

GUIDANCE NOTE

for Health Boards on the Inspection of a Food Business (Revision 1)

Guidance Note No. 1 for Health Boards on the Inspection of a Food Business (Revision 1)

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Abbey Court
Lower Abbey Street
Dublin 1

Tel: +353 1 817 1300 Fax: +353 1 817 1301
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Introduction

The Food Safety Authority of Ireland (FSAI) has been developing Guidance Notes in order to help the food industry to achieve a higher degree of compliance with regulations and accepted good practice. In the regulatory area, the aim has been to provide guidance which will assist in the uniformity and consistency in enforcement and the application of regulatory controls and to provide the food industry with a clear, open indication of what should be expected.

The first Guidance Note to be developed was Guidance Note No. 1 on the Inspection of a Food Business. After three years in circulation, it was appropriate to consider a review of this document to ensure it continues to meet the needs of the enforcement officers and the food businesses.

The result of the revision is a document that builds on the original to be applicable across the wide spectrum of food business operations and expands the practical guidance offered to the enforcement officers.

The Guidance Note series will continue to be developed to meet the aims we have set out and will continue to contribute to the development of the high standards being achieved by the food inspection services in Ireland.

Purpose

The purpose of this Guidance Note is to assist in establishing a consistent approach within the environmental health service when conducting food safety inspections of food businesses for their compliance with statutory controls and/or relevant accepted Industry Codes of Practice/ Guidance Notes.

Scope

This Guidance Note applies to health board environmental health officers (EHOs) carrying out food safety inspections.

Definitions

The following definitions are used for the purpose of this document:

Inspection:

For the purpose of the Guidance Note, inspection refers to a systematic independent examination of a food business to determine whether food safety activities, including premises and facilities, comply with legal requirements.

Food Business:

Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

Food Business Operator:

The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

EHO:

Environmental health officer

Related Documents

The following lists of guidance documents and legislation are relevant to this Guidance Note:

Guidance Documents

National Standards Authority of Ireland

- I.S. 340: 1994 Hygiene in the Catering Sector
- I.S. 341: 1997 Hygiene in Food Retailing/Wholesaling
- I.S. 342: 1997 Guide to Good Hygiene for the Food Processing Industry in accordance with Council Directive 93/43/EEC on the Hygiene of Foodstuffs
- I.S. 343: 2000 Food Safety Management incorporating Hazard Analysis and Critical Control Point (HACCP)
- I.S. 344: 2002 Hygiene and Domestic Scale Food Production
- Guide to Good Hygiene Practice for the Irish Beverage Industry, Irish Business and Employers Confederation

International Standards Organisation

- ISO 15161 – 2001, Guidelines for the application of ISO 9001:2000 for the food and drink industry

Food Safety Authority of Ireland

- Code of Practice No. 1 Risk Categorisation of Food Businesses to Determine Priority for Inspection (2000)
- Guidance Note No. 11 Compliance with Regulation 4.2 of the European Communities (Hygiene of Foodstuffs) Regulation 2000 (S.I. No. 165 of 2000) (2002)
- Code of Practice No. 12 The Inspection of Food Safety Training and Competence, for staff in an operative role (2003)
- Guide to Food Safety Training – Level 1 Induction Skills (2001)
- Guide to Food Safety Training – Level 2 Additional Skills (2002)
- Guide to Food Safety Training – Level 3 Food Safety Skills for Management (2003)

Legislation

A full and up to date list of relevant legislation is included under Schedule I of the service contract between the health boards and the FSAI for which the health board has responsibility. The Schedule will be updated as new legislation is included under the health board remit.

The primary legislation concerned includes:

- Sale of Food and Drugs Acts, 1875-1936
- Health Acts, 1947-1970
- Food Hygiene Regulations, 1950-89
- European Communities (Flavourings for use in Foodstuffs for Human Consumption) Regulations, 1992 (S.I. No. 22 of 1992)
- European Communities (Meat Products and other Products of Animal Origin) Regulations, 1995 (S.I. No. 126 of 1995)
- European Communities (Meat Products and other Products of Animal Origin) Amendment Regulations, 1997 (S.I. No. 175 of 1997)
- European Communities (Official Control of Foodstuffs) Regulations, 1998 (S.I. No. 95 of 1998)
- European Communities (Hygiene of Foodstuffs) Regulations, 2000 (S.I. No. 165 of 2000)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000 (S.I. No. 437 of 2000)
- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matter of food safety
- European Communities (Labelling, Advertising and Presentation of Food) Regulations, 2002 (S.I. No. 483 of 2003)
- Food Safety Authority of Ireland Act, 1998.

Revocation

Guidance Note No. 1 on the Inspection of a Food Business (2001) is revoked and replaced by this document.

Overview

Health boards, in conjunction with the FSAI, will make food business operators aware of the need for food safety inspections to be carried out by enforcing authorities, along with details of what inspections will entail and the obligations on food business operators for ensuring that the requirements of food law are met within the food business under their control. The responsibility for identifying food hazards, controlling risks and complying with food safety legislation rests with the food business operator.

The Food Safety Authority of Ireland Act, 1998 provides for the appointment of authorised officers for the purpose of exercising duties under the Act as required through the service contract with the official agency. In this context, health boards, acting as official agencies, will issue warrants of appointment as an authorised officer to EHOs carrying out enforcement of legislation detailed in the Schedule I of the service contract.

Under the arrangements of the service contracts between the health boards and the FSAI, provision is made for the adoption and maintenance of a Quality Management System (QMS) by the health boards. Such a QMS will include Standard Operating Procedures (SOPs) for visiting food businesses and the appointment of authorised officers and issuing of warrants to EHOs.

This document provides guidance on the procedure of visiting businesses in order to carry out a food safety inspection.

The purpose of an inspection is to:

- Determine the scope of the business activity and the relevant legislative controls that will apply to it.
- Identify the potential 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 legislation.
- Consider appropriate enforcement action, proportionate to risk, to secure compliance with the legal requirements.
- 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 Compliance with Regulation 4.2 of the European Communities (Hygiene of Foodstuffs) Regulations 2000 (S.I. No. 165 of 2000) and Guidance Note No. 12 Inspection of Food Safety Training and Competence should be taken into account when carrying out an inspection.

The Inspection Process

The inspection process consists of:

- Scheduling
- Inspection preparation
- Conduct of inspection
- Outcome of inspection and determination of action
- Record keeping.

Food business records should be held for each food business subject to inspection, containing details of any necessary registrations, licences or approvals, previous inspections, risk categorisation under Code of Practice No. 1, details of any enforcement actions/prosecutions taken and other relevant documents.

Inspections other than Programmed Full and Surveillance Inspections, such as investigating complaints, providing advice and registration may not necessarily be scheduled, but will follow the same process.

Any reasonable food safety precautions which are required by the company or organisation under inspection 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.

I. Scheduling

Inspections will be carried out using a risk based approach which will determine the nature, frequency and type of inspection, with due regard being given to the nature of the risk presented by the business (as categorised by Code of Practice No. 1), the history of compliance with food safety legislation and the outcomes of previous inspections.

Businesses will normally be inspected according to a scheduled plan having regard to the targets and terms set under the arrangement of the service contracts with the FSAI.

An inspection will ordinarily examine the food safety management system operated by the food business operator. The food safety management system can be considered as having various elements, which will include all of:

A Hygiene prerequisite programme

B Supplier control

C Process control

D Management procedures

and as appropriate

E Labelling and/or

F Food additives.

Inspections will take the form of any of the following types:

(a) Programmed Full Inspection

A Programmed Full Inspection will be conducted to consider all of the aspects in each of the 4 elements of the food safety management system (A-D page 6), and as appropriate the aspects of one or both of the additional elements (E and F page 6).

(b) Programmed Surveillance Inspection

A Programmed Surveillance Inspection will cover at least one aspect of each of the 4 elements of the food safety management system and may include at least one aspect of either of the additional elements as appropriate.

(c) Other e.g. Advisory Visits

Other visits may include visits of an advisory nature or inspections which are such that the focus is on a specific part of a process and not of the extent or detail as described above and any other inspection visit which does not fit into either of the above categories.

Follow-Up Inspections

Follow-Up Inspections, scheduled to coincide with the specified action times on contraventions noted in previous inspections, will normally focus on key areas of a premises operation rather than the full scale. Depending on the particular aspects of the operation which are covered in the inspection, Follow-Up Inspections can be considered a Programmed Surveillance Inspection where the criteria are met. If a Follow-Up Inspection is of such an extent that it covers all of the elements of a Programmed Full Inspection, it should be considered as such an inspection.

Where the extent of a Follow-Up Inspection is such that it can not be considered as either a Programmed Full Inspection or a Programmed Surveillance Inspection it should be classed as an Other Visit.

Complaint Inspections

Inspections as a result of complaints can be considered in the same way as follow-up inspections.

It is possible, therefore, for Follow-Up and Complaint Visits to fall in any of the categories (a-c) above.

Registration / Licensing / Approval

Inspections for registration purposes may also fit into any of the three categories (a-c) above.

Note:

1) When considering the scope of Follow-Up, Complaint, Registration or Other Inspections, regard should be taken to the scheduling of the next programmed inspection with a view to combining the purposes.

2) A visit for the sole purpose of sampling does not constitute an inspection.

Inspection Timing

Recognition must be given to the differing hours of operation for different types of food business and the inspection scheduling needs to take account of business which only operates at restricted hours such as early mornings or evenings.

2. Inspection Preparation

Prior to an inspection, the EHO will need to:

- consider the type, purpose and scope of the inspection.
- review the information held on record about the business, including the history of compliance.
- familiarise themselves 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, authorisations and equipment to carry out the inspection.

The assessment of the food safety risk which the business presents is covered in Code of Practice No. 1.

Inspections will normally be carried out unannounced, though 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. Conduct of Inspection

An inspection should be conducted to include the following:

- a) Preliminary discussion** with the proprietor/person in charge on the purpose, nature and extent of the inspection
- b) Confirmation of the details** held on record about the business
- c) An assessment of the extent** of the business including the customer profile and distribution of the product

- d) Identification, examination and assessment of food safety management systems** (HACCP based) 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 premises, equipment, installations, machinery and records of measurements and checks carried out, as well as the food on the premises
- k) Taking of samples and carrying out other verification checks such as temperatures**
- 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.

During the closing discussion an indication of the likely follow-up action and time scale for the required corrective actions may be given.

The overall conduct of the inspection should be carried out to assess the compliance with the relevant legislation.

Depending on the extent and purpose of the inspection, it will not always be necessary to cover every point as listed (for example, samples will not always be taken), but all inspections should be conducted along similar lines.

To facilitate the inspection process, EHOs may use as an 'aide-memoire' an Inspection Planner form based on the information contained on the relevant aspects of the inspection in Annex I. Officers should, in all cases, record the details of the inspection.

4. Outcome of Inspection and Determination of Action

Actions to be taken as a result of an inspection will be determined by the legal requirements, nature of the risk and the history of compliance of the business.

The following details provide a general outline of categorising noted infringements and suggested action to be taken.

These have been provided as guidance only and are neither exhaustive nor intended to replace the judgement of the EHO in individual circumstances.

Infringements

Infringements are non-compliances with statutory requirements and the following areas should be considered:

- General Hygiene
- Microbiological Contamination
- Other Contamination
- Composition
- Labelling/Presentation
- Hygiene Training
- Risk Assessment/HACCP

Infringements can be divided into the following three categories:

1. Minor Infringement

An infringement where the risk to food safety is of low magnitude and can be rectified and contained easily.

2. Significant Infringement

An infringement which may pose a serious risk but not a grave and immediate danger to public health.

3. Serious Infringement

An infringement where there is grave and immediate danger to public health.

In order to determine the category into which a particular infringement falls, any consideration or rating of an infringement should be based on assessment of risk. The following factors may be considered:

- The history of the food business in complying with food legislation.
- The most recent report of a visit to the business.

- Size of premises and scale of operation.
- Nature and extent of the food business.
- The type of food.
- The nature of the handling or processing.
- The structure, layout and condition of the premises.
- Operational hygiene.
- The control system in place.
- The confidence in the management's ability to manage food safety.
- Culture of food safety within the food business.
- The customer base of the business (vulnerable groups).
- Staff training and hygiene (including exclusion of ill food handlers).

A non-exhaustive list of infringements is given in Table I. In addition:

Registration, Approval and Licensing of a Food Business

Certain classes of food businesses are required to be approved, registered, licensed or hold an occasional food permit in order to operate. Failure to comply with these requirements should be regarded as a "significant infringement".

Obstruction of an Authorised Officer

Wilful obstruction of an authorised officer in the course of his/her duties should always be regarded as at least equivalent to a "significant infringement".

Outcome of Inspection

The outcome of the inspection will either be satisfactory or unsatisfactory, depending on noted infringements. Unsatisfactory outcomes shall be determined by the highest category of individual infringements e.g. if individual infringements are minor and significant then the outcome of the inspection is "significant infringements".

In cases where successive inspections consistently result in a "minor infringement" outcome for the same type of infringements, an EHO may consider treating the outcome as "significant infringement". Similarly consistent "significant infringement" outcomes may be treated as "serious infringement".

Note: For the purposes of the annual statistical returns under the Official Control of Food Directive (89/397/EEC), the definition of infringement is given in the EC Guideline. This definition includes instances where written warnings are issued. However, the FSAI has previously advised that written warnings in relation to minor breaches of legislation need not be recorded as "infringements".

Action required

The outcome of the inspection will determine the action required.

Outcome	Action
Satisfactory	Communication verbal and/or written advice.
Minor Infringement	Communication verbal and/or written advice.
Significant Infringement	Written communication requiring action e.g. warning letter/ Improvement Notice/Order; possible legal action.
Serious Infringement	Closure Order, Prohibition Order, seizure or destruction of food and prosecution as appropriate.

An EHO may accept a proprietor taking voluntarily actions (such as closure or product withdrawal/recall), but this will not preclude enforcement action being taken as set out above.

Immediate Corrective Action

At the time of inspection, there may be infringements noted which will require immediate corrective action. The action taken will need to be determined according to the circumstances but may include bringing food back into temperature control, disposal of food, cleaning or if the infringement is serious and cannot be immediately corrected, closure of the establishment.

Examples, but not an exhaustive list, are given in Table 2 on page 18.

5. Record Keeping

After the completion of an inspection, it is necessary to ensure that all relevant information is updated in any records held electronically or in hard copy.

The food business records should be updated (with the details of the inspection, including copies of any documents, records or readings taken at the time of the inspection) including details of the outcome of inspection and action taken.

Table I**Examples of Infringements**

The following is a non-exhaustive list of examples of minor, significant and serious infringements and should be seen as indicative only and not intended as a substitute for professional judgement and risk assessment.

	Infringement	Minor	Significant	Serious
Labelling & Presentation	Improper net quantity (metric)	✓		
	Absence of commercial label		✓	
	Ingredient not listed		✓	
Additives (FSAI Returns Category – Composition)	Inappropriate use of additives/ colours/flavourings in a manufacturing premises		✓	
Management Procedures (FSAI Returns Category – Hygiene) (HACCP, Training)	Training e.g. lack of knowledge of food safety practices commensurate with the work activities		✓	
	Absence of a risk assessment system based on HACCP principles		✓	
Supplier Control	Torn packaging	✓		
	Contaminated raw materials		✓	
	Supplies stored in unsatisfactory conditions	✓		

	Infringement	Minor	Significant	Serious
Prerequisites Programme (FSAI Returns Category – General Hygiene)				
Cleaning/ Sanitation	Maintenance equipment not properly stored.	✓		
	Absence of regular cleaning.		✓	
	Very poor structural condition and poor equipment and/or poor maintenance of routine cleaning and/or serious accumulation of refuse, filth or other extraneous matter resulting in a risk of food contamination.			✓
Personal Hygiene	Hairnets to cover all hair not worn by staff working in areas where food is being prepared to prevent hair from entering the food.	✓		
Pest Control	Air intake points and opening external windows in the food preparation area not fitted with a fly screen.	✓		
	Serious infestation by rats, mice, cockroaches or other vermin (including birds) or a combination of these infestations resulting in actual food contamination or a risk of food contamination.			✓

	Infringement	Minor	Significant	Serious
Plant & Equipment	Equipment not installed so that there is adequate access under, around and inside the equipment so as to enable it to be effectively cleaned.	✓		
	The food contact surfaces not non absorbent, resistant to corrosion, smooth, free from pits, crevices and sharp corners and areas where product can lodge or build up.		✓	
Premises & Structure	The design of the premises does not give due consideration to the layout of the process and the physical separation of unprocessed and processed foods so as to avoid cross contamination.		✓	
	The size of the premises not adequate to cater for the nature and the extent of the business intended to be carried on therein leading to unacceptable risk.		✓	
Services	Gulley trap cover missing.	✓		
	The level of lighting not sufficient to allow for the safe handling of food, and to enable cleaning to be carried out effectively.		✓	
	A potable water supply not provided.			✓

	Infringement	Minor	Significant	Serious
Storage, Distribution & Transport	Dry goods stored on the floor.	✓		
	Reusable containers such as trays, trolleys and boxes inadequately maintained.	✓		
	Inadequate storage facilities to enable different types of food to be segregated so as to prevent the danger of cross contamination.		✓	
	Vulnerable foods not stored at correct temperature during transportation.		✓	
	The occurrence of cross contamination during storage e.g. blood dropping onto ready-to-eat food.			✓
	The occurrence of cross contamination during transportation.			✓
Waste Management	Refuse bins and refuse bag holders not fitted with self-closing lids.	✓		
	The area where food waste is stored not kept clean and waste not removed as frequently as necessary to prevent it becoming a source of food contamination.		✓	
	Serious drainage defects or flooding of the premises leading to actual contamination or a risk of food contamination.			✓

	Infringement	Minor	Significant	Serious
Zoning	The following activities not carried out in separate defined areas: Preparation of raw food for cooking e.g. meat, poultry, fish and vegetables. Preparation of raw food for consumption e.g. salads. Cooking, roasting, and baking. Portioning, slicing and plating of food etc.		✓	
	A separate route for raw and cooked ready-to-eat foodstuffs in order to avoid a crossover of both processes, not provided.		✓	
Process Control (FSAI Returns Category – Hygiene) (HACCP, Training)	Correct CCP not identified or controlled.		✓	
	Measures for the prevention of cross contamination not in place.		✓	

Table 2: Examples of infringements requiring immediate corrective actions

1	Detergents, disinfectants, cleaning chemicals and cleaning equipment not clearly labelled or marked; not stored in a separate area to food
2	Inappropriate food grade cleaning agents
3	Poor personal hygiene practices observed
4	Wearing of inadequate protective clothing
5	Inappropriate food storage practices e.g. food left in tin cans, utensils left in food containers
6	Unacceptable defrosting practices
7	Unauthorised personnel in food preparation areas
8	No separation of raw and cooked preparation surfaces
9	Raw and cooked food not properly segregated
10	Procedures for dealing with deliveries where vulnerable foods are not dealt with correctly
11	Unfit food
12	Unsuitable arrangements for soap and hand drying at wash hand basin
13	Improper handling of vulnerable foods
14	Food worker suffering from infections, uncovered cuts, burns, etc.
15	Animals on premises
16	Incorrect time – temperature control
17	Colour coded utensils/chopping boards etc being kept/used in the wrong areas of the food rooms
18	Personal belongings in food areas
19	Cleaning equipment in food areas
20	Smoking in food rooms.

Annex I: Inspection Planner - 'Aide Memoire'

The following Inspection Planner is to provide guidance on the aspects to be considered under each of the 4 elements of food safety management systems:

A: PREREQUISITE PROGRAMME

Aspects for Inspection:

- Premises and structure
- Plant and equipment
- Services (ventilation, lighting, ice, water, steam, compressed air)
- Storage, distribution and transport
- Zoning
- Cleaning/sanitation
- Maintenance
- Calibration and use of measuring instruments
- Personal hygiene
- Pest control
- Waste management (solid waste/refuse, drainage/sewerage).

B: SUPPLIER CONTROL

Aspects for Inspection:

- Supplier approval system
- Agreed supplier standards
- Purchase control
- Delivery control
- Documentation
 - Returns policy
 - Rework control.

C: PROCESS CONTROL

Aspects for Inspection:

- HACCP team in place
- Valid product standard (shelf-life, labelling, intended use, risk addressed)
- Critical steps controlled
 - Flow diagram valid and accurate following walk-through
 - Hazards identified - analysis valid
 - Variations in the process taken account of – different times/ingredients/staff
 - Correct CCP's identified
- Critical limits valid (legal/industry standards)
- Reliable monitoring
 - Records to indicate controls adequate
 - Valid analytical/microbiological methods used
- Clear and effective corrective action (restore control and prevent recurrence)
 - Non-conforming product arrangements (segregation/rejection)
 - Cross contamination measures in place
 - Verification methods for each CCP.

D: MANAGEMENT PROCEDURES

Aspects for Inspection:

- Management system and organisation for food safety defined
- Food safety policy defined
- Food safety incidents recorded
- Procedures for recall established
- Provisions to enable traceability
- Management aware of legal obligations,
- Supervision, instruction and/or training commensurate with work activity
 - Food safety training plan/procedure and records

Supervisor Training

- Supervision of food safety
- Effective hygiene, food safety and HACCP
- Internal audit system

The following sections provide inspection guidance which can be used in conjunction with the Inspection Planner above on aspects of the additional elements labelling and additives.

E: LABELLING

Aspects for Inspection:

- Product name
- Ingredients
- Quantitative Ingredients Declaration (QUID)
- Net quantity
- Date of minimum durability
- Storage instructions
- Name and address of manufacturer, packer or seller in the EU
- Country of origin (if likely to mislead)
- Instructions for use
- Alcohol where > 1.2% volume.

In addition:

Nutrition labelling

Novel foods and genetically modified food

Organic food.

Specific commodity and miscellaneous labelling should also be considered on relevant products. The FSAI will issue a specific commodity reference list for this purpose and update it periodically.

F: FOOD ADDITIVES

- Type
- Use
- Approval as appropriate
- Quantity
- Purity
- Declaration

Flavourings:

- Purity
- Declaration.



Food Safety Authority of Ireland
Abbey Court, Lower Abbey Street,
Dublin 1

Údarás Sábháilteachta Bia na hÉireann
Cúirt na Mainistreach, Sráid na Mainistreach Íocht.,
Baile Átha Cliath 1

Tel: +353 1 817 1300

Fax: +353 1 817 1301

Email: info@fsai.ie

Website: www.fsai.ie

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