

# 1 INTRODUCTION

1.1 The purpose of this Guide is to outline the responsibilities of managers in relation to the efficient manufacture and control of food and drink products, thereby ensuring that such products are safe, wholesome and of the nature and quality intended. While it addresses manufacture of food and drink for use in the retail, catering and vending industries, it does not deal with catering and retail activities per se. The Guide is therefore particularly concerned with management practices associated with:

- factors affecting product safety, product legality, product integrity and product quality;
- product manufacture in terms of product and process control and handling of food under hygienic conditions in conformity with product, packaging and labelling specifications; and
- matters such as training of personnel, documentation and record keeping, supplier approval, suitability of premises and equipment and site standards, waste avoidance, recovery and reworking of materials, laboratory management, traceability, verification activities, and preventive and corrective action and the management of customer complaints and product recall.

1.2 It is emphasised that the Guide is concerned with advice based on principles of good manufacturing practice (GMP), and it is recognised that methods other than those described, but which achieve the same ends, may be equally acceptable. Personnel and premises hygiene, because of its importance, is treated as a continuous theme and a subject for consideration throughout the document.

The Guide is in three parts:

- Part I: deals with matters of general application;
- Part II: deals with guidance on specific manufacturing and/or food categories; and
- Part III: covers mechanisms for review of the Guide.

1.3 The Guide does not deal directly with such matters as operative safety and welfare, ethical matters, animal welfare or environmental issues including water and energy conservation. It refers to resource management and waste control, engineering, maintenance and transport and distribution only in respect of those aspects that have a bearing on manufacturing practices. In general it does not deal with matters unrelated to scientific,

technological and organisational aspects affecting product safety, product legality, product integrity and product quality.

- 1.4 The Guide has been written at a time when the United Kingdom (UK) is negotiating a new relationship with the European Union (EU) in terms of legislative harmonisation and trade agreements. To this end legislation still in force at the time of writing has been referenced, but may change post publication of this Guide. This is true of any legislation and/or policy approach in a given country or trading group when referenced by a static publication. The principles of GMP are universal and in many ways transcend the specifics of one nation's current or emerging legislation. Food manufacturers supplying internationally need to be aware of not only the legislation in the country in which they are manufacturing, but also the need for the products produced to comply with the legislation in countries to which they seek to export. There are many instances of product recalls in countries as a result of food products, for example, not complying with the export countries' requirements for food allergen labelling for ingredients such as celery, mustard or milk. It is the responsibility of the reader to refer to current legislation itself or review the contents of this Guide with the support of a competent adviser, and not to rely on an interpretation or an abridged version of legislative requirements as given in this document.
- 1.5 Absolute terms, such as 'ensure that', 'avoid', 'prevent', 'absence of' and so on, have been used in various parts of the Guide. To dispense with them would detract from the intentions of the Guide or would necessitate lengthy explanations on each occasion. Accordingly, readers should note that such terms are to be interpreted in a rational and practical way, for example 'ensure that' should be read as meaning 'ensure, so far as is reasonably practicable, that'. Words such as 'should' are used for non-mandatory advice, and the imperative, for example 'must' or 'shall', is reserved for appropriate mandatory requirements.
- 1.6 Definitions of some of the terms used in this Guide are given in Appendix I. It is appreciated that other definitions may be equally valid or preferred, and the appendix definitions are simply intended to clarify the meanings attributed to a word or phrase when used in the compilation of the Guide.
- 1.7 The Guide is an advisory document with a list of supporting, supplementary references. The Guide may be particularly useful to students studying food manufacture, to new entrants to management and to general managers in smaller companies who may be responsible for a range of management functions, each of which may be the sole concern of one or more specialist senior managers in a larger company as well as regulatory officers.
- 1.8 GMP is not a static concept, but an evolutionary, dynamic mechanism by which overall improvements in manufacturing controls can be developed, implemented and maintained.

- 1.9 The Guide outlines general principles that may already be contained in published guidelines or codes of practice. As appropriate, the Guide will provide references to the original sources that the reader is then advised to consult in full. The Guide will also make reference, where appropriate, to international private standards such as those developed by the Codex Alimentarius Commission.
- 1.10 The initial adoption of the **EC Official Control of Foodstuffs Directive** and the advent of the **UK Food Safety Act 1990** as well as existing provisions of the **UK Trade Descriptions Act** and the **UK Weights and Measures Act** gave increasing emphasis to the need for a manufacturer to be able to prove that (s)/he did everything necessary to comply with the law. Thus under the **UK Food Safety Act 1990**, and other subsequent legislation, a manufacturer, retailer or importer charged with an offence may enter the legal defence that (s)/he **‘took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by the accused or by a person under the control of the accused’**. In this context, it can be considered that ‘precautions’ are the measures taken and ‘diligence’ is the activities undertaken to ensure their effective application. The wording puts the onus of proof on the defendant, and both must be proved and the use of the word ‘all’ implies that ‘some’ or ‘most’ will not be enough. What constitutes ‘all reasonable precautions and all due diligence’ in a particular instance must relate to the nature of the offence and to other related circumstances. Nevertheless in the case of a safety or a ‘nature, substance or quality’ offence, a manufacturer who can **prove** that (s)/he has diligently installed and appropriately applied all the relevant measures in the Institute of Food Science & Technology (IFST) Guide to Good Manufacturing Practice will stand a very good chance of having a successful defence. It must also be pointed out that a manufacturer who does not employ appropriate technically competent personnel to specify the product formulation, factory processes and procedures to design and control the continuous monitoring of their correct operation and undertake such validation and verification activities cannot be said to have exercised either adequate precautions or adequate diligence and is unlikely to have a successful defence.
- 1.11 Responsibility for enforcement within the EU varies from country to country. In the UK it is shared between central, devolved and local government bodies. While the making of legislation in the UK is the function of central and devolved government, the enforcement of food law is primarily (but not solely) the responsibility of more than 400 local authorities (LAs) in the UK, and more specifically LA officers. LA officers can be differentiated as being environmental health officers (EHOs) and trading standards officers (TSOs). The Food Standards Agency (FSA) has a statutory requirement, in consort with other government bodies, to protect public health and consumers’ interests in relation to food. Since the publication of the last version of the GMP Guide

(Version 6) there has been a policy review with regard to food regulation to move to a more **risk-based approach**. A risk-based approach is well established in UK food regulation, for example the food establishment intervention rating schemes. This trend is also considering the use of public and private regulatory activities to develop a form of co-regulation. This would include utilisation of information from both public enforcement activities (e.g. EHO inspections) and information from private surveillance and verification activities such as third-party audits and product sampling activities.

The roles and responsibilities of all the authorities and organisations in the UK involved in monitoring compliance with, and enforcement of, feed and food law, plant health and feed and food law are set out in the Multi-Annual National Control Plan (MANCP) for the UK. It is a requirement of **Regulation (EC) No. 882/2004** that all EU member states have such a national control plan in place. The MANCP is produced jointly by the FSA and the Department for Food and Rural Affairs (Defra), with contributions from national and devolved agencies. The paragraphs below are a broad overview of the UK legislative framework relating to food manufacture and specific arrangements may be different within a geographical area or industry sector so this should be considered when reading this Guide.

The Framework Agreement on Official Feed and Food Controls by LAs provides the FSA with the processes required to implement its powers under the **Food Standards Act 1999**. This agreement gives structure to the FSA's supervision of LA enforcement work. The Food Law Code of Practice (FLCP) sets out the way LAs should apply food law, and how they should work with food businesses. LAs must follow and implement appropriate provisions of the Code. Practical guidance is also provided as a further help to enforcement officers.

The EHOs and TSOs are authorised by their LAs to enforce food legislation. Once they achieve certain qualifications, detailed under the FLCP, they are authorised to carry out certain tasks and are provided with powers (under the **Food Safety and Hygiene (England) Regulations 2013** and other equivalent UK legislation as amended) to, for example, enter premises, take samples, gather evidence, issue notices and, under certain circumstances, close premises.

Depending on the structure of local government in the area in England and Wales, food visits may be from TSOs to examine labelling, compositional standards and food contaminants, and EHOs to check on food hygiene. However, in Scotland, Northern Ireland and some Welsh and English authorities, EHOs are responsible for all the food legislation, with TSOs responsible for weights and measures checks. Further, in some areas LAs have combined their resources to a single unit which operates over a number of LA areas. It is incumbent on the manufacturer to be

aware of the local regulatory framework in the area in which they operate, to have registered their food business and to comply fully with all requirements. Visits to manufacturing sites by LA officers are to ensure compliance with legislation; the frequency of interventions (visits) to a given manufacturing site is determined as previously described by a risk-based approach.

The actual policy and resources allocated to the inspection premises and sampling of product will depend on the individual LA and therefore there are variations in delivery across the country. However, businesses should be able to benefit from a positive relationship with enforcement authorities, receiving detailed written feedback following inspections and receiving results of sampling exercises. Some companies develop a 'Home Authority' or 'Primary Authority' agreement with their LAs. In the UK, the Better Regulation Delivery Office's (BRDO) Primary Authority Scheme gives businesses the right to form a statutory partnership with a single LA that then provides 'robust and reliable advice for other councils to take into account when carrying out inspections or dealing with non-compliance' (see <https://www.food.gov.uk/enforcement/enforcework/compliance/primary-auth>).

**The European Union (EU) Official Controls Regulation 2017/625** entered into force on 27 April 2017 and replaces Regulation (EC) No. 882/2004 on official controls and other legislation. It becomes applicable over time with the main application date being 14 December 2019.<sup>1</sup> This Regulation addresses official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. The Regulation establishes a single legislative framework for the organisation of official controls performed for the verification of compliance with the rules established at EU level or by Member States seeking to apply EU legislation.

- 1.12 Abbreviations, for example GMP, have been used in the text throughout the Guide, but have been reconfirmed at the start of each chapter in case the chapter is read in isolation and therefore to minimise the number of times that the reader has to refer to the abbreviations list (Appendix II).

<sup>1</sup><http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0625>.

