The Setting Up of
Traceability and Product Recall
Systems in a Local Bakery

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Dedicated to my parents
And my sisters, Louise and Dorian
I, the undersigned, hereby declare that the following dissertation is entirely my own work supervised by Ms Marianne Fenech B. Pharm (Hons).

Clive J. Tonna
**Acknowledgements**

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Abstract

Food crisis in Europe during the past years, such as dioxin in chicken feed and mad cow disease, have raised doubts in the consumer’s mind and created a lack of trust and confidence in products put on the market.

Traceability of foods has emerged over the past years, both locally and abroad as a voluntary and regulative framework to bridge the gaps between farmer, food producer, food retailer and consumer. Nowadays traceability has been translated into regulation in many countries including Malta. Today, European legislation such as Regulation (EC) 178 of 2002, which has been transposed into local legislation, constitutes a set of requirements that each company manufacturing, distributing, importing and/or exporting products to and from Europe must comply with.

There are various definitions of traceability, however they all relate to traceability as a system of recordkeeping designed on the ‘one step back - one step forward’ approach. This means that a traceability system must be designed in such a way so as to be able to track and trace the flow of a product or product attributes through the production process or supply chain.

Traceability is related to:

- The origin of food products and ingredients;
- The processing and production methods;
- The relevant distribution and location of the food product after each delivery.
In a modern food industry plant, where hundreds of tonnes of food ingredients may
pass through the factory every day, traceability is an integral part of the safety
standards that ensure that the production meets required hygiene and composition
standards. In the past 10-15 years, computer technology has made traceability of
food possible in new and innovative ways.

In the food industry, food safety problems can lead to expensive product recalls due
to the immediate health risks posed to consumers. Regulations require that if a
problem is found in a food product, food batch or lot, it triggers a total product recall
as all supermarket shelves must be cleared as soon as possible. Locally, regulatory
agencies request that a recall be completed within forty eight hours. Usually, the
producer cannot immediately find out exactly where the problem originated or how
many products are contaminated unless a food safety management program and a
traceability system are in operation.

Total product recalls are a costly measure that attracts media attention. It can do
irreparable harm to a supplier or brand in terms of reputation and consumer
confidence. A massive and highly publicised recall can erode a company’s
shareholder value and market share. Furthermore, due to globalisation, a problem in
an ingredient or food commodity can affect the world’s food trade. Often, consumer
confidence is shaken so severely that enormous amounts of money must be spent to
regain credibility. A more limited or specialized recall, based on product
traceability, can save lives, reduce costs and even limit brand damage. A company
with such systems in place will also command greater respect and loyalty from their
suppliers, retail customers and consumers.
The study concentrated on the setting up of a traceability and recall system in one of the largest bakeries on the island. Current traceability and recall systems at this bakery were assessed and new systems were developed. A paper based traceability system and a semi automated traceability system based on supplier traceability; process traceability and customer traceability were designed. The IT enabled system was preferred by the company to the paper system due to its efficiency, effectiveness and security. Through this system the objective of a traceability system is attained.

A recall plan complete with a set of forms was also drafted to assist the bakery to rapidly and completely remove unsafe, mislabelled or other defective food products from household, retail and/or commercial availability. The Recall Plan was compiled in conformity with Guidance Note No.10 entitled Product Recall and Traceability published in 2002, by the Food Safety Authority of Ireland in view of the fact that guidelines are not available locally.
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Introduction
Introduction

Trends in global food production, processing, distribution and preparation present new challenges to food safety. Food grown in one country can now be transported and consumed halfway across the world. Today people demand a wider variety of foods, they expect foods that are not in season and often dine out. Food safety must be considered across the entire food chain using measures based on scientific findings.

Food safety programmes are increasingly focusing on a farm-to-fork approach as an effective means of reducing food borne hazards. This holistic approach to the control of food-related risks involves consideration of every step in the chain, from raw material to consumption and includes traceability.

A few years ago, food traceability was rarely discussed outside a very small circle of experts. Today traceability has been translated into regulation moving this topic to the front burner. One of the drivers behind this legislation has been the need to react more quickly in the event of major food contaminations, either natural or intentional. Speed in responding to a contamination determines the extent of negative impacts (Boyle et al., 2003).

European Union has fastened on traceability and labelling as solutions to low consumer confidence in the safety of its food supply. Europe has been battered by one food crises after another: mad cow disease, dioxin in chicken feed, foot-and-mouth disease, residues of banned herbicide in organic chicken feed, BSE in cattle, Salmonella and Listeria in fresh produce and bioengineered food products (Genetic
Modified Organisms) amongst others. Food scandals have toppled European governments, caused cabinet ministers to resign and forced a major overhaul of the European Commission, the European Union’s executive branch (Clapp, undated).

These food crisis in Europe have raised doubts in consumer’s mind and created a lack of trust and confidence in products placed on the market. Awareness of consumer has probably never been so high (Leahy et al., 2004). Hence there is an increased demand by the consumers for an accurately documented history of any product in the food chain to ensure food safety and make food producers and handlers accountable for their product.

These same food safety crises showed that it was time to replace what has become a patchwork of rules within the European Union with a simpler and more comprehensive approach. The result was a new piece of legislation known as the General Food Law – Regulation (EC) 178 of 2002 which amongst other things introduced the concept of traceability. This European Commission Regulation has been transposed into local legislation. In other words, food and feed businesses – whether they are producers, processors or importers – must make sure that all foodstuffs, animal feed and feed ingredients can be traced back right through the food chain, from farm to fork. Each business must be able to identify its supplier and which businesses it supplied. This is known as the ‘one-step-backward, one-step-forward’ approach. However, internal traceability within a business, such as linking incoming batches of ingredients to outgoing batches of products, while both good practice and highly desirable, is not a legal requirement. Information on
supplies to a final consumer, such as occurs in retail setting, are also not required (EC, 2004).

Furthermore, European Commission set up the European Food Safety Authority to bring under one roof the work previously done by a range of scientific committees and to make the scientific risk assessment process more public and reinforced the rapid alert system which the European Commission and EU governments use to act quickly in the event of a food and/or feed safety scare (EC, 2004).

Good product quality and product safety contribute to build up consumer confidence and consequently strengthen the image of a company or a brand in the consumer’s mind. Failure to respect consumer’s needs and expectations may lead, in the long term and the worst case, to damage of a company and its brand image and in some cases for the business partners and the whole industry. This is what is at stake when quality and safety are compromised.

However, despite all the efforts deployed to ensure optimum product quality and all the precautions taken every day, incidents do happen where inappropriate products reach consumers. Once identified, it is the onus of the producing company to identify such product and rapidly locate and remove from the market. This principle is linked to the ability of a company to trace products along the supply chain, to withdraw them from distribution whenever necessary and recall them from consumers whenever required (Leahy et al., 2004).
My project deals with the setting up of a traceability and recall systems in one of the largest bakeries on the island. The aim of the study is to assess present traceability and recall system at this bakery and develop or recommend changes, if any, so that the minimum traceability and withdrawal requirements mandatory since 1st January 2005 will be fulfilled.
Chapter 1

General Overview of Traceability

1.1 What is traceability?
1.2 Why is traceability needed?
1.3 How is traceability implemented
1.4 Traceability in practice
1.5 The missing links
A General Overview of Traceability

1.1 What is traceability?

According to the Webster’s Dictionary, ‘Traceability’ is “the ability to follow or study out in detail, or step by step, the history of a certain activity or a process”.

A more rigorous and targeted definition was provided by the International Organization for Standardization (ISO standard 8402:1994) and supported by EC regulation 178 of 2002, which defines ‘Traceability’ as “the ability to trace and follow a food, feed, food producing animal or ingredients, through all stages of production and distribution”. Under this regulatory framework, enforced in 2005 a much higher burden of responsibility will be placed on all links of the production chain of food for human consumption, starting with the farmers and food producers and ending up at the market. Thus, traceability is generally viewed as a potential risk management tool for public health purposes.

Codex Alimentarius Commission of the Food and Agriculture Organisation and the World Health Organisation, which promotes the co-ordination of international food standards, adopted a definition of traceability/product tracing during its annual meeting held between 28th June and 3rd July 2004 in Geneva, Switzerland. The definition, which has been approved by the Codex Committee on General Principles, states that ‘Traceability/product tracing is the ability to follow the movement of food through specific stage(s) of production, processing and distribution (personal communication).
Traceability enables consumers to be provided with targeted and accurate information concerning products. This is especially important in cases where the consumer is willing to pay a higher price for products that are produced under certain guaranteed circumstances such as organically produced food or that are coming from a desired origin. Thus, source verification, supported by proper labelling, is part of the traceability process and provides the ability to trace products from their initial components (for example, from seeds) through a production and distribution system to the end user.

Traceability should provide a verifiable documentation for an effective food control system and should aim at limiting the discontinuity of the information throughout the food supply chain. In practice, the term traceability stands for a system of recordkeeping and documentation by operators that enables tracking of the movement of a product or ingredient through the production and distribution.

1.2 Why is traceability needed?

Local statistics on food safety, as can be seen in annex 1, show that many people are affected by food borne illness yearly. This results in strong loss of confidence towards production processes from the consumer side. There is a general belief that consumer confidence will be restored if food products are clearly labelled and ingredients can be traced backward to the source and forward to the customer. Breakdown in good manufacturing practices can have far-reaching repercussions, and withdrawals of particular foods are sometimes necessary to protect public health. It is much easier, and straightforward for the industry, if the batches of food in question can be identified and their process of production traced and verified.
Furthermore, many researchers endorse the premise that the further away from the true biological cause a measurement system gets, the more likely it is that the effect can be the result of other causes (Sarig, 2003). Thus, a traceability system is required to ensure that all the chain process effects are addressable and measurable. Measurement of only down-stream effects would impair the consumer’s capability to identify the various “players” accountability for the safety of the product.

In most countries, traceability of foods have emerged over the past century as a way to produce and market high-quality foods, including bread, sausages, cheese, oils and wine of a specific origin. For example, geographical or regional indicators point to varieties of grapes or olives that can yield foods that are sought after by consumers in food stores at a large distance from the actual production. Certain regions, like Champagne or Cognac in France, depend on identity preservation schemes and batch traceability as products are traded and sold to consumers. Nowadays, single bean chocolate and coffee from certain varieties or regions are commanding premium prices in many markets.

A study carried out by the British Food Standards Agency suggested that robust traceability systems in the food chain allow food, ingredients, feed and animals to be effectively and reliably traced and thus, play an important role in protecting consumer’s interests with regard to food safety and public health.

1.3 How is traceability implemented?

The system of traceability should allow for an effective tracking methodology from the source materials to the end product or ‘from farm to fork’, which will include traceability models to ensure the products’ compliance with the established
requirements. It consists of collecting all relevant data pertaining to the history of a product and the development of an easily accessible information system that will cover all stages of the ingredients to processing to distribution of a food product. Thus, it is a major issue of knowledge management, which in essence is a question of collecting and then connecting the dots.

Collecting all the relevant data entails a measuring capability of all relevant factors that relate to safety issues. It should be characterized by fast and cost-effective performance, user’s friendly and remote sensing if necessary.

1.4 Traceability in practice

The realized great importance of traceability has prompted the development of many systems, codes and procedures, following specific procedures and set of rules that may differ from each other.

The issue of knowledge management pertaining to traceability is a major one, since it involves dealing with an exceptionally high volume of data. It has been already addressed in part by several companies and organisations in different places in the world, but unfortunately, with no contact, cooperation, or attempts to coordinate the development work. Nevertheless, the results of some of these uncoordinated works have been implemented already in their respective countries and may be incorporated in the future in a universally accepted information management system, if and when developed.

An on-line management network – ‘AGROSAFE’ has been developed, for example, in Israel, to assist all levels of the agricultural production chain in the monitoring and documentation conforming to the EUREPGAP standards, as well as facilitating
daily crop management. It is an innovative, internet-based system, designed to provide a multi-directional flow of data, shared (upon predetermined authorization) between growers, packing houses, marketing chains and consumers (Sarig, 2003).

The National Food Research Institute in Japan has developed the ‘SEICA’, which is the XML web service system, in which any grower can easily create a catalogue of his produce on the web site. The system issues a unique catalogue number for each registration of the catalogue. With the catalogue number and web site address of SEICA attached to the produce, product identification is achieved at any place and any time (Sarig, 2003).

Two data collecting system addressing the safety of the product have been developed in France. ‘Tracenet’ is a database which defines a unique standard of potato production with respect to the safety of the product; and the Agri Confiance scheme: the ‘SIREME’ project, developed by CEMAGREF aimed at organizing traceability between organizations of growers (Sarig, 2003).

The European Commission of Standards (CEN/TC) published a pioneering work of a traceability protocol in October 2002 in its standard for the “Traceability of fishery products – Specification of the information to be recorded in captured fish distribution chains”. The Tracefish concept, an electronic system of chain traceability, was developed under the patronage of the European Commission in its Concerted Action Project QLK1-2000-0064.

As its starting point, the TraceFish team adopted the ISO definition of traceability and applied it to sea fish and farmed fish chains. The ISO definition is far more powerful than that in the EU principles of food law, as it includes the constituents
and processing history of products – what the food is made of and what has happened to it, not merely, where it has been. This is crucial for food safety and for a number of other reasons such as labelling (Olsen, 2003).

The outbreak of the BSE disease prompted the initiation of several systems for tracking livestock, especially beef, and some of them are well advanced. Certain criteria have been already identified, and major beef producing countries, such as Brazil, Argentina, Australia, UK and Ireland, has agreed upon specified, and proposed regulations. These include identification (classification-type, gender and age; origin) labelling (name of cut; weight; price; packaging date); information procedure-data collected, processed, stored and made publicly available whenever necessary, and certification and auditing (Sarig, 2003).

The milk sector has also been active in putting in place a number of traceability systems. Some of the large distribution companies of milk in Italy and their derivatives are already offering product traceability systems that keep track of: milk hauling in the farms and management of the herd at the farm of origin; storage tanks used for handling the milk and even the processing of milk products. Likewise, the application of radio frequency identification (RFID) technology to the consumer goods supply chain in the U.S. is approaching a major milestone. By attaching tiny microprocessors and antennas to products and packages, goods can be traced throughout their path in the supply chain. Ultimately, each item can be identified by a unique electronic product code (EPC) contained in the memory of the chip. While this technology is not available yet to a single food produce (but applicable to food packages), it is conceivable that with further development, all food products could be included. However, no solution is available yet to the data proliferation, which is
more than can be handled by current networks, once the technology is broadly applied at the item level (Sarig, 2003).

1.5 The missing links

While traceability is both recognized, and the concept established by the European Union, the U.S. and several other countries, the means of achieving full traceability has not been determined. A clear definition is still missing on what products, what information and which agri-food chains are to be traced. Traceability, where and if applied, is nationwide in scope with different approaches, not only between Europe and the U.S., but also within the EC countries. Many non-EU countries see traceability as disproportionate and thus claim that it is unlikely that there will be any international agreement on mandatory traceability in the near future. Many claim that governments should no longer be the primary gatekeepers of the safety of a food supply that has grown internationally more diverse and exotic. Instead, consumers should increasingly rely on those selling food to keep it safe.

Moreover, a great disparity exists between developed countries, which recognize the importance of food safety (and are ready to pay for it) and less developed countries for which the mere availability of food takes priority over food safety.

There is also a concept mix up of quality with food safety issues. These two have obvious links, but food quality is primarily an economical issue decided by the consumer, while the food safety is a governmental commitment to ensure that the food supply is safe for consumers and that food and feed meet foreign and domestic regulatory requirements. Unfortunately, no coherent, uniform, well-established and internationally accepted procedure is yet available. In fact, there is already inflation
A prudent implementation of the traceability process entails the establishment of a common approach to all aspects of traceability. Subsequently, the development of a generic framework, based on a range of simple principles that will take existing systems into account and ensure smooth and efficient transfer of information through every stage of the chain.

An efficient transfer of information requires both, diverse capabilities for measurement-methods and instrumentation, and appropriate IT procedures. Both, unfortunately, are not adequate at present in less developed countries.
Chapter 2

Overview of Regulations and Guidelines on Traceability and Withdrawal

2.1 Regulation (EC) 178 of 2002
2.2 Food traceability guidelines as set out by European Union
2.3 Guidelines No. DPH/XII/05
2.4 Regulation (EC) 1935 of 2004
Overview of Regulations and Guidelines on Traceability and Withdrawal

The following is an overview of regulations and guidelines on traceability and recall. The following regulations and guidelines issued by the European Commission and the local Food Safety Commission have been considered for the purpose of this study:

1. Regulation (EC) 178 of 2002  
2. Guidance on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law  
3. Guidelines No. DPH/XII/05  
4. Regulation (EC) 1935 of 2004

2.1 Regulation (EC) 178 of 2002

This Regulation was adopted by the Council of Ministers on 28 January 2002. It came into force on 20 February 2002, but certain provisions will not apply until significantly later. This is a regulation and as such will be directly applicable to Member States and will therefore does not need implementing legislation. However this Regulation requires that Member States ensure that existing National Legislation conforms to the Food Law Principles contained within it by the 1 January 2007 at the latest.
Chapter I of this Regulation covers the Scope of the Regulation and establish important definitions, which are now legally binding definitions (since 20 February 2002) across the community. The Regulation is intended to provide the basis for the assurance of a high level protection of human health and consumers' interest in relation to food. It establishes common principles and responsibilities and makes it clear that it will apply to all stages of production, processing and distribution of food and feed. It contains definitions of food, feed, retail, food and feed business. It also defines risk, risk assessment, risk analysis, risk management and risk communication, hazard, traceability together with a number of other important definitions (Griffiths, 2002).

Chapter II of the Regulation lays down the general principles of food law and lays down the general requirements of risk analysis. It states in equivocal terms the precautionary principal which stated simply means 'if in doubt, take the safe option'. Articles covering the protection of consumer interest and the need to demonstrate transparency by consultation and public information are also laid down. Articles now in force cover food and feed imported into the Community, food and feed exported from the Community and international standards. Importation into the Community must comply with the relevant requirements of food as laid down in the Community or as recognised by the Community to be at least equivalent thereto. Community food law must apply to food and feed exported unless otherwise requested by the authorities of the importing country (Griffiths, 2002).

The Regulation also imposes a number of responsibilities and requirements on food and feed businesses such as traceability, product recall and withdrawal, and the
notification of unsafe food to competent authorities. These responsibilities and requirements contained within articles 14 to 20 of the Regulations came into effect since 1 January 2005. The industry is still coming to grips with these legal requirements.

The numerous food scares within the Community have shown that the functioning of the internal market can be jeopardised, where it is impossible to trace food and feed. The cost of not having traceability led the European Commission to act. The Commission believes that it is necessary to establish a legal framework to require food and feed businesses to establish comprehensive systems of traceability. These should be so targeted that accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems (Griffiths, 2002).

Article 2 of the Regulation contains the definition of ‘food’.

- **Food** includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

‘Food’ shall not include:

(a) feed;

(b) live animals unless they are prepared for placing on the market for human consumption:
(c) plants prior to harvesting:
(d) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2):
(e) cosmetics within the meaning of Council Directive 76/768/EEC (3):
(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971:
(h) residues and contaminants.

Article 3 of the Regulation contains the following relevant definitions:

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

- **Food business operator** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

- **Risk assessment** means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.
**Traceability** means the ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

**Final consumer** means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

**Primary production** means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

**Stages of production, processing and distribution** means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed.

In summary Regulation (EC) 178 of 2002:

- Gives principles on how food operators have to ensure traceability: the principle of tracking and tracing one step backward and one step forward.
- Regulates that food and feed operators are responsible for the feed, food and products they put on the market.
Is applicable to products imported into and exported out of the EU Community.

Establishes the European Food Safety Authority, who may demand information from food operators.

Imposes 1st January 2005 as the deadline for conformance by all food operators (Leahy et al., 2004).

The Articles of the European “General Food Law” that deal with traceability are Articles 13, 14, 17, 18 and 19. The statements set out in these articles represent the minimum requirements that each company needs to implement in order to comply with the law.

The following are some of the key extracts from the Regulation:

Article 13: The legal text says: “Without prejudice to their rights and obligations, the Community and the Member States shall:

(a) Contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;

(b) Promote the coordination of work on food and feed standards undertaken by international governmental and nongovernmental organisations;

(c) Contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;

(d) Give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries:
(e) Promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced."

Article 14: It says that food placed on the market should be safe. It also clearly states that a traceability system where batch or lot traceability is not used will result in the withdrawal of all items produced of a specific product as a result of an incident or crisis. If the problem cannot be attributed to a specific product batch or lot, then the entire production must be withdrawn. The level of traceability, measured through lot numbering and the defined size of lots is a decision to be taken by every individual business along the supply chain (Leahy et al., 2004).

The legal text says: "Food shall not be placed on the market if it is unsafe." "6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe."

Article 17: relates to the responsibility and ability of food and feed business operators to ensure that foods and feeds satisfy the European requirements and verify that such requirements are met at all stages of production, processing and distribution under their control (Leahy et al., 2004).

The legal text says: "Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure
that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution."

Article 18: relates to the responsibility and the permanent ability of each food and feed business operator to trace one-step backward and one step forward. The main requirements are that: each food and feed business operator must be able to identify at any time of the process who (i.e. any person) has supplied them with what (i.e. any food, any feed, any food-producing animal or any substance intended to be, or expected to be incorporated into a food or feed) and must be able to identify the businesses to which their products have been supplied.

A food and feed operator is responsible for making the required information available to the competent authorities on demand.

Food and feed placed on the Market must be adequately labelled or identified to facilitate its tracing (Leahy et al., 2004).
The legal text says: "The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures, which allow for this information to be made available to the competent authorities on demand. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions."

Article 19: relates to the necessity for each food and feed operator to have proven withdrawal / recall and crisis management procedures. The main requirements are that:

1. Each food operator must immediately initiate procedures to withdraw from the market any food (imported, produced, processed, manufactured or distributed), which is not in compliance with the European requirements, and inform the competent authorities. The operator must also inform consumers on the reason of the withdrawal, and if necessary recall the products.
Chapter 2  Overview of Regulations and Guidelines on Traceability and Withdrawal

2. Each business operator responsible for retail or distribution activities must initiate procedures to withdraw from the market products not in compliance with the European requirements and shall contribute to the safety of food by passing on relevant information, cooperating in the action taken by producers, processors, manufacturers and / or the competent authority. It must also immediately inform the competent authorities if it considers or has reason to believe that a food, which it has placed on the market, may be injurious to human health (Leahy et al., 2004).

The legal text says: "If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information
necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food, which it has placed on the market, may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied."

2.2 Food traceability guidelines as set out by European Union

In 2004, the European Commissions Health & Consumer protection unit established a working group with a number of experts from member states to examine and reach consensus on issues concerning the implementation of Regulation (EC) No. 178 of 2002. The Commission organised a meeting with industry to discuss issues relating to the law which was held on 19th April 2004. Following discussions, the Standing Committee on the Food Chain and Animal Health reached a number of conclusions in December 2004.

The specific requirements covered in this guidance document include the traceability of food products, withdrawal of dangerous food products from the market, operator
responsibilities and requirements applicable to imports and exports. While welcomed by the food industry and consumer groups, this drive towards complete supply chain traceability is nonetheless putting incredible pressure on food manufacturers, especially private-label processors.

"The new requirements in the EU food law include important elements like rules on traceability and the withdrawal of dangerous food products from the market," said Markos Kyprianou, Commissioner for Health and Consumer Protection (Kyprianou, 2005).

"Their effective implementation will benefit public health and make trade between EU Member States easier. The guidelines address many of the practical issues raised in recent months by food and feed business operators and will help both businesses and national authorities to implement the new requirements." (Kyprianou, 2005).


The Guidance Document states that there are two categories of information that should be kept

1. Information to be made available to the Competent Authorities on demand
   - Name, address of supplier & nature of products supplied
   - Name, address of customer & nature of products delivered
   - Date of transaction delivery

This type of information should be immediately made available to the competent authorities.
2. Information that is highly recommended to be kept

- Volume Quantity
- Batch
- More detailed description of product (e.g. raw, processed, and bulk)

This information shall be made available as is reasonably practical.

Article 18 does not foresee a minimum period of time for keeping records. However, most commercial records are registered for a period of 5 years. This 5 year period from date of manufacturing or delivery would be likely to meet the objective.

Article 18 also intends that some level of internal traceability is put in place so that targeted and accurate withdrawals can be undertaken.

Indeed, the new EU guideline specifically defines the criteria that would trigger the withdrawal or recall of a dangerous product from the market. Situations where operators are required to inform competent authorities of this withdrawal are also specified.

Ultimately, the guideline underlines the fact that food manufacturers are responsible for the safety of the food that they produce and put on the market.

2.3 Guidelines No. DPH/XII/05

Locally the Food Safety Commission approved and published the Department of Public Health Guidelines No DPH/XII/05 on the 16th February 2005. These guidelines request that all health inspectors are to be conversant with Regulation (EC) 178 of 2002 which is to be treated as local legislation. Furthermore, it requested that all health inspectors are to be aware and well versed in guidelines
approved by the Health and Consumer Protection Directorate-General of the European Commission on the 20th December 2004 on the implementation of the main General Food Law requirements.

2.4 Regulation (EC) 1935 of 2004 – Food Contact materials

The new European Union Regulation (EC) 1935 of 2004 on materials and articles intended to come into contact with food was adopted as a regulation on 27th October 2004 and published on 13th November 2004. It replaces framework directives 80/590/EEC and 89/109/EEC. This regulation requires mandatory traceability of food contact materials and articles; mandatory approval of active and intelligent packaging materials; the declaration of compliance, approval of recycling processes and quality management systems for post-consumers plastics used in manufacturing, and protocols to ensure safety of recycled plastics.

It states that traceability of materials and articles intended to come into contact with food should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. Business operators should at least be able to identify the businesses from which and to which, the materials and articles are supplied.

For the purpose of this regulation, traceability is defined as the ability to trace and follow a material or article through all stages of manufacture, processing and distribution.

Article 4 of this regulation defines active and intelligent packaging and sets the frame for the application for food. Any active or intelligent system needs to be evaluated by the European Food Safety Authority (EFSA) with final authorisation.
by the Commission. Active and intelligent materials and articles shall be adequately labelled to indicate that the materials or articles are active and/or intelligent.

A declaration of compliance is required under Article 16. This article requires that all the specific measures shall require that materials and articles covered by those measures, be accompanied by a written declaration, stating that they comply with the rules applicable to them. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

Article 17 deals with traceability. It states:

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labeling or relevant documentation or information.
This article will enter into force on 27\textsuperscript{th} October 2006. This new framework Regulation aims to harmonise and align with Food Traceability (Art 18 of Regulation (EC) 178 of 2002) (Dainelli, 2004)
Chapter 3

Traceability

3.1 Introduction
3.2 Food business considerations
3.3 Objectives of a traceability system
3.4 Creating a traceability system
3.5 Reviewing the traceability system
Traceability

3.1 Introduction

A traceability system is an essential element of a food safety management system. It is also multi-disciplinary in the sense that many departments within a food business will be involved in its development and its implementation. A reliable traceability system is the means by which a food company can track and trace any foodstuffs that is unsafe. In the event of a food incident, it would be more difficult and extensive to affect a product recall/withdrawal without such a system in place (FSAI, 2002).

Traceability is also mentioned in ISO 9001:2000 as one of the aspects that should be considered in a quality management system. Nowadays many food businesses are therefore interested to have traceability systems, whether it’s a legal requirement or not.

3.2 Food business considerations

Despite great results already achieved in terms of product quality and consumer safety, progress will never be synonymous with zero risk. Science and technology allow us to work on reduction of risks but not its complete elimination. Industry, despite all the improvements achieved, may have to face the threat of product quality failure (Leahy et al., 2004).

The following are the major aspects that should be considered when reviewing or assessing traceability and incident management at company level.
One of the aims of quality management systems is to produce safe products. Although all procedures may be managed according to established norms, standards and laws, it is not possible to give total assurance against a possible critical incident.

The first priority of product traceability and incident management processes is to protect the consumer and ensure a fast product withdrawal or recall. The second priority is to manage the economic aspects related to the company and this is best achieved through the precise identification and location of all nonconforming products (Leahy et al., 2004).

Depending on the degree of implementation and the infrastructure selected by a company, product traceability processes may require significant investment. The benefits and savings are not obvious at first glance and the expenditure should be considered as a long-term strategic investment because it is linked to consumers' perception, the image of the company and the trust consumers' display when buying a product (Leahy et al., 2004).

Not everyone within the food chain understands better information as a value added to the product and many decisions rely on a physical inspection of quality. The cost of implementation of traceability systems is likely to vary enormously between businesses and sectors depending on the type of technology adopted, the amount of information required to be stored and the complexity of the supply chain. It is most likely that systems will be introduced rapidly where commensurate benefits exist in logistics and process control or where brand market share would be jeopardised without the introduction of such systems (Leahy et al., 2004).
It is clear that product traceability comes at a cost. But the costs of not having it, or having inefficient systems in place may be severe for consumers, individual companies, the sector in which they trade and at a national and international level for Governments.

3.3 Objective of a traceability system

The objective of a traceability system is to identify a unique batch of product and the raw materials used in its production and then follow that batch and each individual unit comprising the batch, through the production and/or distribution process, to the immediate consumer (FSAI, 2002)

Role of food industry

In accordance with Regulation (EC) 178 of 2002 and Chapter 449 - Food Safety Act, 2002, of the local legislation, the primary responsibility for the safety and suitability of the food for human consumption is borne by the food industry. Consumer demand for information and the public health protection are also key drivers for an effective traceability system. Food industry is responsible for the establishment of a satisfactory traceability system.

For a complete traceability systems food industry must implement the following:

- Supplier traceability of raw materials and ingredients
- Process traceability within processing and packaging
- Customer traceability of the end product to the immediate customer (FSAI, 2002)
Track from the raw material to the consumer unit

Figure 1: Trace forward from raw material to consumer unit.
Source: EAN UCC Traceability Implementation

Trace back from one consumer unit to raw material

Figure 2: Trace back from consumer unit to raw material.
Source: EAN UCC Traceability Implementation
For a traceability system to be effective and to ensure safety and public health, it must operate in the whole food chain that is from ‘farm to table’. Every producer/seller at every step of the food chain has an important role.

Mandatory traceability requirements do not require process traceability that is the linking up of all inputs to outputs. However the adoption of process traceability remains a business decision and it makes great sense for a business company to implement such a beneficial system.

To ensure the reliability of this process, the following questions need to be asked about every link in the supply chain:

How can we deliver safe products to customers and consumers?
What goods have been received and what goods have been despatched?
From who were goods received and to whom have they been delivered?
What is the Lot Number / Serial Number of the goods received and despatched?

The answers to these questions must be available through:

- Quality management
- Product coding and traceability procedures
- Organisation put in place to ensure efficient daily operations
- Product recall and product withdrawal procedures
- Incident/Crisis Management Procedures (Leahy et al., 2004)
3.4 Creating a traceability system

In the setting up of a traceability system, the following steps should be undertaken:

- Define scope of traceability system.
- Document traceability system.
- Set up mechanism to periodically review traceability system.
- Test traceability system when testing recall procedures (FSAI, 2002)

3.4.1 Defining the scope of a traceability system

Food businesses should define the scope of their traceability system before starting to develop it. The traceability system should be capable of efficiently and accurately follow food products through the food chain. Additional considerations when developing the scope of a traceability system is the definition of a batch since the broader a batch is the less detailed the batch coding is but the greater the volume of product that may be recalled in the event of a food incident (FSAI, 2002).

Furthermore manufacturers of foodstuffs delivered in bulk may only be able to define a product batch within a defined time frame such as a day’s production. Other manufacturers or caterers may be able to define a batch as an individual saleable unit (FSAI, 2002).
### 3.4.2 Documenting the traceability system

Traceability system should be documented. Documentation should include the following:

- Scope of traceability system.
- Details of traceability system.
- Any associated operational documentation.
- Arrangements for review (FSAI).

There is a range of systems in place from paper based to IT enabled systems. However, the increased efficiency, effectiveness and security of IT enabled systems are recognised and they are being slowly rolled out throughout the food chain.

Simple hand-written or printed labels are being rapidly replaced or supplemented by machine-readable identification such as barcodes and radio frequency tags. The amount of information that can be carried by identification systems has been increasing rapidly. As a matter of fact, many systems can now carry over 2000 characters of information, while magnetic and electronic identification can store up to 64K of information which is equivalent to a moderately complex spreadsheet.

Radio frequency identity tags (RFID), involves tagging products or containers to record logistical movements and capture information such as environmental conditions. This data is then stored in databases that can be searched via a new generation of Web browser-based traceability software, such as Intentia Trace Engine. Some collaborative supply chain applications including Intentia’s enable disparate computer systems to deposit transactions into a single repository and
provide Internet-based viewing capability that encompasses all stages in a supply chain (Unknown, 2005).

While regulatory requirements are a pressing issue, they are not the only reason why tracing techniques are beginning to generate such interest. Far from being just a time and resource consuming compulsory exercise that diverts the attention of the business away from day to day concerns, enhancing traceability capabilities also offers a new marketing opportunity for businesses to establish product differentiation, boost client loyalty and ultimately improve profits.

Investment in more effective traceability capabilities should also be viewed as an integral part of running a successful food export business, not simply as a compliance issue and financial burden.

3.4.3 Supplier traceability

A food business should be able to ensure that foodstuffs and packaging entering their premises are traceable to supplier. This can be achieved by creating the following documents:

- Purchasing control system
- Each and every individual incoming unit of ingredient/ primary packaging/finished product should carry a means of tracing its source of supply and history. In situations where this is not possible an identification lot or mark should be given (FSAI, 2002)
An example of a paper-based document on traceability of raw material intake can be found in *annex 2*.

When creating goods inwards documents for all deliveries the following information should be included in documents:

- Supplier name.
- Supplier batch codes.
- Delivery date.
- Confirmation of acceptance.
- Number of units.
- Weight of units.
- Lot number if assigned on delivery.
- Durability date.
- Date of production if available.
- Reference to any in house quality control records associated with the delivery.

In the case of bulk delivery of ingredients into bulk storage facilities, it may not be possible to ensure that only ingredients from one batch are present. The delivery dates, identification of storage facility and weight/volume of the delivery may be the only way of identifying an ingredient. In this event, it is necessary that the contents of a bulk storage facility are traced through production (FSAI, 2002)
3.4.4 Process traceability

Process traceability is the second step in the development of a business traceability system. The important elements are:

- A product batch must be identified.
- To ensure that a product batch is a true batch it must be separated by a clean break from other product batches made using the same equipment. If this is not possible then batches may not be unique and a recall/withdrawal may require the removal of the affected product batch plus any other product batches where carryover of ingredients is likely.
- Internal documentation accompanying the product batch.
- Traceability codes of ingredients and primary packaging used in the production of a product batch should be recorded and associated with the product batch code.
- Production and quality records should contain all the necessary information relating to ingredients, packaging and process times to allow traceability to the finished product (FSAI, 2002).

Relevant information should include:

- The product name.
- The product batch code.
- The date of production.
- The time of start and end of production.
- The sealable unit size
- Number of sealable units
Reference to in-house quality control records associated with the product batch

Reference to in-house packaging control records associated with the product batch

Any food business engaged in rework must ensure that the documentation associated with the product batch contains all the information necessary to allow traceability of any rework incorporated (FSAI, 2002).

Ambient temperature of production areas and food temperature
The latter should be included if product being manufactured is considered as high-risk food.

For the purpose of this study, an example of a paper based system annex 3, of process traceability has been designed.

Each processor involved in business to business trade should be able to ensure that foodstuffs leaving the control of the business are traceable to the immediate customer. Hence customer traceability is the third step in the development of a full traceability system.

The important elements are:

- A list of immediate customers, including details of the products purchased and full contact details. Lists must be updated regularly.

- Any documentation accompanying product to a customer should contain all the information necessary for traceability to be maintained through the distribution chain (FSAI, 2002).
Examples of relevant information as shown in annex 4 are:

- Name, address and contact details of the customer.
- Name of delivery man.
- Transport vehicle.
- Any additional information associated with product such as temperature of vehicle during transport and temperature of product on loading/delivery.
- Full list of products purchased by customer, including product name, batch code/s, number of sealable units.

A system should be in place to deal with product that is rejected by the customer for food safety reason. If returned, the rejected product must be quarantined pending investigation and maintained separately from product cleared for release. System should detail the reasons for rejection and ensure that the documentation held by food business reflects the fact that the rejected product remains in the possession of the food business. It is of ultimate importance that the non-conforming product is traced so that business can be sure of what product is on the market at any one time.

3.5 Reviewing the traceability system

Traceability system should be reviewed by food business at least yearly to ensure that it is delivering the required level of traceability. A multi-disciplinary team comprising members from each of the functional areas of the business should meet with senior management. The team should audit the traceability system. An audit should consist of a horizontal and vertical assessment of the system. The horizontal check should consist of an audit of several batches at the same point in the process to ensure all identification marks and documentation is correct. The vertical check
should follow several batches from the customer to the supplier to ensure all identification marks and documentation is correct. On the basis of the audit areas for improvement that are identified or any non-conformances arising, should be addressed. The review procedure should be documented and signed off by senior management (FSAI, 2002).
Chapter 4

Implementation of traceability in bakery

4.1 History of bakery
4.2 Company organisation
4.3 Manufacturing of bread
4.4 Automatic ingredients dispenser
Implementation of traceability in bakery

4.1 History of bakery
Bakery has been in operation since the 26th February 1986. At the time, the objectives of trading included the production of bread and confectionery items for the local market. In 1992 the whole operation was shifted to another premises. In 2001 the company took strategic decisions in order to restructure its operation. Most of machinery and equipment was replaced and a new pastry section was added which is Hazard Analysis Critical Control Point (HACCP) complaint.

The Company’s operation includes four basic categories, namely the manufacturing of sliced sandwich bread, fancy bread, Maltese bread, pastry and confectionery items. Although method of operation may seem similar from one product to another, these four sectors require different technical skills, ingredient materials and equipment. In 2003 works was commissioned to bring premises in line with current regulations and requirements prior to the implementation of HACCP procedures. Modern machinery and equipment was installed and pre-requisites of HACCP continued to be implemented. Staff also attended courses in food hygiene and application of HACCP principles.

The bakery nowadays enjoys a substantial market share in both retail business and also in the hotels and catering sector. In order to sustain and improve the standard of quality and food safety, the company has entered into a supply and technical support agreement with a major European food ingredient manufacturer whereby all products being used are certified to comply with European standards and free from
genetically modified organisms. The bakery is also supported by a Hygiene and Nutrition Consultants in the maintenance and auditing of HACCP and food analysis.

4.2 Company organisation

The company’s operations are managed by the General Manager. There are six departments under his responsibility these include the bakery section, pastry section, sales department, quality assurance department, accounts and administration and maintenance department.

![Company organisation diagram]

**Figure 3. Company organisation**

The Company is committed that the bakery be full HACCP compliant in the near future and currently the pre-requisites of HACCP are being implemented, such as the training of staff, implementation of a complaint follow up system and traceability system amongst others.

During the author’s visit to this factory about a year ago, it was noticed that management was aware of their needs and obligations concerning food safety and traceability. As a matter of fact they are looking forward for the implementation of
traceability as this will enhance their product quality, instil confidence in customers and enhance their branding besides reaching their objectives of inventory management, regulatory compliance, documentation to substantiate brand claims, recall containment, contract compliance and brand assurance.

Knowing that the basic characteristics of traceability system, that is identification, information and the links between are common in all systems independent of the type of product, production and control systems that are served, the company invested in an IT system complimented with the installation of software and an ingredient dispenser. This obviously requires an amount of investment however it was preferred from a paper system, such as the one shown in annexes 1, 2 and 3 as it is more reliable than the latter. Furthermore management believes that the image of the company and the branding of products will benefit by installing such a system.

4.3 Manufacturing of bread

Various types of sliced sandwich bread, fancy bread, Maltese bread, pastry and confectionery are manufactured in this factory. The study focused on the manufacturing of all types of bread.

All ingredients are imported by the company itself from a major European food ingredient manufacturer or bought from ISO or HACCP compliant manufacturers. These are kept in dry goods store. White flour and wholemeal flour supplied by a local manufacturer is kept in six silos, of which five are used for white flour and the remaining one is used for wholemeal flour. All goods are marked with batch identification as can be seen in figures 5 and 6, with the exception for flour. The
silos as shown in figure 4. are large enough to contain one whole delivery of commodity. This is important for traceability purposes as flour can be given a lot number by storekeeper corresponding to date of delivery. Silos are filled on alternative days. A stock control system based on batches and dates of durability is already in place. A first-in-first-out system is adopted.

Figure 4. One of the six silos used for the storage of flour.
Figure 5. Raw materials marked with lot identification and durability date.

Figure 6. Containers with oil showing batch and expiry date.
Preparation of recipe according to standard recipes is currently being carried out by the storekeeper. Mixing of ingredients with water and flour is then carried out in the mixing area. These steps are common for all types of bread. Following these initial steps, manufacturing as shown in the flow diagram – *figure 8*, is performed in two different sections of the bakery.

Manufacturing of a single type of bread is only done once daily so the lot number given to that type of bread will correspond to a production carried out in a particular time and day. Presently Maltese type bread is not packed hence this will create a problem in trace back. It is part of the Maltese culture that this type of bread is sold unpacked; however, the company is currently working on the branding of all products including Maltese type bread. All fancy bread is packed in the packaging area and label includes ingredients, typical nutritional analysis, address of manufacturer, weight/quantity and durability date and lot identification number.

*Figure 7. Panel showing the amount of flour contained in a specific silo.*
Figure 8. Flow diagram showing the manufacturing of fancy bread and Maltese type bread and similar products.
Bread is given a five day shelf life from day of production, this being reduced to three days during the summer months.

Currently process traceability can only be determined through invoices and batches. Such a system besides being time consuming is also not so efficient and reliable.

However following a cost/benefit analysis the company concluded that to attain objectives of traceability as regulated by Regulation (EC) 178 of 2002 and also achieve the company’s objective which includes inventory management, recall containment, contract compliance and brand assurance, the company embarked on a new project.

4.4 Automatic ingredients dispenser

Fully automatic ingredients dispenser as shown in figures 9 and 10 constructed from stainless steel and aluminium is being installed complimented with an IT system. Its main function is the dosing of ingredients and weighing of components like powder, crystalline, grainy or granular products (salt, sugar, spices, flour etc) following computer controlled recipe workout.

Ingredients are stored in the compo-containers and dosed to the conveyor belt scale at an accuracy of +/- 5g. After dosing and weighing of all components of recipe, the conveyor belt transports the ingredients automatically to the mixing bowl (personal communication).
Figure 9. Different types of ingredients dispensers.

Source: hb-technik, undated.

Figure 10. Fully computerised ingredients dispenser being installed in a bakery.

Source: hb-technik, undated.
All ingredients used in the manufacturing of bread will be dispensed through this machine with the exception of flour and water. Flour will be dispensed through the silos furnished with a dispensing meter as shown in figure 7 and chilled water is supplied through chilled water dosing system furnished with a water meter.

The benefits of this system are the consistency of recipe as human errors whilst preparing recipe will be omitted, reduce waste and provide traceability of all ingredients included in that particular recipe.

The new system will work as follows:

- On delivery of raw material items are checked by storekeeper, batch number, durability date and supplier will be noted and entered into database.
- Lot numbers of ingredients fed in ingredient dispensing machine will be inputted in the computer system.
- On choosing a particular recipe, a batch number for production is assigned and ingredients are dispensed automatically from machine and mixed with flour from a single silo.
- Mixing takes place, followed by manufacturing of bread as shown in figure 8.
- Products will then be labelled according to product and batch number assigned at the beginning of production, which will be printed on packaging.
- All information related to that batch of product, including batch number of packing material will be kept on a database.
- Customer traceability will be kept through sales records.
The only operator being included in the system is the storekeeper since he has to enter information in database related to raw materials. The system being adopted should be adequate, considering the short shelf life of the product and since bread is not considered as a high-risk food. Through this system the objective of a traceability system, which is identifying a unique batch of product and the raw materials used in its production and then follow the batch through production/distribution will be attained. The idea of branding all bread including Maltese type bread will certainly help the company in achieving its objective.

This IT enabled system was preferred to a paper system due to its efficiency, effectiveness and security. Through this system, information can be used to trace back to find the source of a problem, stop the problem or prevent it from happening again. In the event of a withdrawal or recall, products that have already been forwarded can be traced.
Chapter 5

Recall

5.1 Introduction
5.2 Objective of product recall
5.3 Classification of the level of product recall
5.4 Stages of a product recall procedure
5.5 Testing and reviewing of a product recall plan
5.6 Managing a product recall
5.7 Closing the product recall
5.8 Reviewing product recall following an incident
Recall

5.1 Introduction

Even the best businesses make occasional mistakes. This may be as a result of a packaging defect, a preservation failure, a production problem, a storage problem, a problem with ingredients of a foodstuff or any other reason. When a potential unsafe product is discovered, withdrawing it from the distribution chain is the first obvious step. But, there is also the problem of products which have already been sold to consumers. To deal with this, it is vital that food businesses carry out a rapid and thorough recall. This is the only way to sustain consumer safety, the reputation of the food business and compliance with the law.

Successful removal of food from sale relies on the clear assignment of responsibilities within the food business and the competent execution of a tested product recall plan. A fully functional traceability system is the only effective way of identifying the location of unsafe product within the distribution chain. The effectiveness and efficiency of attempts to remove a food from sale will be hindered without a traceability system (FSAI, 2002).

Hence it is important that food businesses assume that an eventual food safety issue may arise with their products and therefore plan ahead. A company must thrive to ensure that its recall procedure is efficient and successful as such systems can prove to be complex and quite costly at times. Systems and plans must be periodically tested to ensure that they are comprehensive and serve to remove an unsafe product from consumers and/ or the distribution chain as effectively as possible. Food
businesses can remove products from market for reasons other than food safety (CDHSFDB, undated).

5.2 Objective of product recall

The objective of product recall is to protect public health by informing consumers, if necessary, of the presence on the market of a potentially hazardous foodstuff and by facilitating the efficient, rapid identification and removal of unsafe foodstuffs from the distribution chain thus ensuring that unsafe foodstuffs are either destroyed or rendered safe (FSAI, 2002).

5.3 Classification of the level of product recall

Where food safety is concerned, there are only two levels of product recall. These are:

Recall

This is the removal of unsafe food from the distribution chain and extends to food sold to customers and therefore involves communication with the consumers.

Recall should be initiated when a foodstuff is identified as unsafe, is a potential risk to public health and has been distributed to the consumer (FSAI, 2002).

Withdrawal

This is the removal of an unsafe foodstuff from the distribution chain but does not extend to food sold to the consumer.
Withdrawal should be initiated when a foodstuff is identified as unsafe, is a potential risk to public health but it can be demonstrated that the unsafe foodstuff remains wholly in the distribution chain and has not reached the consumer (FSAI, 2002).

The Role of the Food Industry

The primary responsibility for the safety and suitability of the food for human consumption is borne by the food industry as requested in the Food Safety Act Chapter 449 of the laws of Malta and Regulation (EC) 178 of 2002.

In April 2005 Director General, Health and Consumer Protection issued a leaflet as shown in annex 5, to remind commercial operators of food business premises their obligations in accordance with the General Food Law.

Consumer demand for information and public health protection are also key drivers for an effective product recall system. Product life cycle management and category and brand protection are also very important considerations for any company. As a result, every food business should have a written and visible product recall policy, supported by a product recall procedure.

5.4 Stages of a product recall procedure

The objective of a product recall procedure is to facilitate the efficient and effective removal of unsafe foodstuffs from the market.
There are seven steps to a product recall procedure:

- Development of a product recall policy.
- Development of a product recall plan.
- Testing of a product recall plan.
- Notification and initiation of a product recall.
- Management of a product recall.
- Closing of a product recall.
- Review of a product recall and amendment of the product recall plan.

5.4.1 Product recall policy

Food businesses should develop a product recall policy to demonstrate the company’s commitment to protect public health. It should clearly state the objective of the product recall plan and the management’s commitment to providing the necessary resources to ensure successful removal of unsafe foodstuffs from the market. The product recall policy can be a stand alone document or incorporated into the company’s quality management system. A product recall policy should be clear and unambiguous. This should be in place prior to the development of the product recall plan (FSAI, 2002).

5.4.2 Developing a product recall plan

A product recall plan is a documented procedure designed to ensure the professional, efficient and effective removal of unsafe food from the market. A multi-disciplinary recall team should develop the product recall plan.
The following should be incorporated into the plan:

- Reference to product recall policy.
- List of members of the recall team.
- Definition of roles and responsibilities for product recall team.
- Contact names and details including email, home telephone and mobile phone number of product recall team and management, suppliers of all ingredients, distribution and business customers, source of technical advice and regulatory authorities.
- Definitions of the two classifications of a product recall.
- A product recall decision tree.
- Mechanisms of notification of a product recall.
- Reference to the company’s traceability system.
- Guidelines for media contact.
- Sample press release.
- Sample product recall notices.
- A product recall plan testing procedure.
- A product recall review procedure.

### 5.4.3 Product recall team

The product recall team could consist of personnel from production, quality, purchasing, marketing, sales, legal services, distribution and supply chain and consumer affairs or public relations. These may be represented by one or more people depending on the size of the company (FSAI, 2002).
Responsibility of the team is to develop the company’s recall plan, manage the testing and adjustment of the product recall plan, regularly update the product recall plan, direct the company’s product recall activities and recommend changes in the operating procedures within the company that will reduce the possibility of having to remove unsafe foodstuffs from the market (CDHSFDB, undated).

A product recall co-ordinator should be appointed. He should be responsible for the activities of the product recall team and should be authorised to make decisions concerning the product recall procedures. He should further liaise with management before proceeding with initiating a recall or a withdrawal of an unsafe foodstuff.

5.4.4 Definition of roles and responsibilities

For an effective product recall, all employees should be clear about their roles and boundaries of their responsibilities. This is best achieved using a product recall ‘role and responsibility’ diagram as shown in appendix E (FSAI, 2002).

5.4.5 Product recall contact list

This is an essential feature of a good product recall plan. Unfortunately it is the element that becomes inaccurate quickly. Often contact list are not updated and this frequently becomes an issue during a product recall. Updating the contact list is of paramount importance during a recall and should never be updated during a recall. Responsibility for updating the list should be specified in the product recall role and responsibility diagram and accuracy of the list should be frequently checked by the product recall team.
Contact list as shown in appendix E, should best contain the following:

- The product recall team and management.
- Suppliers of all ingredients.
- Distribution and business customers.
- Source/s of technical advice and support.
- Regulatory authorities (FSAI, 2002).

5.4.6 Product recall decision tree

The decision tree should form part of the product recall plan (refer to Appendices 4 pg 6). This should be designed to clarify the thought process leading to a final decision on the necessity of product recall and the appropriate type of action that is whether recall or withdrawal is to be undertaken. Timely and effective removal of unsafe food from the market is dependent on careful considered risk assessment. Risk assessment should be carried out by a technical competent person who could evaluate the severity and impact of food safety hazards in foodstuffs (FSAI, 2002).

5.4.7 Notification of a product recall

Once the decision to initiate a withdrawal is undertaken, three levels of notification are to be undertaken as follows:

- Within the company.
- Distribution chain.
- Regulatory authorities or the Food Safety Commission (FSC) as stipulated in the Food Safety Act 2002.
If a recall is initiated then four levels of notification are to be undertaken as follows:

- Within the company.
- Distribution chain.
- Regulatory authorities such as the FSC
- Consumers.

Notification to distribution chain should contain detailed methods for stopping product distribution, retail sale or catering use. It is important that plans are developed with business customers to store removed product safely and in isolation from safe foodstuffs when it is outside of the control of the company responsible for the product recall. Recovered product should be labelled appropriately as recalled or withdrawn. Thus, the company should have a clearly identified quarantine area. Special consideration is needed to ensure that the methods for product recall work for the catering business.

Procedures for notifying consumers should detail which media sources are to be used and how contacts will be informed.

Regulatory authorities such as the Food Safety Commission should be informed on all activities being undertaken both prior to recall or withdrawal and during exercise. Recall should be closed when the Commission is notified in writing.
The following information should be supplied:

- Name of company and contact details.
- Name of product.
- Batch/s affected.
- Product details including packaging size and type.
- Date of durability.
- Amount of unsafe product on market.
- Distribution details.
- Particulars of outlets selling to customers.
- Nature of food safety risk.
- Results of any investigations or tests.
- Level of product recall being considered i.e. Recall or Withdrawal
- Public notification
- Timings for product recall and communication (FSAI, 2002).

Food business should be clear when communicating with regulatory authorities about information which is commercially sensitive.

5.4.8 Communicating a product recall

Initial notification to trade should be by telephone and followed up by written communication as shown in appendix E. Written notification should contain all the information necessary to allow the business customer to remove the correct product from sale or distribution.
Notification should be clearly entitled to ensure that notification is acted upon quickly. Details included should facilitate immediate and unambiguous identification of the product (FSAI, 2002).

**Paid advertisements**

These are necessary in the case of a Recall or Withdrawal when the company cannot identify all its business customers in the distribution chain. A sample should be included in recall plan along with instructions for placing in the media as shown in appendix E.

When a food business is engaged in a withdrawal but for whatever reason it is not possible to contact all relevant customers then food business should consider expanding withdrawal to recall.

Product recall notice should contain the following information:

- A clear indication of what notice is about.
- Information on affected product like name, brand and description.
- State what is wrong with the product and be specific and truthful.
- Incident should not be downplayed, as this may not prevent customers from eating product.
- Give clear details to help customers identify the product and avoid confusion with other similar products. Information should include lot/s and durability date/s affected.
If possible, include a photograph or illustration indicating where the identification can be found.

Inform consumers what to do with product.

If hazard is serious then include details of clinical symptoms and advice to consult a practitioner.

Details for consumers to contact the company should also be included.

Finally apologise for any inconvenience caused.

Press release

In addition to paid advertisement, a press release should also be considered, as these have the advantage of reaching the media and do not suffer from delays that could accompany paid advertisement. However, this should only be used as a backup as one cannot rely on the uptake of a press release (FSAI, 2002).

5.5 Testing and reviewing of a product recall plan

Product recall plan should specify periods for review and the responsible person/s to undertake such review. Plan should be examined for errors, particularly contact list or in light of any changes in the company’s product recall policy or trading status. It is recommended that product recall plan should be reviewed at least twice a year following a documented procedure, which is held as part of the product recall plan itself.

Product recall plan should be tested through a product recall exercise. This is important so as to validate the product recall plan. This procedure should also be documented and held as part of the product recall plan itself. This is important so as
to eliminate any problems which might be encountered during a recall involving real food safety incident (CDHSFDB, undated).

It is far easier and definitely more cost effective to alter a product recall plan when the food safety incident is part of an exercise without any pressures than during a real situation. Product recall plans should be validated once yearly or more frequently if appropriate. Ideally test should be unannounced and not prepared in order to determine a company's preparedness and speed to action. If possible customers should be included in exercise to increase the value of the exercise itself. Once test is completed, a review must be carried out with the relevant product recall team members to amend and improve the process as necessary (FSAI, 2002).

5.6 Managing a product recall

Management of a product recall should be driven by the product recall plan, which in turn should carry all the details necessary for the product recall coordinator/s to manage a product recall successfully.

Product recall team should always get their facts first hand. Information concerning the food safety hazard, product details, likely distribution and extent of problem is vital for good decision making. A high probability that information gathered during the early stages of an investigation will be faulty or flawed, hence this needs to be accounted for in the initial risk assessment, which should always take a precautionary approach by placing the protection of the consumers' health high on the list of priorities (CDHSFDB, undated).
Initial information on a potential food safety incident can come from a variety of sources (for example through quality and production records, sales representatives, employees, ingredient suppliers, packaging suppliers, regulatory agencies, distributors, media, consumers etc), and it is likely to rest with only one or two individuals in an organisation. Hence it is important that all individuals within company are aware of the product recall plan and they take the necessary steps to ensure that this information is convened to the product recall team or management. Staff should be trained how to handle information appropriately. Information obtained should be verified at once by the product recall team.

Product recall team should aim to collect information as much as possible on a suspected food safety incident. Data should include the product name and description, batch/s involved, quantity of product implicated, distribution details, whether product has reached consumers and the hazard involved. Data should then be verified and then through risk assessment process one can decide on plan of action (CDHSFDB, undated).

**Risk Assessment**

Product recall is a risk management decision that requires food business to be able to identify potentially unsafe food. Business should be able to decide whether the unsafe food can cause a potential risk to public health and if so, determine the level of adverse effect and the affected population profile and size. Hence a food business is required to assess the potential risk resulting from problem with the food. Therefore it is important that risk assessments are only performed by competent technical people. Food businesses should follow an accepted model for risk
assessment such as the one developed by Codex Alimentarius (which is the joint food standards programme of the Food and Agricultural Organisation of the United Nations and the World Health Organisation) based on the following four steps (FAO, 2001):

**Hazard Identification:** The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

**Exposure Assessment:** The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

**Hazard Characterisation:** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard.

**Risk Characterisation:** The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.

Food business must adopt the precautionary principle in its risk assessment activities to ensure that public health is protected at all times. Furthermore, food businesses
faced with the production of an unsafe food should aim to document their hazard identification and risk assessment logic.

All the information gathered by the product recall team should be documented along with the date, time and provider of information. An incident log should also be set up. This will be useful as a reference in case that facts need to be checked, a means by which the recall can be reviewed and may serve as a legal document to prove due diligence should it become necessary. All decisions should be inputted in the incident log. Sequence of events and actions taken will be very important during the review (CDHSFDB, undated). All physical evidence and records related to product complaints must be handled carefully, so that a company cannot later be accused of being negligent in handling, storing and testing product samples or other evidence related to a recall.

**Regaining control of affected food**

A food business that has initiated a product recall may regain control of the potentially unsafe food but must also account for all missing stock. In certain instances, the food business may request the customer or consumer to destroy affected product however, it should be ensured that they are actually destroyed in an appropriate manner. Best practice is that the food business collects from the market the affected product. Product is then kept in site separate from any other food products. Accurate records must be kept of the amounts of recovered product together with batch or lot numbers of that product. If recovered product is unfit for human consumption, this may be destroyed under the supervision of the company
management or representative and officials of the regulatory authority as directed. (CDHSFDB, undated)

5.7 Closing the product recall

Product recall must be formally closed so as to be clear to all parties involved that the incident has ended. Regulatory authorities should also be informed in writing that product recall has been officially closed (FSAI, 2002).

5.8 Reviewing product recall following an incident

A product review should be initiated once a product recall has been closed. This should be documented as part of the product recall plan (CDHSFDB, undated). Every food business involved in product recall should take the opportunity to learn and improve the systems used in that business. Review should include investigations and analysis performed on returned products, stock reconciliation, management structures, training plans to improve awareness of the problem and ensure it is not repeated, policy and cause of issue (FSAI, 2002).

5.8.1 Reviewing the product recall process

The product recall process should be reviewed and the product recall plan should be amended if necessary. Effectiveness of the process, problems encountered during recall, effectiveness of communication, accuracy of media coverage, customer care line, true cost of product recall and lost sales, accountabilities of product recall team, and lessons learnt through such incident are all points that should be considered during product recall process review (FSAI, 2002).
5.8.2 The effectiveness of the product recall

The product recall notification must reach as far as the product has been distributed to be effective. Effectiveness is assessed on the basis of the amount of product returned as a proportion of the amount of product that has left the food business, while taking into account the retail turnover of the product (CDHSFDB, undated).

During product recall progress must be reviewed so that its success can be monitored. If it decided that there is now little risk to the public, the product recall is judged as having been a success and brought to an end. On the contrary if there have been few returns and little response to a high risk problem, then the product recall procedure must be reassessed. In these circumstances the product recall may have to be repeated using a different method to reach the consumer (FSAI, 2002).

5.8.3 Final reports and recommendations

A final report should be compiled on the circumstances leading to recall, action taken and should also including recommendations to prevent a recurrence of the problem (FSAI, 2002). Prevention of recurrence could mean amending the HACCP Plan or effect changes in a process.
Chapter 6

Implementation of the recall system in the bakery

6.1 Objective of plan
6.2 Classification of the level of product recall
6.3 Recall team
6.4 Handling product recalls and withdrawals
6.5 Recall status report
Implementation of Recall System in the Bakery

Although the bakery has an outstanding safety record, the risk is still there. Situations may sometimes arise leading to action by the processor and/or request from the regulatory agency to withdraw or recall a product from the marketplace. While the food company has never conducted a recall or market withdrawal, management is aware of their responsibilities, however no recall plans are in hand. Currently a recall of a product can only be done by following the durability date and through the delivery/invoicing system. However with such a system a lot of time and effort may be wasted by the company should a need for a product recall or withdrawal arise.

A documented complaint system is already in place. Once a complaint is lodged either by consumers, food businesses or regulatory authority, details of person, firm or authority making complaint, detail of alleged problem with food product and details of incriminated food product are taken by the Quality Assurance Manager. Investigations are then undertaken by the Sales Manager who reports to QA Manager and General Manager. Should the need arise the Company’s Hygiene and Nutrition Consultants are also involved in the investigation. Action is then taken based on findings. All complaints and investigations are documented and entered into a database.

The study concentrated on building on this system by implementing a recall plan complete with a set of forms as can be seen in appendix E. Such a recall plan would assist the Bakery to rapidly and completely remove unsafe, mislabeled or other
defective food products from household, retail and/or commercial availability. Since guidelines on product recall are not available locally, the Recall Plan was compiled in conformity with Guidance Note No. 10 entitled Product Recall and Traceability published by the Food Safety Authority of Ireland in 2002 and as requested by Regulation (EC) 178 of 2002.

The development of the plan ensured that the manufacturer would be able to rapidly initiate or respond to a recall situation. Recall preparation and readiness should be a routine part of the business. It is important that one considers recall plans as an insurance policy. The idea is that, although one would probably never use the recall plan, one should never be caught without one. For this reason every food processor or dealer should be familiar with the basic steps that should be taken and have plans in place to implement these steps should such action become necessary.

It is very important that management appreciate the importance of recalls since they are generally rare in frequency and are financial, resource and morale draining events. Conducting a recall properly makes good business sense and limits the liability of the firm while it demonstrates product responsibility to the public and overseeing regulatory agencies. In deciding whether to initiate a product withdrawal or recall, food processors should be aware of the regulatory and consumer environment in which they operate today.
On preparing the product recall plan the following categories of product emergencies were considered in terms of appropriate actions to be taken.

- **False alarms.** Most potential emergencies are resolved upon examination of production records, interviews with employees, additional checks of the product, or through other means.

- **Bacterial contamination.** Contamination by spoilage organisms or harmful bacteria can occur due to processing equipment malfunction, a crucial mistake in the production process, or other causes. These situations are often difficult due to the number of different organisms that may cause illness, the time required to test for their presence, and the problem of identifying the point at which an organism was introduced into the product.

- **Chemical contamination.** Inadvertent contamination of food products by chemicals may cause an adverse situation for food processors.

- **Foreign objects.** Foreign objects like glass, plastic or metal fragments can finish in the product through different routes. These may be present in raw materials or finish in the product through production line mishaps.

- **Packaging defects.** Undetected packaging defects which may cause some product emergencies.
• **Faulty ingredients.** Product components that contain an unlabeled ingredient (such as an inadvertent allergen) or one that is not part of the product’s standard of identity may create adverse situations.

• **Worker illness or disease.** Some food processors have experienced food safety scares as a result of potential contamination of their products by workers suffering from illness or disease.

• **In-house sabotage.** Food manufacturers sometimes suspect their own workers of deliberately causing product defects.

• **Tampering and tampering threats.** A real dilemma is created when a company receives a tampering threat should it remove the targeted product from distribution or conclude that the tampering threat is a hoax and leave it on grocery shelves?

• **Misbranding.** Food products may be misbranded and subject to recall if deficiencies on labels are considered as critical non-conformity as stipulated in Guidelines DPH/II/04 issued by the Department of Public Health.

Critical non-conformities in mentioned guidelines includes unlabelled food product, tampered durability date, lack of durability date, lapsed ‘use by’ date, misleading/false claims or information whereby these claims may have health implications, banned additives or additives exceeds established limits, nutritional information not present (if product require such information), lack of declaring that
product contain a source of phenylalanine, lack of declaring alcohol strength and any irregularly labelled product.

The need for a product recall may arise from a variety of situations in addition to the situations described above, including:

- **Real and fraudulent consumer claims.** Some companies have been forced to withdraw or recall product from distribution as a result of consumers claiming they were injured or made ill by a product, even when the product was not at fault. Consumers are increasingly airing their complaint with regulatory agencies or with the media about a product, especially when they believe the company is ignoring them.

- **Scientific reports.** Regulatory agencies may require food companies to take action regarding certain products following a sample taken as part of a sampling program or analysis undertaken as part of an investigation following a complaint lodged by public.

- **Company generated information.** The need for a recall is commonly identified by companies themselves finding problems through record review, product examination, etc.

### 6.1 Objective of plan

The objective of product recall plan was prepared to show the company's commitment to protect public health.
6.2 Classification of the level of product recall

Product recall was classified in two levels, recall or withdrawal.

A decision tree was also included in recall plan to help the recall team to determine whether to handle problem as a complaint in the case of no health hazards involved, withdrawal if the unsafe food product remains wholly in the distribution chain and recall if unsafe product has reached the consumer.

6.3 Recall Team

The Recall Team is an important factor for the successful recall or withdrawal of an unsafe food product. A well-prepared company Recall Team can help assure that recalls and withdrawals are handled smoothly, with the least possible disruption to ongoing company operations. The Recall Team includes representatives from the production, quality assurance, distribution, accounts, Hygiene and Nutrition Consultants and legal counsel. The Recall Team reports directly to the Recall Coordinator. Recall team was developed and assigned roles and responsibilities according to the company’s organisation structure.

The General Manager was identified as the Recall Co-ordinator and in his absence this role will be taken by the Master Baker. The Recall Coordinator is empowered by management to convene meetings of the Recall Team and other company personnel whenever the need arises, regardless of the other activities that may be underway.
The Recall Coordinator must also systematically record facts about each situation in a master file that will ultimately contain all details and decisions made about the recall or other action taken by the company.

Each member of the Recall Team should have a current list of office and home telephone numbers, including mobile phones, fax numbers, and e-mail addresses for every member of the team. For this reason a Product Recall Contact List was formulated. List includes the company’s contact list, suppliers’ list, customers/distribution list and regulatory authorities.

Members of the recall team were assigned the following responsibilities:

- Reviewing existing operating procedures (production, quality assurance, distribution) and recommend any changes that will lesson the probability of having to withdraw defective products from distribution and that will make recalling product easier when necessary.

- Review existing product recall procedures every six months and, if necessary, develop a revised Recall Plan.

- Should a suspected problem arise, assess the situation to determine what data are needed and whether or not the problem is real; then manage any stock recovery, market withdrawal, or recall, including communications with the trade, regulatory authorities, the news media, and consumers.
Recommend to management and to the responsible agency, steps to be taken to recondition, re-label or destroy returned product.

Keep Bakery employees and customers informed of actions being taken by the company.

After a potential crisis, review the actions taken, assess the effectiveness of the plan and any changes needed in the food safety management programme, the traceability system or the Recall Plan itself and determine actions needed to prevent similar incidents.

Update contact lists monthly.

On developing the recall plan attention was given so that the recall team should easily and rapidly develop answers to such questions as the following:

“How did the problem come to the company’s attention?”

“How reliable is the information that suggests a problem exists?”

“How serious is the problem in terms of possible harm to consumers?”

“How much product is affected?”

“Where is the product?”

“Have we fixed the problem?”
The General Manager was identified as the individual who will be the company’s spokesperson in the event print or broadcast news media request interviews about the company’s action. All media inquiries should be directed to him and it is imperative that no one else talks to the media about the recall action. Spokesperson is usually on the firing line, and must be backed fully by management and given all reasonable support and training he needs to serve as the company’s voice during a crisis situation.

Clear, concise, and accurate communications during a product emergency is critical. Hence, the Recall Plan includes who in the company is to be notified of key developments at various stages of the recall or withdrawal process. The plan also states which outside parties – regulatory agencies, distributors and customers, and news media – are to be notified and at what stages of the process. Samples of press release, adverts and notifications are included in plan.

The Team should conduct practice or “mock” recalls to ensure that the plan really works. These trial runs should test the Team’s ability to use the Recall Plan to conduct a ready review of records related to processing, raw product, ingredients and containers, and to determine the distribution of a given product. Such exercises can also determine a distributor’s ability to locate product rapidly.

Review of the Recall Plan is to be conducted every six months by the Recall Coordinator, QA Manager and Sales Manager. Documentation and any changes to recall plan are to be reflected in amendments to plan.
6.4 Handling product recalls and withdrawals

The Recall Plan also describes the steps to be taken to determine if a problem warrants recalling product and who will be responsible for various action steps required regaining the product.

6.5 Recall status reports

The Company through the QA Manager should file periodic recall status reports on its effectiveness checks with the Food Safety Commission. Frequency depends on interval agreed with Commission. Although the regulatory authority does not have a specific requirement for recall status reports, this practice is in the best interest of the company thus a list of points that should be addressed and referred to regulatory authority has been included.

As can be seen the recall plan is a ‘living document that should be updated as needed to reflect changes in company operations and organisational structure.
Conclusion and Recommendations
Conclusion

The aim of this study was the setting up of traceability and recall systems in a local bakery. Two types of traceability systems were considered. These included a paper based traceability system and an IT enabled system. The company opted for the latter aided with a computerised ingredient dispenser. Through this system the company can also offer its products to its customers with an improved consistency.

The heavy reliance on a paper system has its drawbacks especially when relying on system on tracing a batch from raw material through to the retailer’s shelf. This type of system will invariably prove inadequate in a crisis. Paper records are inherently problematic, since they are often illegible, missing, or inaccurate and may not be contemporaneous. With a paper based system, considerable time and resources accessing traceability information is taken. Today’s e-commerce requirements are driving industry to move toward a complete paperless manufacturing environment.

The implementation of a traceability system requires upfront investments. All benefits were taken into consideration when implementing the traceability system. Through a cost/benefit analysis all benefits including the risks that are managed with the system were analysed. The company did not adopt a minimal compliance at minimal cost but used the regulation as a catalyst for better business practices.

As can be seen in chapter two of this study mandatory local and European traceability requirements do not request process traceability, which is the linking up
of the raw material with the process and finally the product. However a complete traceability system makes business sense and is beneficial in a number of ways.

Depending on the degree of implementation and the infrastructure selected by a company, product traceability processes may require significant investment. The benefits and savings are not obvious at face value. However the expenditure should be considered as a long-term strategic investment because it is linked to consumers’ safety through recalls of defective batches, the image of the company and the trust that consumers display when buying a product.

The scope of the traceability system is an important aspect in creating a good and reliable system. Time spent in defining the scope will be the most important investment one can make in designing a traceability program.

Issues considered prior to the implementation of traceability included the inventory management, regulatory compliance, management of raw material to specifications, documentation related to brand claims, recall containment, contract compliance and brand assurance.

It is of great importance that a company decides on the exact product specification and the batch (or lot) sizes prior to implementation of a traceability system. Batch sizes can be based on production or run time, on volume, or on the expiry date. Knowing that any food product manufactured by this company is undertaken once daily, it was decided that the batch size will reflect a day’s production.

This is very important as generally, being able to trace to the detail (product or a small batch level) will increase the costs in the traceability system. On the other
hand deciding on big batches will probably make the system less costly, but will increase the risks because if a problem arises, more products will be involved than would have otherwise been necessary.

Through the traceability system being adopted a company must identify characteristics of both incoming raw materials and outgoing processed materials and identify profit opportunities by correlating raw material supply attributes with improved outgoing product. The ‘value traceability hypothesis’ is that correlating these incoming attributes with outgoing product quality pays dividend.

Case studies have shown how companies have used traceability tools and services to improve the performance characteristics of existing products and create new products. Both activities relate to companies building, maintaining and differentiating their brands in the marketplace.

Another way traceability programs will affect the brand relates is through recall management. The traceability system will allow the company to perform minimal, quick and quiet recalls when and if needed. Such a system will provide brand protection or risk management services for the company. Investments in this system should also be measured as undertaken to reduce liability risks.

The study included the drafting of a Recall Plan according to the company’s organisation system.

It is evident that traceability is an issue much bigger than complying with regulatory requirements. Traceability is fundamental to the strategy of any branded food
company, retail or foodservice provider that has a direct relationship with the consumer.

High-performance traceability systems are a small investment that can be deployed to protect a company’s most valuable asset – the brand and the relationship with the customer and regulatory authorities. If firms fail to prepare adequately for contamination incidents and respond too slowly to problems, one can be certain that the regulatory authority will step in to fill this void.

When implementing a traceability system, the added value of such a system needs to be considered. Traceability systems can serve many purposes and may lead to the following benefits. Here are a few examples:

- Ensure a fast product withdrawal or recall, thus protecting the consumer.
- Minimise the impact of such a product recall, by limiting the scope of product implicated and providing traceability tools. The financial impact of recalling an entire commodity or brand versus a specific grouping of product (e.g., a lot) can be enormous.
- Enabling companies to demonstrate that their product is not implicated in a given product recall, by ensuring proper segregation and clear identification of product.
- Address concerns of food-sabotage or tampering.
- Strengthen consumer confidence, through the businesses’ ability to promptly identify and recall potentially unsafe product.
- Providing internal logistical and quality related information, improving efficiency.
Create a feedback loop to improve product quality, condition and delivery.

Providing reliable information between business to business; business and consumers; business and regulatory agencies such as the health inspectorate and business to financial or technical auditors.

Establishing the responsibility and liability for a certain problem.

Facilitate protection of company and/or brand name.

It is clear that traceability comes at a cost, but the cost of not having it or having an inefficient system in place may be severe for consumers, individual companies, government and the food industry as a whole.

Recommendations

Six silos containing flour and its control should not be left as a stand-alone system but should be incorporated in the traceability system being adopted.

Packaging material be included in the traceability system being implemented.

Although process traceability is incorporated in the system, it is recommended that this system is adopted in the confectionery area as well and should include the following:

- The time of start and end of production.
- Ambient temperature of food production areas.
- Temperature of food reached during manufacturing.
The system should be reviewed at least yearly through an audit consisting of a horizontal and a vertical assessment of the system. Audit should be documented and any improvements that are identified should be rectified immediately.

Once the new traceability system is adopted by the company, the Recall Team as identified in the drafted Recall Plan should carry out a mock recall to verify the effectiveness of the Recall Plan. This should be documented and any changes be reflected in the plan.

**Limitations of the study**

In view of the fact that the manufacturer is still installing an ingredient dispensing machine and related IT system, the traceability system and thus a mock recall based on the Recall Plan designed and presented in this dissertation could not be conducted. This would have been ideal to verify whether the Bakery is in fact prepared to affect such a recall.

A future study on the verification and validation of the systems being adopted may be undertaken to support this dissertation.
Annexes

Annex 1  Cases involved in outbreaks during 2004
Annex 2  Raw material intake
Annex 3  Product traceability
Annex 4  Consumer traceability
Annex 5  The key obligations of food and feed business operators
Cases involved in outbreaks during 2004

<table>
<thead>
<tr>
<th>Notifiable Disease</th>
<th>Jan-Mar</th>
<th>Apr-Jun</th>
<th>Jul-Sep</th>
<th>Oct-Dec</th>
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<tr>
<td>Food Poisoning, <em>Campylobacter</em></td>
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<tr>
<td>Food Poisoning unspecified</td>
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<td>103</td>
<td>8</td>
<td>41</td>
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*Source: Disease Surveillance Unit - Annual notifiable infectious disease report 2004*
### Raw Material Intake

**Supplier Details:**

**Item:**

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<tr>
<th>Batch Codes</th>
<th>Delivery Date</th>
<th>No. of units</th>
<th>Weight of units</th>
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<tr>
<td>1233</td>
<td>21/06/2005</td>
<td>10 BOXES</td>
<td>4 X 5L</td>
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Product Traceability

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<td>Lot No.</td>
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<tr>
<td>Best Before</td>
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<tr>
<td>End:</td>
<td></td>
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<td>Date of Production:</td>
<td></td>
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<tr>
<td>Time Started:</td>
<td></td>
</tr>
<tr>
<td>Ended:</td>
<td></td>
</tr>
<tr>
<td>Quantity Produced:</td>
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<table>
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<tr>
<th>Ingredients:</th>
<th>Quantity:</th>
<th>Batch:</th>
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</tbody>
</table>

Packaging material:  
Type: 
Code: 
Consumer Traceability

Customer:
Address
Telephone:
Delivery man:
Transport Vehicle
Temperature of vehicle during transport: \(0^\circ C\)
Temperature on delivery \(0^\circ C\)
List of Products: Quantity: Batch:

Signature of customer: ____________________________
THE KEY OBLIGATIONS OF FOOD AND FEED BUSINESS OPERATORS

Safety
Operators shall not place on the market unsafe food or feed

Responsibility
Operators are responsible for the safety of the food and feed which they produce, transport, store or sell

Traceability
Operators shall be able to rapidly identify any supplier or consignee

Transparency
Operators shall immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe

Emergency
Operators shall immediately withdraw food or feed from the market if they have a reason to believe that it is not safe

Prevention
Operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points

Co-operation
Operators shall co-operate with the competent authorities in actions taken to reduce risks

These obligations derive from the EU food safety legislation.

For further information, see
Website: http://europa.eu.int/comm/dgs/health_consumer/foodsafety.htm
Appendix A  Regulation (EC) 178 of 2002
Appendix B  Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 & 20 of Regulation (EC) 178/2002 on General Food Law
Appendix C  Guidelines No. DPH/XII/05
Appendix D  Regulation (EC) 1935 of 2004
Appendix E  Recall Plan
Appendix A

Regulation (EC) 178 of 2002
laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95, 133 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Having regard to the opinion of the Committee of the Regions (3),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (4),

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.

(4) There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

(5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.

(6) Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC (5) and 98/83/EC (6), it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/EC.

(7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.

(8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.

(2) OJ C 155, 29.5.2001, p. 32.
(9) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.

Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.

(10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.

(11) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.

In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.

(12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.

(13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.

It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

(14) For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.

(15) Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.

The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.

(16) Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.

(17) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis — risk assessment, risk management, and risk communication — provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.

(18) For the same reason, it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.

(19) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

(20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.

(21) In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.

(22) Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.
(23) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements; it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe food and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.

(24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.

(25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.

(26) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.

(27) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.

(28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

(29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

(30) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.

(31) Similar requirements should apply to feed and feed business operators.

(32) The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.

(33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority, hereinafter referred to as 'the Authority', should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.

(34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.

(35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.
The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not linked to the safety of the food supply chain should be limited to the provision of scientific opinions. The Authority’s mission should also cover scientific advice and scientific and technical support on human nutrition in relation to Community legislation and assistance to the Commission at its request on communication linked to Community health programmes.

Since some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be assessed by the Authority in accordance with the relevant legislation.

In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC (1) and without prejudice to the procedures established therein.

The Authority should contribute through the provision of support on scientific matters, to the Community’s and Member States’ role in the development and establishment of international food safety standards and trade agreements.

The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.

To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence and a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.

The Authority should have the means to perform all the tasks required to enable it to carry out its role.

The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.

The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.

The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.

In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.

The Authority’s role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions between scientific bodies, procedures should be in place to resolve the divergence or provide the risk managers with a transparent basis of scientific information.

The establishment of the Authority should enable the Commission to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Member States prevent duplication of effort. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.

The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for.

Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.

The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.

It is necessary to ensure that a balance is struck between the need to use national organisations to carry out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.

The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.

The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.

Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.

In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups.

The Authority should be financed by the general budget of the European Union. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.

It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.

A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety (1). The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom (2).

Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.

Recent food crises have also shown the benefits to the
Commission of having properly adapted, more rapid
procedures for crisis management. These organisational
procedures should make it possible to improve coordi-
nation of effort and to determine the most effective
measures on the basis of the best scientific information.
Therefore, revised procedures should take into account
the Authority’s responsibilities and should provide for its
scientific and technical assistance in the form of advice
in the event of a food crisis.

In order to ensure a more effective, comprehensive
approach to the food chain, a Committee on the Food
Chain and Animal Health should be established to
replace the Standing Veterinary Committee, the Standing
Committee for Foodstuffs and the Standing Committee
for Feedingstuffs. Accordingly, Council Decisions 68/
361/EEC (\(^1\)), 69/414/EEC (\(^2\)), and 70/372/EEC (\(^3\)), should
be repealed. For the same reason the Committee on
the Food Chain and Animal Health should also replace the
Standing Committee on Plant Health in relation to its
competence (for Directives 76/895/EEC (\(^4\)), 86/
362/EEC (\(^5\)), 86/363/EEC (\(^6\)), 90/642/EEC (\(^7\)) and 91/
414/EEC (\(^8\)) on plant protection products and the
setting of maximum residue levels.

The measures necessary for the implementation of this
Regulation should be adopted in accordance with
down the procedures for the exercise of implementing
powers conferred on the Commission (\(^9\)).

It is necessary that operators should have sufficient time
to adapt to some of the requirements established by the
present Regulation and that the European Food Safety
Authority should commence its operations on 1 January
2002.

It is important to avoid confusion between the missions
of the Authority and the European Agency for the Evalu-
ation of Medicinal Products (EMEA) established by
Council Regulation (EEC) No 2309/93 (\(^10\)). Conse-
quently, it is necessary to establish that this Regulation is
without prejudice to the competence conferred on the
EMEA by Community legislation, including powers
conferring by Council Regulation (EEC) No 2377/90 of
26 June 1990 laying down a Community procedure for
the establishment of maximum residue limits of veter-
inary medicinal products in foodstuffs of animal
origin (\(^11\)).

It is necessary and appropriate for the achievement of
the basic objectives of this Regulation to provide for the
approximation of the concepts, principles and proced-
ures forming a common basis for food law in the
Community and to establish a European Food Safety
Authority. In accordance with the principle of propor-
tionality as set out in Article 5 of the Treaty, this Regu-
ation does not go beyond what is necessary in order to
achieve the objectives pursued.

The measures necessary for the implementation of this
Regulation should be adopted in accordance with
down the procedures for the exercise of implementing
powers conferred on the Commission (\(^9\)).

**CHAPTER I

SCOPE AND DEFINITIONS**

1. **Aim and scope**

   It establishes common principles and responsibilities, the
   means to provide a strong science base, efficient organisational
   arrangements and procedures to underpin decision-making in
   matters of food and feed safety.

   It lays down procedures for matters with a direct or indirect
   impact on food and feed safety.

2. **For the purposes of paragraph 1, this Regulation lays
down the general principles governing food and feed in
general, and food and feed safety in particular, at Community
and national level.**

   It establishes the European Food Safety Authority.
3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Article 2

Definition of 'food'

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

(a) feed;

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2);

(e) cosmetics within the meaning of Council Directive 76/768/EEC (3);

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4);


(h) residues and contaminants.

Article 3

Other definitions

For the purposes of this Regulation:

1. 'Food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;

2. 'Food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

3. 'Food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

4. 'Feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

5. 'Feed business' means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

6. 'Feed business operator' means the natural or legal persons responsible for ensuring that the requirements of feed law are met within the feed business under their control;

7. 'Retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

8. 'Placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;

9. 'Risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

10. 'Risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

11. 'Risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

12. 'Risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
13. 'risk communication' means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

15. 'traceability' means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

16. 'stages of production, processing and distribution' means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;

17. 'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;

18. 'final consumer' means the ultimate consumer of a food-stuff who will not use the food as part of any food business operation or activity.

CHAPTER II
GENERAL FOOD LAW

Article 4
Scope

1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.

2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.

3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.

4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

SECTION 1
GENERAL PRINCIPLES OF FOOD LAW

Article 5
General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.
**Article 7**

**Precautionary principle**

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be renewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

**Article 8**

**Protection of consumers' interests**

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

   (a) fraudulent or deceptive practices;
   
   (b) the adulteration of food; and
   
   (c) any other practices which may mislead the consumer.

**SECTION 2**

**PRINCIPLES OF TRANSPARENCY**

**Article 9**

**Public consultation**

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

**Article 10**

**Public information**

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

**SECTION 3**

**GENERAL OBLIGATIONS OF FOOD TRADE**

**Article 11**

**Food and feed imported into the Community**

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

**Article 12**

**Food and feed exported from the Community**

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.
Article 13

International standards

Without prejudice to their rights and obligations, the Community and the Member States shall:

(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;

(b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations;

(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;

(d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;

(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.

SECTION 4

GENERAL REQUIREMENTS OF FOOD LAW

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from imposing restrictions or its being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 15

Feed safety requirements

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

2. Feed shall be deemed to be unsafe for its intended use if it is considered to:

— have an adverse effect on human or animal health;

— make the food derived from food-producing animals unsafe for human consumption.
3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 16
Presentation

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Article 17
Responsibilities

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 18
Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19
Responsibilities for food: food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.
2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Article 20

Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

Article 21

Liability

4. The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

5. The mission of the Authority shall also include the provision of:

(a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;

(b) scientific opinions on other matters relating to animal health and welfare and plant health;

(c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

6. The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to those of the Authority.

8. The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

9. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

**Article 23**

**Tasks of the Authority**

The tasks of the Authority shall be the following:

(a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;

(b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;

(c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;

(d) to commission scientific studies necessary for the accomplishment of its mission;

(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;

(f) to undertake action to identify and characterise emerging risks, in the fields within its mission;

(g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;

(h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;

(i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

(k) to express independently its own conclusions and orientations on matters within its mission;

(l) to undertake any other task assigned to it by the Commission within its mission.

**SECTION 2**

**ORGANISATION**

**Article 24**

**Bodies of the Authority**

The Authority shall comprise:

(a) a Management Board;

(b) an Executive Director and his staff;

(c) an Advisory Forum;

(d) a Scientific Committee and Scientific Panels.
The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

2. Members' term of office shall be four years, and may be renewed once. However, for the first mandate, this period shall be six years for half of the members.

3. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.

4. The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.

5. The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

6. The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.

7. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

8. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities(1) and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

Article 26

Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the Official Journal of the European Communities and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.

2. The Executive Director shall be the legal representative of the Authority and shall be responsible for:

(a) the day-to-day administration of the Authority;

(b) drawing up a proposal for the Authority's work programmes in consultation with the Commission;

(c) implementing the work programmes and the decisions adopted by the Management Board;

(d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;

(e) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

(f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;

(g) all staff matters;

(h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

3. Each year, the Executive Director shall submit to the Management Board for approval:

(a) a draft general report covering all the activities of the Authority in the previous year;

(b) draft programmes of work;

(c) the draft annual accounts for the previous year;

(d) the draft budget for the coming year.

The Executive Director shall, following adoption by the Management Board, forward the general report and the programmes to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

Advisory Forum

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.

2. Members of the Advisory Forum may not be members of the Management Board.

3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.

4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:

(a) avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;

(b) in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;

(c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);

(d) where the Authority or a Member State identifies an emerging risk.

5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the initiative of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.

6. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.

7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.

Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

Scientific Committee and Scientific Panels

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.

2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on intersectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.

Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.

3. The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.

4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:

(a) the Panel on food additives, flavourings, processing aids and materials in contact with food;

(b) the Panel on additives and products or substances used in animal feed;

(c) the Panel on plant health, plant protection products and their residues;

(d) the Panel on genetically modified organisms;

(e) the Panel on dietetic products, nutrition and allergies;

(f) the Panel on biological products;

(g) the Panel on contaminants in the food chain;

(h) the Panel on animal health and welfare.

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 58(2).

5. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the Official Journal of the European Communities, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.
6. The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules. These procedures shall relate in particular to:

(a) the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;
(b) the number of members in each Scientific Panel;
(c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;
(d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;
(e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;
(f) the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;
(g) the possibility of organising public hearings.

SECTION 3

OPERATION

Article 29

Scientific opinions

1. The Authority shall issue a scientific opinion:

(a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;
(b) on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:

(a) the procedure to be applied by the Authority to the requests referred to it;
(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

7. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 30

Diverging scientific opinions

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.
3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or presenting a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 31

Scientific and technical assistance

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which do not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.

Article 32

Scientific studies

1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 33

Collection of data

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

   (a) food consumption and the exposure of individuals to risks related to the consumption of food;
   (b) incidence and prevalence of biological risk;
   (c) contaminants in food and feed;
   (d) residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

(a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;

(b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 34

Identification of emerging risks

1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.
3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 35

Rapid alert system

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.

Article 36

Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority’s mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 38(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.

4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.

SECTION 4

INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION

Article 37

Independence

1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

Article 38

Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

(a) agendas and minutes of the Scientific Committee and the Scientific Panels;

(b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;

(c) without prejudice to Articles 39 and 41, the information on which its opinions are based;

(d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings.
(e) the results of its scientific studies;
(f) the annual report of its activities;
(g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

7. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority’s activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 39

Confidentiality

1. By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

Article 40

Communications from the Authority

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission’s competence to communicate its risk management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

Article 41

Access to documents

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking full account of the general principles and conditions governing the right of access to the Community institutions’ documents.

Article 42

Consumers, producers and other interested parties

The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

SECTION 5

FINANCIAL PROVISIONS

Article 43

Adoption of the Authority’s budget

1. The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.

2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.

3. In good time, before the date referred to in paragraph 5, the Executive Director shall draw up an estimate of the Authority’s revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward them to the Commission, and the States with which the Community has concluded the agreements referred to in Article 49. On the basis of that draft, the Commission shall enter the relevant estimates in the preliminary draft general budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty.
6. After the adoption of the general budget of the European Union by the budgetary authority, the Management Board shall adopt the Authority's final budget and work programme, adjusting them where necessary to the Community's contribution. It shall forward them without delay to the Commission and the budgetary authority.

Article 44

Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.

2. Control of commitment and payment of all expenditure and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.

3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Council, shall give a discharge to the Authority's Executive Director in respect of the implementation of the budget.

Article 45

Fees received by the Authority

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.

SECTION 6

GENERAL PROVISIONS

Article 46

Legal personality and privileges

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

Article 47

Liability

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.

2. In the case of non-contractual liability, the Authority, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.

Article 48

Staff

1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.

2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

Article 49

Participation of third countries

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.
CHAPTER IV
RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES

SECTION 1

RAPID ALERT SYSTEM

Article 50

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;

(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;

(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Article 51

Implementing measures

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

Article 52

Confidentiality rules for the rapid alert system

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.
However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

2. However, in EMERGENCIES, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.

Article 54

Other emergency measures

1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.

SECTION 3

CRISIS MANAGEMENT

Article 55

General plan for crisis management

1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.
1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.

**CHAPTER V**

**PROCEDURES AND FINAL PROVISIONS**

**SECTION 1**

**COMMITTEE AND MEDIATION PROCEDURES**

**Article 58**

**Committee**

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.

2. Where reference is made to this paragraph, the procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

**Article 59**

**Functions assigned to the Committee**

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.

**Article 60**

**Mediation procedure**

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

**SECTION 2**

**FINAL PROVISIONS**

**Article 61**

**Review clause**

1. Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level.
The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Before 1 January 2005, the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

3. The reports and recommendations referred to in paragraphs 1 and 2 shall be forwarded to the Council and the European Parliament.

Article 62

References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feeding-stuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.


3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community Regulations, Directives and Decisions.


Article 63

Competence of the European Agency for the Evaluation of Medicinal Products


Article 64

Commencement of the Authority's operation

The Authority shall commence its operations on 1 January 2002.

Article 65

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Communities.

Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.

Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the 'C' series of the Official Journal.

This Regulation shall be binding in its entirety and directly applicable in all Member States.


For the European Parliament
The President
P. COX

For the Council
The President
J. PIQUÉ I CAMPS

Appendix B

Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) 178/2002 on General Food Law
GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 16, 17, 18, 19 AND 20 OF REGULATION (EC) N° 178/2002 ON GENERAL FOOD LAW

CONCLUSIONS OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
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VI. ARTICLE 12: EXPORT OF FOOD AND FEED
INTRODUCTION

Regulation (EC) N° 178/2002\(^1\) (hereafter “the Regulation”) was adopted on 28 January 2002. One of its objectives is to establish common definitions and to lay down overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection and the effective functioning of the internal market.

Chapter II of the Regulation seeks to harmonise at Community level general food law principles (Articles 5 to 10) and requirements (Article 14 to 21), already existing in Member States’ legal history, placing them in the European context and providing the basic framework of definitions, principles and requirements for future European food law.

Following an informal working practice, the Commission's Health and Consumer protection Directorate General has set up a Working Group with experts from Member States in order to examine and reach consensus on a series of issues concerning the implementation and interpretation of the Regulation.

In addition, in the interest of transparency, the Commission has encouraged all parties concerned to discuss the implementation and application of the Regulation openly and in forums where Member States can be consulted and where different socio-economic interests can express an opinion. To this end the Commission has organised a meeting with representatives from Member States, producers, industry, commerce and consumers to discuss general issues relating to the implementation of the Regulation (held on 19 April 2004). However, it should be noted that matters relating to the non-compliance of national legislation with the Regulation remain outside the scope of this exercise and will continue to be dealt with in accordance with established Commission procedures.

Finally, the Standing Committee on the Food Chain and Animal Health has approved the following conclusions at its meeting of 20 December 2004 and considers that this useful procedure should continue in the light of the experience gained by the full application of the Regulation from 1 January 2005. These conclusions shall be made widely available to interested parties.

The present document aims to assist all players in the food chain to better understand and to apply correctly and in a uniform way the Regulation. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

It is also mentioned that some issues, specific to a category of food business operators, have been subject to written position from the Commission\(^2\).

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\(^2\) Written question E-2704/04 of W. Pieck on the implementation of traceability requirements to charities.
The following issues will be addressed:

- Responsibilities (Article 17);
- Traceability (Article 18);
- Withdrawal, recall and notification for food and feed (Articles 19 and 20) in relation to food and feed safety requirements (Articles 14 and 15);
- Imports and exports (Articles 11 and 12).
I. ARTICLÉ 17

RESPONSIBILITIES

Article 17

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.
I.1. **Rationale**

- This Article lies within the objective that was set in the White Paper on Food Safety to define the roles of competent Member States authorities and all categories of stakeholders in the food and feed chains—indicated thereafter by the term “food chain” (i.e. farmers, feed and food manufacturers, importers, brokers, distributors, public and private catering businesses).

- Given that a food business operator is best placed to devise a safe system for supplying food/feed and ensuring that the food/feed it supplies is safe, it holds **primary legal responsibility** for ensuring compliance with food law and in particular food safety.

I.2. **Implications**

- Article 17 (1) imposes on food business operators an obligation according to which they must actively participate in implementing food law requirements by verifying that such requirements are met. This general requirement is closely linked to other mandatory requirements laid down by specific legislation (i.e. HACCP implementation in the field of food hygiene).

- Thus Article 17 (1) implies a responsibility of the operators for the activities under their control pursuant to the classical liability rules according to which any person should be held liable for things and acts under his control. It consolidates this requirement in the Community legal order applicable in the field of food law (not only food safety legislation but also other food legislation), and thus prohibits Member States from maintaining or adopting nationally legal provisions which would exonerate any food business operator from this obligation.

- Though the requirement laid down in Article 17 (1) is directly applicable from 1 January 2005, the liability of food business operators should flow in practice from the breach of a specific food law requirement (and from the rules for civil or criminal liability which can be found in the national legal order of each Member state). The liability proceedings will not be based on Article 17 but on a legal basis to be found in the national legal order and in the specific infringed legislation.

- Article 17 (2) establishes a general duty for the competent Authorities in the Member States to monitor and control that food law requirements have comprehensively and effectively been enforced at all stages of the food chain.

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3 For the understanding of the present document, the term “food business operator” covers both food and feed business operators.

4 For the understanding of the present document, the term “food law” covers both food and feed law and the term “food safety” covers both food and feed safety.
1.3. **Contribution/Impact**

1.3.1. **General Compliance and verification requirement**

- From 1 January 2005 this rule becomes a general requirement applicable in all Member States and all areas of food law.

- The consolidation of this requirement should eliminate disparities resulting in barriers to trade and competitive distortion between food business operators.

- It takes full account of the fundamental role of food businesses to the **farm to table policy** - covering all sectors of the food chain, in particular in ensuring food safety.

1.3.2. **Allocation of liability**

- Article 17 aims at:
  
  - Defining responsibilities of food business operators and differentiating them from those of Member States and,
  
  - Extending to all areas of food law, the principle according to which primary responsibility for ensuring compliance with food law, and in particular the safety of the food, remains with the food business.

- The Article does not have the effect of introducing a Community regime regulating the allocation of liability among the different links of the food chain. Determining the facts and circumstances which may render an operator liable to criminal penalties and/or civil liability is a complex matter which depends very much on the structure of the different national legal systems.

- It should be noted that any discussion related to matters of responsibility should take into account the fact that interactions between producers, manufacturers and distributors are becoming increasingly complex. Thus for example, in many cases primary producers have contractual obligations to manufacturers or distributors to meet specifications which cover quality and/or safety. Distributors increasingly have products produced under their own brand-name and play a key role in product conception and design.

  This new situation should then result in greater joint responsibility throughout the food chain, rather than dispersed individual responsibilities. However, each link in the food chain should take the measures necessary to ensure compliance with food law requirements within the context of its own specific activities, applying HACCP-type principles and other similar instruments.

Where a product is found failing food law requirements, the liability of each link in the chain should be reviewed according to whether or not it has properly fulfilled its own specific responsibilities.

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## II. ARTICLE 18

### TRACEABILITY

**Recital 28**
Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

**Recital 29**
It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

**Article 3 Point 15**
‘Traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

**Article 18**

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).
II.1. Rationale

Recent food scares (BSE and dioxin crisis) have demonstrated that the identification of the origin of feed and food is of prime importance for the protection of consumers. In particular, traceability helps facilitate the withdrawal of food and enables consumers to be provided with targeted and accurate information concerning implicated products. Traceability does not itself make food safe. It is a risk management tool to be used in order to assist in containing a food safety problem.

- Traceability has different objectives such as food safety, fair trading between operators and reliability of the information provided to consumers. The Regulation introduces the traceability requirement with in particular the objective to ensure food safety and to assist in enabling unsafe food/feed to be removed from the market.

- Traceability is meant to ensure that targeted and accurate withdrawals or recalls can be undertaken, appropriate information can be given to consumers and food business operators, risk assessment can be performed by control authorities and unnecessary wider disruption of trade can be avoided.

II.2. Implications

- Article 18 requires food business operators:
  - to be able to identify from whom and to whom a product has been supplied;
  - to have systems and procedures in place that allow for this information to be made available to the competent Authorities upon their request.

The requirement relies on the “one step back”-“one step forward” approach which implies for food business operators that:

- They shall have in place a system enabling them to identify the immediate supplier(s) and immediate customer(s) of their products.
- A link “supplier-product” shall be established (which products supplied from which suppliers).
- A link “customer-product” shall be established (which products supplied to which customers). Nevertheless, food business operators do not have to identify the immediate customers when they are final consumers.

II.3. Contribution/impact

- Although traceability is not a new notion in the food chain, it is the first time that the obligation for all food business operators to identify the suppliers and direct recipients of their food/feed is stipulated explicitly in a horizontal community legal text. Consequently, Article 18 creates a new general obligation for food business operators.
• Article 18 is worded in terms of its goal and intended result, rather than in terms of prescribing how that result is to be achieved.

Without prejudice to specific requirements, this more general approach leaves industry with greater flexibility in the implementation of the requirement and is thus likely to reduce compliance costs. However, it requires both food businesses and the control authorities to take an active role in ensuring effective implementation. This may present some difficulties, although the elaboration of industry codes of practices could alleviate the problem.

II.3.1. Scope of the traceability requirement

i) Covered products.

• The wording of this Article and in particular the part “any substance intended to be, or expected to be, incorporated into a food or feed” should not be interpreted in the sense that veterinary medicinal products, plant protection products, fertilisers may fall into the scope of the requirement. It should be noted that some of these products are covered by specific Regulations or Directives that may even impose more stringent requirements on traceability.

• The covered substances are those intended or expected to be “incorporated”, as a part of a food or feed during its manufacture, preparation or treatment. This would cover for example all types of food and feed ingredients, included grain when incorporated in a feed or food. But it excludes grain when used as seed for cultivation.

• Similarly, packaging material does not make part of food as defined under Article 2 and does not fall into the scope of Article 18 despite the possible unvoluntary migration of its constituents into the food. The traceability of those food packaging materials has been covered by specific rules, adopted on 27 October 2004.

• Furthermore, the new food hygiene Regulation (EC) N° 852/2004 and the forthcoming feed hygiene Regulation should ensure, from the 1st of January 2006, a link between food/feed and veterinary medicinal and plant protection products, covering this gap as farmers will have to keep and retain records on these products.

ii) Covered operators

• Article 18 of the Regulation applies to food business operators at all stages of the food chain, from primary production (food producing animals, harvests), food/feed processing to distribution. This includes charities. However, Member States should take into consideration the particular situation of charities and donation activities in the context of enforcement and sanctions.

• Article 3 Points 2 and 5 defines a food business operator as "any undertaking carrying out any of the activities related to any stage of production, processing and distribution of food/feed". Transporters and storage operators, as undertakings involved in the distribution of food/feed, are covered by this definition and are required to comply with Article 18.

• Where transportation is integrated within a food business, the business as a whole must comply with the provision of Article 18. For the transport unit, maintaining records of products supplied to customers may be sufficient as other units within the business would maintain records of products received from suppliers.

• The manufacturers of veterinary medicinal products, agricultural production inputs (such as seeds) are not subject to the requirements of Article 18.

iii) Applicability to third country exporters (in connection with Article 11)

• The traceability provisions of the Regulation do not have an extra-territorial effect outside the EU. This requirement covers all stages of production, processing and distribution in the EU, namely from the importer up to the retail level.

• Article 11 should not be construed as extending the traceability requirement to food business operators in third countries. It requires that food/feed imported into the Community complies with the relevant requirements of EU food law.

• Exporters in trading partner countries are not legally required to fulfil the traceability requirement imposed within the EU (except in circumstances where there are special bilateral agreements for certain sensitive sectors or where there are specific Community legal requirements, for example in the veterinary sector).

• The objective of Article 18 is sufficiently fulfilled because the requirement extends to the importer. Since the EU importer shall be able to identify from whom the product was exported in the third country, the requirement of Article 18 and its objective is deemed to be satisfied.

• It is common practice among some EU food business operators to request trading partners to meet the traceability requirements and even beyond the "one step back-one step forward" principle. However, it should be noted that such requests are part of the food business's contractual arrangements and not of requirements established by the Regulation.

II.3.2. Implementation of traceability requirement

i) Identification of suppliers and customers by food business operators

   - A food business operator should be able to identify any "person" from whom it received its food/raw materials. This person can be an individual (for example a hunter or a mushroom collector) or a legal person. Recital 29 stipulates that a food business
must identify at least the business from which the food/feed or substance that may be incorporated into a food/feed has been supplied.

It should be clarified that the term “supply” should not be interpreted as the mere physical delivery of the food/feed or food producing animal (e.g. truck driver who is an employer for a certain operator). Identifying the name of the person physically delivering is not the objective pursued by this rule and it would not be sufficient to guarantee the traceability along the food chain.

- A food business operator must identify only the other businesses (legal entity) to whom it provides its products (excluding final consumers). In case of trade between retailers, such as a distributor and a restaurant, the traceability requirement is also applicable.

ii) Internal traceability

- It is in the logic of Article 18 that a certain level of internal traceability would be put in place by food business operators. Article 18 has to be read in conjunction with Recital 28 which refers to a “comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken, thereby avoiding the potential for unnecessary disruption in the event of food safety problems”.

- An internal traceability system will benefit the operator by contributing to more targeted and accurate withdrawals. Food business operators would save costs in terms of time of a withdrawal and in avoiding unnecessary wider disruption.

- Without prejudice to more detailed rules, the Regulation does not compel operators to establish a link (so called internal traceability) between incoming and outgoing products. Nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches.

- In summary, food business operators should be encouraged to develop systems of internal traceability designed in relation to the nature of their activities (food processing, storage, distribution etc). The decision on the level of detail of the internal traceability should be left upon the business operator, commensurate with the nature and size of the food business.

iii) Traceability systems laid down by specific legislations

Apart from specific legislations establishing food safety traceability rules for certain sectors/products in line with the “spirit” of Article 18, there is a set of specific regulations laying down marketing and quality standards for certain products. These regulations that often have fair trade purposes contain provisions about the identification of the products, the transmission of the documents accompanying the transactions, the keeping of records, etc.

Any other system of identification of products existing within the framework of specific provisions may be used to satisfy the requirement established by Article 18, insofar as it
allows the identification of the suppliers and of the direct recipients of the products at all stages of production, processing and distribution.

However, the traceability requirements of the Regulation are general requirements and are therefore always applicable. The determination whether sectoral traceability provisions already meet Article 18 requirements would need a detailed analysis of those provisions.

iv) Types of information to be kept

Article 18 does not specify what types of information should be kept by the food and feed business operators. All relevant information for traceability purpose should be kept depending on each traceability system features.

However, to fulfil the objective of Article 18, the registration of the following information is considered necessary. This information can be classified in 2 categories according to its level of priority:

- The first category of information includes any information which shall be made available to the competent Authorities in all cases:
  
  - Name, address of supplier, nature of products which were supplied from him.
  - Name, address of customer, nature of products that were delivered to that customer.
  - Date of transaction / delivery.

  The registration of date of transaction/delivery flows directly from the registration of the two other items. When a same type of products is provided several times to a food business operator, the sole registration of name of supplier and nature of products would not ensure the traceability requirement.

- The second category of information includes additional information which is highly recommended to be kept:
  
  - Volume or quantity
  - Batch number, if any.
  - More detailed description of the product (pre-packed or bulk product, variety of fruit/vegetable, raw or processed product).

The information to be registered has to be chosen in light of the food business activity (nature and size of business) and the characteristics of the traceability system.

Food crises in the past have shown that tracing the commercial flow of a product (by invoices at the level of a company) was not sufficient to follow the physical flow of the products. Therefore, it is essential that traceability system of each food / feed business operator is designed to follow the physical flow of the products: the use of delivery notes (or registration of the address of producing units) would ensure more efficient traceability.
v) Time of reaction for traceability data availability

- Article 18 requires food and feed operators to have in place systems and procedures to ensure the traceability of their products. Although the Article does not provide any details about these systems, the use of terms "systems" and "procedures" implies a structured mechanism able to deliver the needed information upon request from the competent Authorities.

- The most crucial point in having a good traceability system in place that would satisfy the objective pursued as described in Recital 28, is the time needed to deliver fast and accurate information. A delay in the delivery of this relevant information would undermine a prompt reaction in case of crisis.

- The minimal information which belongs to the first category defined above shall be immediately available to the competent authorities.

- The information belonging to the second category shall be available as soon as reasonably practicable, within deadlines appropriate to circumstances.

vi) Time of records keeping

Article 18 does not foresee a minimum period of time for keeping records. On a broad basis, it is considered that commercial documents are usually registered for a period of 5 years for taxation controls. This 5 year period, where applied from date of manufacturing or delivery to traceability records, would be likely to meet the objective of Article 18.

However, this common rule would need to be adapted in some cases:

- For products\(^7\) without a specified shelf life, the general rule of 5 years applies;

- For products with a shelf life above 5 years, records should be kept for the period of the shelf-life plus 6 months;

- For highly perishable products, which have a “use by” date less than 3 months or without a specified date\(^8\), destined directly to final consumer, records should be kept for the period of 6 months after date of manufacturing or delivery.

Finally, it should be taken into account that, apart from the traceability provisions of Article 18 of the Regulation, many food businesses are subject to more specific requirements in terms of record keeping (type of information to be kept and time). Competent authorities should ensure that they comply with these rules.

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\(^6\) more particularly to records belonging to the first category of information foreseen in paragraph II. 3. 4.

\(^7\) Products such as wine.

\(^8\) Products such as fruits, vegetables and non pre-packed products.
III. ARTICLE 19

WITHDRAWAL, RECALL AND NOTIFICATION

BY FOOD BUSINESS OPERATORS

**Article 19**

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.
III.1. **Rationale**

- The obligations of Article 19 aim at reducing or eliminating the risk due to the placing on the market of unsafe foodstuffs and at preventing, reducing or eliminating the risk due to the placing of the market of food that may be injurious to health.

- The extent of the obligations of operators in relation to withdrawal (or recall) and notification of an unsafe food is correlated to the general safety requirements provided for in Article 14 of Regulation 178/2002.

- To ensure the proportionality of the actions taken to reduce or eliminate a risk, it is important to make reference to relevant criteria for applying the concept of unsafe food, noting that withdrawal and recall are meant to be used when such an immediate action is necessary to eliminate a risk.

- The information of competent Authorities by the food business operators is an important element for market surveillance as it enables the competent authorities to monitor whether the business operators have taken the appropriate measures to address the risks posed by a food placed on the market and to order or take additional measures if necessary for avoiding the risks.

III.2. **Implications**

- Article 19 imposes specific obligations from 1\textsuperscript{st} January 2005 on food business operators to withdraw from the market food that does not meet the food safety requirements and to notify this to competent authorities. Where the product may have reached the consumer, the operator shall inform the consumer and if necessary recall from consumers' products already supplied to them.

- Article 19 provides for the necessary cooperation between the food chain operators in order to ensure the withdrawal of unsafe food from the market.

- Article 19 imposes a specific obligation on the food business operator to inform the competent authorities should it considers or has reason to believe that a food which it has placed on the market may be injurious to health.

- It specifies a general obligation of cooperation of the food business operators with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.
III.3. Contribution/ Impact

III.3.1. Article 19 (1)

i) Obligation to withdraw

Article 19 (1) imposes the specific obligation on food business operators to withdraw from the market a food that does not meet the food safety requirements and inform the competent authorities thereof.

Regarding a definition of withdrawal, reference can be made to the definition laid down in Directive 2001/95/EC on General Product Safety which states that “withdrawal means any measure aimed at preventing the distribution, display or offer of a product dangerous to the consumer”.

It has to be underlined that in the context of Article 19:

- The withdrawal from the market may take place at any step along the food chain and not only at time of delivering to the end consumer;

- The obligation to notify a withdrawal to the competent Authorities is a consequence of the obligation to withdraw;

- The obligation to withdraw from the market applies when the following two cumulative criteria are met:

  ➢ First criterion triggering a withdrawal: the food in question is considered by the operator as not being in compliance with the food safety requirements

Article 14 of Regulation 178/2002 provides for the approach to follow in making this type of consideration.

Paragraphs 2, 3, 4 and 5 provide for general criteria that have to be taken into account to consider a food unsafe.

- Article 14 (2) provides that a food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption.

- Article 14 (3) provides that in determining whether any food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and to the information provided to the consumer.

- Article 14 (4) and 14 (5) provide that in determining whether any food is injurious to health or unfit for human consumption regard shall be had to certain criteria.
In more concrete terms, Article 14 (7) and Article 14 (9) specify that food compliant with the specific Community provisions (or in their absence, with national provisions) governing the safety of the food in question is deemed to be safe.

Finally the wording of Article 14 (8), even if it is explained in the framework of the actions of the competent authorities, confirms that despite the conformity of a food to applicable specific provisions, this food can be found unsafe.

Second criterion triggering a withdrawal: a food is on the market and has left the immediate control of the initial food business

This criterion derives from the wording used in Article 19 (1) "withdrawal from the market", which implies that the food was placed on the market. In addition, Article 19 (1) provides that a withdrawal shall be undertaken only when the food in question has left the immediate control of the initial operator.

Therefore, the scope of the withdrawal foreseen in the framework of Article 19 (1) does not concern actions of withdrawal undertaken before the placing on the market of a product. Furthermore, withdrawals of food that has not left the immediate control of the operator are not defined as withdrawal within the meaning of Article 19 (1).

The wording "has left the immediate control of the initial operator" stresses that when there is the possibility for the food business operators to remedy the non compliance by their own means, without a need to request/require cooperation from other operators, the obligations of Article 19 (1) do not apply. The additional words "of the initial operator" are important. It implies that the food has left for example the processing unit and is in the hands of an other operator (change of step inside the food chain).

The scope of the withdrawal defined in Article 19 (1) does not limit the scope of withdrawal that can be decided by competent authorities. Food business operators can be required to withdraw a food which is under their immediate control as directed by a competent authority whenever such measures are justified.

The scope of the withdrawal defined in Article 19 (1) is without prejudice to the legal obligation on food business operators to ensure, within the businesses under their control, that foods satisfy the requirements of food law (e.g. Article 17 (1) above).

ii) Practical approach

In the framework of the approach established in Article 14, two types of cases will need to be considered:

The food does not comply with the specific Community (or national) provisions governing its safety:

A food compliant with the specific Community (or national) provisions governing its safety is deemed safe in accordance with Article 14 (7) and (9).

As defined in Article 2 of Reg.178/2002
When the food does not comply with the specific Community (or in their absence, national) provisions governing its safety, it can be presumed that the food is unsafe and the general criteria set up in paragraphs 2, 3, 4 and 5 of Article 14 have to be taken into account.

These criteria are general and have to be considered on a case by case basis. In particular, these criteria have to be considered in the light of the specific legislation applicable to the food involved.

For example, Article 14 (3) provides that in determining whether any food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution. This general criterion will need to be considered in the framework of the applicable legislation.

Specific legislative provisions provide for example for different levels of safety according to the destination of the food (food intended for direct human consumption and food not for direct human consumption but intended for secondary treatment). These specific legislations usually provide for additional requirements ensuring that a food not intended for direct human consumption will not be provided to a final consumer or used as an ingredient before undertaking secondary treatment and these requirements must be respected.

Factual questions such as satisfactory representativeness of samples or the sensitivity of analytical methods might also need to be addressed.

National legislation or guidelines may also help for the determination of the unsafe character of a food (some national legislation includes in particular provisions on food injurious to health or unfit for human consumption). These national legislation or guidelines will have to be in conformity with Article 14 or EU sectoral legislation when this legislation provides for a definition of an unsafe food. In particular, considering that the purpose of Article 14 is the setting up of food safety requirements, these provisions shall be limited to identifying cases where there is a direct or indirect risk for human health deriving from the food.

This section has been particularly identified as requiring further discussion and eventual revision in the light of the experience gained.

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10 Article 4 (3) of Regulation N 466/2001 setting up maximum levels for certain contaminants in foodstuff provides that “groundnuts, nuts and dried fruits not complying with the maximum level of aflatoxins laid down in point 2.1.1.1 of Annex I and cereals not complying with the maximum levels laid down in point 2.2.2.1 can be placed on the market provided that these products a) are not intended for direct human consumption or used as an ingredient in foodstuffs; b) comply with the maximum levels laid down in point 2.1.1.2 of Annex I for groundnuts and point 2.1.1.3 of Annex I for nuts and dried fruits c) are subjected to a secondary treatment involving ( ) c) are labelled clearly showing their destination and bearing the indication “product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs.”

11 For example Article 5 of Regulation N 2377/90 on maximum residues limits of veterinary medicinal products in foodstuffs of animal origin provides that the substances included in Annex IV are substances for which no residues limits are possible because residues of the substances concerned at whatever limit, constitute a hazard to the health of consumer. In addition, the current discussion on the establishment of EU microbiological criteria contemplates two sets of food safety criteria. One of this criteria, “a food safety criterion”, is defined as a criterion defining the safety and acceptability of a product or a batch of foodstuff applicable to products ready to be placed on the market or which are already on the market. It sets a limit value above which a product or a batch of foodstuffs is considered “unsafe”.
The food complies with the specific Community (or in their absence, national) provisions governing its safety but there are reasons to consider that it is unsafe

When an operator considers or has reason to believe that a food is unsafe, despite its conformity with the specific Community (or in their absence, national) provisions governing its safety, it shall also withdraw the food in question from the market.

This type of case might happen because of accidental (or intentional) contamination not foreseen in legislation. For example when an operator has reason to believe, because of information in its possession, that the consumption of a food that if has placed on the market is causing food poisoning or otherwise injuring the health of consumers, it shall withdraw the food in question.

The presence in a food of foreign material with the potential to cause injury (e.g. glass, metal) would fall in this category. It is not a case always explicitly foreseen in existing legislation but the food is considered unsafe.

This type of case can also arise when new scientific information is available on a substance authorised in legislation. In this type of case, the percentage of uncertainty is in some cases high and it will fall in practice in the situation covered by Article 19 (3).

iii) Notification of the withdrawal to the competent authorities

When a food business operator withdraws a food in accordance with Article 19 (1), it shall notify this withdrawal to the competent authorities which supervises his establishment. It is up to the national authority to trigger the RASFF according to point III.3.5 if relevant.

It is useful to emphasise that when a food business operator takes out of the food chain a food that does not meet the food safety requirements but that is under its immediate control, there is no obligation to notify the competent authorities under the provisions of Article 19 (1).

Agreed guidelines between national competent authorities and food business operators may provide for this information.

iv) Modalities of the notification to the competent authorities

Modalities of the notification procedure to the competent authorities should be left to subsidiarity (up to national or regional competent Authorities).

v) Recall and information to the consumers

When the same circumstances as the ones mentioned for withdrawal are met and when in addition, the product may have reached the consumer, Article 19 (1) requires the food business operators:

- To inform the consumer of the reason for withdrawal
and,

- If necessary to recall from consumers products already supplied to them - i.e. to take “any measure aimed at achieving the return of a unsafe product that has already been supplied or made available to consumers by a food business operator”. The recall is necessary when other measures are not sufficient to achieve a high level of health protection.

**vi) Responsibility for the application of Article 19 (1)**

All food business operators (who have imported, produced, processed, manufactured or distributed a food) are covered by the provisions of Article 19 (1) (withdrawal and/or recall and notification) and shall apply them within the limits of the activities under their control and in proportion to their responsibilities.

Retailers shall also apply Article 19 (1) since they distribute food to the final consumers. Some of their activities might affect the packaging, labelling safety or integrity of the food. In addition, it can be noted that in some cases, production or processing activities (for example bakery) are undertaken in shops.

As explained in relation to Article 17, Regulation 178/2002 has no incidence on the legal national systems regulating the liability of the operators (civil, criminal liability).

It should be emphasised that when an operator withdraws a raw material or an ingredient under its immediate control because it is non compliant with the food safety requirements, it will normally inform its supplier of this non compliance.

The supplier thus informed, will be in possession of information, giving him reason to consider or to believe that a food not under its immediate control, is non compliant with the food safety requirements. This supplier shall therefore apply the obligations of withdrawal and subsequent notification of this withdrawal to the competent authorities.

If this operator considers that the information in its possession is such that the food may be injurious to health, the obligations provided for by Article 19 (3) will be applicable. This reasoning also applies to similar cases such as when the internal controls of a distributor lead to a withdrawal of a food supplied by a producer or processor.

Cooperation between each level of the food chain will be necessary to achieve the objectives of Article 19 (1).

**III.3.2. Article 19 (2)**

Article 19 (2) constitutes a requirement on food business operators responsible for retail\(^\text{12}\) or distribution activities, which do not affect the packaging, labelling, safety or integrity of food. The purpose of this provision is to ensure that such food business operators also play their part in withdrawal of food not in compliance with food safety requirements, and in passing on relevant information. For example, when a producer withdraws/recalls a food for which it is responsible, the distributor and/or the retailer is/are required to participate as necessary.

\(^\text{12}\) Retail is defined in Article 3 Point 7
Article 19 (2) provides for an important section of the cooperation between the different operators of the food chain. It does not cover all situations where cooperation might be needed and it will be essential that the food business operators investigate how to promote an efficient cooperation between them to ensure the application of Article 19.

III.3.3. Article 19 (3)

Article 19 (3) places an information requirement on food business operators when they consider or have reasons to believe that a food that they have ‘placed on the market’ may be ‘injurious to health. In this case, they shall immediately inform the competent authorities and detail the action taken to prevent the risk.

Article 19 (3) does not impose systematically a withdrawal but provides for immediate information of the competent authorities of a potential risk and the action taken to prevent it.

The following conditions need to be met to trigger the application of Article 19 (3):

- The food in question is placed on the market\(^{13}\). The ‘placing on the market’ also covers food products which have already been produced by food business operators or imported and are being held with a view to sale or supply free of charge. It does not include food products which are still under processing, or raw materials provided by suppliers.

and

- The food in question may be injurious to health.

The objective of this Article is to ensure that the competent authorities are informed in case of a potential risk for health.

Article 19 (3) can be applied in different types of cases such as:

- New information in possession of the operator leading to consider the food as injurious to health but this information diverges from other information. For example, when an operator withdraws internally an unsafe food and informs thereof the supplier of this food, the supplier might consider that the information sent contradicts other information in its possession.

- Information that the product is injurious to health, but this information is not yet completely confirmed

- Information on an emerging risk.

It should facilitate a global prevention of risks by enabling the competent authorities to receive early warnings or to identify potential (possibly emerging) risks in order to ensure the most efficient and proportionate ways to manage it.

In some cases, for example when further or more validated information confirms that the product is injurious to health, the obligations set up in Article 19 (1) will apply.

\(^{13}\) ‘Placing on the market’ is defined in Article 3.8 as ‘the holding of food (or feed) for the purposes of sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves’
The operator responsible for providing the information to the competent authorities is the operator that has placed the product on the market.

The second part of Article 19 (3) is designed to prevent food business operators from discouraging their employees from cooperating with competent authorities where this may prevent, reduce or eliminate a risk arising from food.

III.3.4. Article 19 (4)

It requires that the food business operators will cooperate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied. For example, food business operators should contact the competent authorities when they need help in determining how to fulfil their obligations.

In accordance with the general objective of prevention set up in Article 19 (3), operators, in particular small operators should be encouraged to contact the competent authorities in case of uncertainty on the risk at stake.

Assistance should be given by the competent authorities when operators contact them in the framework of Article 19.

III.3.5. Notification to the Rapid Alert System for Food and Feed (RASFF)

A clear distinction should be made between the RASFF and the obligation of notification provided by Articles 19 and 20. The RASFF involves only competent Authorities (Commission, Member States and EFSA). Food operators have an obligation, under certain circumstances (see part III on notification), to notify only the competent authorities (at appropriate level depending on Member States rules) and not the RASFF.

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IV. ARTICLE 20

WITHDRAWAL, RECALL AND NOTIFICATION

BY FEED BUSINESS OPERATORS

Article 20

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.
IV.1. **Rationale**

- The objectives of this Article are the same as those of Article 19, applied to feed mutatis mutandis.
- However, some of the wordings used in 20 (I) are specific to the feed sector and need to be explained.
- In the context of feed, it is important to take into account that some type of feed in some of its raw state prior to processing is not fit for animal consumption.

IV.2. **Implications**

- Mostly similar to those of Article 19, except that Article 20 (I) provides in particular for the destruction of the feed or batch of feed considered as non compliant with the feed safety requirements, unless the competent authority is satisfied otherwise.
- In the context of feed, the information on withdrawal will concern the users (farmers) of the feed and not consumers.

IV.3. **Contribution / Impact**

IV.3.1. Article 20 (I)

i) **Withdrawal and notification to the competent authorities**

The first sentence of Article 20 (I) “If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof” contains a similar wording to the one used in Article 19 (I).

Therefore, the same approach as the one explained for Article 19 (I) can be followed with the following differences:

- The first cumulative criterion to be met for the application of Article 19 (I) is worded slightly differently in Article 20 (I). The withdrawal of the feed is a withdrawal from the market, which implies that the product is on the market. However, the further condition “which has left the immediate control” is not included in Article 20 (I). This will mean that the feed operators will have to withdraw and notify unsafe feed that is placed on the market but that might still be under their immediate control. In practice, this will concern the holding of feed for the purpose of sale (e.g. definition of “placing on the market” in Article 3.8). The holding for sale takes place once all internal processes making a product ready for sale have been applied. Therefore, actions, including taking the product out of the food chain, undertaken before the product is ready for sale are not meant to be withdrawals in the meaning of Article 19 (I) and do not have to be notified.

- The second cumulative criterion “the feed is considered by the operator as not meeting the feed safety requirements” is similar to the one used in Article 19 (I). Therefore, the feed safety requirements mentioned in Article 15 will need to be taken into consideration. In particular, Article 15.2 specifies the intended use of a feed has to be taken into
consideration to consider it unsafe. For example, it is notable that for certain contaminants, processing that results in the removal of the contaminant could be allowed under certain conditions, laid down by the relevant specific legislation.

- In addition, since Article 15 provides that feed shall be deemed to be unsafe for its intended use if it is considered a) to have an adverse effect on human or animal health, b) to make the food derived from food-producing animals unsafe for human consumption, the requirements of Article 14 in relation to the determination of an unsafe food have to be taken into account to implement Article 15.

ii) Destruction

The second sentence of Article 20 (1) is specific to the feed sector. It provides that in addition to the withdrawal and the information of the competent authorities, the feed considered as not meeting the feed safety requirement and any related batch, lot or consignment which is considered not to meet the feed safety requirement as provided for in Article 15 (3), shall be destroyed, unless the competent authority is satisfied otherwise. It is the case, for example, where another measure, specified by the relevant legislation, could be used.

Destruction shall be therefore the rule unless the competent authority is satisfied otherwise. In addition, in accordance with Article 15 (3) any related batch, lot or consignment shall be presumed unsafe and destroyed, unless following a detailed assessment there is no evidence that it fails to satisfy the feed safety requirement.

Therefore, when informing the competent authority of the withdrawal of an unsafe feed (and any related batch, lot or consignment) the feed operator shall specify if the destruction is planned or propose alternative measures ensuring that no unsafe feed shall be placed on the market or fed to any food-producing animal. An agreement of the competent authority on the alternative measures proposed is necessary in order for the operator to apply such measures, under the conditions laid down by the specific legislation.

iii) Information of users and recall

The comments made under Article 19 (1) in relation to information and recalls are applicable mutadis mutandis. However, as this provision applies in the context of feed, the information on withdrawal will usually concern the users of the feed, usually farmers, and not consumers.

IV.3.2. Article 20 (2), (3) and (4)

The comments made for the application of paragraphs 2, 3 and 4 of Article 19 are valid mutadis mutandis for the application of paragraphs 2, 3 and 4 of Article 20.
V. ARTICLE 11

IMPORT OF FOOD AND FEED

**Article 11**

*Food and feed imported into the Community*

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

The traceability provisions of the General Food Law do not have an extra-territorial effect outside the EU. This requirement covers all stages of production, processing and distribution in the EU, namely from the importer up to the retail level.

Article 11 should not be construed as extending the traceability requirement to food/feed business operators in third countries. It requires that food/feed imported into the Community complies with the relevant requirements of EU food/feed law.

Exporters in trading partner countries are not legally required to fulfil the traceability requirement imposed on operators within the EU by Article 18 of Reg. 178/2002. However, there may be circumstances where there are special bilateral legal requirements for certain sectors or where there are specific Community legal requirements, for example in the veterinary sector, where certification rules require information concerning the origin of the good. These requirements are not affected by the traceability provisions of the general food law.

The objective of Article 18 is sufficiently fulfilled because the requirement extends to the importer. Where the EU importer is able to identify from whom the product was exported in the third country, the requirement of Article 18 and its objective is deemed to be satisfied.

It is common practice among some EU food business operators to request trading partners to meet the traceability requirements and even beyond the “one step back-one step forward” principle. However, it should be noted that such requests are part of food business’ contractual arrangements and not of requirements established by the Regulation.

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14 cf explanations in chapter II. 3. 1. iii).
VI. ARTICLE 12

EXPORT OF FOOD AND FEED

Article 12

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. When the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.
VI.1. **Rationale and objective**

As it is clearly stated in recital 24, it is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.

The objective was to take into account the level of protection established by importing countries. It was also considered essential to prevent the “exportation” of crisis. When a new risk arises, all countries are likely not to have set up relevant safety requirements to prevent this risk. Therefore, it is essential to ensure that in such circumstances, food and feed can only be exported or re-exported with the agreement of the competent authorities of the country of destination and only after these authorities have been fully informed of the reasons for which the food or feed concerned could not be placed on the Community market. In addition, when in such a case food are injurious to health or feed are unsafe, they cannot be exported or re-exported even with the agreement of the importing countries.

The scope of this Article is limited to food/feed produced within the EU (exported) or food/feed that has been put on the EU-market after having been imported (re-exported). This Article is not applicable for feed and food rejected at the external border of the EU.

VI.2. **Article 12 (1)**

This first subparagraph of Article 12 (1) provides for a general rule: “food and feed intended for export or re-export must comply with the relevant requirements of food law, unless otherwise required by the authorities, legislation or administrative procedures of the importing country”. The situation referred to is the most usual one: third countries have set their own level of protection for a particular food or feed and exporting operators must then comply with the requirements set up by importing countries.

Where no requirements are set up by the authorities of the importing countries (legislation or administrative procedures), the food and feed intended for export or re-export must comply with the relevant requirements of Community food law.

The second subparagraph of Article 12 (1) provides for the approach to be taken in cases other than the ones covered in the first paragraph of Article 12 (1).

In these other cases, i.e. if there is no relevant Community food law requirement and the third country has not set any specific requirements applicable to imports, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons why the food or feed could not be placed or remain on the market within the EU. However in such circumstances, where food is injurious to health or feed is unsafe, the food or feed cannot be exported or re-exported and a safe disposal must be ensured.

For food and feed rejected at the external border of the EU and which can be re-dispatched, Article 21 of the Regulation (EC) No 882/2004 of the European Parliament and of the Council
of 29 April on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules\textsuperscript{15} applies from 1 January 2006.

VI.3. **Article 12 (2)**

Article 12 (2) refers to the situation where a Member State or the Community have concluded a bilateral agreement with a third country. In such a case, the rules to comply with are the rules laid down in that agreement.

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Appendix C

Guidelines No. DPH/XII/05
DEPARTMENT OF PUBLIC HEALTH

Guidelines on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No. 178 of 2002

Published on 16th February, 2005
1. Objectives
These guidelines are intended to make uniform the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of EC Regulation No. 178 of 2002.

2. Scope
These guidelines applies to all food businesses.

3. Commencement Date
These guidelines shall come into force with immediate effect.

4. Definitions
'DG SANCO" stands for The Health & Consumer Protection Directorate-General of the European Commission

5. General Food Law
All Health Inspectors are to be conversant with EC Regulation 178 of 2002 and, being a regulation, is to be treated as local legislation.

For ease of reference this is being attached to these guidelines.

6. DG SANCO Guidelines
All Health Inspectors are to be also aware and well versed in guidelines approved by DG SANCO on the 20th December, 2004 on the implementation of the main General Food Law requirements, a copy of which is also being attached.
Appendix D

Regulation (EC) 1935 of 2004
of 27 October 2004
on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:

(1) Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (3) established general principles for eliminating the differences between the laws of the Member States as regards those materials and articles and provided for the adoption of implementing directives concerning specific groups of materials and articles (specific directives). This approach was successful and should be continued.

(2) The specific directives adopted under Directive 89/109/EEC in general contain provisions which leave little room for the exercise of discretion by the Member States in their transposition besides being subject to frequent amendments required to adapt them rapidly to technological progress. It should therefore be possible for such measures to take the form of regulations or decisions. At the same time it is appropriate to include a number of additional subjects. Directive 89/109/EEC should therefore be replaced.

(3) The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

(4) New types of materials and articles designed to actively maintain or improve the condition of the food (active food contact materials and articles) are not inert by their design, unlike traditional materials and articles intended to come into contact with food. Other types of new materials and articles are designed to monitor the condition of the food (intelligent food contact materials and articles). Both these types of materials and articles may be brought into contact with food. It is therefore necessary, for reasons of clarity and legal certainty, for active and intelligent food contact materials and articles to be included in the scope of this Regulation and the main requirements for their use to be established. Further requirements should be stated in specific measures, to include positive lists of authorised substances and/or materials and articles, which should be adopted as soon as possible.

(5) Active food contact materials and articles are designed to deliberately incorporate 'active' components intended to be released into the food or to absorb substances from the food. They should be distinguished from materials and articles which are traditionally used to release their natural ingredients into specific types of food during the process of their manufacture, such as wooden barrels.

(6) Active food contact materials and articles may change the composition or the organoleptic properties of the food only if the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC (4) on food additives. In particular, substances such as food additives deliberately incorporated into certain active food contact materials and articles for release into packaged food or the environment surrounding such foods, should be authorised under the relevant Community provisions applicable to food and also be subject to other rules which will be established in a specific measure.

In addition, adequate labelling or information should support users in the safe and correct use of active materials and articles in compliance with the food legislation, including the provisions on food labelling.

(7) Active and intelligent food contact materials and articles should not change the composition or the organoleptic properties of food or give information about the condition of the food that could mislead consumers. For example, active food contact materials and articles should not release or absorb substances such as aldehydes or amines in order to mask an incipient spoilage of the food. Such changes which could manipulate signs of spoilage could mislead the consumer and they should therefore not be allowed. Similarly, active food contact materials and articles which produce colour changes to the food that give the wrong information concerning the condition of the food could mislead the consumer and therefore should not be allowed either.

(8) Any material or article intended to come into contact with food which is placed on the market should comply with the requirements of this Regulation. Nevertheless, materials and articles supplied as antiques should be excluded as they are available in restricted quantities and their contact with food is therefore limited.

(9) Covering or coating materials forming part of the food and possibly being consumed with it should not fall within the scope of this Regulation. On the other hand, this Regulation should apply to covering or coating materials which cover cheese rinds, prepared meat products or fruit but which do not form part of food and are not intended to be consumed together with such food.

(10) It is necessary to lay down various types of restrictions and conditions for the use of the materials and articles covered by this Regulation and the substances used in their manufacture. It is appropriate to establish those restrictions and conditions in specific measures having regard to the technological characteristics specific to each group of materials and articles.

(11) Pursuant to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (1), the European Food Safety Authority (the Authority) should be consulted before provisions liable to affect public health are adopted under specific measures.

(12) When specific measures include a list of substances authorised within the Community for use in the manufacture of materials and articles intended to come into contact with food, those substances should undergo a safety assessment prior to their authorisation. The safety assessment and authorisation of those substances should be without prejudice to the relevant requirements of the Community legislation concerning the registration, evaluation, authorisation and restriction of chemicals.

(13) Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of substances used in the manufacture of materials and articles intended to come into contact with food may hinder the free movement of those materials and articles, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level. In order to ensure harmonised safety assessment of those substances, the Authority should carry out such assessments.

(14) The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorised substances.

(15) It is appropriate to provide for the possibility of an administrative review of specific acts or omissions on the part of the Authority under this Regulation. This review should be without prejudice to the role of the Authority as an independent scientific point of reference in risk assessment.

(16) Labelling supports users in the correct use of the materials and articles. Methods used for such labelling may vary according to the user.

(17) Commission Directive 80/590/EEC (1) introduced a symbol that may accompany materials and articles intended to come into contact with foodstuffs. This symbol should, for reasons of simplicity, be incorporated in this Regulation.

(18) The traceability of materials and articles intended to come into contact with food should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. Business operators should at least be able to identify the businesses from which, and to which, the materials and articles are supplied.

In the control of the compliance of the materials and articles with this Regulation, it is appropriate to take into account the special needs of developing countries, and in particular of the least developed countries. The Commission has been committed by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (1) to support developing countries with regard to food safety, including the safety of the materials and articles in contact with food. Special provisions have therefore been established in that Regulation which should be applicable also to the food contact materials and articles.

It is necessary to establish procedures for the adoption of safeguard measures in situations where a material or article is likely to constitute a serious risk to human health.


It is appropriate to protect the investment made by innovators in gathering the information and data supporting the decision documents (2) applies to documents held by the Authority.

Community and national reference laboratories should be designated to contribute to a high quality and uniformity of analytical results. This objective will be achieved within the framework of Regulation (EC) No 882/2004.

The use of recycled materials and articles should be favoured in the Community for environmental reasons, provided that strict requirements are established to ensure food safety and consumer protection. Such requirements should be established taking also into account the technological characteristics of the different groups of materials and articles mentioned in Annex I. Priority should be given to the harmonisation of rules on recycled plastic material and articles as their use is increasing and national laws and provisions are lacking or are divergent. Therefore, a draft of a specific measure on recycled plastic materials and articles should be made available to the public as soon as possible in order to clarify the legal situation in the Community.

The measures necessary for the implementation of this Regulation and amendments to Annexes I and II hereto should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (3).

Member States should lay down rules on sanctions applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Such sanctions must be effective, proportionate and dissuasive.

It is necessary for business operators to have sufficient time to adapt to some of the requirements established by this Regulation.

Since the objectives of this Regulation cannot be sufficiently achieved by the Member States because of the differences between the national laws and provisions and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Directives 80/590/EEC and 89/109/EEC should therefore be repealed.

HAVE ADOPTED THIS REGULATION:

Article 1
Purpose and subject matter

1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.
2. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles (hereinafter referred to as materials and articles) which in their finished state:

(a) are intended to be brought into contact with food;

(b) are already in contact with food and were intended for that purpose;

(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

3. This Regulation shall not apply to:

(a) materials and articles which are supplied as antiques;

(b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food;

(c) fixed public or private water supply equipment.

Article 2
Definitions

1. For the purposes of this Regulation, the relevant definitions laid down in Regulation (EC) No 178/2002 shall apply, with the exception of the definitions of 'traceability' and 'placing on the market', which shall have the following meanings:

(a) 'traceability': the ability to trace and follow a material or article through all stages of manufacture, processing and distribution;

(b) 'placing on the market': the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

2. The following definitions shall also apply:

(a) 'active food contact materials and articles' (hereinafter referred to as active materials and articles) means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;

(b) 'intelligent food contact materials and articles' (hereinafter referred to as intelligent materials and articles) means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

(c) 'business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles;

(d) 'business operator' means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the business under their control.

Article 3
General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

(b) bring about an unacceptable change in the composition of the food;

(c) bring about a deterioration in the organoleptic characteristics thereof.

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Article 4
Special requirements for active and intelligent materials and articles

1. In the application of Article 3(1)(b) and 3(1)(c), active materials and articles may bring about changes in the composition or organoleptic characteristics of food on condition that the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC on food additives and related implementing measures, or, if no Community provisions exist, with the national provisions applicable to food.
2. Pending the adoption of additional rules in a specific measure on active and intelligent materials and articles, substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of this Regulation and its implementing measures.

These substances shall be considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC (1).

3. Active materials and articles shall not bring about changes in the composition or organoleptic characteristics of food, for instance by masking the spoilage of food, which could mislead consumers.

4. Intelligent materials and articles shall not give information about the condition of the food which could mislead consumers.

5. Active and intelligent materials and articles already brought into contact with food shall be adequately labelled to allow identification by the consumer of non-edible parts.

6. Active and intelligent materials and articles shall be adequately labelled to indicate that the materials or articles are active and/or intelligent.

Article 5
Specific measures for groups of materials and articles

1. For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended in accordance with the procedure referred to in Article 23(2).

Those specific measures may include:

(a) a list of substances authorised for use in the manufacturing of materials and articles;

(b) list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, or list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for these substances and/or the materials and articles in which they are incorporated;

(c) purity standards for substances referred to in (a);

(d) special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used;

(e) specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;

(f) an overall limit on the migration of constituents into or on to food:

(g) provisions aimed at protecting human health against hazards arising from oral contact with materials and articles:

(h) other rules to ensure compliance with Articles 3 and 4;

(i) basic rules for checking compliance with points (a) to (h);

(j) rules concerning the collection of samples and the methods of analysis to check compliance with points (a) to (h);

(k) specific provisions for ensuring the traceability of materials and articles including provisions regarding the duration for retention of records or provisions to allow, if necessary, for derogations from the requirements of Article 17;

(l) additional provisions of labelling for active and intelligent materials and articles;

(m) provisions requiring the Commission to establish and maintain a publicly available Community Register (Register) of authorised substances, processes, or materials or articles;

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(n) specific procedural rules adapting, as necessary, the procedure referred to in Articles 8 to 12, or making it appropriate for the authorisation of certain types of materials and articles and/or processes used in their manufacture, including, where necessary, a procedure for an individual authorisation of a substance, process, or material or article through a decision addressed to an applicant.

2. Existing specific directives on materials and articles shall be amended in accordance with the procedure laid down in Article 23(2).

Article 6
National specific measures

In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.

Article 7
Role of the European Food Safety Authority

Provisions liable to affect public health shall be adopted after consulting the European Food Safety Authority, hereinafter referred to as 'the Authority'.

Article 8
General requirements for the authorisation of substances

1. When a list of substances as referred to in points (a) and (b) of the second subparagraph of Article 5(1) is adopted, anyone seeking an authorisation for a substance not yet included in that list shall submit an application in accordance with Article 9(1).

2. No substance shall be authorised unless it has been adequately and sufficiently demonstrated that, when used under the conditions to be set in the specific measures, the final material or article satisfies the requirements of Article 3 and, where they apply, Article 4.

Article 9
Application for authorisation of a new substance

1. To obtain the authorisation referred to in Article 8(1), the following procedure shall apply:

(a) an application shall be submitted to the competent authority of a Member State accompanied by the following:

(i) the name and address of the applicant;

(ii) a technical dossier containing the information specified in the guidelines for the safety assessment of a substance to be published by the Authority;

(iii) a summary of the technical dossier;

(b) the competent authority referred to in (a) shall:

(i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) inform the Authority without delay;

and

(iii) make the application and any supplementary information supplied by the applicant available to the Authority;

(c) the Authority shall without delay inform the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.

2. The Authority shall publish detailed guidelines concerning the preparation and the submission of the application (1).

Article 10
Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application, as to whether, under the intended conditions of use of the material or article in which it is used, the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4.

The Authority may extend the said period by a maximum period of a further six months. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.

(1) Pending such publication, applicants may consult the 'Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation':  
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until that information has been provided. Similarly, the time limit shall be suspended for the time allowed the applicant to prepare oral or written explanations.

3. In order to prepare its opinion, the Authority shall:

(a) verify that the information and documents submitted by the applicant are in accordance with Article 9(1)(a), in which case the application shall be regarded as valid, and examine whether the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4;

(b) inform the applicant, the Commission and the Member States if an application is not valid.

4. In the event of an opinion in favour of authorising the evaluated substance, the opinion shall include:

(a) the designation of the substance including its specifications:

and

(b) where appropriate, recommendations for any conditions or restrictions of use for the evaluated substance and/or the material or article in which it is used:

and

(c) an assessment as to whether the analytical method proposed is appropriate for the intended control purposes.

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.

6. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 20.

Article 11

Community authorisation

1. The Community authorisation of a substance or substances shall take place in the form of the adoption of a specific measure. The Commission shall, where appropriate, prepare a draft of a specific measure, as referred to in Article 5, to authorise the substance or substances evaluated by the Authority and specify or change the conditions of its or their use.

2. The draft specific measure shall take into account the opinion of the Authority, relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft specific measure is not in accordance with the opinion of the Authority, the Commission shall provide without delay an explanation for the reasons for the differences. If the Commission does not intend to prepare a draft specific measure after a favourable opinion by the Authority, it shall inform the applicant without delay and provide the applicant with an explanation.

3. Community authorisation in the form of a specific measure, as referred to in paragraph 1, shall be adopted in accordance with the procedure referred to in Article 23(2).

4. After the authorisation of a substance in accordance with this Regulation, any business operator using the authorised substance or materials or articles containing the authorised substance shall comply with any condition or restriction attached to such authorisation.

5. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment.

6. The granting of an authorisation shall not affect the general civil and criminal liability of any business operator in respect of the authorised substance, the material or article containing the authorised substance, and the food that is in contact with such material or article.

Article 12

Modification, suspension and revocation of authorisation

1. The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance may, in accordance with the procedure laid down in Article 9(1), apply for modification of the existing authorisation.

2. The application shall be accompanied by the following:

(a) a reference to the original application;

(b) a technical dossier containing the new information in accordance with the guidelines referred to in Article 9(2); and

(c) a new complete summary of the technical dossier in a standardised form.
3. On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion or the authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 10, where applicable. The Authority may, where necessary, consult the applicant.

4. The Commission shall examine the opinion of the Authority without delay and prepare a draft specific measure to be taken.

5. A draft specific measure modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attached to that authorisation.

6. A final specific measure on the modification, suspension or revocation of the authorisation shall be adopted in accordance with the procedure referred to in Article 23(2).

**Article 13**

**Competent authorities of Member States**

Each Member State shall notify to the Commission and to the Authority the name and address, as well as a contact point, of the national competent authority or authorities designated to be responsible in its territory for receiving the application for authorisation referred to in Articles 9 to 12. The Commission shall publish the name and address of the national competent authorities as well as the contact points notified in accordance with this Article.

**Article 14**

**Administrative review**

Any act adopted under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to undo its act or to remedy its failure to act.

**Article 15**

**Labelling**

1. Without prejudice to the specific measures referred to in Article 5, materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by:

   (a) the words 'for food contact', or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Annex II; and

   (b) if necessary, special instructions to be observed for safe and appropriate use; and

   (c) the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community; and

   (d) adequate labelling or identification to ensure traceability of the material or article, as described in Article 17; and

   (e) in the case of active materials and articles, information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component so as to enable food business operators who use these materials and articles to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food, including the provisions on food labelling.

2. The information referred to in paragraph 1(a) shall not, however, be obligatory for any articles which, because of their characteristics, are clearly intended to come into contact with food.

3. The information required by paragraph 1 shall be conspicuous, clearly legible and indelible.

4. Retail trade in materials and articles shall be prohibited if the information required under paragraph 1(a), (b) and (c) is not given in a language easily understood by purchasers.
5. Within its own territory, the Member State in which the material or article is marketed may, in accordance with the rules of the Treaty, stipulate that the labelling particulars shall be given in one or more languages which it shall determine from among the official languages of the Community.

6. Paragraphs 4 and 5 shall not preclude the labelling particulars from being indicated in several languages.

7. At the retail stage, the information required under paragraph 1 shall be displayed on:

(a) the materials and articles or on their packaging;

or

(b) labels affixed to the materials and articles or to their packaging;

or

(c) a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; for the information referred to in paragraph 1(c), however, this option shall be open only if, for technical reasons, that information or a label bearing it cannot be affixed to the materials and articles at either the manufacturing or the marketing stage.

8. At the marketing stages other than the retail stage, the information required by paragraph 1 shall be displayed on:

(a) the accompanying documents;

or

(b) the labels or packaging;

or

(c) the materials and articles themselves.

9. The information provided for in paragraph 1(a), (b) and (c) shall be confined to materials and articles which comply with:

(a) the criteria laid down in Article 3 and, where they apply, Article 4;

and

(b) the specific measures referred to in Article 5 or, in their absence, with any national provisions applicable to these materials and articles.

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**Article 16**

**Declaration of compliance**

1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

2. In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles.

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**Article 17**

**Traceability**

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

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**Article 18**

**Safeguard measures**

1. When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that the use of a material or article endangers human health, although it complies with the relevant specific measures, it may temporarily suspend or restrict application of the provisions in question within its territory.

It shall immediately inform the other Member States and the Commission and give reasons for the suspension or restriction.
2. The Commission shall examine as soon as possible, where appropriate after obtaining an opinion from the Authority, within the Committee referred to in Article 23(1) the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to the relevant specific measures are necessary in order to remedy the difficulties referred to in paragraph 1 and to ensure the protection of human health, those amendments shall be adopted in accordance with the procedure referred to in Article 23(2).

4. The Member State referred to in paragraph 1 may retain the suspension or restriction until the amendments referred to in paragraph 3 have been adopted or the Commission has declined to adopt such amendments.

Article 19
Public access

1. Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidentiality, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.

2. Member States shall process applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 20
Confidentiality

1. The applicant may indicate which information submitted under Articles 9(1), 10(2) and 12(2) is to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2. Information relating to the following shall not be considered confidential:

(a) the name and address of the applicant and the chemical name of the substance;

(b) information of direct relevance to the assessment of the safety of the substance;

(c) the analytical method or methods.

3. The Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.

4. The Authority shall supply the Commission and the Member States with all information in its possession on request.

5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health.

6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information provided, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.

Article 21
Sharing of existing data

Information given in an application submitted in accordance with Articles 9(1), 10(2) and 12(2) may be used for the benefit of another applicant, provided that the Authority considered that the substance is the same as the one for which the original application was submitted, including the degree of purity and the nature of impurities, and that the other applicant has agreed with the original applicant that such information may be used.

Article 22
Amendments to Annexes I and II

Amendments to Annexes I and II shall be adopted in accordance with the procedure referred to in Article 23(2).

Article 23
Committee procedure


2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 24
Inspection and control measures

1. Member States shall carry out official controls in order to enforce compliance with this Regulation in accordance with relevant provisions of Community law relating to official food and feed controls.
2. Where necessary and on the request of the Commission, the Authority shall assist in developing technical guidance on sampling and testing to facilitate a coordinated approach for the application of paragraph 1.

3. The Community reference laboratory for materials and articles intended to come into contact with food and national reference laboratories established as laid down in Regulation (EC) No 882/2004 shall assist Member States in the application of paragraph 1 by contributing to a high quality and uniformity of analytical results.

Article 25
Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive. Member States shall communicate the relevant provisions to the Commission by 13 May 2005 and shall communicate to it without delay any subsequent amendment affecting them.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 27 October 2004.

For the European Parliament
J. BORRELLI FONTELES
For the Council

Article 26
Repeals

Directives 80/590/EEC and 89/109/EEC are repealed.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 27
Transitional arrangements

Materials and articles that have been lawfully placed on the market before 3 December 2004 may be marketed until the stocks are exhausted.

Article 28
Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union. Article 17 shall apply from 27 October 2006.
ANNEX I

List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood
Symbol
### ANNEX III

**Correlation table**

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Appendix E

Recall Plan
PRODUCT RECALL PLAN
# Table of Contents

1. Objective  
2. Definitions  
3. Levels of product recall  
4. Roles and responsibility  
5. Product recall contact list  
6. Product withdrawal/recall decision tree  
7. Notification of a product recall  
8. Closing a product recall  
9. Testing and reviewing of a product recall  
9. List of Appendices

Appendices 1 - Product recall contact list  
Appendices 2 - Product recall notification for distribution chain  
Appendices 3 - Product recall advert  
Appendices 4 - Press Release
1. Objective

The company is committed to investigate and take necessary and appropriate action in the shortest possible time by rapid identification and removal of unsafe food from the distribution chain and to ensure that unsafe food is either destroyed or rendered safe.

The company is further committed to protect public health by informing consumers, if necessary, of the presence of a potentially hazardous food on the market.
Recall plan: This is a documented procedure designed to ensure the professional, efficient and effective removal of unsafe food from the market.

Recall team: The recall team consist of personnel from the food business whose main functions are the formulation, maintenance, verification and update of the recall plan.

Recall: This is the removal of unsafe food from the distribution chain and extends to food sold to customers and therefore involves communication with the consumers.

Withdrawal: This is the removal of an unsafe foodstuff from the distribution chain but does not extend to food sold to the consumer.

Traceability: Means the ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

Hazard identification: The identification of known or potential health effects associated with a particular agent.

Risk Assessment: The qualitative or quantitative evaluation of the degree of intake likely to occur.

Hazard characterisation: The qualitative or quantitative evaluation of the nature of the adverse effects associated with the hazard.

Risk characterisation: The integration of hazard identification, hazard characterisation and exposure assessment into an estimate of the risk and its associated uncertainties.

Regulatory agency: Regulatory agencies includes the following:

- Food Safety Commission.
- Health Inspectorate.
- Food and Veterinary Regulatory Division.
This recall plan deals with two levels of product recall where food safety is concerned i.e. Recall and Withdrawal

Recall

This is the removal of unsafe food from the distribution chain and extends to food sold to customers and therefore involves communication with the consumers.

Withdrawal

This is the removal of an unsafe foodstuff from the distribution chain but does not extend to food sold to the consumer.

If withdrawal is engaged but due to various reasons it is not possible to contact all relevant customers then withdrawal should be expanded to recall.
## 4. Roles and Responsibilities

The Recall team is formed as follows:

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<tr>
<th>Role</th>
<th>Responsibilities</th>
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<tr>
<td><strong>Recall Co-ordinator</strong></td>
<td>1. Liaise with directors before initiating a withdrawal or recall of an unsafe food product.</td>
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<td></td>
<td>2. Co-ordinate product recall team.</td>
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<td></td>
<td>3. Authorised to take decisions concerning product withdrawal/recall.</td>
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<td></td>
<td>5. Prepare response for consumers.</td>
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<td>6. Answer all consumer questions.</td>
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<td>7. Handle press releases - all media.</td>
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<td>8. Records facts about each situation in a master file that will ultimately contain all details and decisions made about the recall or other action taken by the company.</td>
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<tr>
<td><strong>General Manager</strong></td>
<td>1. Prepare batch identification through traceability records.</td>
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<td>2. Check all records.</td>
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<td></td>
<td>3. Notify sales manager.</td>
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<td></td>
<td>4. Notify regulatory agency.</td>
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<td></td>
<td>5. Keep regulatory agency informed about recall status.</td>
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<tr>
<td><strong>Quality Assurance</strong></td>
<td>1. Stop all distribution of questionable material and arrange for return of product.</td>
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<tr>
<td><strong>Manager</strong></td>
<td>2. Prepare inventory and distribution status of product showing where, when, quantity and to whom product was distributed.</td>
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<td>3. Notify dispatch officers.</td>
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<td>4. Remove product from distribution chain within 48 hours.</td>
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<td>5. Arrange for proper credit to be given.</td>
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<tr>
<td><strong>Sales Manager</strong></td>
<td>1. Obtain batch identification and samples.</td>
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<td>2. Obtain product analysis to determine if pick-up or destruction is necessary.</td>
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<td></td>
<td>3. Consult with Food Safety Commission if a recall is required.</td>
</tr>
<tr>
<td><strong>Hygiene and Nutrition</strong></td>
<td>1. Obtain batch identification and samples.</td>
</tr>
<tr>
<td><strong>Consultants</strong></td>
<td>2. Obtain product analysis to determine if pick-up or destruction is necessary.</td>
</tr>
<tr>
<td></td>
<td>3. Consult with Food Safety Commission if a recall is required.</td>
</tr>
</tbody>
</table>
1. Set up stock reconciliation system to determine cost of recall.
2. Aid in contacting customers.

1. Handle legal implications.

In the absence of the General Manager, the Master Baker will replace him and thus takes the role of the Recall Co-ordinator

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5. Product Recall Contact List

The list should be updated monthly by Quality Assurance Manager on the information given by the Sales Manager. Refer to appendix 1 of the Recall Plan.

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6. Product Withdrawal/Recall Decision Tree

Decision tree (shown in next page) is to be used by the team to clarify the thought process leading to a final decision on the necessity of product recall and appropriate type of action i.e. whether to handle as a complaint with no health hazards involved or initiate withdrawal or recall.
Decision Tree to be followed:

Complaint or notification of product problem

Report received – initial details taken

Notify QA Manager or other manager as appropriate

QA Manager makes preliminary risk management

Potential health hazard

No health hazard

Handle as complaint or quality recall

Notify Company Directors

Notify Food Safety Commission

Invoke recall plan

Suspend distribution of product

Convene Recall Team

Collate all product and production information

Collate all traceability information

Initiate product analysis as necessary

Conduct documented thorough Risk Assessment

Health hazard confirmed

No health hazard

Handle as complaint or quality recall

Update Food Safety Commission

Product distributed to consumers

Product not distributed to consumers

CARRY OUT RECALL

CARRY OUT WITHDRAWAL
7. Notification of a Product Recall

Withdrawal

Once a decision to initiate a withdrawal is undertaken, **three levels** of notification are to be followed as follows:

1. **Within Company.** Recall Co-ordinator is to hold a meeting for staff concerned and brief everyone on decision taken and action to follow.

2. **Distribution Chain.** QA Manager with the help of the Sales Manager and Accounts is to inform by telephone and followed up in writing Distribution Chain – refer to appendix 2 of the Recall Plan.

3. **Regulatory Authorities.** Food Safety Commission Secretariat and Environmental Health Officers are to be informed in writing by Quality Assurance Manager on initiation of a product recall or withdrawal. Details are to include:

   1. Name of company and contact details
   2. Name of product involved
   3. Durability date and batch/s affected
   4. Product details including packaging size and type
   5. Amount of unsafe product on the market
   6. Nature of food safety risk
   7. Distribution details
   8. List of outlets selling to consumers
   9. Results of any investigations or tests
   10. Level of product recall being considered
   11. Public notification timings for product recall and communication.
Recall

Further to steps 1, 2 and 3 consumers are also to be informed through media.

An advert as shown in appendix 3 is to be placed in the following newspapers:
1. Newspaper 1
2. Newspaper 2
3. Newspaper 3

Press release as shown in appendix 4 is to be referred to all radio stations, television stations and newspapers editors.

The Regulatory agencies are to be regularly updated by the QA Manager through a Recall or Withdrawal Status Report. The report is to include the following information:

1. Number of consignees notified of the recall, the date and method of notification.
2. Number of consignees responding to the recall communication and the amount of product each had at hand at the time it was received.
3. Number of premises contacted by the Company.
4. Quantity of product returned and/or held by each consignee.
5. Estimated additional time required completing the recall.
8. Closing a Product Recall

Recall is to be considered completed by Recall Co-ordinator once he determines that all reasonable efforts have been made to remove or correct the product in accordance with the original recall strategy, and when it is clear that all possible product subject to the recall has been removed from distribution and proper disposition and/or correction has been made by the manufacturer.

Once the Product Recall Co-ordinator is sure that unsafe products have been removed from distribution chain; regulatory authorities are to be informed.

If products are being destroyed necessary permits are to be obtained from WasteServ and destruction be supervised by environmental health officers.

QA Manager is to update Regulatory Agencies by sending a final report on outcome of recall.

The Recall Team’s written records should be retained in the master file, the up keeping of which is the responsibility of the recall coordinator. This file should include the following details:

1. Names, addresses and phone numbers of persons claiming an illness or injury and facts about how the alleged occurrence was initially reported and discovered.
2. The type of alleged illness or injury with as many details as possible, including name, address, and phone number of the attending physician and his or her assessment of the case.

3. Complete identification of affected product, the involved lot number, durability date.

4. Name and address of the outlet where the product was purchased, including names and telephone numbers of outlet personnel involved or aware of the incident.

5. Location of any remaining product and/or the original product that is the source of the complaint and an assessment of whether or not a sample can be obtained for testing.

6. Names, titles, addresses, and phone numbers of any health authorities and law enforcement officials who already are involved or may become involved.

7. Results of any laboratory testing of samples from suspect products.

8. Information on whether the affected consumer/s communicated with legal counsel and intends to institute legal action. Information should include the name, address, and telephone number of consumer/s.

9. Any action by individual stores or retail chains to remove product from store shelves.
10. All documentation is to be kept for at least 5 years from date of incident.

Upon completion of a recall, the manufacturer should notify all brokers, distributors, and retail customers. This communication should include an expression of thanks for their assistance and reassurance that the problem has been identified and corrected and that the product currently in distribution is not involved in the action

Closing meeting is to be held by Recall Co-ordinator for all staff concerned and any recommendations are to be noted and implemented.

Reviewing of this Recall Plan is to be undertaken every 6 months by the following:

1. Recall Co-ordinator
2. Quality Assurance Manager
3. Sales Manager
4. Master Baker

Review is to be documented and any changes be reflected in recall plan.

Recall Plan is to be validated once yearly following an unannounced test initiated by Recall Co-ordinator or Quality Assurance Manager.

Recall Plan is to be reviewed and updated to reflect significant changes in company operations, organisational structure, personnel, product line and areas of distribution.
## List of Appendixes

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</tr>
</thead>
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</tr>
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</tbody>
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## Company Contact List

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Telephone</th>
<th>Email address</th>
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<tbody>
<tr>
<td><strong>Owner</strong></td>
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<td><strong>Recall Co-ordinator</strong></td>
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<td><strong>Quality Assurance Manager</strong></td>
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<tr>
<td><strong>Sales Manager</strong></td>
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<tr>
<td><strong>Hygiene and Nutrition Consultant</strong></td>
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<tr>
<td><strong>Financial Controller</strong></td>
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<td><strong>Legal Counsel</strong></td>
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## Suppliers List

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Contact Person</th>
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Customers/Distributors List

<table>
<thead>
<tr>
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Regulatory Authorities

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>Officer</th>
<th>Telephone</th>
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Food Safety Commission<br>Secretariat<br>34, The Annex, Antonio Nani Street, Ta Xbiex<br>Manager Health Inspector<br>Dept of Public Health<br>37/39, Rue D’Argens, Msida<br>WasteServ<br>Phoenix Building<br>Old Railway Track<br>Santa Venera<br>Food & Veterinary Regulation Division<br>Albertown<br>Marsa<br>Malta Environment & Planning Authority<br>St Francis Revelin, Floriana<br>Malta Standards Authority<br>Food stuffs, Chemical & Cosmetics<br>Evans Building<br>Valletta
Appendix 3  Product recall advert

WARNING

FOOD PRODUCT RECALL

Brand
Product Name
Product description
Pack size
Durability Date and Lot

Details of what is wrong with affected product

Actions consumer should take

XXX apologise for any inconvenience caused

Contact Person & Company details

An illustration of implicated food product should be included to help consumers identify easily food product implicated in recall

Clear information (in bold and not in block capitals) on food product affected should be entered here

Problem with food product, hazard and how consumer can avoid the hazard are to be inserted here

Consumer should be informed of what to do with product and whom to contact in case of difficulty
FOR IMMEDIATE RELEASE DATE

(Manufacturer) RECALLS (food product)
BECAUSE OF POSSIBLE HEALTH RISK

(Manufacturer and Address), is recalling its (name of food product) because they (give reason for recall). (Give a brief description it may have on consumers)

The recalled (food product) were distributed in (mention where example retail, catering etc). The product comes in a (weight and packaging) marked with lot (give lot number and position package) and best before date (insert durability date and position on package).

The potential for contamination was (give a brief description how the product may have been rendered unsafe). Production of the product has been suspended while the company continues their investigation as to the source of the problem.

Consumers who have purchased (weight and name of food product) are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at (give telephone number).

(Company) apologise for any inconvenience this causes.
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URL: http://www.intentia.com/www/resource.nsf/pub/Trace_Article_international.pdf/$FILE/Trace_Article_international.pdf

Unknown, (undated). Ingredient dispenser machine hb-technik
URL: http://www.hb-technik.cc/en/