



Food Safety
AUTHORITY OF IRELAND

23

GUIDANCE NOTE

**Development and Assessment of
Recognised National Voluntary
Guides to Good Hygiene Practice and
the Application of HACCP Principles**

**Guidance Note No. 23: Development and Assessment of Recognised National
Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles**

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National Voluntary Guides to Good Hygiene Practice
and the Application of HACCP Principles

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CONTENTS

INTRODUCTION	1
SCOPE	3
SECTION 1: RECOMMENDED PROCESS FOR DEVELOPING A RECOGNISED GUIDE TO GOOD PRACTICE	4
STEP 1: Notification of the Authorities	4
Who should notify the authorities?	4
What should be submitted?	4
What happens with a notification?	5
What happens to existing recognised guides to good practice?	5
STEP 2: Development of a Draft Guide for Consultation	6
Who develops the draft guide?	6
What format should the guide take?	6
STEP 3: Final Consultation	7
Who is responsible for the final consultation?	7
STEP 4: Recognition of Draft Guides to Good Practice	8
What is the role of the notifying body?	8
What is the role of the authorities?	8
Status of Recognised Guides to Good Practice	9
SECTION 2: ADVICE ON WRITING GUIDES TO GOOD PRACTICE	10
Introduction	10
Purpose	10
Scope of guides to good practice	10
Terms and definitions	11
Technical content	11
Recommended format	12
Pre-requisite programme and training	12
Procedures based on the principles of HACCP	13

INTRODUCTION

On 1st of January 2006, new hygiene regulations came into force in the European Union. Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, applies to all food business operators throughout the food chain. 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, applies additional rules for food business operators involved in the manufacture and distribution of foods of animal origin.

Articles 7 and 8 of Regulation (EC) No. 852/2004 allow for the development of national guides to good practice for hygiene and for the application of HACCP principles (guides to good practice). A similar provision was available under the previous 'hygiene of foodstuffs' Directive (93/43/EEC)¹, now revoked. Food business operators may use the guides on a voluntary basis as an aid to compliance with the food hygiene requirements.

The legislation requires that:

- Member States encourage the development and dissemination of national guides to good practice
- guides shall be developed and disseminated by the food business sectors
- production of guides must be in consultation with representatives of parties whose interests may be substantially affected
- guides must also have regard to any relevant codes of practice of the Codex Alimentarius and any relevant Community guidance notes
- guides may also be developed under the aegis of a national standards institute which in Ireland's case, is the National Standards Authority of Ireland (NSAI).

Member States are required to assess national guides to good practice to ensure that they have been developed in accordance with requirements of Regulation (EC) No. 852/2004, that they meet all the criteria of relevant EU Regulations and that the contents are practicable for sectors to which they refer.

¹ This allowed for the development of guides under the aegis of the National Standards Authority of Ireland:

- IS3219: 1990 Code of practice for hygiene in the food and drink manufacturing industry
- IS340: 1994 Hygiene in the catering sector
- IS341: 1998 Hygiene in food retailing and wholesaling
- IS342: 1997 Guide to good hygienic practice for the food processing industry in accordance with the Council Directive 93/43/EEC on the hygiene of foodstuffs
- IS343: 2000 Food safety management
- IS344: 2002 Hygiene and domestic scale food production

The Food Safety Authority of Ireland (FSAI) and the relevant competent authority will assess national guides and a formal recommendation for recognition of guides will be sent to the relevant Government Department. The relevant Government Department will make the decision to recognise a guide or not, and if recognised, the guide will be forwarded to the European Commission as required in Regulation (EC) No. 852/2004. The European Commission will be responsible for developing Community guides.

SCOPE

This is a guidance document for the food industry. However, it only applies to food business sectors developing guides for food chain activities that come under the scope of the Food Safety Authority of Ireland Act, 1998 as amended. It contains a recommended process for the development of guides to good practice for hygiene and for the application of HACCP principles².

This guidance document lays down the preferred process for interaction between the authorities and the food industry. However, this is not a mandatory process providing that the requirements of legislation laid down in Articles 7 and 8 of Regulation (EC) No. 852/2004 and outlined in the introduction are complied with.

This guidance document has been written to meet Ireland's obligation under Regulation (EC) No. 852/2004 to encourage the development of guides. It is designed to facilitate the development of guides in all sectors of the food industry **except primary production**.

- Section 1 briefly sets out the preferred process for the development of guides including notification, drafting and recognition phases.
- Section 2 provides advice on the development of guides.

² Referred to hereafter as Guides to Good Practice or Guides

SECTION I: RECOMMENDED PROCESS FOR DEVELOPING A RECOGNISED GUIDE TO GOOD PRACTICE

Step I: Notification of the Authorities

It is preferable if a food business sector wishing to develop a guide to good practice notifies the FSAI **or** their appropriate competent authority prior to commencing work. This ensures that the opinions of the competent authorities are taken into account at the earliest stage of the development of guides.

Who should notify the authorities?

Food business sectors are responsible for taking the initiative for developing guides to good practice relevant to their sector and should notify the FSAI **or** their appropriate competent authority before commencing work. There is no need for notification of more than one authority as the FSAI and competent authority will ensure that each other are aware of the notification and are involved in the process.

Guides may also be developed by a food business sector under the aegis of the NSAI who may then act as the notifying body.

What should be submitted?

The notification should contain:

- the name and address of the notifying body and a contact name therein
- a title for the guide
- a scope (including the sector and types of food business to which the guide will apply)
- a list of parties whom it is planned to consult with during the development of the guide.

Notifications to the FSAI can be made via the FSAI Advice Line info@fsai.ie or by mail to the Director of Food Science and Standards Division, Food Safety Authority of Ireland, Abbey Court, Lower Abbey Street, Dublin 1.

Notifications to the Department of Agriculture, Fisheries and Food can be made to the Food Safety Liaison Unit, Department of Agriculture, Fisheries and Food, Agriculture House, Kildare Street, Dublin 2.

Notifications to the Department of Health and Children can be made to the Principal Officer, Food Unit, Department of Health and Children, Hawkins House, Hawkins Street, Dublin 2.

Notifications to the Sea-Fisheries Protection Authority can be made to the Sea-Fisheries Protection Authority, Clonakilty, Co. Cork.

Notifications to other competent authorities may be made through the FSAI as above and dealt with via the established liaison process, e.g. Local Authorities Veterinary Service and the Health Service Executive.

What happens with a notification?

The FSAI and competent authority will consult with each other on the proposal. A meeting with the notifying body may be arranged if necessary. The notifying body will receive an acknowledgement of the proposal containing:

- the name and address of the person who will be their contact point for any subsequent correspondence with the authorities including consultation with the authorities on draft and finalised guides
- any initial observations from the competent authority and/or FSAI on the development of the proposed guide.

A response will be provided in as short a timescale as is possible and the notifying body should seek confirmation of a suitable timescale at the time of notification.

What happens to existing recognised guides to good practice?

All existing guides to good hygienic practice and HACCP principles that were developed under Commission Directive 93/43/EEC on the Hygiene of Foodstuffs can continue to apply after entry into force of Regulation No. 853/2004 on the hygiene of foodstuffs on the 1st January 2006, providing they are compatible with the objectives of the Regulation. A list of recognised guides is maintained by the European Commission which is currently maintained at this web location: http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf

Step 2: Development of a Draft Guide for Consultation

The notifying body should proceed to develop the draft guide to good practice taking into account any initial comments received in the response from the authorities.

Who develops the draft guide?

Food business sectors or the NSAI, as appropriate, are responsible for developing guides to good hygiene practice. The legislation requires that they do so in consultation with “representatives of parties whose interests may be substantially affected”, e.g. relevant companies and/or trade associations and the authorities. It is also a legal requirement that the guides have regard to relevant codes of practice of the Codex Alimentarius. They must also be compliant with all applicable EU and national food law.

There is no prescribed method for achieving these requirements. However, the relevant Government Department(s) cannot recognise guides that have not met these requirements and will require evidence that, in particular, the consultation requirement has been met. As a general guide, current best practice suggests that guides are developed by a working group that should, as far as possible, be representative of the sector for which the guide is intended as defined in the scope. Working groups should contain members of both the small and large businesses if their interests are affected by the guide. Representatives of the FSAI and the competent authority should always be invited to participate and this can be done through the contact person designated by the FSAI or competent authority. Working groups should include consumer groups where appropriate.

If, for whatever reason, the FSAI and competent authority are not represented on the working group then it is desirable that they should be consulted on drafts by correspondence during the development process. This can be co-ordinated via the contact person designated by the FSAI or competent authority subject to prior agreement.

What format should the guide take?

There is no prescribed format for guides to good practice in the food legislation. However, in the interests of clarity, they should be written in a manner that enables food business operators in the sector to apply the requirements easily and effectively. Advice on the content and structure of a guide to good practice is given in Section 2 of this document.

Step 3: Final Consultation

The legislation requires that guides are developed in consultation with “representatives of parties whose interests may be substantially affected”.

Who is responsible for the final consultation?

The notifying body is responsible for ensuring that the legal requirement for consultation is met. Therefore, the notifying body should arrange any necessary final consultation by any means that ensures compliance with the legal requirement.

It is best practice to send the final draft guide for comment to a broad selection of food businesses and representative trade associations affected by the guide as well as the following bodies as appropriate:

- Food Safety Authority of Ireland
- State marketing board (as appropriate for the sector)
- Consumers Association of Ireland
- National Consumer Agency
- Safefood
- Competent authority
- Department of Agriculture, Fisheries and Food
- Sea-Fisheries Protection Authority
- Department of Health and Children
- Health Service Executive
- Environmental Health Officers Association
- Local Authority Veterinary Service
- Veterinary Officers Association
- Office of the Director of Consumer Affairs.

All parties should be given ample time to respond with comments and all comments should be considered before the final draft guide is completed. Consultation with the enforcement authorities may be co-ordinated via the contact person designated by the FSAI or competent authority but only by prior agreement. It is the responsibility of the notifying body to consult with all other relevant bodies individually.

Step 4: Recognition of Draft Guides to Good Practice

What is the role of the notifying body?

The notifying body should send a copy of the final draft guide to the contact person designated by the FSAI or competent authority, along with evidence that the legal requirement for consultation has been met. The evidence referred to may take the form of copies of communications to stakeholders or any other form deemed appropriate by the notifying body.

In the event of concerns being raised by the authorities following the assessment process, the notifying body should address these issues and re-submit the draft guide.

Once a guide is recognised, the notifying body is responsible for disseminating the national guide to good practice.

What is the role of the authorities?

The FSAI and competent authority will assess final draft guides to good practice to ensure that:

- it has been developed in accordance with these guidelines, which reflect the criteria laid down in article 8 of Regulation (EC) No. 852/2004
- it is practical for the sectors and foodstuffs to which they refer
- it is suitable as a guide to compliance with the relevant legal hygiene requirements.

Where necessary, the process will be assisted by any other expert person or expert body deemed appropriate.

Any necessary alterations to the guide resulting from this procedure will be requested by the authorities and carried out by the notifying body by a process of consultation between the two parties.

The FSAI or competent authority, as appropriate, will forward a copy of the final guide to the relevant Government Department(s) responsible for recognising the guide. The copy of the guide will be accompanied by a letter recommending acceptance or rejection.

The decision to formally recognise a guide in accordance with the legal requirements of the legislation rests solely with the relevant Government Department(s).

The notifying body, FSAI and competent authority will be notified of the status of the guide by the relevant Government Department(s).

If formally recognised, the relevant Government Department(s) will forward the guide to the European Commission in accordance with the requirements of Regulation (EC) No. 852/2004.

The authorities are responsible for encouraging the use and dissemination of recognised national guides.

Status of Recognised Guides to Good Practice

Guides that are formally recognised will be acknowledged by the officers of the competent authorities conducting official controls when a food business has indicated voluntary use of the guide and has implemented its recommendations in their business. Where a food business is clearly following advice in a recognised guide, the enforcement officer will take this into account when assessing compliance with the food law. Therefore, recognised guides can be used with confidence by food businesses as a practical guide to compliance with the relevant hygiene legislation.

However, the implementation of the requirements laid down in recognised guides is voluntary and food businesses may use other ways of meeting the legislative requirements and demonstrating compliance when required.

SECTION 2:ADVICE ON WRITING GUIDES TO GOOD PRACTICE

There is no legislative prescription on how guides to good hygiene practice should be written. Therefore, a notifying body can decide on format that best suits their purpose. However, the document should be clearly written and easily interpreted by its target audience and it should be clear who that target audience is. This section contains a recommended template for a guide to good hygiene practice that can be utilised and adapted as necessary by the notifying body.

Introduction

Each guide should have a brief introduction of less than a page that outlines the background to the development of the guide and the reasons for its development.

Purpose

Each guide should have a written purpose which briefly outlines what the guide is intended to do. This should include reference to Article 8 of Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

Scope of guides to good practice

Each guide should have a written scope that briefly describes what is covered by the guide and what is not covered by the guide. The scope should describe clearly:

- the food business sector and the types of businesses to be covered (nature and size)
- whether the focus is on a specific foodstuff or restricted list of foodstuffs which should then be specified
- whether the guide is restricted to a specific function within a food chain, e.g. beef slaughter, or if it covers more than one part of the food chain to provide a food safety continuum, e.g. production, processing and distribution of fresh beef
- whether or not quality and management elements are included or if the guide is restricted to all or certain aspects of food safety management
- whether the guide extends beyond compliance with the legislation and into best practice or animal welfare etc.

Note: The guide should apply nationally rather than regionally. If a food business sector wishes to have a guide that is applicable both in the Republic of Ireland and in Northern Ireland it should discuss this requirement with both the Food Standards Agency (Northern Ireland) (FSA (NI)), the FSAI and competent authority prior to notification.

Terms and definitions

This section should be included to clarify terms used in the document. Terms defined in the food legislation should not be redefined in the guide but should be included verbatim with reference to the specific legislation where they are defined. In addition, other terms not defined in European or national legislation should be consistent with relevant Codex Alimentarius documentation. If terms are used that are not covered in these forms of documentation or in relevant FSAI Guidance Notes, then the term should be defined by the working group including them under the words 'for the purposes of this document....'.

Technical content

The remainder of the guide should be written in a clear and logical form that will enable a food business operator to easily and effectively apply the guide requirements to their business. Devices to aid presentation and understanding should be utilised and diagrams or other suitable means should be employed to illustrate complex issues. The use of jargon and technical language should either be avoided or should be suitably explained either in the text or in a glossary.

The advice given should be consistent with achieving the objectives of the hygiene legislation, principally food safety and consumer protection. The guide should at least contain guidance on compliance with the following legislation:

- Articles 3,4 and 5 of Regulation No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs
- where applicable - Regulation No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin
- any Commission Regulations containing implementing measures regarding Regulation No. 852/2004 and Regulation No. 853/2004 (advice can be sought from the FSAI).

The guidance must have regard to European or national guidance notes on aspects of the above legislation as well as relevant Codex standards including commodity standards and general hygiene standards (advice can be sought from the FSAI).

Depending on its scope, the guide may also contain guidance on compliance with other relevant legislation, e.g. labelling, general principles of food law, animal welfare. However, in this case, the guidance should be consistent with the legal requirements.

Recommended format

It is recommended that the flow of the document is consistent with the concept of a food safety management system. In this regard, it should at least address the following issues in separate sections or as an integrated single section:

- general hygiene and training (pre-requisite programme)
- maintenance of the cold chain
- a permanent procedure or set of procedures based on the principles of HACCP.

However, consideration should also be given to providing guidance on other aspects of the pre-requisite programme such as:

- purchasing systems
- recall and traceability systems (consistent with Regulation (EC) No. 178/2002)
- calibration of equipment
- management responsibilities.

Pre-requisite programme and training

The guide should clearly distinguish between the legal obligations of food business operators and other aspects required by quality systems if these are being considered in the scope.

The guide should provide guidance, consistent with the legal requirements, on the following elements of the pre-requisite programme:

- premises structure and layout, e.g. construction, materials, location, etc.
- zoning (separation and layout of operations to prevent cross contamination)
- plant and equipment
- services, e.g. compressed air, water, energy etc.
- storage, distribution and transport
- personal hygiene
- cleaning and sanitising
- maintenance
- pest control
- waste management
- maintenance of the cold chain.

It is not sufficient for a guide to restate the legal requirements without further elaboration. The guide should provide guidance to the relevant sectors on the terms “where necessary”, “where appropriate”, “adequate”, “sufficient” and “unless food business operators can satisfy the competent authority that are appropriate” when these are stated in legal requirements. However, in doing this, the guidance provided should be evidence based, technically sound and should be sufficiently detailed to stand alone as a guide to the sector identified without reference to detail in other guides.

Guides to good practice should also provide appropriate guidance on how food businesses can satisfy the requirement for training and/or instruction as appropriate, in hygiene and procedures based on HACCP principles. Relevant training guides from the FSAI or a competent authority should be taken into consideration.

Procedures based on the principles of HACCP

The guide should, whenever possible, address the application of the Hazard Analysis and Critical Control Point (HACCP) system. The legislative requirements on this subject are laid down in Article 5 of EC Regulation No. 852/2004 and further elaborated in a European Commission guidance document on the application of flexibility to the HACCP requirement.

Regulation No. 852/2004 permits a flexible approach to the application of HACCP. Businesses are, therefore, not necessarily required to follow the classical HACCP approach laid down by the Codex Alimentarius Commission³, but such an approach is not precluded if the food industry sector decides that this is appropriate. Further advice on HACCP flexibility is given in FSAI Guidance Note No.11 (Revision 2).

The guide should contain advice on HACCP-based procedures that are appropriate and proportionate to the size and nature of businesses covered in the scope as well as the level of risk that is presented by the foodstuffs handled on the premises. The HACCP based procedures should nevertheless enable businesses to demonstrate compliance with the specific requirements of Article 5 if the advice is followed.

Guides to good practice are expected to elaborate on the likely food safety hazards in the businesses covered in the scope, appropriate control measures, critical control points, critical limits and corrective actions. However, the level of detail provided is for the working group to determine. Consideration can be given to providing generic examples of HACCP systems but this should be presented in the guide with a clear indication to the user that the system will have to be adapted to each food business situation.

³ Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application: Annex to Recommended International Code of Practice: General Principles of Food Hygiene, CAC/RCP 1-1969, rev 4-2003

Reference should be provided to any relevant expert advice available from external sources. Specific advice should be provided on documentation with an understanding that the extent of record keeping should be proportionate to the size and nature of businesses covered in the scope as well as the level of risk that is presented by the foodstuffs handled on the premises. Model documentation and records may be included where appropriate.

Verification and validation procedures should be addressed and practical advice provided that will allow all businesses covered by the scope to meet this requirement. Checklist for verification purposes may be included in the guide.

NOTES

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