

Food & Drink –

Good Manufacturing Practice

A Guide to its Responsible Management

PART I – GENERAL GUIDANCE

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 catering and vending industries, it does not deal with catering and retail activities per se. The Guide is therefore particularly concerned with advice to management on:

- matters affecting product safety, including health and hygiene of personnel relating thereto;
- product manufacture in terms of product and process control and handling under hygienic conditions in conformity with product, packaging and labelling specifications; and
- associated 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 on principles, 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 product safety and integrity. In general it does not deal with matters unrelated to scientific, technological and organisational aspects affecting product quality and safety.
- 1.4 **EU Regulation (EC) 853/2004**, laying down specific hygiene rules for the hygiene of foodstuffs, requires Approval of any establishment producing foods of animal origin. Any change in production may affect the status of such Approval. This includes (although not exclusively so) changes to product range and to product descriptions, changes in the production process, changes in equipment and in establishment design and layout. In such cases re-approval may be required and FBO's should contact their Local Food Authority.

The Leading case **Allan Rich Seafoods v. Lincoln Magistrates' Court [2009] EWHC 3391** confirmed that changes in the Food Business Operator (FBO) also require re-approval of such an establishment.

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- 1.5 The Guide will also make reference to international standards such as those developed by the Codex Alimentarius Commission. It is then the responsibility of the reader to refer to current legislation itself or review with the support of a competent adviser, and not to rely on an interpretation or an abridged version of the requirements as given in this document.

In addition to mandatory legal requirements, the Guide is concerned with advisable practices some of which may already be contained in published guidelines or codes of practice. The Guide outlines general principles and gives references that the reader is advised to consult in full.

- 1.6 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 **Food Safety Act**

1990, and other subsequent legislation such as the **General Food Regulations 2004** and the **Food Hygiene Regulations 2006**, 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 himself or by a person under his control’**. 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 (GMP) will stand a very good chance of 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.

- 1.7 Responsibility for enforcement within the EU varies from country to country. In the UK it is shared between central and local government bodies. While the making of legislation in the UK is the function of central 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 environmental health officers (EHOs) and trading standards officers (TSOs).

The responsibilities of all the enforcement authorities in the UK are set out in the Single Integrated National Control Plan for the UK; this demonstrates the complexity of structures of enforcement across the UK, and the paragraphs below are a broad overview for those in food manufacturing and arrangements may be different within your geographical area or industry sector.

The Food Standards Agency (FSA) interaction with enforcement officers is set out in the Framework Agreement on Local Authority Enforcement. This document gives a structure to the Agency’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. Practical guidance is also provided as a further help to enforcement officers.

The EHOs and TSOs have to be authorised by their LAs to enforce the 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 Act 1990) to, for example, enter premises, take samples, gather evidence, issue notices and, under certain circumstances, close premises.

Depending on the structure of the 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. Visits to manufacturing sites are to ensure compliance with legislation; the frequency of interventions (visits) is assessed according to the risk assessment system detailed in the FLCP, and most manufacturing units can expect a visit at least once a year.

The actual policy and resources allocated to the inspection premises and sampling of product will depend on the LA and therefore there are variations in delivery. However businesses should be able to benefit from a positive relationship with enforcement authorities receiving detailed written feedback following inspections and receive results of sampling exercises. Companies who develop a 'Home Authority' or 'Primary Authority' agreement with their LAs can expect a more detailed and possibly, a more supportive relationship with the benefits of the Better Regulation agenda.

- 1.8 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.
- 1.9 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.
- 1.10 The Guide is an advisory document with a list of supplementary references intended to assist all grades of management. It 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.

- 1.11 GMP is not a static concept, but an evolutionary, dynamic mechanism by which overall improvements can be made and maintained.
- 1.12 Abbreviations, for example, GMP, have been used in the text 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).

