Absence in 25g [4]		EN/ISO 6579	Products placed on the market and during their shelf life
Listeria monocytogenes	Ready-to-eat foods **able** to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	5	0	100 cfu/g [5]		EN/ISO 11290-2	Products placed on the market and during their shelf life
		5	0	Absence in 25g [4, 6]		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator who has produced it
	Ready-to-eat foods **unable** to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	5	0	100 cfu/g [5]		EN/ISO 11290-2	Products placed on the market and during their shelf life

1 n = number of units comprising the sample
c = number of sample units giving values over m or between m and M

2 When testing against food safety criteria provides unsatisfactory results, the product or batch of foodstuffs must be recalled or withdrawn from the market in accordance with Article 19 of Regulation 178/2002. However, products which are placed on the market but are not yet at retail level and which do not fulfill the food safety criteria, may be submitted to further processing to eliminate the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

3 The use of alternative analytical methods is acceptable when they have been validated against the analytical reference method. If a proprietary method is used, it must be certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols. If the food business operator wishes to use analytical methods other than those validated and certified as described, the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority.

4 Interpretation of results:
- satisfactory, if all of the values observed indicate the absence of the bacterium
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

5 Interpretation of results:
- satisfactory, if all of the values observed are $\leq$ the limit
- unsatisfactory, if any of the values are $>$ the limit.

6 This criterion applies to products before they have left the immediate control of the producing food business operator, when s/he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

Table 2: Process hygiene criterion for *E. coli* in Pre-cut fruit & vegetables (ready-to-eat) as specified in Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs

Food category	Organism	Sampling plan [1]		Limit [2]		Analytical reference method [3]	Stage where the criterion applies	Action in case of unsatisfactory results [4]
		n	c	m	M			
Pre-cut fruit & vegetables (ready-to-eat)	*E.coli*	5	2	100 cfu/g	1000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

[1] n = number of units comprising the sample
c = number of sample units giving values between m and M

[2] Interpretation of results:
- Satisfactory: if all the values observed are ≤ m
- Acceptable: if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m
- Unsatisfactory: if one or more of the values observed are >M or more than c/n values are between m and M.

[3] The use of alternative analytical methods is acceptable when they have been validated against the analytical reference method. If a proprietary method is used, it must be certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols. If the food business operator wishes to use analytical methods other than those validated and certified as described, the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority.

[4] Corrective actions defined in the food businesses HACCP based procedures and other actions necessary to protect the health of consumers should also be undertaken.