

## GUIDANCE NOTE

# Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 3)



# **Guidance Note No. 1**

## **Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 3)**

Published by:  
Food Safety Authority of Ireland  
The Exchange, George's Dock  
IFSC, Dublin 1  
D01 P2V6

Tel: +353 1 817 1300

Email: [info@fsai.ie](mailto:info@fsai.ie)

Website: [www.fsai.ie](http://www.fsai.ie)

© FSAI

2019

Applications for reproduction should be made to the FSAI Information Unit



ISBN 1-904465-33-1

# CONTENTS

<b>PART 1. GENERAL</b>	<b>1</b>
1.1 Introduction	1
1.2 Purpose	2
1.3 Structure of the Guidance	3
1.4 Scope	3
1.4.1 Inspection and audit	3
1.5 Review	3
1.6 Definitions	4
1.7 Related Documents	4
1.7.1 Guidance documents	4
1.8 Legislation	5
<b>PART 2. RISK CATEGORISATION OF FOOD BUSINESSES TO DETERMINE FREQUENCY OF INSPECTION</b>	<b>6</b>
2.1 Notification and Registration of Establishments	6
2.2 Official Controls	6
2.3 Determining Frequency of Inspection	7
2.3.1 Risk profiling of establishments to determine risk category	7
2.3.2 Risk categorisation	8
2.3.3 Frequency of Planned Inspection	8
2.3.4 Deviation from standard frequency of Planned Inspection	9
<b>PART 3. INSPECTION OF A FOOD BUSINESS</b>	<b>11</b>
3.1 Introduction	11
3.2 The Inspection Process	12
3.2.1 Determining the type and scope of inspection	13
3.2.2 Scheduling	16
3.2.3 Inspection preparation	17
3.2.4 Conduct of inspection	18
3.2.5 Inspection findings	19
3.2.6 Inspection outcome assessment	21
3.2.7 Action in the case of non-compliance	24
<b>PART 4. PRIORITISATION OF INSPECTION</b>	<b>26</b>
4.1 Introduction	26
4.2 Prioritising Inspections	26
4.3 Priority Action List	27
<b>APPENDIX 1. RISK PROFILING OF FOOD BUSINESSES</b>	<b>28</b>
<b>APPENDIX 2. PROCESS FLOW FOR THE INSPECTION OF FOOD BUSINESSES</b>	<b>30</b>
<b>APPENDIX 3. INSPECTION: ELEMENTS AND ASPECTS</b>	<b>31</b>

# PART I. GENERAL

## I.1 INTRODUCTION

All food business operators must comply with relevant food law and as a consequence, are subject to official control by officials to check compliance. Food law requires that these official controls are carried out regularly, on a risk basis and with appropriate frequency. Account must be taken of the identified risks, the food business operator's record of compliance, the reliability of the systems they have in place and any non-compliances.

Inspections are one of the methods of official control which may be used to check compliance. The aim of this guidance is to assist environmental health officers (EHOs) in the Health Service Executive (HSE) in the development of risk-based inspection programmes, the inspection process and decisions on appropriate action where necessary.

Inspections will focus on food businesses which pose the greatest potential risk by virtue of the business being carried on or when identified during official control activities. Where significant or serious risks are identified, these food businesses will be prioritised for action. Appropriate and timely action will be taken by the environmental health service (EHS) of the HSE to ensure the food business no longer poses an unacceptable risk to consumers. Where, following inspection, an EHO forms the opinion that a food business is not likely to pose a risk to public health, the frequency of inspection may be reduced.

This guidance will also be of interest to food business operators in understanding the approach taken to inspections of food businesses by the HSE. Food business operators are responsible for ensuring that the requirements of food law are met within their businesses, including identifying food hazards and controlling risks and only placing safe food on the market.

This guidance was prepared by the Food Safety Authority of Ireland (FSAI) and the EHS of the HSE. This guidance replaces earlier FSAI guidance, namely:

- *FSAI Guidance Note No. 1 for Health Boards on the Inspection of a Food Business (Revision 1)*
- *FSAI Code of Practice No. 1 for the Health Service Executive on the Risk categorisation of Food Businesses (Revision 1)*

## **I.2 PURPOSE**

The HSE and the FSAI are obliged to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency and verify that the relevant requirements of food law are fulfilled by food business operators at all stages of production, processing and distribution. This is achieved in part through their inspection programmes of food businesses.

The purpose of this guidance note is to support the development of the HSE inspection programmes by:

- Setting out the process for:
  - Risk categorisation of food businesses to determine the frequency of scheduled inspections
  - Inspection
  - Determining action in the case of non-compliance
  - Prioritisation of inspection
- Facilitating the EHS of the HSE in scheduling official food control inspections and prioritising inspections of food businesses by targeting:
  - Food businesses which pose the greatest potential risk to the population should a food safety control failure occur
  - Food businesses identified during official control activities as posing a significant or serious risk due to the increased likelihood of food safety failures
- Facilitating a consistent approach within the EHS of the HSE in prioritising and conducting inspections of food businesses aimed at verifying and/or securing compliance by food business operators with relevant food law and/or relevant accepted industry codes of practice/ guidance notes.

## **I.3 STRUCTURE OF THE GUIDANCE**

This guidance is set out in 4 parts:

### **Part 1. General**

**Part 2. Risk Categorisation of Food Businesses** outlines a methodology for risk assessment of food businesses based on the type of operation, the potential impact should a food safety failure occur, and categorisation of food businesses to determine a standard frequency of inspection

**Part 3. Inspection of a Food Business** outlines the inspection process, the identification of non-compliances, assessment of risk and appropriate enforcement action

**Part 4. Prioritisation of Inspection** outlines which inspections should be prioritised

This guidance places the highest priority on ensuring that identified non-compliances that pose significant or serious risks to the consumer are promptly controlled.

## **I.4 SCOPE**

This guidance is for EHOs of the HSE carrying out inspections of food businesses to verify compliance by the food business operator with relevant food law. It applies to the inspection of food businesses to which European Communities (Hygiene of Foodstuffs) Regulations, 2006 (S.I. No. 369 of 2006) as amended, applies. Food businesses supervised by the HSE to which European Communities (Food and Feed Hygiene) Regulations, 2009 as amended apply, are outside the scope of this guidance. It includes the inspection of catering/other food businesses operated by or on behalf of the HSE. Such food businesses must be treated in the same manner as all other food businesses.

### **I.4.1 Inspection and audit**

Inspections and audits (as defined in Regulation (EC) No 882/2004) or a combination thereof are undertaken as appropriate by EHOs in respect of each food business under their supervision. Inspection and audit are referred to as 'inspection' throughout the document for ease of reading.

## **I.5 REVIEW**

This guidance will be reviewed in 2012 in light of experience gained during implementation and the introduction of the food component of the environmental health information system which is being developed.

## **I.6 DEFINITIONS**

Words and phrases used in this guidance have the same meaning as defined in the following legislation:

- Regulation (EC) No 882/2004 on official controls performed to verify compliance with feed and food law, animal health and welfare rules
- Regulation (EC) No 178/2002 on the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs

## **I.7 RELATED DOCUMENTS**

The following list of guidance documents and legislation are of particular relevance to this guidance note:

### **I.7.1 Guidance documents**

#### **FOOD SAFETY AUTHORITY OF IRELAND**

- *Guidance Note No.11 Assessment of HACCP Compliance (Revision 2)*
- *Guidance Note No.12 The Inspection of Food Safety Training and Competence, for staff in an operative role (2003)*
- *Guidance Note No.13 Use of Enforcement Powers under the Food Safety Authority of Ireland Act, 1998*
- *Guidance on the Interpretation of S.I. No. 117 of 2010*
- *Guidance on the Interpretation of S.I. No. 344 of 2011*
- Other subject matter specific FSAI guidance notes and codes of practice

FSAI guidance notes and codes of practice are available at:

[http://www.fsai.ie/resources\\_publications.html](http://www.fsai.ie/resources_publications.html)



## **EUROPEAN COMMISSION**

- *Guidance Document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses*
- *Guidance Document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs*
- *Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002*

European Commission guidance is available at:

[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide\\_en.htm](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm)

## **NATIONAL STANDARDS AUTHORITY OF IRELAND**

- *I.S. 340: 2007: Hygiene in the Catering Sector*
- *I.S. 341: 2007: Hygiene in Food Retailing/Wholesaling*
- *I.S. 432: 2010: Packaged Ground Water*

## **INTERNATIONAL STANDARDS ORGANISATION**

- *ISO 22000:2005: Food Safety Management Systems*

## **I.8 LEGISLATION**

A full and up-to-date list of relevant food legislation to be enforced by the HSE is set out in Schedule I of the HSE service contract. The schedule is updated as new legislation is included under the HSE remit.

The latest version of the HSE service contract is available at:

[http://www.fsai.ie/about\\_us/service\\_contracts/health\\_service\\_executive.html](http://www.fsai.ie/about_us/service_contracts/health_service_executive.html)

The food legislation section on the FSAI website provides a reference and guide to the various Acts, Regulations and Orders made at national level as well as those Directives and Regulations made at EU level. This is available at:

[http://www.fsai.ie/legislation/food\\_legislation.html](http://www.fsai.ie/legislation/food_legislation.html)

The European Commission provides access to all European law through EUR LEX. This is available at: <http://eur-lex.europa.eu/en/index.htm>

## **PART 2. RISK CATEGORISATION OF FOOD BUSINESSES TO DETERMINE FREQUENCY OF INSPECTION**

### **2.1 NOTIFICATION AND REGISTRATION OF ESTABLISHMENTS**

Every food business operator supervised by the HSE is required under Regulation (EC) No 852/2004 and S.I. No. 369 of 2006, to notify the HSE of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each establishment. An establishment is a unit of a food business. The HSE maintains a register of these establishments. This register facilitates the organisation of the official control inspection programme by the HSE.

While the majority of food businesses operate out of one establishment, some food businesses have multiple establishments under their control. Other food businesses do not have associated establishments, e.g. brokers, importers, distributors, distance selling. Nevertheless, all of these food businesses are required to notify the HSE.

### **2.2 OFFICIAL CONTROLS**

Regulation (EC) No 882/2004 [on Official Controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules] sets out general obligations regarding the organisation of official controls.

Article 3 states:

*1. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:*

- (a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;*
- (b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;*
- (c) the reliability of any own checks that have already been carried out;*  
*and*
- (d) any information that might indicate non-compliance.*

## **2.3 DETERMINING FREQUENCY OF INSPECTION**

To determine the frequency of inspection for a particular food business, the following steps should be completed:

- Conduct a risk profile of each establishment
- Assign a risk category from 1-6 based on the risk profile
- Assign a standard frequency of inspection based on the risk category
- Consider if a deviation from the standard frequency of inspection is warranted

### **2.3.1 Risk profiling of establishments to determine risk category**

The risk profile is based on the nature and extent of the food business taking account of the following:

- Type of food handled/processed/manufactured
- Method of handling/processing/manufacturing
- Scale of the operation
- At risk consumers

EHOs must risk profile each establishment. Where a food business comprises of more than one establishment, each establishment must be risk profiled. This should be done on a once-off basis and again only if the nature and extent of the business changes. The criteria to be applied are set out in the template in Appendix I.

Some food businesses, by virtue of the business being carried on, do not require to be risk profiled. Such businesses comprise:

- Pharmacies (selling food supplements and foods for particular nutritional uses only)
- Internet sales with no associated establishment
- Food distributors, agents, brokers or importers with no associated establishment
- 'Network sales' operations, e.g. door-to-door sales with no associated establishment
- Non-food retail businesses selling incidental or seasonal low-risk ambient foods (novelty products etc)
- Cookery demonstrations (commercial) in third party venues, e.g. private homes for family and friends or hotels
- Cookery schools (commercial)
- Head offices of multiples where remote from its establishments
- Other food business types identified and agreed between the HSE and the FSAI

The nature and extent of every food business should be reviewed following each inspection.

### 2.3.2 Risk categorisation

Risk categories range from 1 - 6 in descending order of risk. In general, each establishment will be assigned to a risk category from 1 - 6 based upon its risk profile. The food businesses or establishments outlined in Section 2.3.1 which do not require being risk profiled, should be placed in Category 6.

### 2.3.3 Frequency of Planned Inspection

The standard frequency of Planned Inspections is based on the risk category into which a particular food business or establishment falls. Notwithstanding this, where a possible risk to public health is identified, this will be prioritised over scheduled inspections. See Part 4.

Table 1 sets out the standard and minimum frequency of inspection for each risk category. In any event, the HSE should ensure that all food businesses are inspected no less than at the minimum frequency set out in Table 1.

**Table 1. Frequency of Planned Inspection**

Risk Profile Range	Risk Category	Standard Frequency of Inspection	Minimum Frequency of Inspection
≥65	1	2 Planned Inspections/year	2 Planned Inspections/year
≥45 to <65	2	1 Planned Inspection & 1 Planned Surveillance Inspection/year	1 Planned Inspection/year
>30 to <45	3	1 Planned Inspection & 1 Planned Surveillance Inspection/18 months	1 Planned Inspection/18 months
>15 to ≤30	4	1 Planned Inspection/18 months	1 Planned Inspection/2 years
0 to ≤15	5	1 Planned Inspection/2 years	1 Planned Inspection/3 years except where other targeted programme takes place
N/A	6	*Inspections to be scheduled as required	*Inspections to be scheduled as required

\* Initial inspection to verify details of notification and extent of activity, then inspected only as deemed necessary (notified changes to business, complaints, food incidents/alerts, targeted inspections of the business type etc)

Some activities only operate seasonally. In considering the timing of inspection of such food businesses, the HSE should ensure that as far as possible, the scheduling coincides with the period of operation.

### **2.3.4 Deviation from standard frequency of Planned Inspection**

The frequency of Planned Inspection may be reduced or increased to take account of the requirements of Article 3 (b), (c) and (d) of Regulation (EC) No 882/2004 once an inspection history is established. Following inspection, the appropriate frequency of inspection for each food business or establishment must be determined, taking account of the following:

- Comprehensiveness of the prerequisite programme
- Past history of compliance (including history of foodborne illness, complaints etc.)
- Confidence in the food safety management system: Reliability of food businesses own checks based on HACCP principles
- Information that might indicate non-compliance
- Seasonality

The risk category assigned to each individual food business or establishment will remain constant (unless the nature and extent changes) even though the frequency of inspection may be altered.

#### **REDUCED FREQUENCY OF PLANNED INSPECTION**

Where following inspection, the EHO determines that the food business is not likely to pose a risk to public health, the frequency of Planned Inspection may be reduced to the minimum frequency of inspection for the assigned risk category. To determine that, the following criteria must be considered:

1. Prerequisites – Satisfactory or minor non-compliances only in accordance with Part 3
2. Past record of compliance – Inspection outcome is Grade 1: Satisfactory or Grade 2: Minor non-compliance only in accordance with Part 3 following the last two inspections.
3. Procedures based on HACCP principles – Compliance with legal requirements
4. Supervision/Training – Compliance with legal requirements
5. Other information – Complaints, food alerts, non-complaint samples

In determining compliance with points 3 and 4, the FSAI's Guidance Notes Nos 11 and 12 provide useful references.

Where the standard frequency of Planned Inspection is to be reduced, the principal environmental health officer (PEHO)/designate must be informed and the reason and date of decision recorded.

### **INCREASED FREQUENCY OF PLANNED INSPECTION**

Where following inspection, non-compliances are identified, the frequency of inspection should be reviewed and may be increased. Where there is an identified increased risk due to the nature of the activity which is in addition to that provided for in Appendix I, the frequency of inspection should be increased to reflect this.

Where the standard inspection frequency is to be increased, the PEHO/designate must be informed and the reason and date of decision recorded.

## PART 3. INSPECTION OF A FOOD BUSINESS

### 3.1 INTRODUCTION

This part provides guidance on the process for inspecting food businesses to verify compliance with relevant food law.

The key objective of the inspection process is to verify that the relevant requirements of food law are fulfilled by food business operators at all stages of production, processing and distribution. To this end, the EHO is required to undertake inspections of food businesses under his/her supervision to:

- Determine the scope of the business activity and the relevant legislative controls that will apply to it
- Assess the hazards and associated risks to public health the business poses
- Assess the effectiveness of process controls in place to ensure safe food and the implementation of a food safety system based on the principles of HACCP
- Identify the contraventions of and compliance with the applicable food law
- Consider appropriate enforcement action proportionate to risk, to secure compliance with the legal requirements to ensure consumer protection
- Promote good practice through the application of relevant guidance notes, industry codes of practice and national standards

Other relevant guidance notes issued by the FSAI including *Guidance Note No. 11 Assessment of HACCP Compliance (Revision 2)* and *Guidance Note No. 12 Inspection of Food Safety Training and Competence* should be taken into account when carrying out food safety inspections.

Depending on the scope of the inspection, other specific FSAI guidance notes or Irish standards may need to be considered, e.g. recall and traceability, beef labelling, food supplements, food stalls, food contact materials, cook-chill and labelling.

## 3.2 THE INSPECTION PROCESS

Inspections are aimed at: assessing compliance with all relevant food law pertaining to each food business, identifying non-compliance(s), taking enforcement action commensurate with the risk identified and prioritising further official controls to ensure identified risks are appropriately addressed.

The inspection process consists of:

- Determining the type and scope of inspection
- Scheduling
- Inspection preparation
- Conduct of inspection
- Inspection findings, outcome assessment and determination of action
- Record keeping

Food business records should be held for each food business supervised by the HSE, containing details of:

- Registration or approval (if required) of each establishment
- Previous inspections - visit record, controls carried out, records or readings taken, particularly where they are unsatisfactory, sample results, non-compliances against each control carried out, if any
- Risk profile assessment (if required) and risk categorisation
- Any enforcement/legal actions taken
- All correspondence and other relevant documents

Key business details, summary inspection history and any other relevant information should be readily available to the EHO. These should be updated as necessary.

When an inspection is completed, all relevant information should be updated on the food business record held electronically or in hard copy.

Contemporaneous notes taken during inspection or interviews must be appropriately managed.

The EHS of the HSE must produce a record/report of the inspection it has carried out. It must include a description of the purpose of the inspection, the control methods applied, the results of the inspection and where appropriate, action that the food business operator concerned is to take.



## **PRECAUTIONS BY INSPECTING EHOS**

Care should be taken by the inspecting EHO not to be a source of contamination of any establishment. Any reasonable food safety precautions required by the food business operator of inspectors or visitors should be respected. Where a food business requires visitors to wear specific protective clothing provided, it should be worn by the EHO where it is at least equivalent to that provided by the officer.

### **3.2.1 Determining the type and scope of inspection**

When considering the type and scope of an inspection, the EHO will:

- Review the information held on record about the business, including the history of compliance
- Familiarise himself/herself with the full extent of the business (including specific processes)
- Review the assessed food safety risk the business presents and prepare themselves accordingly with appropriate records, authorisation and equipment to carry out the inspection

## **INSPECTION ELEMENTS**

An inspection can be considered as having various elements, which include the examination of:

- A** Hygiene Prerequisite Programme (structural)
- B** Hygiene Prerequisite Programme (operational)
- C** Procedures based on HACCP principles
- D** Management systems
- E** Relevant food legislation other than food hygiene legislation

These elements are sub-divided into specific aspects. Details of the elements and aspects of A - E are set out in Appendix 3.

The scope of the inspection is based on the food law which applies to the business. The choice of control methods is based on the matter to be examined or verified.

## **INSPECTION TYPE**

There are 5 types of inspection:

- I. Planned
  - a. Inspection
  - b. Surveillance inspection
2. Enforcement
3. Complaints/Food incidents/Food alerts
4. Food legislation other than food hygiene
5. Visits

### **I. Planned inspection**

There are 2 types of Planned Inspection:

#### **(a) Planned inspection**

A Planned Inspection is conducted having regard to each of the aspects in the 4 elements of the food safety management system (A - D) and relevant food law (other than general food hygiene) applicable to the individual food business (E). Inspection types 2 - 4 may also be considered as a Planned Inspection where they meet the criteria.

#### **(b) Planned surveillance inspection**

A Planned Surveillance Inspection is conducted primarily to check at least 1 aspect of each of the 4 elements of the food safety management system (A - D) and relevant food law (other than general food hygiene) applicable to the individual food business (E). Inspection types 2 - 4 may also be considered as a Planned Surveillance Inspection where they meet the criteria.

Where 1 or more of the aspects of the 4 elements A - D above are deemed to be compliant, the following Planned Surveillance Inspection(s) should be focused on aspect(s) other than those deemed to be compliant during previous inspections.

Planned inspections/Planned surveillance inspections can be conducted as part of a risk-based targeted and documented inspection programme subject to the criteria above being met.

## **2. Enforcement inspection**

An Enforcement Inspection is conducted to ensure that identified significant or serious non-compliances are remedied.

This inspection focuses on key areas where significant or serious non-compliances were observed. While it may be as comprehensive as a Planned Inspection/Planned Surveillance Inspection, it may not necessarily meet the criteria for such inspections. If possible, an Enforcement Inspection should be incorporated into a Planned Inspection or a Planned Surveillance Inspection.

The scheduling of an Enforcement Inspection should be determined by the nature of the risk posed to the consumer.

An Enforcement Inspection may include, but is not limited to an inspection of a food business flagged in the Priority Action List (See Part 4).

## **3. Complaint, food incident or food alert inspection**

A complaint, food incident or food alert inspection is conducted specifically to investigate a complaint, a food incident or a food alert. If possible, this type of inspection should be incorporated into a Planned Inspection or a Planned Surveillance Inspection.

## **4. Food legislation other than food hygiene inspection**

A food legislation other than food hygiene inspection is conducted to verify compliance with legislation other than general food hygiene. It is targeted primarily at food businesses that manufacture or import food. The nature and extent of the activity, the complexity and range of legislation that is applicable and the impact of non-compliance, need to be considered when determining if a separate inspection is warranted or if verification of compliance can be incorporated into a Planned Inspection or a Planned Surveillance Inspection.

## 5. Visit

A visit may take place which does not fall into the above inspection types. It includes:

- Visit of an advisory nature
- Follow-up visit. The inspection will generally focus on acquiring additional information to confirm the inspection outcome or assessing the effectiveness of food business operator action to address previously identified non-compliance outlined in the Environmental Health Service report.

**Note:** Sampling for the purposes of official control to verify compliance with food law should be incorporated into the inspection process where practicable. A visit solely for sampling purposes does not constitute an inspection.

### 3.2.2 Scheduling

Planned inspections are scheduled based on the risk category and frequency of inspection of food businesses as set out in Part 2. All other inspections (2-5) are reactive and will be prioritised based on risk (See Part 4).

Scheduling inspections forms an integral part of official controls. This must afford suitable priority in particular to:

- Investigation of:
  - Food/waterborne outbreak
  - Food alert/follow-up to a RASFF notification
  - A complaint or a food incident
- The Priority Action List (See 4.3)
- Risk Category 1 or 2 food business not inspected in the previous 12 months

These must receive priority ahead of Planned Inspections. Priority is dependent on the outcome of the inspection and/or the risk posed to the consumer (See Part 4).

Food businesses should normally be inspected according to a schedule. The schedule should have regard to the targets and terms set in the service contract with the FSAI and the provisions of Part 2 of this guidance or any agreed priorities with the FSAI.

### **3.2.3 Inspection preparation**

When preparing for an inspection, EHOs should use the information contained on the relevant elements and aspects of the inspection in Appendix 3.

The business record and associated file must be reviewed by the EHO prior to undertaking the inspection. It is important to assess the history of compliance, the nature and extent of non-compliances and not just focus on the outcome of the last inspection.

All necessary equipment which may be required to assist the inspection shall be considered and made available for the inspection.

In certain cases, it may be advisable to have 2 EHOs carry out the inspection, e.g. due to the nature, extent or complexity of the food business, outbreak investigation, out of hours inspections or history of obstruction or non-cooperation.

#### **INSPECTION TIMING**

In general, inspections should be undertaken while the business is in operation. In exceptional circumstances, e.g. where there is a closure order, inspections may need to take place when the business is not in operation.

#### **UNANNOUNCED INSPECTIONS**

In general, inspections must be carried out without prior warning. Exceptions would include appointments to meet with the food business operator to discuss the outcome of inspection, to provide advice, to assess a registration/approval application and audits where prior notification of the food business may be required. For large, complex or manufacturing businesses, it may be necessary to advise businesses of an intended visit to ensure that appropriate personnel (management, quality control) are available to discuss matters arising during the course of the inspection.

### 3.2.4 Conduct of Inspection

An inspection should be conducted and may include the following:

- a) **Preliminary discussion** with the food business operator/person in charge on the purpose, nature and extent of the inspection
- b) **Confirmation of the details** held on record about the business including registration/ approval details
- c) **An assessment of the nature and extent** of the business including the type of food business/food product, customer profile and distribution of the product
- d) **Examination and assessment of procedures based on HACCP** in place
- e) **Observation** of the work practices being carried out
- f) **Assessment of the hazards and risks** posed by the business and the food business operators' understanding of them
- g) **Assessment of the training**, supervision and instruction of staff
- h) **Examination and assessment of documentary systems** in use for food safety management including supplier control
- i) **Discussion with staff** responsible for monitoring controls and initiating corrective actions to assist in assessing the effectiveness of control measures in place
- j) **Physical examination** of the establishment, equipment, installations, machinery and records of measurements and checks carried out, as well as the food in the establishment
- k) **Taking of samples and carrying out other verification checks such as temperature measurements**
- l) **Closing discussion** outlining any identified control failures, statutory non-compliances, corrective actions and recommendations on good practice. Recommendations on good practice should be clearly distinguished as such. An indication of the inspection outcome, resulting action and time scale for the required corrective actions may be given.

The overall conduct of the inspection should be carried out to assess compliance with the relevant food legislation. Depending on the extent and purpose of the inspection, it will not always be necessary to cover every point as listed, e.g. samples will not always be taken, but all inspections should be conducted along similar lines

### 3.2.5 Inspection findings

When the inspection is complete, the findings must be recorded. Any non-compliance observed (elements and aspects A – E) must be identified and recorded by type and sub-type as follows:

#### **NON-COMPLIANCE – FOOD HYGIENE**

Non-compliances with food hygiene legislation requirements include the following:

- General hygiene
- Microbiological contamination
- Other contamination
- Composition
- Labelling/presentation (general)
- Hygiene training
- Risk assessment/HACCP
- Notification/approval
- Traceability

#### **NON-COMPLIANCE - FOOD LEGISLATION OTHER THAN FOOD HYGIENE**

Non-compliances with food legislation other than food hygiene requirements include the following:

- Labelling (specific)
- Import control of product of non-animal origin subject to increased controls
- Contaminants
- Specified risk material
- Packaged water
- Materials in contact with foodstuffs
- Nutrition and health claims
- Food supplements
- Foods for particular nutritional uses
- Marketing standards
- Food additives
- Foodstuffs treated with ionising radiation
- Novel foods and genetically modified foods
- Food fortification

## **CLASSIFICATION OF NON-COMPLIANCES**

All non-compliance must be assessed based on the risk posed and classified accordingly. In general, non-compliances can be divided into the following 3 classes:

- 1. Class I:** Non-compliance (s) where the risk to food safety is of low magnitude and can be rectified and contained easily
- 2. Class II:** Non-compliance(s) which may or is likely to pose a significant risk but is not a grave and immediate danger to public health
- 3. Class III:** Non-compliance(s) where there may be a grave and immediate danger to public health

However, non-compliance with certain aspects of food legislation, while not posing a risk to food safety, should nonetheless be considered as significant or serious, e.g. having no traceability system. These must be considered on a case-by-case basis.



### 3.2.6 Inspection outcome assessment

There are 5 inspection outcomes:

1. Grade 1: Satisfactory
2. Grade 2: Minor non-compliance
3. Grade 3: Unsatisfactory
4. Grade 4: Unsatisfactory Significant
5. Grade 5: Unsatisfactory Serious

The EHO must determine the overall inspection outcome having regard to a) the classes of non-compliance observed and b) taking the following factors into consideration:

- The history of the food business in complying with food legislation
- The recent inspection report(s)
- The risk profile of the establishment
- The confidence in the management's ability to manage food safety
- The culture of food safety within the food business
- Any other relevant information

In general and taking the above factors into account, if all non-compliances are Class I, the inspection outcome can be Grade 1, Grade 2 or Grade 3. If one or more of the non-compliances is Class II, then the inspection outcome should be at least Grade 4 and where one or more of the non-compliances is Class III, then the inspection outcome should be Grade 5. See Table 2. However, where there are successive inspection outcomes other than Grade 1: Satisfactory, consideration should be given to escalating the inspection outcome to the next level:

- Grade 2: Minor Non-Compliance Inspection Outcome to Grade 3: Unsatisfactory
- Grade 3: Unsatisfactory to Grade 4: Unsatisfactory Significant
- Grade 4: Unsatisfactory Significant to Grade 5: Unsatisfactory Serious

The decision as to whether to escalate the inspection outcome as outlined above should be determined on a case-by-case basis in consultation with the PEHO/designate.

#### **OBSTRUCTION OF AN AUTHORISED OFFICER**

Willful obstruction of an authorised officer in the course of his/her duties should always be regarded as at least equivalent to a Grade 4: Unsatisfactory Significant Inspection Outcome.

**Table 2. Assessment of Inspection to Determine Outcome and Action**

Assessment	Outcome	Action
No non-compliances have been noted or non-compliances do not impact on food safety	Grade 1: Satisfactory	Verbal or written report (no non-compliances observed) Written report (non-compliances observed) Inspection frequency may be reduced
Non-compliances have been noted - the risk to food safety is of low magnitude	Grade 2: Minor non-compliance	A written report must be sent to the food business operator Written report requiring action
Non-compliances are not significant or serious  <b>or</b>  Where 2 or more consecutive inspections result in Grade 2: Minor non-compliance outcomes and it has been determined that it merits escalation	Grade 3: Unsatisfactory	A written report must be sent to the food business operator identifying the defects and requiring action  Legal action may be considered

Assessment	Outcome	Action
<p>Non-compliances noted and risk to food safety assessed as significant</p> <p><b>or</b></p> <p>Where 2 or more consecutive inspections result in Grade 3: Unsatisfactory outcomes and it has been determined that it merits escalation</p>	<p>Grade 4: Unsatisfactory Significant</p>	<p>As a minimum:</p> <ol style="list-style-type: none"> <li>1. Written report requiring action, e.g. report indicating defect; action required and time frames for compliance and warning that enforcement action may be taken in the event of non-compliance not being remedied within the timeframe set</li> <li>2. EHO to schedule an inspection type and timing as appropriate relative to the associated risk</li> <li>3. Food business added to Priority Action List where there has been two or more consecutive Grade 4: Unsatisfactory significant outcomes</li> </ol> <p>One or more of the following actions should be taken as appropriate having regard to the associated risk:</p> <ul style="list-style-type: none"> <li>• Immediate corrective action by the food business operator (reported in writing to the food business operator)</li> <li>• Improvement Notice/Order</li> <li>• Closure Order [S.I. No. 117 of 2010 only]</li> <li>• Prohibition Order [S.I. No. 117 of 2010 only]</li> <li>• Legal action</li> <li>• Product withdrawal or recall</li> <li>• Seizure, removal and detention of product(s)</li> <li>• Destruction of product(s)</li> <li>• Re-export of non-compliant product(s)</li> </ul>
<p>Non-compliances noted and risk to food safety assessed as likely to pose a grave and immediate danger to public health</p>	<p>Grade 5: Unsatisfactory Serious</p>	<p>EHO must consult with PEHO/designate and agree appropriate action dependent on the nature of the risk posed. Food business must be added to Priority Action List</p> <p>Appropriate action must include at least one of the following:</p> <ul style="list-style-type: none"> <li>• Immediate corrective action (reported in writing to the food business operator)</li> <li>• Legal action</li> <li>• Closure Order [FSAI Act 1998 where there is a grave and immediate danger]</li> <li>• Prohibition Order [FSAI Act 1998 where there is a grave and immediate danger]</li> <li>• Product withdrawal or recall</li> <li>• Seizure, removal and detention of product(s)</li> <li>• Destruction of product(s)</li> <li>• Re-export of non-compliant product(s)</li> </ul>

### **3.2.7 Action in the case of non-compliance**

#### **REPORT TO THE FOOD BUSINESS OPERATOR**

The HSE must provide the food business operator with a copy of the report it has prepared following the inspection at least in the case of non-compliance.

#### **ACTION**

Where non-compliances are identified, the HSE must take appropriate action to ensure that the food business operator remedies the situation. Action must be based on the inspection outcome (See Table 2).

Account must be taken of the legal requirements, the nature of the non-compliance, nature of the risk, confidence in management and the history of compliance of the business. Regulation (EC) No 882/2004 as transposed by European Communities (Official Control of Foodstuffs) Regulations, 2010 [S.I. No. 117 of 2010] sets out specific requirements for action in the case of non-compliance. See the FSAI's guidance on the interpretation of S.I. No. 117 of 2010.

Inspection outcomes where the non-compliances noted do not impact on food safety or the risk to food safety is of a low magnitude should be followed up at the next Planned Inspection or Planned Surveillance Inspection.

Inspection outcomes where the non-compliances noted impact on food safety and where the risk is significant (two consecutive inspections) or serious, must be prioritised for action and placed on the Priority Action List. See 4.3.

Enforcement inspections must be carried out where the inspection outcome is Grade 4: Unsatisfactory Significant or Grade 5: Unsatisfactory Serious and appropriate action taken in accordance with Table 2. Where enforcement action is taken the food business must be placed on the Priority Action List. See 4.3.

Each PEHO must ensure that there is a Priority Action List in place for his/her area and food businesses must be placed on the Priority Action List in accordance with 4.3.

A food business operator may choose to take voluntarily action (such as closure or product withdrawal/recall). However, appropriate enforcement action, determined on the basis of risk, must be taken by the EHO, regardless of the voluntary actions. Follow-up action by the EHO regarding non-compliances must be recorded.

In the event of non-compliance with food legislation leading to official controls exceeding the normal control activities, the HSE must charge for the expenses arising from the additional controls in accordance with Article 28 of Regulation (EC) No 882/2004 as transposed by European Communities (Official Control of Foodstuffs) (Amendment) Regulations, 2011 [S.I. No. 344 of 2011]. See FSAI guidance on the interpretation of S.I. No. 344 of 2011.

If, in exceptional circumstances, none of the actions set out above is appropriate, an alternative action plan must be agreed and noted on the business file.

### **IMMEDIATE CORRECTIVE ACTION**

At the time of inspection, there may be non-compliances noted which will require immediate corrective action. The action taken will need to be determined according to the circumstances but may include controlling the temperature of food, disposal of food, cleaning or if the non-compliance is serious and cannot be immediately corrected, closure of the establishment.

Any immediate corrective action taken to bring the food business into compliance should be recorded on the business file. Any such action must be communicated in writing to the food business operator. Refer to FSAI Guidance Note No. 13 and guidance on the interpretation of S.I. 117 of 2010.

## **PART 4. PRIORITISATION OF INSPECTION**

### **4.1 INTRODUCTION**

Inspections of food businesses where non-compliances identified are or are likely to pose a risk to public health must receive priority over scheduled inspections. The level of priority will be determined by the severity and the likelihood of the risk occurring.

### **4.2 PRIORITISING INSPECTIONS**

1. Priority must be given to each of the following:
  - Food/waterborne outbreak directly related to the establishment
  - Food alerts: Category 1 and follow-up to RASFF notifications where there is a serious risk to consumers
  - Food complaints about the establishment or the food, information from third parties where there is serious risk to consumers
  - Food businesses where enforcement action is current or may be required following inspection, i.e. Improvement Notice; Improvement Order; Prohibition Order; Closure Order or Legal Action pending
  - Insufficient confidence in management and /or the food safety management systems to ensure food safety
  - Where the inspection outcome is Grade 5: Unsatisfactory Serious or where there have been 2 or more consecutive Grade 4: Unsatisfactory Significant inspection outcomes
  - In the case of obstruction
2. A risk analysis must be carried out to determine the priority to be given to the following:
  - Food/waterborne illness - general investigation
  - Food businesses in Risk Categories 1 or 2 which have not been inspected in over 12 months
  - Food alerts: Category 2
  - Outdoor events (large scale) which are time critical
  - Unsafe food laboratory report (pathogen indicator/chemical/physical/allergen)
  - New food business
  - Agreed priorities including targeted programmes, surveys and ad hoc issues arising, e.g. head shops

### **4.3 PRIORITY ACTION LIST**

The following food businesses must be placed on the Priority Action List:

- Where enforcement action is current or may be required following inspection, i.e. Improvement Notice, Improvement Order, Prohibition Order, Closure Order or legal action pending
- Where confidence in management and/or the food safety management systems is insufficient to ensure food safety
- Where the inspection outcome is Grade 5: Unsatisfactory Serious or where there have been 2 or more consecutive Grade 4: Unsatisfactory Significant inspection outcomes
- In the case of obstruction

If an EHO is concerned about a particular food business but it does not meet the above criteria, the EHO has the discretion to add the food business to the Priority Action List.

Food businesses on the Priority Action List must be prioritised for action until there is no longer an unacceptable risk to consumers.

When a food business no longer poses an unacceptable risk to consumers, i.e. the inspection outcome is no higher than Grade 3: Unsatisfactory, it should be returned to normal scheduling in accordance with Part 2 and inspections carried out in accordance with Part 3.

There must be regular review of the food businesses on the Priority Action List by the team leader/PEHO/designate. An update must be put on the business file for each food business on the Priority Action List following review.

## APPENDIX I. RISK PROFILING OF FOOD BUSINESSES (MAY 2016)

Name:

Local Area Ref:

Date of Assessment:

Type of food handled/processed/manufactured <sup>1,2</sup>	Points – choose one only
High-risk (ready-to-eat and can support the growth of pathogens; potential for hazard to increase along the food chain, e.g. pathogens, mycotoxins)	10
Medium-risk (support the growth of pathogens but requires heat treatment or other processing effective to eliminate or reduce pathogens to an acceptable level)	5
Low-risk (does not support the growth of pathogens; ambient product; food additives; food supplements)	0

<sup>1</sup> Where there is a range of foods, base determination on foods that pose greatest risk

<sup>2</sup> The risk to be applied relates to the product as offered to the customer being supplied from the establishment, e.g. risk is based on final products produced rather than the ingredients used

Method of handling/processing/manufacturing*	Points – choose one only
Storage/distribution/sale of pre-packaged food only – ambient	0
Storage/distribution/sale of pre-packaged food only – maintenance of the cold chain required	5
Limited handling/preparation at point of sale to final consumer, e.g. loose food; slicing/ portioning pre-prepared cooked meats; soft whip ice-cream production; unwrapping and serving of pre-prepared sandwiches; reheating pre-prepared products such as meat pies; service of beverages, fruit and vegetables or storage/distribution and maintenance of the hot chain	10
**Substantial handling/processing of low-risk food, e.g. bakery, crisp/snack manufacture; <b>or any</b> foods that are not ready-to-eat, e.g. raw butcher, fishmonger, filling/packing of exposed food supplements or food additives	15
**Substantial handling/processing of medium/high-risk foods that are ready-to-eat, e.g. sandwich bars; retail preparation and sale of hot food	20
**Substantial handling/processing of medium/high-risk foods that are ready-to-eat – extensive menu; gourmet; complex preparation	25
Specialised method of processing applied to reduce/eliminate pathogens: e.g. cook-chill (commercial); thermal processing; commercial vacuum packing; commercial blast –chilling; modified atmosphere packaging; sous-vide; certain food supplement manufacturing where there may be a microbiological risk	30
Specialised method of processing applied to reduce / eliminate chemical risk e.g. food supplement manufacture (including mixing, compounding, formulation or blending) ; food additives manufacture	

\* Where more than one type of activity is carried out, base determination on highest risk activity

\*\* Involving one or more of the following: heat treatment; chilling; reheating; temperature controlled distribution



Scale of the Operation	Points Allocate points to each
<b>*Consumer profile:</b>	
Small	0
Medium	5
Large	10
<b>Distribution:</b>	
Local/direct consumption	0
Regional – national/international	5
<b>Stage in supply chain:</b>	
Food business not supplying other food businesses	0
Food business supplying other food businesses including marginal, localised and restricted	10

\* In terms of defining a food business as 'small, medium or large'

- Service sector e.g. take-away, pub, restaurant, hotel with no function catering – base on number of covers on busiest day i.e. small is  $\leq 100$  covers, medium is  $>100$  to  $\leq 300$  covers and large is  $>300$  covers. A hotel with function catering should be considered as at least medium. If it is a very large hotel with function catering it should be considered as large.
- Retail – a corner shop/independent retailer should generally be considered small, the neighbourhood retail chains should be considered medium and the main supermarkets in rural areas, towns and cities should be considered as large
- Manufacturer and wholesaler or distributor – linked to distribution. If the distribution is 'local/direct consumption' then assume the consumer profile is small, i.e. total is 0. If the distribution is regional/national/international, assume the consumer profile is large, i.e. total is 15.

At risk consumers	Points
<ul style="list-style-type: none"> <li>• Main consumer group is vulnerable</li> <li>• Manufacture of PARNUTS; products specifically targeted as being suitable for allergen sufferers</li> <li>• Direct supply of food to vulnerable groups, e.g. hospitals, nursing homes, day care centres</li> </ul>	20
Crèche serving full meals (prepared on site)	10

Assignment of points to categories:

Category 1:  $\geq 65$

Total:

Category 2:  $\geq 45$  to  $> 65$

Category 3:  $> 30$  to  $< 45$

Risk Category:

Category 4:  $> 15$  to  $\leq 30$

Category 5: 0 to  $\leq 15$

Category 6: Not profiled (see page 10)

## **APPENDIX 2. PROCESS FLOW FOR THE INSPECTION OF FOOD BUSINESSES**

### **1. Risk Categorisation of Food Businesses to Determine Frequency of Inspection**

- a. Risk profile establishments
- b. Assign a risk category based on risk profile
- c. Assign a standard frequency of inspection based on risk category
- d. Consider if a deviation from standard inspection frequency is warranted

### **2. Inspection of a Food Business**

- a. Determine type and scope of inspection
- b. Inspection process
  - i. Schedule the inspection
  - ii. Prepare for the inspection
  - iii. Conduct the inspection
  - iv. Identify any non-compliances
  - v. Classify non-compliances
  - vi. Assess the non-compliances
  - vii. Determine the inspection outcome
  - viii. Determine the action in the case of non-compliance
  - ix. Update food business record
  - x. Report to the food business operator

### **3. Prioritisation of Inspection**

- a. Determine priority – severity and likelihood of risk occurring
- b. Place food businesses on the Priority Action List if necessary
- c. Take action as appropriate to remove unacceptable risk

## **APPENDIX 3. INSPECTION: ELEMENTS AND ASPECTS**

This appendix provides guidance on the aspects to be considered under each of the four elements of food safety management systems (A-D). When determining the scope of each inspection, i.e. what elements/aspects of A-D to be included, the EHO should take account of the implementation of the hygiene requirements and the application of procedures based on HACCP principles (Articles 4 and Annex II and Article 5 of Regulation (EC) No 852/2004)

The following is based on Food Safety Management Systems – Requirements for any organisation in the food chain (I.S. EN ISO 22000:2005), DG SANCO guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs and Commission Notice 2016/C 278/01 on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation / flexibility of the implementation in certain food businesses.

### **A. PREREQUISITE PROGRAMME – STRUCTURAL**

#### **Aspects of Inspection:**

- Infrastructure - building, zoning etc.
- Plant and equipment
- Temperature control of storage environment
- Pest control: focus on prevention
- Services: water and air control
- Technical maintenance and calibration

## **B. PREREQUISITE PROGRAMME – OPERATIONAL**

### **Aspects for Inspection:**

- Maintenance of the cold chain
- Cleaning and disinfection
- Control of incoming products / services
- Food and material storage
- Microbial, physical and chemical contamination from production environment
- Monitoring practices – pre-requisites
- Allergen controls – process
- Personnel hygiene and illness

## **C. PROCEDURES BASED ON HACCP PRINCIPLES**

### **Aspects for Inspection:**

- Identify the hazards
- Determine the critical control points (CCPs)
- Establish critical limit(s)
- Monitor control of the CCP
- Establish the corrective action
- Establish procedures for verification / validation
- Establish documentation

## **D. MANAGEMENT**

### **Aspects for Inspection:**

- Waste management
- Working methodology
- Allergen controls – intake
- Personal hygiene and health status
- Raw materials – supplier selection, specifications
- Traceability
- Product withdrawal / recall
- Supervision and instruction / training

## **E. RELEVANT FOOD LEGISLATION OTHER THAN FOOD HYGIENE**

Please refer to specific legislation, relevant FSAI and EU guidance and the HSE service contract for details of the requirements to be verified.

- Labelling
- Import control of product of non-animal origin subject to increased controls
- Contaminants
- Specified risk material
- Packaged water
- Materials in contact with foodstuffs
- Nutrition and health claims
- Food supplements
- Foods for particular nutritional uses
- Marketing standards
- Food additives
- Foodstuffs treated with ionising radiation
- Novel foods and genetically modified foods
- Food fortification

**NOTES**





**Food Safety Authority of Ireland**  
The Exchange, George's Dock, IFSC,  
Dublin 1, D01 P2V6

T +353 1 817 1300  
E [info@fsai.ie](mailto:info@fsai.ie)

 Join us on LinkedIn

 Follow us on Twitter @FSAInfo

 Say hi on Facebook

 Visit us on Instagram

 Subscribe to our Youtube channel

[www.fsai.ie](http://www.fsai.ie)

ISBN: 1-904465-85-4