Food & Drink

7TH EDITION

Good Manufacturing Practice

A GUIDE TO ITS RESPONSIBLE MANAGEMENT

Institute of Food Science + Technology ifst

WILEY

FOOD & DRINK –
GOOD MANUFACTURING PRACTICE

A GUIDE TO ITS RESPONSIBLE MANAGEMENT

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A GUIDE TO ITS RESPONSIBLE MANAGEMENT

Seventh Edition

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Foreword

In the United Kingdom we all depend upon the food industry, our largest manufacturing sector, to deliver high standards when it comes to food that is safe to eat, and food that is what it says it is. We all want the public to be able to trust the food they eat, at home and whilst out and about. It is the industry's responsibility to ensure that food is safe and authentic, and to deliver and sustain strong foundations for public trust in food.

The 7th edition of the IFST Guide to Good Manufacturing Practice is an important resource for food businesses. With thorough and detailed guidance, it sets out how businesses meet their legal obligations and shows how to deliver public confidence and trust. I welcome the increased focus on food authenticity and integrity in this edition, which will help to protect businesses and consumers alike from the risks of food fraud. It is an area we at the Food Standards Agency are also focused on. We wish to extend the remit and scale of the National Food Crime Unit, working in partnership with other agencies, and we are revitalising our surveillance approach to keep pace with constant change in our national and global food system. Regulation needs to adopt new and innovative ways of delivering, and to keep refreshing the relationships between regulator and industry to succeed against new threats and challenges. This guide will help business get it right, and help us all deliver a safe, secure and trusted food sector into the future.

Heather Hancock
Chair of the Food Standards Agency

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Preface to the Seventh Edition

The 6th edition built on previous editions and provided additional content in the area of food safety management systems and quality management systems, their design, validation, implementation and verification. Consideration of what good manufacturing practice (GMP) is, and evolves to be, has led to the need for a number of new chapters in this 7th edition. The melamine incident in China, fipronil in eggs and the horsemeat incident 2013 in Europe has caused food manufacturing organisations, the food supply chain and those involved in wider food policy development and implementation to consider issues around food integrity, food crime and general malpractice in the food chain and how protocols to mitigate risk need to be included within GMP. The rapid development in testing programmes to demonstrate the provenance of food materials and food products means that manufacturers can now more easily verify labelling information and the claims they make on their products. As a result, the 7th edition focuses on the growing interest in food integrity management systems and how manufacturers need to demonstrate they have done everything reasonable to ensure the integrity of their products, the processes they employ, the data and information they often rely upon, and the people who undertake the tasks critical to ensuring food safety, legality and quality.

Louise Manning
7th Edition

Acknowledgements

A list of many of the organisations and individuals from whom help, information or comment has been received for this edition is presented as Appendix V. This is inevitably incomplete and cannot include acknowledgement of numerous verbal comments received. However, I welcome the opportunity to thank all who participated and particularly the members, both past and present, of the GMP Working Groups. Especially, I would thank Professor J.R. Blanchfield, who as Editor and Convener of the GMP Working Group, 4th edition, made an enormous contribution to the development of the 5th and 6th editions of this Guide.

As with the previous editions that I have edited, the preparation of this 7th edition has been an enjoyable and thought-provoking experience.

Louise Manning
7th Edition

Decision Makers' Summary

This summary is especially addressed to the decision makers within food and drink company chairmen, presidents, chief executives, directors and general managers, who are not normally directly involved in detailed design and implementation of good manufacturing practice (GMP) systems, but whose responsibility it is to establish GMP policies and strategies for their companies, and to provide the necessary authority, facilities and resources to the functional managers and staff to implement the requirements effectively.

In this Guide, GMP is considered as that part of a food and drink control operation that is aimed at ensuring that products are safe, legal, meet integrity criteria and are of the required quality. Effective GMP ensures that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with manufacturing practices, food safety, legality, quality and integrity management systems.

The ever-increasing interest among consumers, retailers, enforcement authorities and other stakeholders such as insurers or shareholders in the conditions and practices employed in food manufacture and distribution heightens the need for the food manufacturer to operate with a clearly defined strategy with high-level policies together with associated operational procedures and protocols. The ability to demonstrate that the principles and measures identified in this Guide have been fully and effectively implemented could, in the event of a product incident, consumer complaint or formal prosecution, assist the manufacturer in demonstrating that all reasonable steps had been taken to prevent the cause of the incident from occurring, or indeed avoid an offence being committed. Enlightened self-interest alone should persuade food manufacturers to follow these guidelines.

The manufacturer of a food product must comply with the relevant legal requirements of the country for which the food is intended, for example those of composition, safety, hygiene and labelling. While fulfilling these, however, she/he has a concept of the market at which she/he is aiming and its requirements (e.g. in the case of a food or drink product, its appearance, flavour, texture, presence or absence or amount of particular nutritional components, inbuilt convenience, shelf life, presentation and price). These factors determine the formulation, processing and packaging of the product. Product quality is defined in a product specification that should encompass all of these requirements and express them in a clear, unambiguous manner.

The retailer may approach a manufacturer with a new product concept and request that a manufacturer design a product or process to meet the specific criteria. Of course, the manufacturer's assessment of what the market wants may be correct or incorrect. While the concept effectively meets all of the law's requirements, it may, or may not, effectively meet purchasers' expectations, but unless and until the manufacturer or retailer changes it, the product specification remains the standard with which the product should conform, and GMP is designed to achieve this.

Uniform conformance with product specifications is difficult with food and drink products. The main raw materials for food and drink manufacture derive from nature and are subject to natural variations. In primary production, wide variations may occur among cultivars and also because of seasonal, weather and cultivation differences. In animals, apart from differences between individuals, variance between breeds and rearing systems leads to the potential for inconsistency. Therefore the additional task of the food or drink manufacturer, aided by the knowledge and skills of food science and technology, is to make a reasonably uniform product from variable raw materials by an appropriate combination of raw material selection, raw

material pretreatment, formulation adjustment and processing out variation which is outside the boundaries of the product specification.

The Basis for GMP

GMP has two complementary and interacting components: the manufacturing operations and wider management systems [which, for the purposes of this Guide, the Institute of Food Science & Technology (IFST) has designated 'food control'] (see Figure 1). Both these components must be well designed and effectively implemented. The same complementary nature and interaction must apply to the respective management of these two functions, with the authority and responsibilities of each clearly defined, agreed and mutually recognised. This is not to disregard the importance of other key functions essential to the effective functioning of a company, or indeed of those functions contributing direct services or advice to the manufacturing operation (e.g. purchasing, cost accounting, work study, production planning and engineering maintenance). These terms are explored in more detail in Chapter 2.

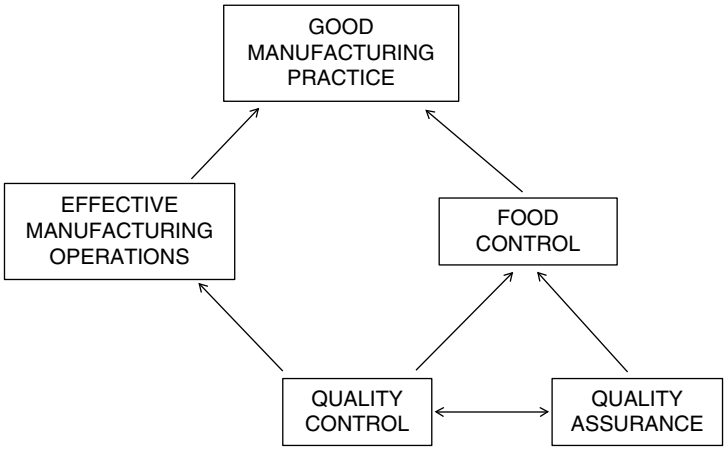

Figure 1

What constitutes 'well designed' in these two contexts mentioned above is not just a matter of common sense, or something that would be self-evident to non-technical business people. As well as management skills, it also involves extensive and up-to-date knowledge of current and emerging quality issues, food safety hazards and best practice in terms of food science and technology relating to the ingredients, processes, packaging and products concerned.

Effective Manufacturing Operations

GMP requires that every aspect of manufacture is fully defined in advance and that all the resources and facilities are specified, namely:

- specific measures undertaken at critical control points (CCPs) based on food safety hazard analysis and food integrity threat analysis, or critical quality points (CQPs) identified in the quality planning process;

- adequate design of premises and suitable manufacturing and storage space;
- suitable process flow with process design to streamline the process and minimise the potential for cross-contamination;
- correct and adequately maintained equipment;
- appropriately trained people;
- correct raw materials, processing aids and packaging materials;
- appropriate storage and transport facilities;
- documented operational procedures and cleaning schedules;
- appropriate management and supervision; and
- adequate technical, administrative and maintenance services

are provided, in the right quantities, at the right times and places, and are utilised as intended. In order to ensure that operations do proceed according to plan, it is also necessary to:

- provide operators with documented procedures in clear unambiguous instructional language (with due regard to reading, numeracy and language problems);
- train and motivate the operators to carry out the procedures correctly;
- undertake formal review to ensure that training and instruction have been effective;
- avoid, if possible, incentive bonus schemes, but, if unavoidable, to build into any incentive bonus schemes adequate safeguards against unauthorised 'short cuts' or trade-offs;
- provide a food control programme working along the lines indicated below;
- ensure that genuine records are completed during production and that they demonstrate that specified procedures were in fact complied with, and to enable the history of manufacture and distribution of a batch subsequently to be traced should a problem arise or a product withdrawal or recall be necessary;
- establish a well-planned and effective system to carry out a product withdrawal or recall, should that prove necessary; and
- establish a tried and proved business continuity and crisis management procedure in case of need.

Effective Food Control

The other and complementary major component of GMP is effective food control. Effectiveness requires:

- well-qualified and appropriately experienced individuals working in food control management participating in the development and validation of process controls and specifications that address the safety, legality, quality and integrity of food;
- competent staff and adequate facilities to undertake all the relevant inspection, sampling and testing of materials, and monitoring of process conditions and relevant aspects of the production environment (including all aspects of hygiene) and management of potential food safety hazards and food integrity threats;
- verification activities that are developed and implemented by appropriately experienced personnel in order to demonstrate that the food products and the process are consistently under the appropriate level of control and identify areas for preventive action where system weaknesses and vulnerabilities are detected; and
- rapid feedback of information (accompanied where necessary by advice) to manufacturing personnel, thereby enabling prompt adjustment or corrective action to be taken and enabling processed material to be approved as fit for either further processing or sale, or to be segregated for decision as to appropriate disposition, for example reject, regrade or reprocessing.

Responsible Management

Of course, the requirements of effective manufacturing operations and of effective food control mentioned above are merely headings and within each there are very many aspects that are considered more fully within the body of this Guide. The Institute hopes that the Guide will prove of help to the management of food and drink companies, to those concerned with private and public verification activities, food law enforcement and consumer protection, to the students who will be the food technologists, engineers and production managers of tomorrow and to those responsible for training them.

The full title of the Guide is *Food & Drink – Good Manufacturing Practice: A Guide to its Responsible Management*. The reference to responsible management is deliberate. GMP can only stem from policy firmly and uncompromisingly stated and continuously pursued by a company board and general management, which, moreover, provides adequate physical, financial and human resources for the purpose.

PART I – GENERAL GUIDANCE

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The Institute of Food Science & Technology Trust Fund.

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,

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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.[1] 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).

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

2 QUALITY MANAGEMENT SYSTEM

Principle

There should be a comprehensive quality management system (QMS), so designed, documented, implemented, reviewed and continuously improved, and so furnished with personnel, equipment and resources, as to ensure that specifications set to achieve the intended product quality standards are consistently met. The attainment of this quality objective requires the involvement and commitment of all concerned at all stages of manufacture.

Explanatory Note

2.1 A manufacturer has to comply with the legal requirements relevant to the product manufactured, both in the country where manufacture takes place and the countries where the product is destined for export. The term 'manufacturer' is used here not in an abstract sense, but instead referring to the person who has overarching responsibility for the manufacturing operation and for ensuring that good manufacturing practice (GMP) is embedded into the day-to-day operation of the organisation. From a legal perspective, it is this person, for example in United Kingdom (UK) legislation they are termed the 'business operator', that ultimately has responsibility for ensuring all food products are safe and legal. While embracing these legal requirements, she/he or their appointed designate(s) will have also determined the market requirement that she/he aims to meet, and therefore the overall product quality standards the product needs to meet.

These standards can be *intrinsic* (i.e. associated with the innate nature of the food product) or *extrinsic* (i.e. relate to the way the ingredients, or the product as a whole, has been produced and processed often prior to manufacture). Extrinsic standards can include, but are not limited to, farm production standards, worker welfare and other ethical standards, environmental standards and so forth. Thus the product specification that is established as a result embodies both legal requirements (e.g. those of composition, safety, hygiene and labelling) and market requirements (such as product nature, appearance, flavour, texture, presence or absence and quantity of particular nutritional components, nature of pack, pack size, degree of inbuilt convenience, shelf life, presentation, extrinsic standards and price and so forth). While some commercial and marketing considerations affecting the market requirement specification are outside the scope of this Guide, those relating to the principles of design and development of products and processes to comply with that specification are dealt with in Chapter 12. The product and process design, when completed and validated, then becomes a part of the full product specification. Once established it remains permanent until formally changed. All references in this Guide to compliance with product specifications imply compliance with all of

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the foregoing requirements described as being embodied in the term 'specification'.

2.2 In order to achieve the objectives of GMP, it is necessary to have in place:

1. *Quality Assurance:* that is, to design and plan, as relevant, raw material specifications, ingredients formulation, adequate resources such as processing equipment and environment, processing methods and conditions, intermediates specifications, appropriate packaging and labelling specifications, specification for quantity per pack, specifications for management and control procedures, a specified distribution system and cycle, and appropriate storage, handling and preparation instructions, which, taken all together, are capable of resulting in products consistently complying with the product specification and providing confidence that the products will consistently meet the product specification. These will form elements of the quality plan for the product (see 12.9). Furthermore, an effective verification system confirms that the quality plan, and associated quality activities, and the manufacturing operations will consistently deliver products of the specified quality both at a given point in the production process and throughout the product's shelf life.
2. *Effective Manufacturing Operations:* that is, to validate and manage the operational production/distribution practices to ensure that the capability is translated into reality, so that firstly the process itself adheres to specified design parameters and secondly that the resulting products actually do consistently comply with the product specification (see Decision Makers' Summary). This is relevant for quality, legislative and food safety criteria. Within the manufacturing operations there will be steps in the process where it is critical at that point to effectively manage quality. These points are often termed critical quality points (CQPs) and will also be included in the organisation's quality plan(s) with associated criteria, quality limits and monitoring and verification plan. Within the manufacturing operations there will be steps in the process too where it is critical at that point to control food safety. These points are often termed critical control points (CCPs) and will be identified in the organisation's food safety plan with associated preventative (control) measures, critical limits and monitoring and verification plan (see Chapter 3).
3. *Quality Control:* that is, to have in place an effective monitoring system that checks compliance with specified requirements and defines suitable corrective action in the event of 'out-of-control' occurrences.
4. *Food Control:* that is, to have in place an effective management system that ensures food safety, legality, quality and integrity criteria are consistently met (see Decision Makers'

Summary). An effective food control system requires well-qualified and appropriately experienced individuals working in food control management participating in the development and validation of process controls and specifications that address the safety, legality, quality and integrity of food; competent staff and adequate facilities to do all the relevant inspection, sampling and testing of materials, and monitoring of process conditions and relevant aspects of the production environment (including all aspects of hygiene) and management of potential food safety hazards and food integrity threats; verification activities that are developed and implemented by appropriately experienced personnel in order to demonstrate that the food products and the process are under the appropriate level of control; and rapid feedback of information (accompanied where necessary by advice) to manufacturing personnel, thereby enabling prompt adjustment or corrective action to be taken, and enabling processed material to be approved as fit for either further processing or sale, or to be segregated for decision as to appropriate disposition, for example reject, regrade or reprocessing.

Good Manufacturing Practice

2.3 Thus, GMP may be viewed as having two complementary components, namely effective manufacturing operations and food control (see Figure 1).

Food Integrity

2.4 The Elliott Review of 2014 considered the integrity and assurance of food supply networks. The Review was written following the 2013 European horsemeat incident where horsemeat was substituted for beef in a range of products. The report produced as a result of the Review stated that food integrity was not only concerned with the nature, substance and quality and safety of food, but also involved other aspects of food production such as the way food has been 'sourced, procured, and distributed and being honest about those areas to consumers'.[1] The design of food integrity management systems (FIMS) in food manufacturing is in its infancy as this version of the Guide is being written. The writing of a Codex Alimentarius Commission Standard that focuses specifically on food integrity has begun, but its issue will postdate this Guide. Food crime, the design of FIMS, food crime risk assessment, security and countermeasures are addressed in Chapters 5 to 7 of this Guide.

Quality Management Systems

2.5 Many manufacturers will have developed their own QMS, but increasingly are attaining or seeking to attain certification to a private QMS standard. EN ISO 9000:2015 is an international standard concerned with QMS design, and it describes the requirements of a QMS to assure conformance of product and

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/350726/elliot-review-final-report-july2014.pdf.

production to specified requirements. BS EN ISO 22000:2005 is a complementary standard that addresses food safety management systems (FSMS) and the requirements for any organisation in the food chain. As a result of the increasing globalisation of food production, other private QMS standards have been developed specifically for food manufacturing. These include the British Retail Consortium (BRC) Global Standard for Food Safety. The Global Food Safety Initiative (GFSI) Standard has been developed to benchmark international private standards and both of these documents are referred to within this Guide.

Effective Manufacturing Operations

2.6 An effective manufacturing operation is one where, as appropriate:

(a) the manufacturing process, equipment, activities, precautions and so on are fully specified in advance, and systematically reviewed in light of experience;
(b) the necessary facilities and resources are provided, including:
  (i) appropriately qualified personnel,
  (ii) adequate premises and space,
  (iii) suitable equipment and services,
  (iv) specified materials, including packaging,
  (v) specified policies and procedures, including cleaning procedures, and
  (vi) suitable storage and transport;
(c) the relevant written procedures are provided in instructional form and using clear and unambiguous language, and are specifically applicable to the facilities provided;
(d) operators are trained, instructed and motivated to carry out the procedures correctly, and refresher training is undertaken at appropriate intervals;
(e) records are made (whether manually, by recording instruments or both) during all stages of manufacture, which demonstrate that all the processing steps required by the defined procedures were in fact carried out, and that the quantity and quality of product produced were those expected;
(f) records are made and retained in legible and accessible form, which enables the history of the manufacture and distribution of a batch to be traced;
(g) a system is available to withdraw or recall from sale or supply any batch of product, if that should become necessary; and
(h) a review system is in place to consider actual operational performance against proposed performance and drive the implementation of appropriate preventive and corrective action where appropriate.

Quality Control

2.7 Quality control is the function concerned with determining the compliance of finished products with specifications and with the activities ancillary thereto. It includes the undertaking of inspections and tests to determine the degree of compliance with specifications, the examination of process control data and the provision of rapid information and advice leading to corrective

action where necessary. It is therefore a 'lag' activity designed to detect product and process failure rather than, in the case of quality assurance activities, to prevent product and process failure in the first place. The term is also used to designate the department responsible for this function within a manufacturing organisation. What is described in this guide in terms of quality control personnel and their activities does not preclude automatic process adjustment by negative feedback from automatic process monitors/recorders, or production operators receiving such information on-screen and then taking appropriate action, provided that they are suitably trained, and that such procedures are written into the quality control system and that any actions undertaken by personnel are recorded.

Food Control

2.8 The Institute of Food Science & Technology (IFST) uses the term 'food control' to describe a comprehensive system that encompasses the QMS, the FIMS and a FSMS based on the principles of hazard analysis critical control point (HACCP). It is vital that the FIMS and the FSMS, and associated prerequisite programmes (PRPs) and countermeasures (see Chapter 7), interlink with aspects of quality assurance and quality control within the QMS that are appropriate to the products and processes involved and the inherent level of food safety and food integrity risk (see Chapters 3 and 6).

In describing the role of the quality manager below, it is recognised that alternative job titles may be used in a particular setting, but it is important for all food manufacturing organisations to distinguish clearly the management roles of quality assurance (failure prevention) and quality control (failure detection), especially where these are in practice managed by the same person. Effective food control requires that, where appropriate:

(a) the quality manager participates, with others as necessary, in the assurance role of development and approval of specifications, liaising with suppliers in agreeing product specifications and service requirements, and the control function of assessing and approving suppliers on the basis of their ability on an ongoing basis to supply reliably in compliance with the specifications;
(b) adequate resources, facilities and staff are available for sampling, inspection, testing and sensory assessment of starting materials (including packaging materials), intermediates and finished products, and for monitoring process and storage conditions and relevant aspects of the production environment (including all aspects of hygiene);
(c) all samples used for inspection and testing are representative of the batch being sampled, and are collected by personnel under the direction of, and examined with methods approved by, the quality manager. The results of such examination(s) need to be formally assessed against the specification by the

quality manager or a competent person designated by him/her to undertake the task;

(d) established procedures are developed, validated, implemented and verified that ensure starting materials and all intermediates are approved unconditionally for use, alternatively are rejected or thirdly designated for a treatment that is intended to bring them within specification, in line with any inspection/test results obtained;

(e) there is rapid feedback of information (accompanied, where appropriate, by advice) to manufacturing personnel, enabling prompt adjustment or corrective action to be taken when necessary, and, in the case of raw material, rapid feedback to the purchasing/procurement function;

(f) a positive release procedure exists, where appropriate, whereby batches of finished products are temporarily quarantined until formally released for rectification, or into normal stock, or for distribution. The use, or lack of use, of a positive release procedure should be determined by an appropriate risk assessment process which is formally undertaken, documented and then reviewed at a frequency deemed necessary in light of operational changes or incidents that may occur;

(g) sufficient reference samples of raw materials and packaging, or records of the result of their inspection, where deterioration could occur, should be retained to permit future examination and analysis, if necessary;

(h) sufficient reference samples of finished products are retained for shelf-life tests and to permit future examination and analysis, if necessary;

(i) customer/consumer complaint samples are examined, the causes of defects are investigated where possible, and appropriate measures are advised and implemented for appropriate corrective action to prevent recurrence;

(j) summaries of quality performance data, in an appropriate form, are provided by quality control to operating functions (e.g. general management, production management, purchasing and cost accounting). These summaries may provide input in the determination of food safety and quality objectives for the business whereby data are routinely analysed to determine performance against defined targets and potentially identify areas for improvement;

(k) a direct interest is taken in the activities and quality assurance procedures of the suppliers of raw materials and packaging materials, and close contact is maintained with their quality assurance departments;

(l) ongoing contact is maintained with the relevant enforcement authorities and matters raised by them are investigated and responded to; in the UK the Food Standards Agency (FSA) and the 'Home Authority' will provide useful contacts;

(m) due heed is taken of new developments in food legislation, especially on changes in compositional standards and labelling

requirements that may necessitate changes to specifications for raw materials or finished products, and on European Union (EU) and UK Government proposals for future food legislation and in the countries to which the food manufacturer exports; and

(n) the authority and responsibilities of the production management and the quality management functions, respectively, are clearly defined so that there is no misunderstanding (see Chapter 17).

3 HAZARD ANALYSIS CRITICAL CONTROL POINT

Principle

There should be a comprehensive food safety management system (FSMS), so designed, documented, implemented and reviewed, and so furnished with personnel, equipment and resources, as to ensure that critical limits set to achieve the intended food safety standards are not exceeded. The attainment of this food safety objective requires the design, development and implementation of a hazard analysis critical control point (HACCP) system specific to the manufacturing process and the commitment of all staff to its adoption at all stages of manufacture.

Hazard

3.1 A food safety hazard is an agent or material with the potential to cause harm to the consumer. Classic hazard analysis defines three types of food safety hazard: biological (otherwise called microbiological), chemical and physical. This basic classification of food safety hazards needs to be set in the context of emerging hazards and further hazard types being identified in the future which do not fit easily into this classification, which was developed over half a century ago. Food allergens are constituents of a given food, such as inherent proteins, that have the potential to cause an allergic reaction when handled or consumed by an individual who is sensitive to the said agent (see Chapter 8). In some reference and private system standards, allergens are defined as a separate category of food safety hazard whilst in other documents they are included within the category of a biological hazard. *Intrinsic food safety hazards* arise from the product itself, for example fruit stones, fish bones, bone fragments in meat, or as previously described proteins that can cause an allergenic reaction and so forth. *Extrinsic food safety hazards* arise from people, the manufacturing environment, waste and/or other products being manufactured such as glass, metal, wood, ceramic etc.

Hygienic Practice and Prerequisite Programmes

3.2 The 'hygiene package' of five laws adopted by the European Union (EU) in 2004 aimed to merge, harmonise and simplify the complex hygiene requirements that were hitherto contained within 17 EU Directives. The aim was to create a simple, transparent hygiene policy applicable to all food and all food operators together with effective instruments to manage food safety and food safety management throughout the supply chain. The new hygiene law has applied in member states since 1 January 2006.

Good hygienic practice (GHP) is critical to every aspect of good manufacturing practice (GMP), and throughout this Guide it has been treated as a continuous theme and has deliberately not been made the subject of a separate chapter. The Codex Alimentarius Commission (CAC) recommended international code of practice General Principles of Food Hygiene CAC/RCP 1-1969 (2003; Rev 4) lays down the foundation for ensuring GHP,

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The Institute of Food Science & Technology Trust Fund.

and key aspects are addressed in this Guide. The term for prerequisite programmes (PRP) is often used to identify the procedures, policies and protocols that need to be in place within a food organisation before a HACCP plan can be designed and implemented. A number of these requirements are detailed in the previously mentioned CAC/RCP. Examples of PRPs include GHP, GMP, good agricultural practice (GAP), good distribution practice (GDP) etc. These PRPs contain a number of protocols and standards that define best practice for the construction and layout of buildings, premises, workspaces, storage and transport, personal hygiene protocols, premises hygiene and sanitation procedures, maintenance programmes, calibration, training and pest control programmes, procurement procedures and so forth. The ISO/TS 22002-1:2009 *Prerequisite programmes on food safety – Part 1: food manufacturing* specifies requirements for establishing, implementing and maintaining PRP to controlling food safety hazards. The standard was designed to assist organisations seeking to establish, implement and maintain PRP in order to meet the elements of BS EN ISO 22000:2005 *Food safety management systems: Requirements for any organisation in the food chain*. For further details, consult the Campden BRI Guidelines *Food safety plans: principles and basic system requirements* (2016, Guideline 76, ISBN 978090750388). It is essential that the food business operator or their designate is fully conversant with the requirements of PRP establishment, implementation and verification as they underpin the development of food safety management systems (FSMSs) and good integrity management systems (FIMSs). Whilst the senior management team may delegate the day-to-day operations of FSMSs and FIMSs, they ultimately have the responsibility to ensure they are appropriate for the products manufactured and have been suitably, consistently and effectively implemented. The use of HACCP as a risk assessment tool is only the first step to developing an effective FSMS.

HACCP

3.3 With regard to current legislation in the EU, during the design and implementation of manufacturing operations and control procedures, **HACCP principles must be applied as defined in the EU Regulation (EC) No. 852/2004 of the European Parliament and of The Council, in which Regulation 1 requires:**

- **general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;**
- **guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the [seven] HACCP principles.**

Regulation 2 (a) to (g) defines those [seven] HACCP principles. An EU Regulation has immediate force on the due date in all Member States. Provisions for enforcement and penalties in the

UK are contained in the Food Hygiene (England) Regulations 2005 and similar Regulations for Scotland, Wales and Northern Ireland (as amended).

3.4 It takes more than common sense or business acumen to be able to comply with these legal requirements. In large- and medium-sized food business establishments, it requires suitable numbers of appropriately qualified and experienced personnel. Even in the smallest food business, it is extremely important that the proprietor or some other responsible person has been trained in the principles of food hygiene and food safety, at least to Level 3 standard. There must be senior management commitment to utilising HACCP, which will be implemented through the operation of the FSMS. This means that senior management must commit the resources required to ensure a FSMS is appropriately developed and implemented, and is effective.

Although food safety is the most important factor considered here, the planning and control principles outlined in this chapter are also applicable to preventing or minimising defects during the quality planning process in respect of intrinsic and extrinsic quality attributes too (see Chapter 12).

3.5 The HACCP system and guidelines for its application is published in the *Codex Alimentarius Commission Food Hygiene Basic Texts* (ISBN 9251040214) and identifies seven principles of HACCP:

1. Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards can occur and describe the preventive measures.
2. Identify the critical control points (CCPs) in the process.
3. Establish critical limits for preventive measures associated with each identified CCP.
4. Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.
5. Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit.
6. Establish effective record-keeping procedures that document the HACCP system.
7. Establish procedures for verification that the HACCP system is working correctly.

3.6 In order to undertake HACCP a multi-disciplinary team should be drawn together. The HACCP team needs to contain personnel who have expertise in areas such as production, engineering, quality control, product technology and procurement. The team

members need to have relevant practical experience, knowledge of the products and processes within the study and suitable training on how to undertake a HACCP study and the implementation of HACCP principles. At least one member of the team should have formal HACCP training, but all team members need to be trained on how to utilise HACCP principles in assessing how a food product should be manufactured in order to minimise the potential for a food safety incident occurring. The team is also responsible for ongoing review and management of the HACCP system. In the event that external expertise is sourced to assist with either the development or the maintenance of the HACCP system, it is critical that the management team should not delegate responsibility to the external resource. The management of the HACCP system and the development and implementation of the food safety control system remain the responsibility of the manufacturing organisation. The quality of the external expertise should be formally assessed, including the amount of experience in the food industry and the provision of appropriate references from current clients.

3.7 The scope of the HACCP plan(s), that is, the products produced and processes undertaken at the manufacturing site, should be detailed. Relevant information about food products is usually recorded in a product specification. Product specifications should be reviewed to ensure that they contain the relevant information before the start of the HACCP process and if required should be updated. Relevant information includes:

(a) product composition in terms of ingredients, including the origin of ingredients, nature of the item in the case of fruit or vegetables, whether or not the ingredients or the product itself are, or contain allergens;
(b) the physical and chemical attributes of the food, including those that might limit microbial growth, e.g. salt or sugar content, pH or water activity;
(c) packaging type and standards, e.g. gas modified atmosphere, aseptic packaging or vacuum packed;
(d) storage and distribution requirements;
(e) instructions for use;
(f) intended consumer target group, e.g. the general population or a specific group that may be more vulnerable to the food safety hazards being assessed; and
(g) shelf life and nutrition information.

The nature of the treatment and processing of the ingredients and final product undertaken (e.g. cooking or other heat treatment, chlorine washing, blanching, cooling, freezing, metal detection etc.) may also be defined in the product specification, or an alternative document. This information is especially critical where process activities are specifically designed to reduce the likelihood of a food hazard occurring or surviving the processing treatment, for example heat treatment and foreign body detection.