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Food Safety in the European Union: Progress with the Implementation of HACCP Systems*

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Introduction

In recent years the reported incidence of foodborne diseases has continued to increase worldwide with a number of extremely serious outbreaks occurring on virtually every continent. The reported increase of foodborne diseases is due to a number of factors which include changes that are taking place in food production on the farm, new systems of food processing, longer distribution chains and new food preparation and storage methods. Changing lifestyles around the world are leading to a far greater reliance on convenience foods that are prepared outside the home. The food chain has become longer and more complex, and opportunities for the contamination of food have increased.

The net result of these developments over the past 30 years has been to establish food safety as not only a priority public health concern but for it to emerge as a major political issue. Serious food scares such as bovine spongiform encephalopathy (BSE) leading to new variant Creutzfeldt-Jakob disease (nv-CJD), new foodborne pathogens such as Escherichia coli O157:H7, antibiotic-resistant strains of bacteria and residues of agricultural chemicals in food have all damaged the public's confidence in our food supply. Coupled with this consumers' confidence in both the ability of the regulatory agencies to protect the food supply and in the commitment of the food industry to protecting consumers' health has also been seriously damaged over the past few decades. In Europe, the Belgium Government was voted out of office as a result of the political fallout of dioxin contaminated feed being fed to animals and potentially toxic foods of animal origin being distributed for sale around the world. The first cases of BSE in cattle in Germany led to the resignation of both Ministers of Health and Agriculture. The BSE crisis in the UK has led to the reorganisation of the food control services and a reporting structure to the health ministry and away from agriculture. More recently the illegal addition of pharmaceutical waste containing the hormone medroxy progesterone acetate (MPA) to ani-

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mal feed in Belgium caused another EU-wide food scare with serious economic consequences and food safety concerns.

In this climate, food safety and the protection of the health of the consumer have become international issues. Many national governments are evaluating their food safety controls and reviewing food safety legislation to ensure the best possible levels of consumer protection. For Ireland, the stakes are particularly high. Food production and tourism are major elements of the economy and both depend crucially on a favourable international perception of the safety of Irish food. Foreign exchange earnings from tourism amounted to \$3.3 billion in 1998, about 6.4% of GNP. Tourism supported 126700 jobs – about 8.2% of all employment. The agriculture sector accounts for 10% of Ireland's GDP and 9.4% of Ireland's exports. The output of the food sector in 1999 was \$15.4 billion with exports exceeding \$7 billion. Ireland has a vital economic interest in becoming a centre of excellence in food safety.

Food Safety Authority of Ireland

It was against this background of consumer anxiety about the safety of the food supply that the Food Safety Authority of Ireland (FSAI) was set up. Some other European Union Member States, such as the United Kingdom, Sweden, France, Belgium, and the Netherlands have taken a similar approach. The Authority was formally established as an independent, statutory consumer protection body in January 1999 under the Food Safety Authority of Ireland Act 1998. Its mission is to protect the public's health by ensuring that foods manufactured or sold in Ireland meet the highest standards of safety and hygiene. The FSAI as an independent, science based organisation has to be capable of assessing food safety risks, managing those risks in association with regulatory agencies and the food sector, and communicating risks to consumers, public health professionals and industry alike.

The basic objectives of the Authority are to:

- put consumer interests first and foremost;
- be independent of the vested interest groups that could seek to influence the food safety agenda;
- base its decisions and advice on the best scientific advice available;
- establish a well co-ordinated seamless food inspection service; and,
- gain acceptance by all parties in the food chain of their primary responsibility for the safety of food.

Developments in the European Union

Green paper on the general principles of food law

The European Commission (EC) has placed food safety and consumer protection as a top priority over the past decade as a result of a succession of food scares. In 1997 the Commission reorganised the Directorate-General for Consumer Policy

and Consumer Health Protection (DG24) to incorporate all functions relating to scientific advice, risk analysis and food controls. The main aim of this reorganisation was to separate the departments responsible for legislation, scientific consultation and inspection, and to improve the transparency and dissemination of information. It also published a Green Paper on the general principles of food law in the European Union (EU) where it discussed policy issues relating to how far existing legislation was meeting the needs and expectations of consumers, producers, manufacturers and traders; how the measures to guarantee the independence and objectivity, equivalence and effectiveness of the control and inspection systems were meeting their objectives that is to ensure a safe and wholesome food supply and, finally, how Community food law could be developed in the future to ensure that the regulatory framework covers the whole food chain "from the farm to the plate" (1). The new change in direction was emphasised in the Declaration by the European Council on food safety in 1997 where food safety was recognised as more than ever a matter of major concern for the public and stressed the need for everything to be done to restore public confidence which was severely shaken by the BSE crisis

White paper on food safety

The next major development was in 2000 with the publication of the "White Paper on Food Safety" which pointed the way for food control within the European Union (3). The paper advocated a comprehensive integrated approach, the reinforcement of the concept that primary responsibility for food safety lies with the food industry, the need for full traceability, the need for basing decisions on the principle of sound science, improved surveillance at a European level, enhanced crisis management and risk assessment, and transparency at all levels. The White Paper proposed to set out a major programme of legislative reform to complete the European Union's "farm to table" approach as well as establishing a new European Food Authority.

The White Paper was seen as an important milestone in the development of food safety policy. It set out a coherent framework for action, with a detailed timetable for over 80 separate pieces of legislation aimed at closing identified loopholes and more importantly, restoring and maintaining the confidence of European consumers in the safety of food in the EU.

One of the major initiatives set out in the White Paper was the establishment of an European Food Authority based on the principles of the highest levels of independence, of scientific excellence and of transparency in its operations. The tasks identified for the Authority included management of the relevant scientific committees for scientific advice and risk assessment, information gathering and analysis, risk communication, and the management of the Rapid Food Alert Programme. It is interesting to see the influence of politics in how the proposal to establish the European Food Authority was implemented. To start, the European Parliament insisted

that the name be changed to the European Food Safety Authority (EFSA), clearly demonstrating the political significance of food safety. Management of the EU-wide rapid alert programme was taken out of its core functions which were redefined to focus on risk assessment and risk communication. The tasks of EFSA (4) have now been clarified to include responsibility for:

- the scientific evaluation of risks;
- the collection and analysis of scientific data;
- safety evaluations of dossiers put forward by industry for Community level approval of substances or processes;
- identification of emerging risks;
- scientific support to the Commission particularly in the case of a food safety crisis;
- direct communication to the public and other interested parties of information concerning matters within its remit.

EU food legislation

Since the publication of the White Paper, food legislation of the European Community has been the subject of a major overhaul. Significant progress has been made with the action plan outlined in the White Paper for the new legal framework that covers animal feed, animal health and welfare, hygiene, contaminants and residues, novel foods, additives, flavourings, packaging and food irradiation. A major new piece of legislation was published in 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 (5). This embodies the principles of food safety, including:

- general principles of food law;
- risk analysis and the precautionary principle;
- responsibility of food and feed manufacturers, farmers and food operators;
- food safety requirements;
- traceability of feed, food and its ingredients;
- principles of transparency.

Other major initiatives include the revision of the food labelling regulations, recasting horizontal and vertical Directives on food hygiene, amendments to the Directives on additives, flavours and sweeteners, and novel foods among others. The recasting of the horizontal and vertical Directives on food hygiene have implications for the application of the Hazards Analysis and Critical Control Point (HACCP) system in the food industry.

HACCP in Europe

Since the early 1990s HACCP based requirements have been progressively introduced into European legislation. The Hygiene of Foodstuffs Directive 93/43/EEC requires that food retailers, caterers, and manufacturers of non-animal

origin products apply five of the seven principles of HACCP (as outlined by Codex Alimentarius) to their businesses, documentation and verification being omitted. Separate product specific legislation (the vertical Directives) applies to manufacturers of products of animal origin, namely meat products, fish products and milk products. Some of these Directives (table 1) require HACCP-based "own checks" controls to be in place, the results of which must be documented and retained for inspection. The standards regarding hygiene and the requirements regarding HACCP are different in the various vertical Directives.

Table 1 Current food hygiene directives in the European Union (as amended)

Milk & milk products (89/437/EC) Hygiene of foodstuffs (93/43/EC) Fresh meat (64/433/EC) Egg products (91/492/EC) Bivalve molluscs (91/493/EC) Fresh Poultry meat (71/118/EC) Fishery products (91/494/EC) Fresh meat (72/461/EC) Pigmeat 3rd countries (77/96/EC) Fishing vessels (91/495/EC) Meat products (77/99/EC) Poultry meat -3^{rd} countries (92/45/EC) Animal health/meat (80/215/EC) Rabbit and game (92/46/EC) Minced meat (89/362/EC) Wild game 92/48/EC)

In 2001 Commission Decision 471/2001/EC was adopted and has the effect of extending HACCP and microbiological checks to slaughter and cutting plants approved under Council Directives 64/433/EEC, as amended (Fresh Meat) and 71/118/EEC, as amended (Fresh Poultry Meat).

Currently the European Commission is redrafting both the general and product specific hygiene legislation and shortly the implementation of a harmonised HACCP based system will become obligatory for all food businesses, excluding primary production. While not subject to a full documented HACCP procedure, primary producers will however be required to monitor possible hazards to food safety and to eliminate or reduce these to an acceptable level. There will also be the opportunity for Member States to adapt the general hygiene requirements to accommodate the needs of small food businesses supplying local markets.

HACCP implementation

Internationally it is widely accepted that HACCP is making headway in large food businesses, particularly in developed countries, while small and less developed businesses (SLDBs) and the food industry in developing countries are struggling. A study by *Panisello et al.* (6) identified that for UK companies with less than 50 staff, HACCP implementation decreased proportionally as number of employees decreased.

Despite the introduction of mandatory HACCP in many countries worldwide, there is limited published data on the actual degree of implementation or its effectiveness. In Ireland a telephone survey of 1.098 food businesses conducted by the

Food Safety Authority of Ireland (FSAI), in 2000, produced a response rate of 65 % and revealed that 74 % claimed to have a food safety management system, only 29 % of whom said that this system was documented (7). Less than half (48 %) had actually heard of the term HACCP. Looking at the results within the various sectors the service sector had a better knowledge of HACCP and a greater number of businesses with a food safety management system than the retail sector. Due to small numbers it was not possible to make conclusions regarding the manufacturing sector. An earlier postal survey conducted in the UK by *Mortlock et al.* (8) in 1997 questioned 1.650 managers of food businesses. With a response rate of just 15.3 % the survey revealed that 69 % of manufacturers, 13 % of retailers and 15 % of caterers had a full HACCP system.

Recently the EU co-ordinated a survey on HACCP implementation in retail butcher shops and mass catering establishments via its Co-ordinated Programme for the Official Control of Foodstuffs for 2000. While the final report is not yet available, the Irish results found that 31% of retail butchers and 40% of mass caterers complied with the Article 3 (2) of Directive 93/43/EC in the application of the HACCP principles.

Addressing the lack of implementation

Despite almost 10 years of mandatory HACCP in Europe most Member States are still struggling to implement this food safety control measure. Recently an Irish National Strategy was published which aimed to assist food businesses covered by Directive 93/43/EC to increase their level of compliance. The Strategy was developed based on the outcome of a national workshop, involving both industry and regulators. The Irish HACCP Strategy has six objectives;

- To aggressively promote HACCP at national and regional level.
- To demystify HACCP.
- To develop a targeted approach to ensuring full compliance with the law.
- To facilitate the development of an enhanced role for the industry in its own development of HACCP.
- To develop a consistent approach to implementation and enforcement of HACCP.
- To develop and implement an accurate measure of the success of the strategy.
 To date;
- Considerable promotional work has already been conducted for a number of years at local level. While this will continue it will be backed up by national campaigns.
- Documentation is being developed to describe HACCP and the HACCP terminology in simple language.
- While all food businesses are expected to comply with the law, a targeted approach is being taken to help industry help themselves. The first two target

groups are (i) hotels with mass catering and (ii) hospitals and nursing homes. The aim is to provide guidance material and assistance for these two groups.

- Representatives from both these target groups will be consulted to determine the barriers to compliance and the most effective means of improving compliance.
- In order to address the need for a consistent approach to enforcement of HACCP a guidance on compliance with the HACCP requirement of Directive 93/43/EC has been published (9).
- With these two target groups local enforcement officers will determine the level of compliance at the beginning and end of the target period.

Product specific HACCP

In advance of the introduction of mandatory HACCP at slaughterhouse level the FSAI produced a guide in response to concerns regarding *E. coli* O157:H7 contamination in Irish beef and lamb (10).

Training

FSAI has published two in a series of three guides on food safety training standards (Level 1 – Induction skills and Level 2 – Additional Skills (http://www.fsai.ie/training_index.htm)). The final guide (Level 3) will outline the skills required by a manager/supervisor. In the case of HACCP the guides specifically describe how a food handler or manager/supervisor can demonstrate the skills required and the resources and support the food business will need to supply.

Many companies use external consultants to provide food safety training or to assist them in the design and implementation of their food safety management system (HACCP). A brief guide on what to look for when choosing an external consultant is available on the FSAI website (www.fsai.ie)

Conclusion

Since the early 1960's the European Union has built up a large body of "harmonised" legislation to support the creation of a single market for food across Member States. The harmonised food laws are binding throughout the European Union and once they have been adopted, they can be changed only at Community level. The harmonised rules apply equally to foods that are produced in the European Union and to those that are imported from third countries. The European Union has sought to bring to an end the divergence of the food legislation of its Member States, by the adoption of common legislation, where none previously existed, or by harmonizing the existing rules. European food legislation has evolved over the past 43 years reflecting political and economic priorities of integration. The process of evaluation and revision of food legislative provisions is an ongoing, high priority task within the European Union. The focus has changed from primarily trade related issues to that of ensuring minimum standards of food safety and of protecting consumer health.

The route chosen by European regulators, to introduce HACCP throughout the food chain, is an ambitious one. In the US for example, the food regulatory agencies began by introducing mandatory HACCP for individual sectors of the food industry. Seafood and meat and poultry were the first two sectors legally required to implement HACCP. In Europe progress is being made but is very slow in some sectors and in particular, due to resource issues, in SLDBs.

National governments have the responsibility to ensure citizens enjoy a safe and wholesome food supply. Unfortunately there is widespread public uncertainty about food safety and often a lack of confidence in the integrity of the food chain. As we move ahead into the 21st century, consumers need to be confident in the safety and wholesomeness of the food that they eat. Protection of the public's health from risks associated with the consumption of food should be the aim of nations' food safety control programme.

Summary

Over the past number of years food safety has become a major political issue as a result of a series food scares that have damaged the public's confidence in the safety of the food supply. This has led to the evaluation of food safety control systems and reviews food safety legislation to ensure the best possible levels of consumer protection. Across the European Union Member States have responded by establishing Food Safety Control Authorities. The European Commission (EC) has placed food safety and consumer protection as a top priority on its agenda and has recently established the European Food Safety Authority as its scientific advisory and risk assessment body. One of the major areas identified in 2000 in the "White Paper on Food Safety" for review was food hygiene and the application of the Hazards Analysis and Critical Control Point (HACCP) system in the food industry. Across the EU it is widely accepted that HACCP is making headway in large food businesses while small and less developed businesses are struggling. This paper discusses progress with the application of HACCP in the food sector.

Zusammenfassung

In den letzten Jahren hat die Sicherheit der Lebensmittel eine hohe politische Bedeutung gewonnen, weil immer wieder auftretende Ängste das Vertrauen der Konsumenten in die Sicherheit der Lebensmittelverarbeitung beeinträchtigt haben. Dies hat zur Evaluation der Qualitätskontrollsysteme von Lebensmitteln geführt sowie zum Überdenken der Lebensmittelgesetze, um die grösstmögliche Lebensmittelsicherheit zu gewährleisten. Die Staaten der Europäischen Union haben reagiert und Behörden für die Qualitätssicherung von Lebensmitteln eingerichtet. Auch die Europäische Kommission (EC) hat die Lebensmittelsicherheit sowie den Verbraucherschutz an oberste Stelle ihrer Traktanden gesetzt und kürzlich die «Europäische Lebensmittelsicherheitsbehörde» ins Leben gerufen als wissenschaftliche Beratungsstelle für Risiko-Lebensmittelgruppen. Zu den wichtigsten Bereichen, die im

«White Paper on Food Safety» von 2000 aufgeführt sind, gehört die Lebensmittelhygiene und damit die Anwendung des HACCP-Systems in der Lebensmittelindustrie. In der ganzen Europäischen Union wird HACCP durchwegs akzeptiert und hat den Weg schon in die grossen Lebensmittelbetriebe gefunden, während kleinere und weniger moderne Betriebe noch darum kämpfen. Diese Publikation beschreibt den Fortschritt bei der Anwendung von HACCP im Lebensmittelbereich.

Résumé

Dans les dernières années, en raison d'une série de scandales ayant mis à mal la confiance des consommateurs, la sécurité des denrées alimentaires est devenue un sujet politique de grande importance. Cela a conduit à une évaluation des systèmes de contrôle de la sécurité alimentaire et à des révisions de la législation sur les denrées alimentaires, afin d'assurer le meilleur niveau possible de sûreté des denrées alimentaires. Dans l'union européenne, la réponse des états membres a été la création des agences de contrôle de la sûreté des denrées alimentaires. La commission européenne (CE) a placé la sûreté des denrées alimentaires et la protection des consommateurs parmi ses plus hautes priorités et a établi récemment cette agence de contrôle de la sûreté des denrées alimentaires pour jouer le rôle d'organe de conseil scientifique et d'évaluation des risques. Un des principaux champs d'action identifiés en 2000 dans le «livre blanc sur la sûreté alimentaire » a été l'hygiène alimentaire ainsi que l'application du principe HACCP dans l'industrie des denrées alimentaires. Dans l'union européenne, il est largement reconnu que l'HACCP progresse bien dans les grandes entreprises mais que les petites et moyennes entreprises connaissent plus de difficultés. Cet article discute les progrès dans l'application de l'HACCP dans le secteur alimentaire.

Key words

Food safety, HACCP, European Union, Food legislation, Harmonized food laws

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