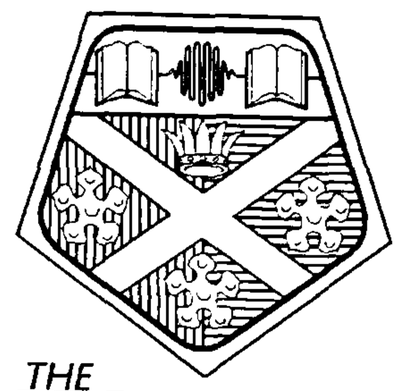

THE UNIVERSITY OF STRATHCLYDE IN GLASGOW

Department of Civil Engineering

Critical Analysis of the Existing Food Sampling Programmes

Raymond Y.P. Wong

A Thesis submitted in full fulfilment of
the requirements for the Degree of PhD
at the University of Strathclyde

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Declaration

Some of the data obtained during this research have been reported elsewhere. These reports are listed below:-

Wong, R. (1999), 'Requirements under the Official Control of Foodstuffs Directive (89/397/EEC)', *Environmental Health Scotland,* Vol.11, No.4, pp.9-13.

Wong, R., Clark, C.F., & Ferguson, N.S. (1998) 'Critical Analysis of Existing Food Sampling Co-ordination in the U.K.', *The International Federation of Environmental Health 5th World Congress 1998 Stockholm, Sweden*, June 1998.

Wong, R., Clark, C.F., & Ferguson, N.S. (2000) 'Food Sampling Practice in the United Kingdom', *The International Federation of Environmental Health 6th World Congress 2000 Oslo, Norway*, June 2000.

To my Father, Mother, Barbara and Joshua

獻給親愛的：父親，母親， 瑞英及卓賢

Abstract

Existing food sampling programmes used by the local authorities, if they exist, operate in a 'hit or miss' fashion, and the use of small sample size is common in the programmes. Although the U.K. food co-ordination network is well developed, the complexity of the three-way systems creates many complications and duplications. Also, compliance with the European legislation generates extra burdens to the U.K. governments. A national survey was undertaken in 1998 to investigate the purpose and effectiveness on local authority food sampling. Although only half of the returns believed that local food programmes contributed significantly to the prevention of foodborne illness, over three-quarters agreed that the programmes could be improved upon. It was clearly shown that U.K. local authorities were eager to advance their sampling regime, but were handicapped by resource constraints. The local authorities stated that improvement could be achieved if sampling activities were increased. Because sampling involves errors due to uncertainties and variations, a statistically validated sampling model was developed in an attempt to determine suitable sample sizes under various sample proportions that would also satisfy good normal approximation in order to reduce margin of error to a minimum. However, the model illustrated that current sampling regimes were far from reaching the minimum requirement. In the main, if sampling has a part in food safety activities, then central government support towards sampling and analysis cost is vital. Routine sampling can be undertaken collectively at a regional basis, and such high cost may be split among local authorities. Alternatively, a requirement can be placed upon food premises to undertake their own sampling, and officers will then carry out local audits. Finally, further investigations should be extended to the determination of many contaminants' limits and the cost benefit analysis along the chain of causality.

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Chapter 1

Introduction

Chapter 1. Introduction

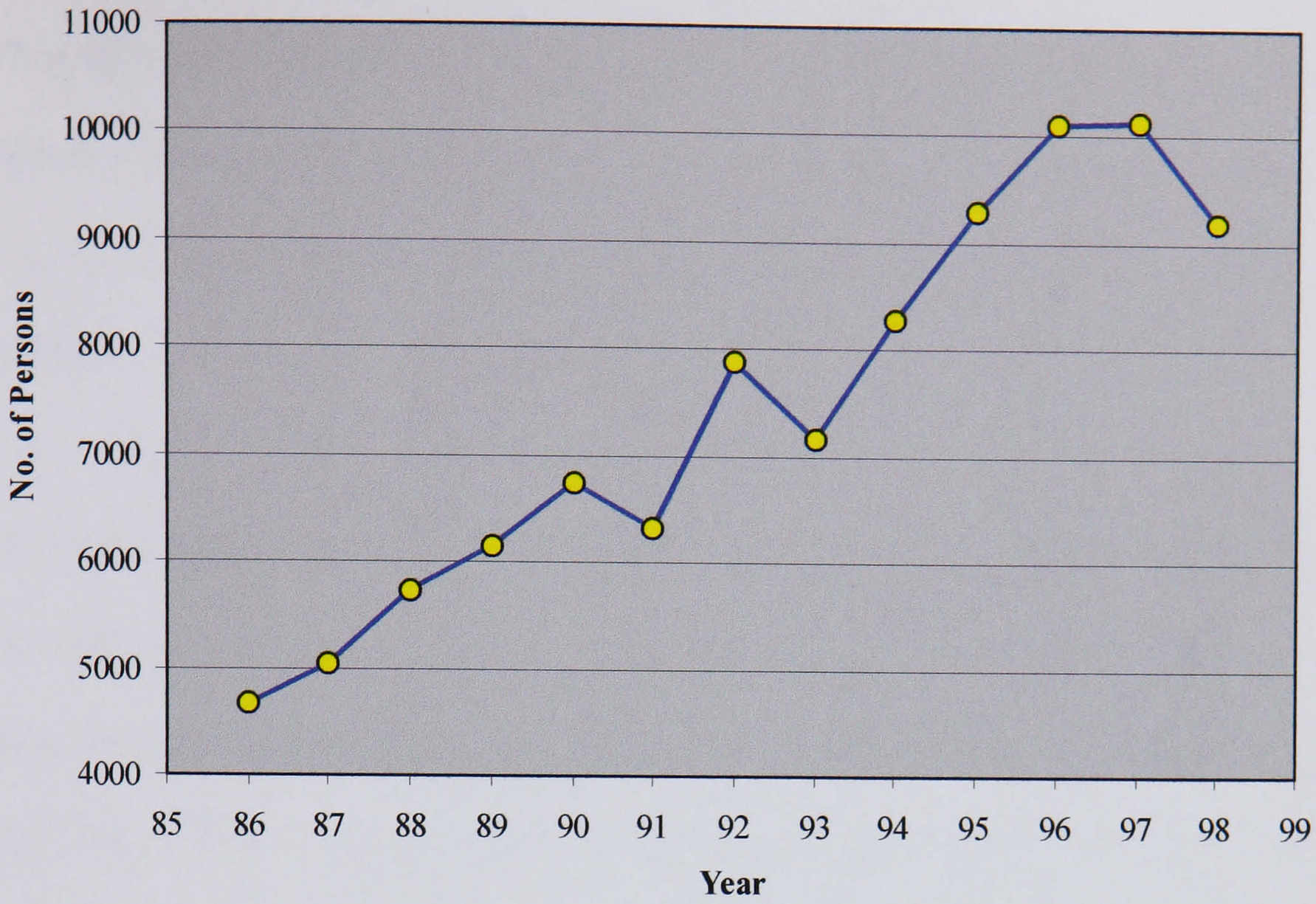
Foodborne diseases are major causes of morbidity and mortality throughout the world (Murrell 1995). Foodborne illness may be defined as an illness caused by the food or drink contaminated by pathogenic micro-organisms or their toxins, or by chemicals. The clinical picture of foodborne illness includes both food poisoning which is generally characterised by diarrhoea and/or vomiting following the consumption of contaminated food, and other illnesses such as listeriosis or butulism which give rise to symptoms and disease in parts of the body other than the alimentary tract (Richmond 1990). Under the Food Safety Act 1990, food intended for human consumption also includes:

- drink,
- substances of no nutritional value which are used for human consumption,
- chewing gum and other products of a like nature and use, and
- substances used as ingredients in the preparation of food or of such products,

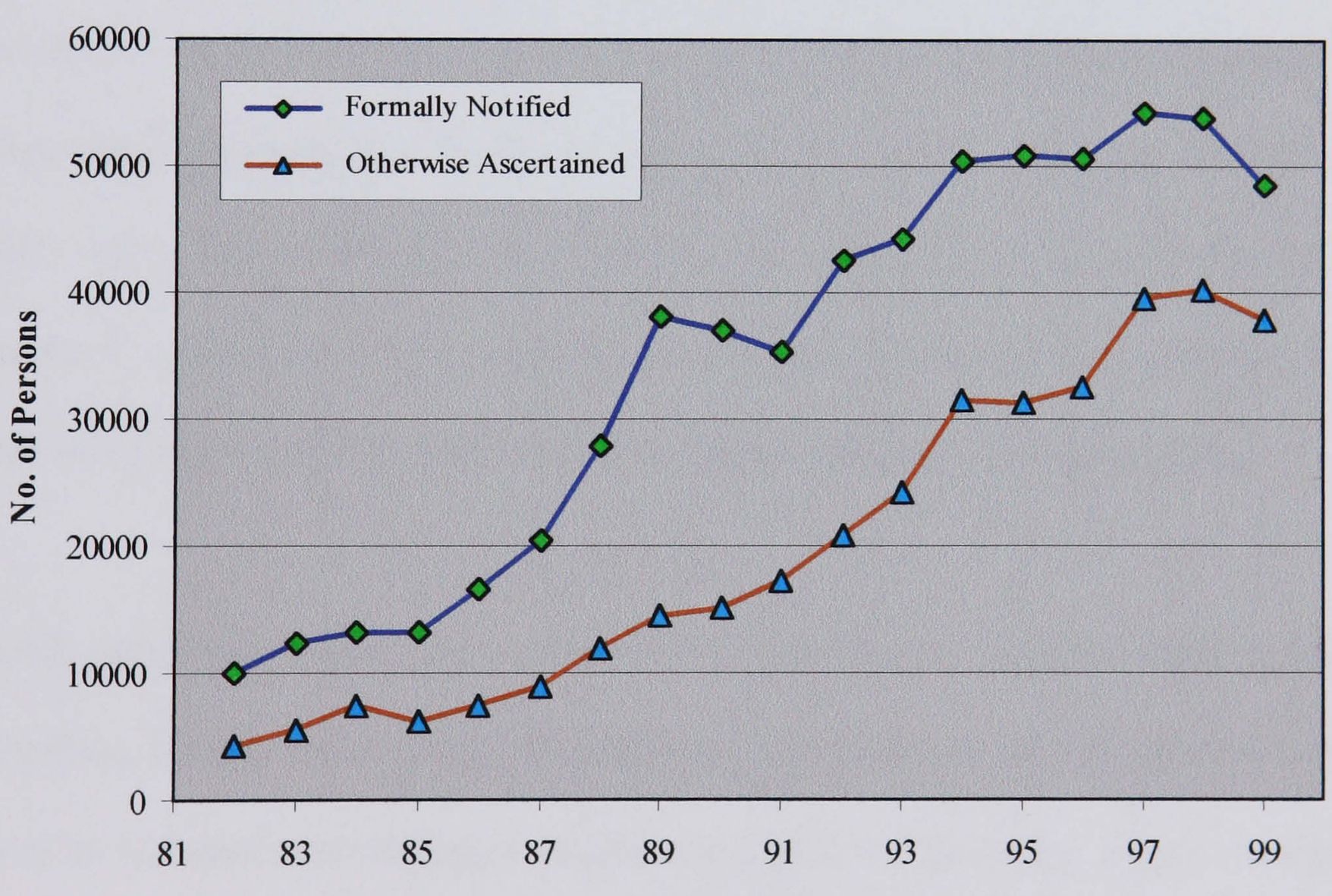
but excludes:

- live animals or birds,
- fodder or feeding stuffs for animals, birds or fish,
- drugs or medicinal products (MAFF, DH, SO & WO 1990).

Statistical data provided by the Common Services Agency (CSA 2000) and Communicable Disease Surveillance Centre of Public Health Laboratory Services (PHLS 2000) indicated an upward trend on the number of people suffering from food poisoning in the U.K., as shown in Graph 1.1(a)-(b).



Graph 1.1(a): Annual Notifications of Food Poisoning in Scotland between 1986-99



Graph 1.1(b): Annual Notifications of Food Poisoning in E&W between 1982-99

It is well represented by the recent *E. coli* O157 outbreak in Scotland between 1996-97 in which 21 people died and hundreds hospitalised (Cox 1998). With the ubiquity of pathogens in the environment, it is inevitable that they are present at all stages of the food chain. However, safety of food produced for human consumption must be ensured.

Under the current Food Act, the responsibility to produce safe and fit food rests with the food industry, while the U.K. government has the obligation to ensure that this legal requirement is fulfilled by food businesses. This responsibility on food safety is normally delegated to the Environmental Health Departments located in local Food Authorities. In Scotland, the majority of the Environmental Health Officers' time is spent on food safety, accounting to an average of 25.7% between 1990-1993 (REHIS 1993). In England and Wales, a lower figure of 15.57% in average is recorded between 1991-97 (CIPFA 1993-98). This reflects the importance placed on the control of foodstuffs and consumer protection. In order to stimulate compliance with food safety legislation and to maintain a good standard of protection, officers are required to carry out their routine food enforcement activities such as food inspection and sampling to monitor and control the operation of the food businesses.

Food sampling within the current food surveillance scheme mainly comprises sampling for microbiological and chemical contamination, as well as other categories such as physical contamination and composition and labelling. There are significant differences between the implications of chemical and microbiological food contamination. Gross chemical contamination sufficient to produce an immediate

toxic effect of chemical food poisoning is usually rare. Therefore, strategies generally focus on long term effects to ensure that chemical contaminants are well controlled below permissible levels so that they will not cause harmful effects to humans even after years of chronic exposure (Richmond 1990). Many chemicals have been identified and their maximum permissible levels in food and tolerable daily intakes were set and agreed both at National and European levels. Also, with the exception of the highly volatile substances, level of chemical contamination is relatively easily ascertained as the residues tend to be stable and often evenly distributed through the food. In the case of microbiological contamination, rapid onset of illness is common after consumption of contaminated food. Pathogens can also easily be transmitted to other people and thus has a possibility of increasing the number of food poisoning cases even after the initial focus of infection has been eliminated. Due to the nature and ability of the micro-organisms to survive and multiply, the level of microbiological contamination in food can increase very rapidly in a short period of time when favourable conditions such as optimal temperature and water activity is reached (Richmond 1990).

In the light of many important differences, the potential of pathogens to cause food poisoning is far from reaching when they are allowed to multiply and transmit even at a short period of time under poor conditions and improper handling of foods. Recent *E. coli* O157 outbreak in North Lanarkshire due to negligence and poor handling of raw and cooked meats is a typical example of food poisoning. Special attention for the development of microbiological surveillance is required to address the problem peculiar to microbiological food contamination. It is believed that there

are in existence some fundamental uncertainties within the system of food surveillance, and these underlying problems has been neglected and avoided. In order to tackle these problems and improve the current situation of food surveillance, this research concentrates on the aspects of food control, and in particular, focused on the microbiological food sampling in Scotland and the U.K. It is important to note that the results of the any food analysis would become meaningless if samples collected for testing were not representative of the lots.

Since food sampling is considered to be an expensive and labour intensive activity, enforcement authorities must plan their food sampling programmes carefully. Also, for the completion of internal market within the European Union, food surveillance carried out by the Member States is an important EU requirement. However, as questions have been raised towards the value of food sampling in a unified approach, no direct solution can possibly be given since the current food sampling in the U.K. has not been co-ordinated and planned in a statistical manner.

Therefore, the objectives of this research were to:

- identify main national and European food legislation for the enforcement of food safety and hygiene,
- examine relevant U.K. governmental bodies' food safety activities within the food co-ordination network,
- investigate current U.K. and European practices and control in respect to food sampling,

- carry out a critical statistical analysis of the existing food sampling programmes used by the local authorities throughout Scotland and the U.K.,
- develop a statistical model to examine the efficiency and effectiveness of the existing food sampling programme,
- assess the value of current food sampling in statistical terms.

The overall aim of this research was to attempt to improve the current U.K. and Scottish sampling regime through the development and application of the statistical model in order to increase awareness the importance of statistical validation and to help local authorities to design their food programmes based on a firm statistical foundation.

Chapter Two overviewed the current food legislation at national and European levels. After the consolidation of the previous Food Acts, a single Food Safety Act 1990 has now become the primary legislation for the U.K. Since U.K. is a member of the European Union, many national food laws were implemented from the EU Directives in order to complete the internal market in foodstuffs. EU Directive 89/397/EEC on the Official Control of Foodstuffs is considered to be one of the important EU food legislation regarding food control and sampling, and its requirements was discussed in detail.

Chapter Three studied the current food co-ordination system in Scotland and the U.K. These organisations included the Environmental Health Departments of the Local Authorities, Local Food Liaison Groups, Public Analysts and food examiners,

Scottish Food Co-ordinating Committee (SFCC), Local Authorities Co-ordinating Body on Food and Trading Standards (LACOTS), Scottish Office, Agriculture, Environment and Fisheries Department (SOAEFD), Department of Health (DH), and Ministry of Agriculture, Fisheries and Food (MAFF). Each of the relevant bodies' objectives and their contribution towards food sampling were critically examined.

Chapter Four examined the current practice of food sampling executed by the environmental health officers in Scotland and the U.K., and the sampling activities at regional, national and international basis. Also, the existing food sampling programmes used by the local authorities throughout Scotland were critically analysed.

Chapter Five extended the research on food sampling at European level. An investigation, in part, was undertaken to visit the European Commission (EC) in Brussels funded by the Royal Environmental Health Institute of Scotland (REHIS). Officials who have direct or related responsibilities towards this requirement were interviewed. The main objectives of this chapter were to investigate the main purpose and benefit of the requirement under the Official Control of Foodstuffs Directive (89/397/EEC), and to discover any hindrances or limitations which prohibit appropriate feedback to Member States on the results of the statistical returns.

Chapter Six reported the national survey designed for the purpose of this research on U.K. food sampling for microbiological and chemical analysis. The survey was conducted in the form of a questionnaire with seven annexes sent to 439 U.K. local

authorities. A response rate of nearly 40% was achieved, and this was considered as highly satisfactory. A detailed analysis of the results was discussed in this chapter.

Chapter Seven investigated the very important aspect of probability and statistical analysis towards the representation and quantification of uncertainty and variation existed in sampling. A statistical model was developed to examine the properties and close relationship between sample size, confidence level, margin of error and precision. Consequently, the understanding of statistically validated sampling can be incorporated into the design of statistically verifiable ideal standard so that verification on whether compliance to legal requirement is met or not can be justified.

Chapter Eight summarised the findings in Chapter One to Seven. Discussions and conclusions on the illustration of the present deficiencies in the U.K. and Scottish sampling regimes were made. Based on the findings by means of the statistical sampling model designed for the purpose of this research, attempt was made to improve the design of the existing food sampling programmes used by the U.K. local authorities.

Chapter 2

Current Food Safety and Hygiene Legislation

Chapter 2. Current Food Safety and Hygiene Legislation

2.1 Introduction

Food law has developed in the U.K. over more than a century and its origins can be traced even further back. Laws comprise a number of primary legal instruments, the Acts, and many secondary legal documents, principally Regulations. Any enforcement system requires that the legislation establish the powers and the responsibilities of the various enforcement officials. Thus the Acts and Regulations applying to food give the essential guidance on enforcement. Prior to 1990, the primary legislative powers relating to food safety in the U.K. were contained under three separate Food Acts:

- England and Wales: Food Act 1984
- Scotland: Food and Drugs (Scotland) Act 1956
- Northern Ireland: Food and Drugs Act (Northern Ireland) 1958

In addition, there were separate detailed requirements for milk, dairies and cream substitutes and separate powers for Regulations covering these products. At the present time, the main national legislative powers are now contained in the Food Safety Act 1990.

2.2 National Food Legislation

Food Safety Act 1990 was a consolidation of the previous U.K. Food Acts, and it came into force on the 1st of January 1991. This Act updated the primary legislation for England, Wales and Scotland. For Northern Ireland, very similar controls are contained in the Food Safety (Northern Ireland) Order 1991. The Food Safety Act is both primary law and an enabling measure. Since more detailed controls towards the scientific and technical requirements of food production is demanded, Ministers are empowered to make Regulations to control many aspects of food, whether production, manufacture, distribution, or indeed any other part of the food chain. Therefore, the general duties are amplified by many Regulations and Orders. Most are fairly prescriptive and have been substantially amended to take account of European Union (EU) Directives, for example, the Food Safety (General Food Hygiene) Regulations 1995 implement the provisions of the EU Directive (93/43/EEC) on the Hygiene of Foodstuffs. Before issuing Regulations, Ministers are usually required to consult with those organisations which may be affected by them. For matters that require more extensive or formal scientific consideration, Ministers will seek advice from independent Committees. The principal one for food is the Food Advisory Committee (FAC) which was constituted in 1983 by combining two previous committees:

- Food Standards Committee (FSC),
- Food Additives and Contaminants Committee (FACC) (Jukes 1994).

The main Statutory Instruments which deal with food sampling in this context is the Food Safety (Sampling and Qualifications) Regulations 1990, and it came into force on 1st January 1991 (MAFF, DH, SO & WO 1991). The Regulations set out the procedures to be followed by enforcement officers when taking formal samples for chemical analysis or microbiological examination, as well as the qualification requirements for Public Analysts and Food Examiners. In order to assist in producing a uniform standard of enforcement, Section 40 of the Act empowers Ministers to issue Codes of Practice to guide food authorities on the execution and enforcement of the Act. The Codes are not legally binding, however, Ministers will be able to give directions requiring food authorities to take specific action to comply with a specific Code of Practice and these directions will be enforceable through the courts. Currently, there are 20 Codes of Practice issued under the Food Safety Act 1990 (see Appendix 1) (MAFF, DH, SO & WO 1990). Code of Practice No.7 provides detailed instructions to officers on procedures of formal sampling for analysis and examination.

2.3 European Food Legislation

Food hygiene and food safety legislation can no longer be viewed in an exclusively national context. It is now a European wide issue. The EU Directive (89/397/EEC) on the Official Control of Foodstuffs may be regarded as one of the principle pull of European food legislation in relation to food control and sampling, and it came into force on 1st April 1991. It is one of the key Directives aimed at achieving a Single

Market in foodstuffs. As differences between national legislation with respect to food control are such as to represent barriers to free movement of goods, the introduction of this Directive aims at ensuring that Member States can have confidence in each others' food law enforcement arrangements in order to remove border controls. The basic principle is that food should be inspected primarily at the point of production. Products intended for consignment to another Member States are inspected with the same care as those intended for marketing on their own territory (MAFF, DH, SO & WO 1996).

Article 14 of the Directive requires competent authorities of the Member States to:

- draw up forward programmes laying down the nature and frequency of the inspections to be carried out regularly over a specific period;
- supply annually details of the number and type of inspections and infringements;
- carry out a co-ordinated food control programme of inspection and sampling.

Being a member of the European Union, the U.K. is required to submit the Statistical Returns to the European Commission on an annual basis. These returns give details of the number of:

- food inspections carried out,
- prosecutions taken,
- results of food samples taken officially, and
- results of food samples taken informally.

Concurrently, results of the Annual EU Co-ordinated Programme are collected and submitted to the European Commission (EU 1992).

Coupled with Directive 89/397/EEC is the EU Directive 93/99/EEC on the subject of Additional Measures concerning the Official Control of Foodstuffs (EU 1993). Again, the introduction of this Directive is to ensure that free movement of goods, persons, services and capital is achieved within the internal market. Official laboratories for microbiological and chemical testing should comply with the general criteria specified in the European Standard. Officials are appointed by the European Commission to monitor and evaluate the equivalence and effectiveness of official food control system operated by the competent authorities of Member States. In order to facilitate administrative assistance in all supervisory procedures related to legal provisions and quality standards applicable to foodstuffs and in all proceedings for infringements of the law applicable to foodstuffs, each Member State is expected to designate a single liaison body. Implementation of this EU requirement into U.K. food legislation is detailed in Code of Practice No.20. Local Authorities Co-ordinating Body on Food and Trading Standards (LACOTS) is appointed as the U.K. single body for the exchange of information between Member States of the EU on routine food control matters (MAFF, DH, SO & WO 1996).

The Official Control of Foodstuffs Directive was also supplemented in June 1993 by the adoption of the Hygiene of Foodstuffs Directive 93/43/EEC (EU 1993). Directive 89/397/EEC concentrates on the inspection, sampling and analysis and should be augmented by provisions aimed at improving the level of food hygiene and increasing confidence in the standard of hygiene of foodstuffs in free circulation.

Directive 93/43/EEC covers general rules of hygiene at the stage of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs not covered elsewhere by product-specific hygiene Directives. Development of guides to good hygiene practice should be encouraged by Member States and guidance such as the Recommended International Code of Practice, Principles of Hygiene of the Codex Alimentarius is suggested to be followed by the food businesses. This directive is brought into U.K. law under the Food Safety (General Food Hygiene) Regulations 1995. Under this Regulation, food business proprietors have the obligations to ensure their activities are carried out in a hygienic way, and adequate food safety procedures are required to be identified, implemented, maintained and reviewed.

2.4 Discussion

Through many years of development and substantial changes of previous food safety laws, the present Food Safety Act 1990 is now strengthened and updated. While the Food Safety Act can be seen as a continuum of the former Food Acts, it has been undergone to one of the most thorough review of the U.K. legislation. The Act is designed to cover areas of food safety from 'farm to fork' and affects everyone working in the production, processing, storage, distribution and sale of food. It replaced the various cumbersome primary laws with one single statute covering the whole of the U.K. Apart from the Government's original aim to increase public confidence in food safety, another important aspect is to ensure proper harmonisation

of EU food law. With so much new legislation coming from Brussels, the U.K. government needs to ensure that it will be effectively implemented in this country in order for the U.K. system to stand equally among other Member States' food law enforcement.

In relation to the area of food sampling, the Food Safety (Sampling and Qualifications) Regulations 1990 supplemented by the Code of Practice No.7 on Sampling for Analysis or Examination provide adequate information and clear instructions to authorised officers on carrying out formal sampling. Qualifications of public analysts and food examiners, as well as recognised laboratories for formal testings, are well listed in the Regulations. However, informal sampling has not been dealt with in accordance with the Regulations. It may be due to the fact that the original intention of informal sampling is for surveillance and surveys purposes only. Therefore, even if the results of the microbiological examination indicate significant contamination and breach of food law, it will hold no critical value as prime evidence in court for successful legal action if samples have not been procured and handled formally. In this circumstance, it is important to consider the true value and significance of the informal samples' results in such a way that it serves to be worthwhile doing rather than just a collection of data. And indeed, Environmental Health officers suggested that there have been occasions where outbreaks were prevented through the course of informal sampling (CIEH 1998).

The U.K. joined the founding six countries (Belgium, France, Germany, Italy, Luxembourg, and Netherlands) of the European Communities (EC) in 1973 at the

same time as Denmark and Ireland. The number of countries in the EC doubled to twelve when Greece joined in 1981 and Portugal and Spain joined in 1986. As a result of the Maastricht Treaty, the new 'European Union' was created in 1993. At present, the membership of the EU has now increased to fifteen when Austria, Finland and Sweden joined in 1995 (Maughan 1995). As a member of the EU, the U.K. has the obligation to follow the EU legislation agreed among the Member States. European legislation is aimed at creating a common market in goods so that products produced anywhere in the Union can be circulated without restriction. Since there are many differences in technical standards contained in national legislation and hinder the movement of goods between Member States, by agreeing common standards through the implementation of EU Directives into national laws, these barriers can be removed. When considering the internal market in foodstuffs, EU Directive (89/397/EEC) on the Official Control of Foodstuffs is undoubtedly one of the key EU legislation adopted for this very purpose. Many more Regulations and Directives have been adopted for the completion of Single Market, and will soon be incorporated into U.K. legislation. Some of the EU requirements may be stringent and may possibly take years to put into effect nationally by the Member States. For example, the overall submission of Annual Statistical Returns to the European Commission by Member States under the requirement of 89/397/EEC has been unsatisfactory. Some Member States may find it difficult to comply with this requirement within the time limit due to various reasons, such as technological deficiency. Pressure for new and amended controls remains, and enforcement bodies as well as industries must remain vigilant in this constantly changing control system.

Chapter 3

Current Food Control System in the U.K.

Chapter 3. Current Food Control System in the U.K.

3.1 Introduction

Current food control system in the U.K. comprises many governmental bodies with the remit of protecting the public on food safety (see Figure 3.1). These bodies cover areas in England and Wales, Scotland and Northern Ireland at local, regional and national levels. As a unique food co-ordination structure, these bodies are combined to form an U.K. networking system. These governmental bodies have major contributions towards the U.K. food surveillance such as initiation of surveys and projects throughout the year. Each of these organisations has the responsibilities on food co-ordination as well as introduction of specific aspects towards food sampling, and the remits of these bodies were discussed in this chapter.

However, there are many deficiencies and loopholes within the entire network from local to central government levels which may directly or indirectly impact the overall food law enforcement as well as influence the decision and performance of food sampling. The continuing rising levels of food-borne infection is but one piece of the evidence of the existing problem. Therefore, it is important to examine the current food co-ordination system and identify these problems within the network before striving to investigate on the aspect of food sampling in the U.K., which will lead to further statistical analysis of the existing food sampling programme to be used by the local authorities.

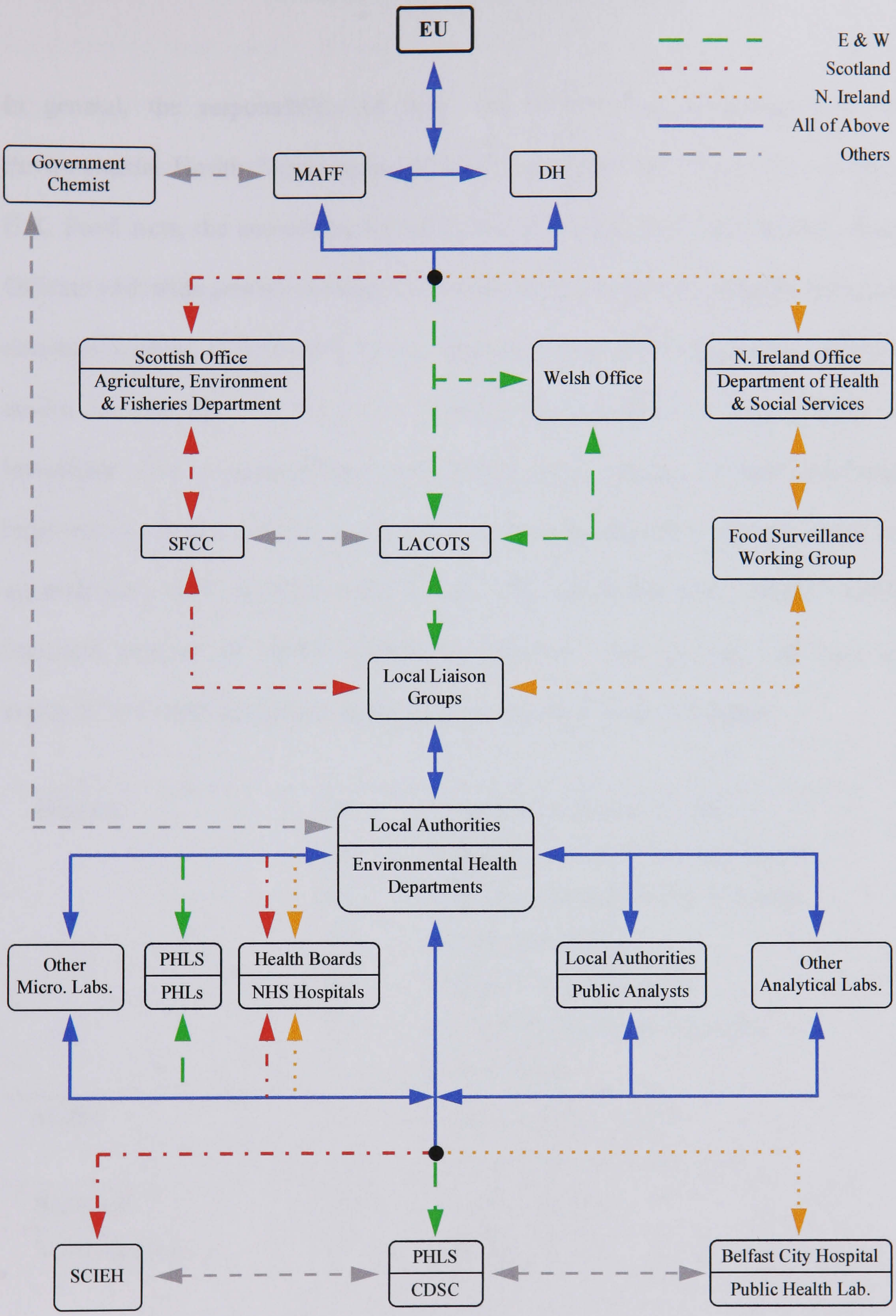


Figure 3.1: Key Features of U.K. Food Co-ordination Scheme before April 2000

3.2 Environmental Health Departments of the Local Authorities

In general, the responsibility of food law enforcement is delegated to the Environmental Health Departments of the Local Authorities. Unlike the previous U.K. Food Acts, the consolidated Food Safety Act provides Environmental Health Officers with wide powers to inspect any stage of the production, manufacturing and distribution chain. Officers also have powers to procure food samples for testing to ensure compliance with food law. Local authorities have a responsibility to investigate food complaints and the officers have powers to issue warnings, improvement notices or take prosecutions against businesses. Currently, there are approximately 6000 Environmental Health Officers in the U.K. (MAFF 1997). Statistics supplied by MAFF - JFSSG in February 2000 reported that there are currently 501 Food Authorities in the U.K., as shown in Table 3.1 below:

England	37	Metropolitan District Councils
	34	Non-Metropolitan County Councils
	238	Non-Metropolitan District Councils
	33	London Boroughs
	46	English Unitary Councils
	27	English Port Health Authorities
	1	Isles of Scilly
Wales	22	Welsh Unitary Councils
	5	Welsh Port Health Authorities
Scotland	32	Unitary Councils
Northern Ireland	26	District Councils

Table 3.1: Breakdown of the Food Authorities in the U.K.

The system of food law enforcement is complex. While the enforcement of legislation on food quality, composition and labelling mainly lie on the Trading Standards Departments, responsibility for surveillance and promotion of food safety and hygiene belongs to the Environmental Health Departments. Table 3.2 below distinguishes clearly the difference in responsibilities between the councils in England and Wales, Scotland and Northern Ireland (MAFF 1997).

	Food Safety & Hygiene	Food Labelling & Composition
England		
Metropolitan District Councils	EHD	TSD
Non-metropolitan County Councils	-	TSD
Non-metropolitan District Councils	EHD	-
English Unitary Councils	EHD	TSD
London Boroughs	EHD	TSD
Wales		
Unitary Councils	EHD	TSD
Scotland		
Unitary Councils	EHD	EHD
Northern Ireland		
District Councils	EHD	EHD

EHD - Environmental Health Departments

TSD - Trading Standards Departments

Table 3.2: Distribution of Food Enforcement within Local Authorities in the U.K.

3.3 Scientific Services

Under Section 27 of the Food Safety Act 1990, each local authority is required to appoint one or more persons to act as analysts within their areas. Altogether, there are 31 Public Analysts Laboratories spread throughout the U.K. with a total of approximately 70 fully qualified and appointed Public Analysts. Some of the laboratories are privately owned, having a contract with one or more local authorities to do their testing, while over half operate as departments owned by the local council. These laboratories might also provide scientific services for their neighbour councils that do not have their own laboratories (Association of Public Analysts 1998).

In Scotland, analytical service is mainly provided by four Public Analysts all of which are under the local authorities:

- Glasgow Scientific Services,
- Edinburgh Scientific Services,
- Dundee Scientific Services,
- Aberdeen Scientific Services.

Glasgow Scientific Services, a division of the Glasgow City Council, provides a statutory analytical service to more than half of the total Scottish Councils. Dundee Scientific Services provides the services to four Local Councils; while five Unitary Councils and two Islands Councils go to Edinburgh Scientific Services. The remaining four Councils appointed Aberdeen Scientific Services as their Public

Analyst. A full list of the Scottish Local Authority appointment for their Statutory Public Analysts is detailed in Appendix 2.

Under Article 3 of the EU Directive 93/99/EEC on the Additional Measures concerning the Official Control of Foodstuffs, Member States are required to take all measures to ensure that official laboratories described in Article 7 of the EU Directive 89/397/EEC comply with the general criteria laid down in European Standard EN 45001 (EU 1993). Due to this requirement, official laboratories have the obligation to ensure that they are accredited for calibration and/or testing. The system of laboratory accreditation provides assurance that testing and analysis are carried out according to documented procedures, and measurements are traceable to national and international standards. In the U.K., United Kingdom Accreditation Service (UKAS) is recognised by the U.K. Government as the national body responsible for providing National Accreditation of Certification Bodies (NACCB) and National Accreditation of Measurement and Sampling (NAMAS). UKAS requirements are aligned with the international standards such as EN 45001 and EN 45003, and ISO 9000 series (RCIC 1997). Article 9 of 93/99/EEC stated that all tested laboratories should become official laboratories before 1st November 1998.

In Scotland, a greatly increased demand for microbiological services was experienced due to the changes in emphasis detailed under the Food Safety Act 1990. Coupled with this modification was the reintroduction of NHS hospitals' trust status. Between 1948-1994, public health service was paid out of NHS budget from the central funding in London. However, a shift in policy effected on 1st of April 1994

demanded that all NHS hospitals in Scotland were required to have their own Trust Status. This means that from April 1994 onwards, local authorities have to pay for the microbiological service through their own budgets. In order to minimise this additional expenditure within their original budgets, some local authorities sought cheaper microbiological examination services as well as reducing the number of samples collected for testing. The overall changes of policy and competition led to the emergence and provision of the microbiological testing service provided by the Public Analysts to the local authorities. For example:

- Since 1994, Microbiological Section of Glasgow Scientific Services has provided examination services to three Scottish Councils: Glasgow City Council, East Renfrewshire Council, and East Dunbartonshire Council.
- Microbiological examination in Dundee Scientific Services has set up in 1997 and it is available for four Local Authorities: Fife Council, Angus Council, Dundee City Council, and Perth and Kinross Council.

At present, 23 Scottish local authorities send their microbiological samples to Public Analyst laboratories, with the remaining 9 authorities continuing to use NHS laboratories (Timbury 1999).

In England and Wales, microbiological testing service is mainly provided by the Public Health Laboratories of the Public Health Laboratory Services (PHLS). There are 49 Public Health Laboratories organised in nine groups distributed across England and Wales, together with the Central Public Health Laboratory (CPHL) and the Communicable Disease Surveillance Centre (CDSC), which are located with the Headquarters of the Services in London (Appendix 3). CPHL is the principal centre

for medical microbiology in the U.K. which provides specialist expertise and advice to the PHLS laboratories and NHS hospital laboratories, community and hospital physicians, environmental health officers, government and industry. CDSC is the centre which contributes to the role of PHLS in protecting the population from infection by the prevention and control of communicable disease through surveillance and independent advice, epidemiological investigation and research (PHLS 1996). An equivalent of CDSC in Scotland is the Scottish Centre for Infection and Environmental Health (SCIEH) which has a similar remit on the control of communicable diseases. Overall, PHLS is a national resource working closely with the National Health Service and funded principally by the Department of Health and the Welsh Office. Its major objective is to provide services to support diagnosis, prevention and control of infection and communicable diseases in England and Wales.

3.4 Local Liaison Groups

Before the local government reorganisation in 1996 effected under the Local Government etc. (Scotland) Act 1994, Scotland used to have seven food liaison groups. The number is now reduced to five liaison groups as listed below:

- North of Scotland Liaison Group,
- Central Liaison Group,
- Western Scotland Liaison Group,
- Fife and Tayside Liaison Group,

- Lothian and Borders Liaison Group (see Appendix 4).

Membership of the liaison groups consist of:

- Qualified Environmental Health Officers,
- Public Analysts,
- Microbiologists,
- Representatives of the Scottish Food Co-ordinating Committee (SFCC), and
- Scottish Office observers.

These local groups consider matters in food safety, quality, composition, labelling and hygiene. They are encouraged to carry out surveys, and these investigations can be considered as preliminary work to identify problem areas in food safety and hygiene. Co-ordination and standardisation of the enforcement activities among the member authorities is undertaken by the liaison groups. A forum for discussion, at local level, is provided towards the operational and financial implications of new legislation and proposals for future legislation. In addition, these groups monitor and highlight poor food trade practices and respond to consumer concerns in their area. The local groups disseminate information and form a link between the SFCC, local authorities, food trade and consumers (SFLG 1992). In relation to the design of sampling programmes at all levels, the existence of liaison grouping plays a very important role.

3.5 Scottish Food Co-ordinating Committee

Under the effect of the Local Government and Planning (Scotland) Act 1982, enforcement of food standards and labelling was transferred to the former District Councils. The necessity to co-ordinate the work of the District and Island Councils in Scotland was recognised and lead to the set up of the Committee in 1983 (SFCC 1989).

The membership is drawn from a wide base of professional disciplines:

- Heads of Environmental Health Officers from Food Enforcement Authorities,
- Public Analysts with each laboratory represented,
- Representatives of the Scottish Microbiology Association,
- Representative of the Royal Environmental Health Institute of Scotland (REHIS),
- Representative of the Society of Chief Officers of Environmental Health in Scotland,
- Representative of the LACOTS Food Standards Panel,
- Representatives of the LACOTS Food Safety Panel,
- Observer from the Scottish Centre for Infection and Environmental Health (SCIEH),
- Observers from the Scottish Office, Agriculture, Environment and Fisheries Department (SOAEFD),
- Observer from the Convention of Scottish Local Authorities (COSLA),
- Observer from the Local Authorities Co-ordinating Body on Food and Trading Standards (LACOTS).

Originally the Committee provided a forum with Public Analysts to communicate with Environmental Health Officers so that access to available expertise on food related matters is available. The primary remit of the committee was to ensure uniformity of standards of enforcement and to provide technical and expert advice to all enforcement authorities. Recognising the need to reflect the changes that are brought about within the industry and the wide influence of our EU partners, this role has expanded in 1994 to include co-ordination of work on food surveillance and food hygiene undertaken by enforcement authorities (SFCC 1989).

SFCC also gives advice to the government's department, local authorities and other bodies on food matters affecting Scotland. The Committee is a consultee of and adviser to:

- Convention of Scottish Local Authorities (COSLA),
- Scottish Office, Agriculture, Environment and Fisheries Department (SOAEFD),
- Local Authorities Co-ordinating Body on Food and Trading Standards (LACOTS),
- Trade Organisations.

It co-ordinates responses to and assesses the implications of existing and proposed EU Directives in relation to food. The Committee can identify loopholes of the existing food legislation, and advise and comment on the new legislation. As it forms a direct link with the local liaison groups, the committee will consider any matters submitted by them. These local groups are the key link in the organisational structure of the SFCC bringing together the enforcement officers, the Public Analysts and the

Food Examiners (SFCC 1989). Issues can be identified and decisions made as to whether these are local interest only or regional or national interest which may require the involvement of other Liaison Groups within the country. Also, it liaises with LACOTS, which itself has a similar role in England and Wales. LACOTS has played an important role in co-ordinating and guiding enforcement on food safety matters throughout the U.K. However, it also recognises the unique role that SFCC has in Scotland with the direct interface not only with Enforcement Officers and Public Analysts but also with Central Government in the form of the Scottish Office and also with general Local Government in the form of COSLA.

Apart from the pure co-ordination of activities, there are sub-committees co-opted to examine specific issues. SFCC has two principal sub-committees:

(i) Food Safety Sub-Committee,

(ii) Food Standards Sub-Committee.

Sub-committees consider all aspects within their respective remits as well as responding to consultation documents issued by Scottish Office Department of Health and Trade Organisations.

3.5.1 Food Safety Sub-Committee

The Food Safety Sub-Committee comprises:

- Liaison Group representatives,
- Scottish Office representatives,
- Microbiologists.

The Sub-Committee considers all food hygiene related matters including Hazard Analysis and guidance to Food Enforcement Officers. It has taken a particular interest in training of Food Enforcement Officers and has arranged low cost training seminars. For example, topics such as:

- Risk Assessment for Smaller Food Businesses,
- Uniformity of Enforcement - Policies,
- Microbiological Standards for Milk,
- Microbiological Surveillance of Food,
- Implementation of Hazard Analysis,

were considered and discussed during 1996-97 (House 1997). Liaison group representatives are expected to raise issues of concern which may have national consequences. In addition, suitable subjects are considered which will benefit food safety enforcement in Scotland (Morgan 1999).

Training of enforcement officers is viewed by the Sub-Committee as an important issue if standards are to be raised, and so localised training courses are organised by the Sub-Committee. For example, five training packages were produced in 1997 that were used by individual liaison groups or councils for in-house training. The subjects of these packages included:

- Cost Benefit Analysis
- Food Processing
- Outside Events
- Emergency Prohibition Procedures
- Food Labelling (House 1997).

3.5.2 Food Standards Sub-Committee

The Food Standards Sub-Committee was established following local government re-organisation in 1996. It succeeds the previous Working Party on Food Surveillance and Risk Assessment. The membership comprises of :

- Representative of each of the four Public Analyst laboratories in Scotland,
- Microbiologist,
- Representative of each of the five Local Food Liaison Groups (normally an environmental health officer),
- Representative of the Scottish Office.

Its terms of reference are wide ranging and cover trends in food production and supply, the identification of aspects prejudicial to consumers in Scotland, and the publication of information. As well as initiating its own surveys the Sub-Committee also co-ordinates Scottish response to surveys organised by other bodies, including the Scottish Office, European Union, Local Authority Co-ordinating Body on Food and Trading Standards and PHLS. The Sub-Committee liaises closely with Liaison Groups in identifying surveillance projects which are applicable across Scotland, as many of the surveys which are organised on a national basis follow on from local surveys. There is a mechanism whereby any matter concerning food composition, microbiological quality or labelling which has been raised at a local level may be referred to the Sub-Committee in order to obtain a wider range of opinions. Its role also includes identifying the appropriate protocol for the surveys concerned, collating the results and producing the final reports on the project (Morgan 1999).

3.6 Local Authorities Co-ordinating Body on Food and Trading Standards

LACOTS, originally known as the Local Authorities Co-ordinating Body on Trading Standards, is a local government central body created by the Local Authority Association in 1978 in response to concerns from government and business about differing standards of enforcement in local authorities throughout the U.K. In 1987, the work of LACOTS was first reviewed by the local authority Associations and LACOTS' efforts to encourage greater uniformity of trading standards was particularly appreciated by the Central Government. In 1991, a second review of LACOTS was undertaken by a team of local authority Chief Executives. The Group clearly identified the need for further co-ordination of food law enforcement and finally appointed LACOTS to take on this role (du Val 1992). Although LACOTS extended its terms of reference on food safety and hygiene matters, it had no remit on any of these issues in Scotland. Instead, all the food law enforcement functions under the Food Safety Act 1990 (i.e. including trading standards on food) are the responsibility of the Environmental Health Departments in Scotland. In 1995, the extension of LACOTS' role on food hygiene matters in Scotland was agreed by the Convention of Scottish Local Authorities (COSLA).

LACOTS is headed by a Management Committee comprised of twelve elected members appointed by the five local authority constituent Associations. The multidisciplinary Advisory and Executive Group (AEG) operates as an officer management team of LACOTS and includes representatives of each of the five constituent Associations, and the Chairmen of LACOTS five National Panels. AEG

is chaired by the Chief Executive of LACOTS. It is designed to facilitate effective operational co-ordination between LACOTS Secretariat, the Panels and the constituent Associations. There used to be five main advisory Panels:

- Food Safety Panel
- Quality Standards Panel
- Fair Trading Panel
- Metrology Panel
- Safety (Product) Panel

which formed the backbone of the co-ordinating structure. Members of the Panels included Chief Officers or Heads of Service appointed by the Associations and reflect a range of multidisciplinary interests. Scientific, fire and petroleum advisors participated in the Panels as well as senior trading standards and environmental health officers drawn from a broad spectrum of local authorities. There were also various Sub-Panels and Working Groups under the main Panels. These Sub-Panels assisted the main Panels on issues such as animal health and welfare, consumer credit, food labelling and hygiene and environmental labelling.

Following local government reorganisation in England and Scotland, LACOTS structure had been reviewed and as a consequence the existing panel system was replaced with a strategic panel supported by focus groups and task forces. The Strategic Panel determines the overall strategies, policies, and priorities and drives the LACOTS agenda. COSLA is invited to nominate representatives from Scotland to participate in the Strategic Panel. Food safety and quality standards panels were replaced by the Focus groups and task groups. The aim is to address problems in the

most cost-effective way and each focus group or task group has a membership appropriate to its needs. Focus groups deal with queries and problems from liaison groups and individual authorities, meet with government departments, respond to consultation documents, codes of practice, industry and trade, and make recommendations on policy to the constituent associations. Task groups tackle live issues which has a more limited life and included representatives from liaison groups. In general terms, the deliberations of a task force refer to the strategic panel who disposes to endorse the recommendations unless some wider local government interest determines otherwise (LACOTS 2000).

Whilst LACOTS' primary aim is to promote consistency in the interpretation and application of regulations, the organisation has extensive terms of reference which include advising Government on the practicality of proposed national and European legislation. Encouragement of good enforcement practices, business partnership and the Home Authority Principle are all provided in accordance with its co-ordinating role. LACOTS continues to contribute to debates concerning service delivery, resourcing, performance standards, deregulation and government scrutiny of enforcement. LACOTS has recently been appointed as the Single Liaison Body to provide administrative assistance on routine food control matters for the United Kingdom under the Additional Food Control Measures Directive (93/99/EEC). As detailed in Code of Practice No.20, LACOTS will be responsible for facilitating the transfer of information to and from EU Member States on routine food control matters. Upon requests from other Member States, it has the obligation for ensuring

that all the necessary and accessible information concerning compliance with U.K. food law is provided without delay (MAFF, DH, SO & WO 1996).

Government departments, agencies, trade associations, consumer organisations and local authorities, via their regional Liaison Group, refer issues to LACOTS Panels for consideration. These issues focus on interpretational inconsistencies in legislation, local authority enforcement practices, proposals for new laws and guidance and other matters involving deregulation, enforcement appeal mechanisms, European enforcement co-operation, and fast track Home Authority conciliation. LACOTS publishes guidance notes and documents to local authorities in co-ordinating the enforcement functions of food authorities in England, Wales, Scotland and Northern Ireland.

The Home Authority Principle is always an important issue of LACOTS' concern. It is a fundamental element in the efficient co-ordination and is the backbone of effective local authority enforcement. The Principle allows local authorities to demonstrate fair, consistent and co-operative treatment of businesses throughout the U.K. and Europe. The Principle has proven successful in minimising incidents of duplication and enforcement inconsistency. It requires commitment from local authorities and enjoys support from the Local Authority Associations, government departments, trade and industry (Morgan 1999). Under the arrangement, each multiple enterprise has allocated to it a home authority. This is the authority where the relevant decision-making base of an enterprise is located. Advice and assistance on the application of trading standards and food hygiene legislation can be sought

from this home authority. Other enforcing authorities are expected to liaise with the home authority before pursuing investigations, enquiries and complaints about the enterprise and goods that it may have produced and distributed. Definitions of Home, Originating and Enforcing Authority are also stated in Code of Practice No.20 under the Food Safety Act 1990 (MAFF, DH, SO & WO 1996).

3.7 Scottish Office, Agriculture, Environment and Fisheries Department

The Scottish Office, Agriculture, Environment and Fisheries Department (SOAEFD) is the main central body in dealing with the overall co-ordination of food matters in Scotland. Through its Food and Dairy Unit, the Scottish Office is the link between Scottish local authorities and central government and provides the interface between local authorities and industry. The Unit can establish the accountability of local authorities by auditing their work and identifying best practice. In addition, the Department provides its general functions by giving an overview and responsibility for all food control and safety matters in Scotland, which is normally delegated at local level. In consultation with all interested organisations, the Department prepares and introduces legislation (mostly at EU level) covering all aspects of food control. It also disseminates information about reported food hazards to local authorities for action as appropriate. There are established links with industry and the Department acts as a point of contact in relation to trade enquiries. It provides industry with guidance and information on food law affecting their particular sector and provides an interface with local authorities to discuss legislation, technical and enforcement

issues. The Scottish Office has a policy of encouraging consumer groups and will provide information, advice and support.

In the main, the Scottish Office simply acts like a 'Post Office' where information at local level is collected and passed onto national level, mainly to the Ministry of Agriculture, Fisheries and Food (MAFF). This chain of co-ordination is particularly important with regard to the European issues. For example, every year the Scottish Office, through MAFF, can appropriately deliver the statistical returns produced by the Scottish local authorities to the European Commission. Unlike in England and Wales, the SOAEFD has a unified approach to food and has responsibilities for both food standards and food safety. The Scottish Office, under existing arrangements, has its own seat at the negotiation table at Brussels. But for simplicity, this responsibility is delegated to MAFF/Department of Health in order that there is only one U.K. voice.

3.8 Ministry of Agriculture, Fisheries and Food

At central Government level, Ministry of Agriculture, Fisheries and Food (MAFF) was the lead department on:

- food standards,
- chemical safety of food,
- food labelling,
- food technology.

MAFF is a national multi-functional ministry which aimed at improving the economic performance of agriculture, fishing and food industries, especially in assisting the expansion of the markets in Europe and other countries. One of its aims was to protect the public by promoting food safety; taking action against diseases with implications for human health; and planning to safeguard essential supplies in any emergency (MAFF 1995). As the U.K. is a member of the EU, food trade within the Single European Market becomes a major issue, and so the food industry and food supply were essential concerns of MAFF.

Each year approximately 130,000 analyses of food were carried out by MAFF with an annual expenditure of £15 million spent on research into food safety (MAFF 1995). Recent research focussed on the detection of pathogens and toxins in foods, the detection of botulinum toxin, viruses and protozoa. Investigation also covered the significance of known and potential microbiological risks to food safety, where microbiological hazards can occur in the food chain and the techniques to provide for objective hazard and risk assessment. The Government's Advisory Committee on the Microbiological Safety of Food (ACMSF) established in 1990 has a major influence on the selection of topics for research. The Committee has the responsibility to advise U.K. Health and Agriculture Ministers on food microbiological issues. In particular, the Committee assessed the risk to humans of micro-organisms which were used, or occur, in or on food and advised ministers on the exercise of powers in the Food Safety Act 1990 relating to the microbiological safety of food. Members of the Committee were drawn from U.K. centres of microbiological expertise, business and enforcement interests and the PHLS which was responsible for much of the

investigation and laboratory work arising from the ACMSF recommendations (Jacob 1998).

Apart from the work of food surveillance and research, MAFF was also responsible for the overall food co-ordination for the U.K. It was the main national central body gathering information from England and Wales, Scotland and Northern Ireland through their Offices. As the increasing demand of compliance with the EU requirement, MAFF also acted like an international agency representing the whole U.K. for the collection and delivery of data to the EU. For example, each year MAFF, acting as the lead U.K. body, was responsible for the overall submission of U.K. Statistical Returns to the European Commission in Brussels. However, as mentioned earlier, part of the role for the exchange of information had now assigned to LACOTS.

In order to prepare the coming of the Food Standards Agency, the Joint Food Safety and Standards Group (JFSSG) had been set up on 1st September 1997. In recognition of this reorganisation, the Department of Health's (DH) Health Aspects of the Environment and Food (HEF) division was divided into a Food Safety and Standards section; which joined the MAFF Food Safety and Standards Groups to form the JFSSG. The rest of HEF became the Health Aspects of the Environment Division (HE) (see Figure 3.2) (MAFF 1997). MAFF also operated co-ordinated programmes of research and monitoring the food supply through this group. It controlled health risks both directly, by regulating the industry, and indirectly, by informing and advising the consumer (MAFF 1998). The Food Standards Agency was officially set

up in April 2000, and the responsibilities under MAFF in relation to food were transferred to the new Agency. MAFF will maintain good working relationship with the Food Standards Agency to ensure efficiency and effectiveness to the protection of public health.

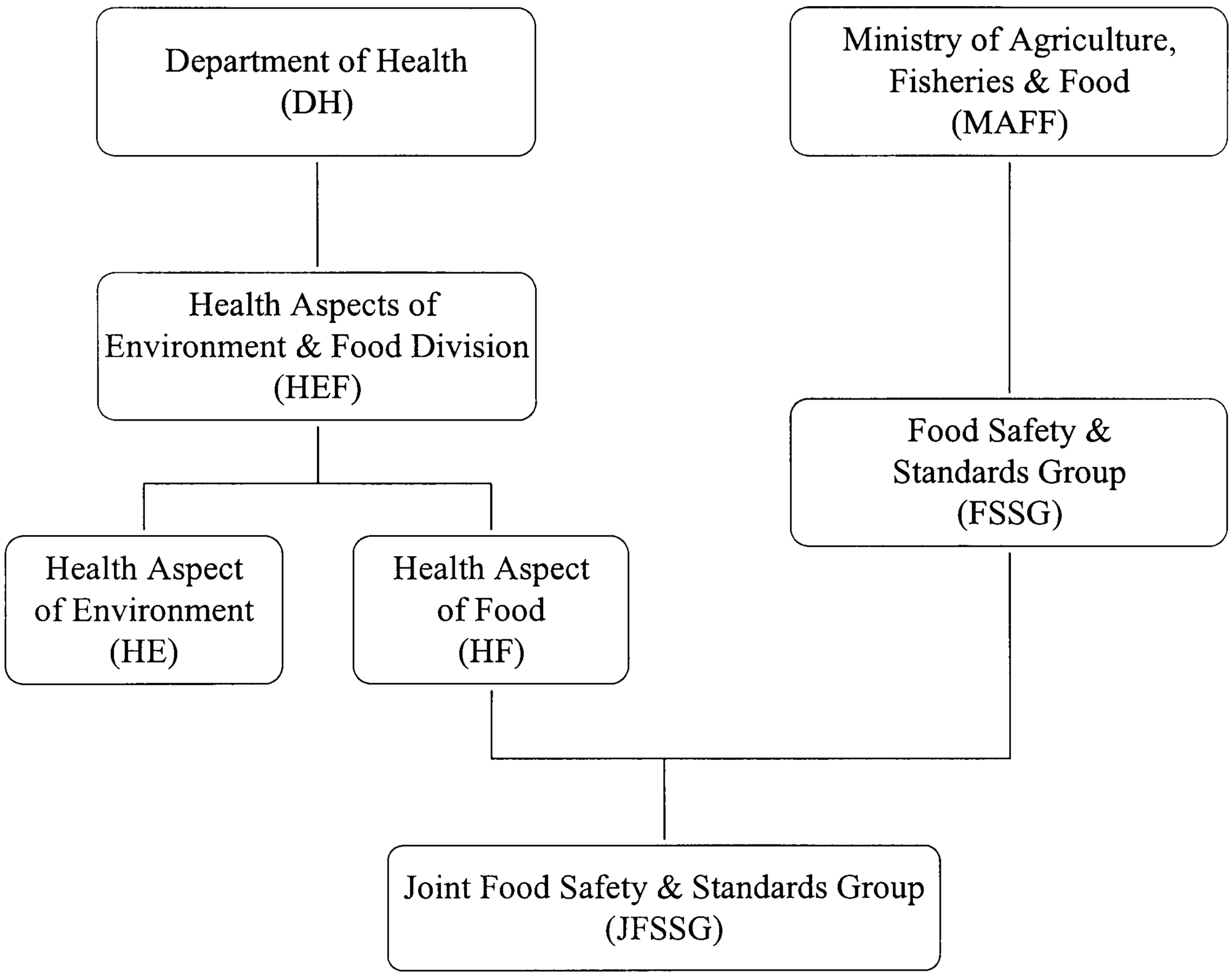


Figure 3.2: The Forming of the Joint Food Safety and Standards Group (JFSSG)

3.9 Department of Health

In contrast with MAFF at central Government level, Department of Health took a lead on issues of:

- Food hygiene,
- Microbiological food safety,
- Nutrition.

The Department is responsible for health and personal social services. It sets overall policy on all health issues, including public health matters and health consequences of environmental and food issues. The overall aim is to improve the health and well-being of the people and to secure the provision of high quality health and social care. The structure of Department of Health is shown in Figure 3.3:

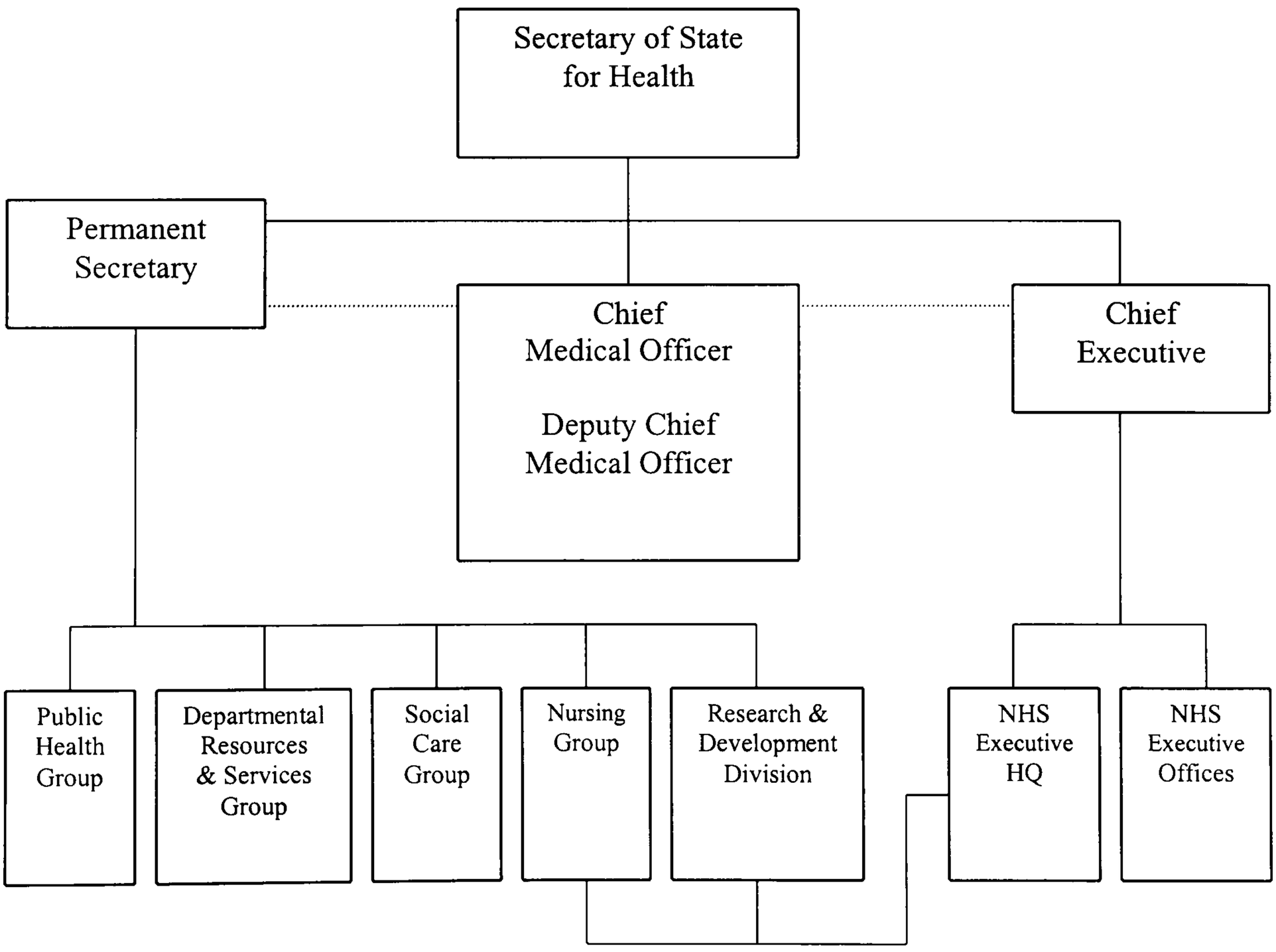


Figure 3.3: Structure of Department of Health

The Department of Health is divided into four main areas:

- NHS Executive,
- Public Health Group,
- Social Care Group, and
- Departmental Resources and Services Group.

The Public Health Group was responsible for the development and implementation of policies to prevent disease, identify emerging public health issues, and promote and protect the health of the public. In carrying these responsibilities, the Group worked closely with other Government Departments and agencies, local authorities, health professional bodies, international agencies and the public. Part of its key objectives were to improve knowledge on the safety of food and water, implement ways to reduce risk and develop a sensible risk-related approach to deregulation. The Group carried out surveys and responds to microbiological, chemical or radioactive hazards. It also considered with other Government Departments, local authorities and health authorities the further needs for central monitoring and surveillance (Department of Health 1998).

There are also Executive Agencies (example: Medical Devices Agency and Medicines Control Agency) and Non Departmental Public Bodies (example: PHLS and National Radiological Protection Board) that provided expertise in specific areas and supported the Department. While food surveillance in Scotland was overseen by the Scottish Office, Department of Health in England and Welsh Office largely carried out their surveillance role by funding PHLS. It carried out most government-sponsored monitoring at the retail end of the food chain either by specific surveys or

in response to requests from local Environmental Health Departments. The Department of Health also commissioned from the PHLS specific surveys in response to particular problems. In terms of research into the microbiological safety of food by the DH, most of its activities flowed from the work of the ACMSF (Richmond 1990). Again, the launch of the new Food Standards Agency in April 2000 took over the responsibilities under DH in relation to food.

3.10 Food Standards Agency

An independent food agency was proposed by the Labour Government in order to restore public's confidence in food safety after the food scares such as *Salmonella* and the recent *E. coli* O157 outbreaks. The report drawn up by Professor Philip James of the Rowett Research Institute in Aberdeen was published on 8 May 1997. It was formally presented to the Prime Minister to make recommendations on the structure and functions of a Food Standards Agency (FSA), aiming at food safety from the 'plough to the plate' (James 1997). The proposal was received warmly on all sides. Professor James proposed that the Agency should be established by statute as an Executive Non-Departmental Public Body. All responsibilities of MAFF for food standards and safety would be taken over by the new agency. Similar aspects of Department of Health's activity would also be incorporated into the new body. By co-ordinating, monitoring and setting standards for local law enforcement activities, the new Agency would develop an effective link in the local authorities' surveillance and enforcement process (Randall 1997). It was suggested that LACOTS' role as the

Single Liaison Body for the U.K. in the E.U. should be taken over by the Local Authority Liaison Unit of the Food Agency, however, LACOTS would retain an important role as a channel for local authorities communication. Therefore, the proposal of the FSA would create a one-stop shop with an overall remit for food safety of the U.K. (James 1997). Over 600 responses were received during the consultation period including representatives from the consumer sector, public health medicine, local government, veterinary services, scientific research, all sectors of the food production and distribution industries and private individuals (FSA 2000).

The White Paper 'The Food Standards Agency: A Force for Change', published on 14th January 1998, was launched in the House of Commons, reflecting the consultation and Professor James' report. It set out plans for a new public body in order to transform the way in which food safety and standards issues were handled. Basic principles from James Report were well accepted and incorporated into the White Paper. The Agency would be given the powers it needed to take action across the whole of the food chain. The Paper was put out to further public consultation between January to March 1998. A draft Bill was presented in January 1999 for consultation in the Command Paper 'The Food Standards Agency: Consultation on Draft Legislation'. This document initiated further consultation on the Government's proposals for changes in the arrangements for handling food safety and standards issues in the U.K. The draft Bill implemented the proposals set out in the White Paper (MAFF 1999). The report on the draft Bill was published by the House of Commons Select Committee - Food Standards Committee in March 1999. The definitive form of the Food Standards Bill was introduced into the House of

Commons in June 1999. The Bill received Royal Assent and became the Food Standards Act 1999 in November 1999. The Food Standards Agency was set up on 1st April 2000 and became operational on 3rd April (FSA 2000).

The Agency has been created to "protect public health from risks which may arise in connection with the consumption of food, and otherwise to protect the interests of consumers in relation to food". The functions of the Agency includes:

- Providing advice and information to the public and to the Government on food safety from farm to fork, nutrition and diet,
- Protecting consumers through effective enforcement and monitoring,
- Supporting consumer choice through promoting accurate and meaningful labelling.

The Food Standards Agency will account to Parliament through Health Ministers, and as a U.K. body to the devolved administrations for its activities within their areas. It has the unique legal power to publish the advice it gives to the government, and it can be seen to act openly and independently in looking after the interests of consumers. The Agency is led by a Board which has been appointed to act in the public interest, not to represent particular sectors. Its members bring a wide range of relevant skills and experience. The Chairman, Deputy Chair, Chief Executive and 12 Board members have been appointed to lead the Food Standards Agency. The Agency Board is responsible for overall strategic direction, ensuring the Agency fulfils its legal obligations so that its decisions or actions take proper account of scientific advice, the interests of consumers and other relevant factors. The Chairman and Deputy Chair were jointly appointed by the Secretary of State for Health,

Scottish Ministers, the National Assembly for Wales and N. Ireland Office Ministers. The Chief Executive was appointed by the Secretary of State for Health with the approval of the Head of the Civil Service. Two Board members were appointed by Scottish Ministers, one by the National Assembly for Wales and one by Northern Ireland Office Ministers. These members have special responsibility for Scottish, Welsh and Northern Irish issues. The other eight Board members were appointed by the Secretary of State for Health. Special Advisory Committees are being established for Scotland, Wales and N. Ireland to advise on food safety and standards issues which are specific to each devolved administration.

The Agency has a U.K. Headquarters based in London, as well as Executive offices in Scotland, Wales, and Northern Ireland. The Meat Hygiene Service which also has the protection of public health as a primary aim is now accountable to the FSA. There are three main groups of the U.K. Headquarters based in London:

- Food Safety Policy Group,
- Enforcement and Food Standards Group,
- Corporate Resources and Strategy Group,

incorporating a range of specialist divisions set up to fulfil the roles and responsibilities of the Agency. The Food Safety Policy Group deals with all aspects of food safety and nutrition. Most of these functions were previously split between MAFF and DH. The Enforcement and Food Standards Group includes two new divisions established to help local authorities improve the effectiveness of the local enforcement of food standards legislation. This group will bring together and develop the work on enforcing food law which was previously divided between DH

and MAFF. The Corporate Resources and Strategy Group supports the Agency as a whole through the work of its three divisions. The structure of the U.K. Headquarters is illustrated in Figure 3.4. The Scottish, Welsh and Northern Irish Executives of the Food Standards Agency have been established to develop and implement policies on food issues that are specific to each country, within the framework set by the Agency as a whole. These Executives provide support to their respective Parliaments, Assemblies, and the Ministers on the Agency's local activities, and prepare legislation as needed to implement the Agency's policies. The FSA is accountable to the relevant devolved legislatures for its activities within and for their geographical areas.

Primary aim of the Food Standards Agency is to protect the health of the public in relation to food and the interests of consumers of food. This aim will be achieved by:

- Developing effective policies relating to food safety or to other interests of consumers in relation to food,
- Providing advice, information and other forms of assistance to all stakeholders on the policies developed by the Agency,
- Building and maintaining a reputation for expertise and excellence in matters connected with food safety and other interests of consumers in relation to food.

The roles of the Agency involve:

- Providing policy advice to Ministers on food safety and standards and aspects of nutrition, for preparing legislation, and for providing the public with information and advice;
- Commissioning research and surveillance across the full range of its activities;

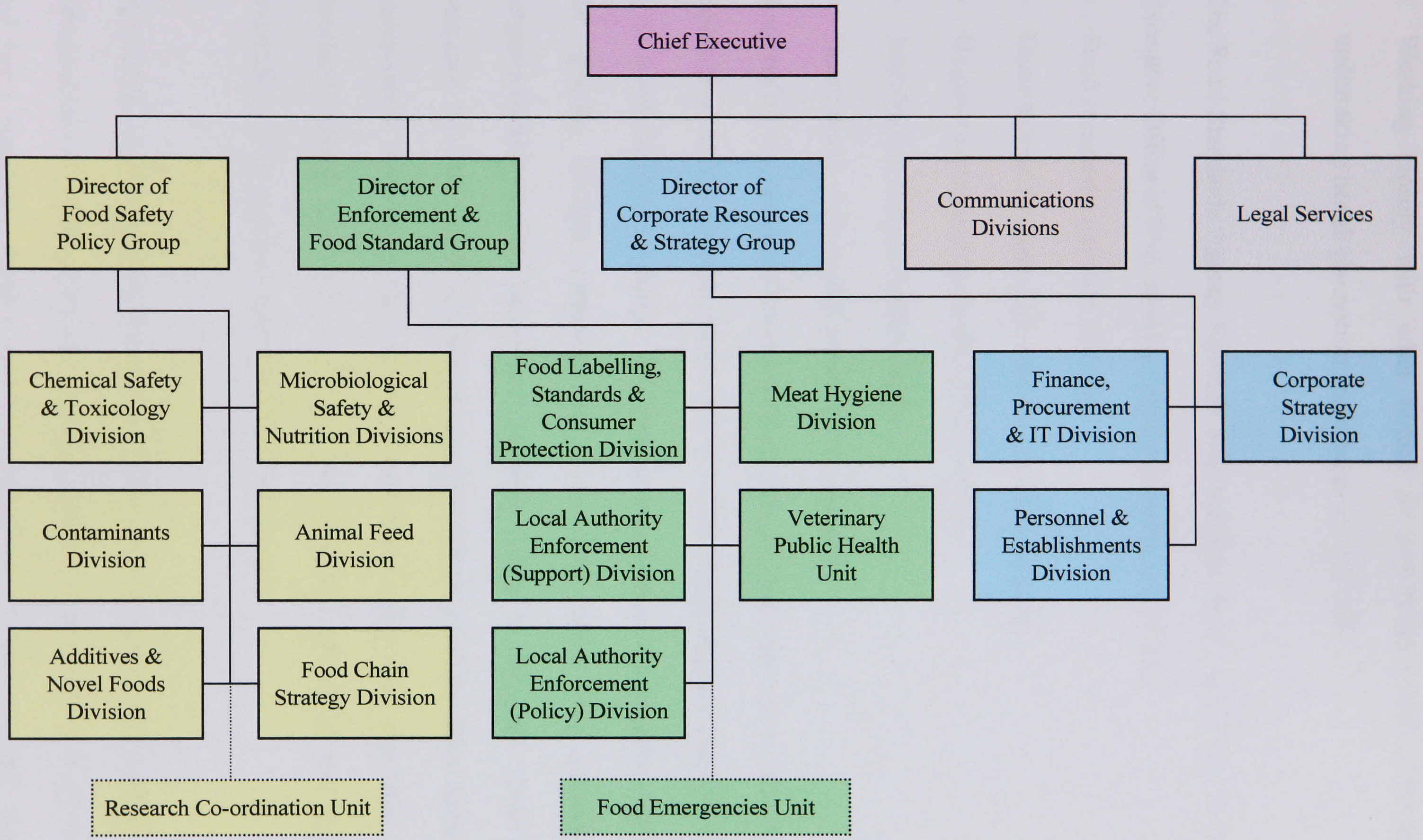


Figure 3.4: Structure of Food Standards Agency - U.K. Headquarters

- Working with local authorities to encourage consistency in enforcement practice;
- Working closely with other bodies in providing public information and undertaking health promotion and education activities.

The Food Standards Agency Scotland was launched on 3rd April 2000. This Scottish Executive Office of FSA handles issues in Scotland involving:

- Food standards, nutrition and diet,
- General food hygiene, fish, shellfish and milk hygiene,
- Hygiene controls on meat and meat products,
- Regulation of animal feeding stuffs,
- Novel foods, radiological safety and emergencies.

Food safety and standards are devolved matters and legislation governing Scotland is determined by the Scottish Parliament. Food Standards Agency operates within the U.K. Food Standards Agency. This ensures consistency of approach while allowing for specific Scottish circumstances to be fully taken into account in the implementation of food safety and standards policy in Scotland. There is also a statutory Scottish Food Advisory Committee which provides FSA Scotland with independent information and advice on all food safety and standards issues in Scotland, taking into account where necessary the advice of the independent scientific advisory committees working in these areas.

In order to maintain good working level relations with other governmental bodies to ensure sufficient communication and co-ordination, concordats were set up between the Food Standards Agency and the Department of Health (DH), Ministry of

Agriculture, Fisheries and Food (MAFF), and Public Health Laboratory Service (PHLS). Since responsibilities on all aspects of food safety, standards and nutrition were previously split between MAFF and DH, it is important that smooth transfer of these duties to the new Food Standards Agency were maintained, and remits of these bodies after the transfer were not ambiguous. The concordats also indicated a clear distinction on sole or share responsibilities on certain matters so that duplication or confusion would be minimised.

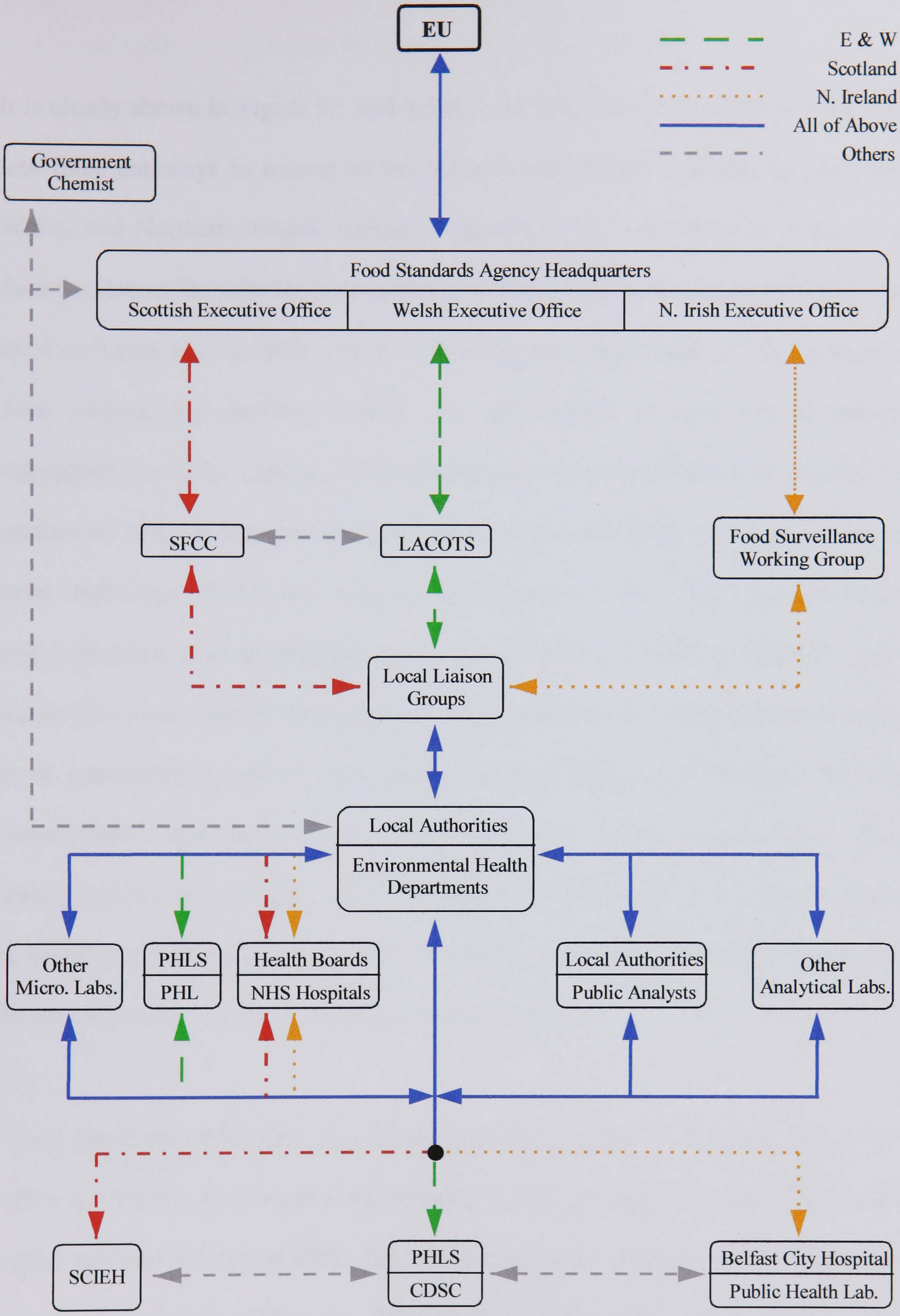


Figure 3.5: Key Features of U.K. Food Co-ordination Scheme after April 2000

3.11 Discussion

It is clearly shown in Figure 3.1 and 3.5 that the U.K. food co-ordination is divided into three pathways in respect to the national boundaries: Scotland, England and Wales, and Northern Ireland. Indeed, responsibility for enforcing the majority of food legislation lies with the local authorities, therefore it is important to ensure that local enforcers execute their actions effectively and consistently. However, experts from various organisations identify that enforcement of food law is uneven throughout the U.K. (James 1997). Deficiencies were considered to be lack of uniformity and varying quality of enforcement practice both within and between local authorities. Food law enforcement competes with other local authority responsibilities, such as education and social services, for funding. Priorities differ across the country and in some areas food law enforcement suffers. Currently, there is no mechanism to ensure that funding allocated to local government for food related work is spent on food issues. For example, £30 million was allocated to local government for enforcement of the Food Safety Act 1990, with £19 million available to improve food hygiene standards after recommendations published in Pennington Report, but funds were not ring-fenced for the purposes.

There has been continuing controversy over the conduct of environmental health officers. Officers were accused of inflicting food businesses by using their powers under the Food Safety Act 1990. The criticism towards EHOs was well illustrated by the judgement of Sheriff Douglas Allan made in 5th December 1995 over the Lanark Blue Cheese Case. Mr. Errington was prosecuted by Environmental Health

Department of former Clydesdale District Council under Section 8 of the Food Safety Act 1990. Lanark Blue cheese produced by the respondent was found to be contaminated with *Listeria monocytogenes* and therefore was condemned by the Council as unfit for human consumption. However, due to the lack of scientific evidence to prove that *Listeria monocytogenes* serotype 3a was indeed 'injurious to health', Sheriff Allan finally decided not to condemn the cheese. Environmental health officers, referred to by the press as 'Food Police', were blamed to be 'over-zealous' on their food law enforcement (Ahmed and Steenson 1996). Contrary to the Lanark Blue Cheese Case, the incident of *E. coli* O157 outbreak in 1996 which killed 21 people through eating contaminated cooked meats from John Barr's butcher's shop in Lanarkshire gave a different devastating view of British public health officials. Sheriff Graham Cox pinned the blame not just on the business that supplied the offending food but on those EHOs who had failed to identify the risks in their previous food inspection. Cox portrayed North Lanarkshire Council's incompetence as a major system failure which played a crucial part in bringing the disaster about (Gilliver 1998). Concerns about over-zealous enforcement have distracted attention from the fundamental task of enforcement authorities to ensure that food businesses are complying with their obligations under the Food Safety Act. Or, as urged by North, EHOs have simply forgotten how to do their job properly because they have become so obsessed with checklist procedures and regulatory rituals that they have lost the ability to recognise genuine hygiene risks (Booker 1998). There is obviously a real need for clearly focused coherent guidance and support for enforcement officers so that consumers and businesses throughout the U.K. can benefit from a consistent and proportionate inspection system.

A major weakness in the current system identified in the James' Report is the fragmentation and lack of co-ordination between bodies involved in food policy and in the monitoring and control of food safety. There are overlaps and gaps between departments dealing with food issues, for example, the confusion between MAFF and DH over the control of food safety. There are many institutional barriers at different points in the food chain. The mechanisms for food surveillance also lack a clear strategy and structure. In the main, the U.K. system is too complex due to the separation of catchment areas between England and Wales, Scotland and Northern Ireland, which may lead to an inadequate system of food surveillance. As indicated in Figure 3.1, there are clearly too many bodies dealing with food safety issues. It may not necessarily be a disadvantage if these bodies are organised and functioned in a consistent approach; however, duplication of work and sampling can be seen throughout the entire system. Also, consultation indicated that people found the present division of responsibilities between different departments of Government to be confusing. Through personal interviews with many officials from local to central governmental levels, an indication of lack of knowledge and understanding towards the complicated three-way food control system was shown. Greater clarity is needed to improve the current situation. The introduction of the Food Standards Agency is believed to produce a one-stop shop which will hopefully ensure that effectiveness of controls on food is not undermined by overlaps, conflicting objectives or incoherence. Where institutional barriers are found in the food chain, responsibilities will be clearly defined and better communication will be encouraged (Figure 3.5).

Another controversial issue is the conflicting role of MAFF. Although it has a major part to play in promoting the economic interests of the agriculture, fishing and food industries, concurrently, it was also responsible for protecting public health throughout the food chain. As a main central body within the system, MAFF had an obligation to examine and estimate the possibility of health risks caused by consumption of unfit foodstuffs and implemented appropriate measures to reduce or even eliminate these occurrences. But there had also been a strong move to deregulate aspects of food laws in order to encourage food businesses. Inevitably at times there would be conflicts between concerns for food safety and economic needs of some industry sectors. Obviously, the previous arrangement of MAFF had not been favourable in serving these dual purposes. A clear separation is needed between promoting safe food and wider consumer interests on one hand and promoting the interests of business on the other.

Currently, the four Scottish City Councils where the Public Analysts are based act as lead authorities and provide services to other local authorities. The four units undertake the full range of analytical work required, but it is suggested that a fully rationalised system would be preferable because four sets of equipment for specialist work would no longer be needed and regional centres of expertise could be established. Therefore, there is a strong case for rationalising the activities of the Public Analysts centres to create a unified Scottish Scientific Service. In England and Wales, as many local authorities prefer to appoint the more competitive private laboratories as their Public Analysts, this make the mechanisms of audit and control more complex.

On the other hand, PHLS takes the lead of providing microbiological examination service to English and Welsh local authorities; while majority of Scottish local authorities now use facilities provided by the Public Analysts laboratories, with the remaining Scottish councils choose to use public health laboratories under the NHS hospitals. Because of the change in climate towards microbiological examination service in Scotland, closure of some Public Health Laboratories in NHS hospitals is inevitable. It is believed to be mainly due to the reduction of microbiological examination previously requested by local councils as well as the pressure of NAMAS accreditation demanded by the EU. However, Dancer claimed that NAMAS was chiefly a standard for the measurement quality of instruments which would not recognise a Scientist's expertise in recognising or identifying potential pathogens (Dancer 1997). The decline of this service might cause the reduction in involvement by Clinical Microbiologists who were able to provide 24 hour consultant cover and perceived potential outbreaks from daily inspection of human and environmental samples processed in the same laboratory. Other disadvantage was the increase in difficulty on management of future outbreaks. Chemicals or expertise might not be readily available in urgent situation where specimens suspected of being involved in an outbreak were required to be processed (Dancer 1997). As the government had already begun to review the current situation of Scientific Services in the U.K., public health safety must be considered as the priority in any decision making process. In Scotland, it was recommended that this would best be managed within the Food Standards Agency which could resolve the current unsatisfactory three way arrangement between the Public Analysts, the NHS Laboratories, and the new local authorities with the potential for cost savings and

promote consistency. The unified Scottish Scientific Service would result in a coherent conjoint approach with local authorities to food surveillance.

The formation of the new Food Standards Agency presents the U.K. with a major opportunity to have an impact on the current reorganisation of food standards, quality and safety. The aforementioned key problems would be taken into consideration in order to restore confidence in U.K. food control system. It is important that the Agency should oversee local authority enforcement activities rather than take them over. General food law enforcement benefits from the inspector's local knowledge and that there are good reasons why local authorities should retain their current enforcement responsibilities, for example, food inspection and sampling. The Agency's role generally will be supportive rather than operational, except where an incident requires management beyond the local level or where the responsible authorities at local level fail to manage an incident successfully. This new body will also play a major role in co-ordinating surveillance, and will work with those currently engaged in such activities and with the U.K. Health and Agriculture Departments. With the establishment of Food Agency there should be an opportunity for the U.K. to play a major role in setting European Standards of audit and enforcement as well as food safety scientific assessments. There would be an opportunity to improve the credibility of the U.K. in EU negotiations and could play an important role in shaping the future of food policy matters in Europe. For example, the requirement for the submission of statistical returns detailed in EU Directive 89/397/EEC can well be revised towards its actual benefits and effectiveness.

Chapter 4

Food Sampling in the U.K.

Chapter 4. Food Sampling in the U.K.

4.1 Introduction

Under Sections 29-30 of the Food Safety Act 1990, authorised officers of enforcement authorities have the power to procure food samples for analysis and/or examination. The Act recognises that the microbiological examination of food is a separate activity from its analysis. Section 53 of the Act defines 'analysis' as including microbiological assay and any technique to determine the composition of food, while 'examination' in Section 28 relates solely to microbiological examination (MAFF 1990). Food samples are procured either officially or informally for the purposes of: (i) Proactive routine random sampling, (ii) Reactive investigational sampling for food complaints, and (iii) Food surveys or projects, at various levels to determine the acceptability or safety of a batch of food intended for human consumption. It is suggested by EHOs through visits to the local Environmental Health Departments and statistical data shown in Table 4.5(a) and (b) that the majority of food samples are collected informally for monitoring purposes. If the results of analyses indicate significant contamination (For example: the presence of pathogenic micro-organisms), official sampling will then be followed so that the formal results may be used as the evidence for legal proceedings. Samples taken officially must be dealt with in accordance with the Food Safety (Sampling and Qualifications) Regulations 1990 supplemented by the Code of Practice No.7 on Sampling for Analysis or Examination. However, no guidance is given on samples taken informally.

4.2 Sampling Officers of the Food Authorities

Food samples are taken by authorised officers of enforcement authorities who are properly trained in the appropriate techniques. Through the implementation of the EU Directive 93/99/EEC on the subject of Additional Measures concerning the Official Control of Foodstuffs (EU 1993), the guidance laid down in Code of Practice No.19 refers the 'Authorised Officer' as:

'Any officer appointed under Section 5(6) of the Food Safety Act 1990, by the Food Authorities referred to in Section 5(1), 5(2) and 5(3) of the Act to enforce the Act and regulations made under it' (MAFF 1996).

According to the Food Safety Act 1990, Food Authorities are categorised as:

- London Borough Councils, District Councils, and Non-Metropolitan County Councils,
- The Common Council of the City of London,
- The appropriate Treasurer of the Inner and Middle Temples,
- Unitary and Island Councils in Scotland,
- The Council of the Isles of Scilly,
- Port Health Authorities to which the functions under the Act have been assigned (MAFF 1990).

Authorised officers carrying out their duties of food sampling should be suitably qualified or experienced in food law enforcement. The duties of the authorised

officers vary throughout the U.K. Some authorities may focus mainly on the provisions of the legislation relating to food safety and hygiene, while other authorities may target the provisions relating to food standards, and the rest will equally enforce both. Therefore, it is important to ensure that officers have the appropriate qualifications, knowledge and experience in food hygiene and/or food standards. Code of Practice No.19 detailed the qualifications that are considered as suitable for the authorised officers for the tasks (MAFF 1996), and this is shown in Appendix 5.

4.3 Official Sampling Procedure

Procurement of food samples may be undertaken either by 'purchasing' or 'taking'. The choice as to whether or not a sample should be purchased is a matter of enforcing bodies' discretion. Environmental Health Officers from various Scottish Local Authorities suggested that purchasing of food samples with proper receipts is preferred. By doing so, it has a dual advantage. Firstly, this will avoid giving rise to financial consequences for the owners of the food, especially when large sample sizes are required. Secondly, proper receipts also act as proof of purchases from the chosen food premises and these will be useful in court when prosecutions are involved. The nature and quantity of food samples procured should enable satisfactory chemical analysis and/or microbiological examination to be made (MAFF 1991).

4.3.1 Samples for Chemical Analysis

Formal sample subjected for chemical analysis should as soon as possible be carefully divided into three representative (resultant) parts. Where practicable, the division should be carried out on the food premises and the owner/seller is invited to observe the sampling and division. One of the three final samples will be:

- submitted to the Public Analyst for testing;
- given to the owner of the food where analysis can be undertaken by privately owned analytical laboratories if disagreement of Public Analyst's results arises;
- retained by the Food Authorities for submission to Government Chemist at a later date either if the owner of the food disagrees with the Public Analyst's results or it is demanded under a court order (MAFF 1991).

Since sampling of imported foods at the port of entry may pose particular difficulties, division on the premises or the presence of any representative of the owner/seller or importer may be unnecessary. There may be situations where division of food samples is not reasonably practicable or may impede analysis. For example:

- there is insufficient product available;
- there are problems of storage of final samples;
- food is not homogeneous and division into three parts may not ensure that each part contains the same proportion of each ingredient.

In the case where sealed containers are sampled, and if opening of these containers would impede the analysis, then three unopened containers may constitute the final sames. It is important to ensure that these containers are originated from the same batch or lot by bearing the same code or lot numbers. Foods which are considered best be left in unopened containers are shown in Appendix 6.

Food samples that are unpacked or opened cans or packets of foods should first be placed in clean, dry leak-proof containers. The containers must be clean and dry, and the use of cleaning and sterilising methods that may leave residues on the instruments and containers and could affect the results of the analysis must be avoided. Suitable container such as:

- wide-mouth glass bottles,
- food quality plastic jars,
- stainless metal cans, or
- disposable food quality plastic bags,

can be used. In order to prevent leaks or contamination during normal handling, containers should be closed with suitable caps, and disposable plastic bags should be securely sealed after filling. Samples of alcoholic drinks should be placed in glass bottles. The contained sample should then be secured with a tamper evident seal, and labelled specifying:

- Name of the food,
- Name of the officer,
- Name of the local authority,

- Place, date and time of sampling,
- Identification number.

A second container, such as a transparent plastic bag, can be used and sealed to ensure that the sample cannot be tampered with.

Final samples which are perishable are kept under refrigeration or in a frozen state. The choice of storage method depends on the final submission point, either to the public analyst or the government chemist. Also, the type of analysis to which the samples to be subjected to must be taken into consideration when choosing the method of storage. For example, milk which is to be tested for composition will separate out if frozen; while milk which is tested for antibiotics should be frozen in order to preserve the level of antibiotic which may be present. After sampling, the samples are expected to be transported as soon as practicable to the public analyst, especially those which may deteriorate or dissipate with time. Resultant samples that are required to be maintained at low temperature are kept inside insulated metal or plastic cool boxes with ice packs during transportation from food premises to the public analyst. Under recommendation by the public analyst, retained samples that may need to be stored for several months before submission to the government chemist should be properly stored (MAFF 1991).

4.3.2 Samples for Microbiological Examination

Unlike samples for chemical analysis, division of formal samples for microbiological examination into three parts is not required. This is due to the fact that no two

samples can be measured the same because of the non-homogeneous distribution of bacterial contaminants. It is also inappropriate to retain a part for latter examination since bacteria may greatly multiply when optimum condition is reached for reproduction, or may fail to survive at extreme stage under prolonged storage (Hobbs & Roberts 1997).

It is suggested under the Code of Practice No.7 that the minimum weight of each sample should be at least 100 grams. The nature of the samples will depend on the purpose for which examination is being undertaken. For example, the testing of various food types may be organism-specific (eg: test for the presence of pathogenic *Escherichia coli* O157); or where national surveys are involved, the examination would be commodity-specific (eg: total viable counts of sandwiches). Due to the microbiological properties of bacteria which can multiply in very large numbers within a short period of time when the conditions become optimal, extra care is required during sampling, transport and storage. Also, appropriate measures are needed in order to avoid contamination of samples.

All samples for microbiological examination are placed in suitable containers before submission to the food examiners. The type of containers used for this purpose is the same as those used for chemical analysis. Also, the sampling procedure is the same for both types of testing, but the containers and instruments such as spoons and gloves used for microbiological sampling must be sterile to prevent cross contamination.

Temperature control is the key factor during transportation and storage of final samples to ensure that changes in microbial numbers are inhibited:

- Frozen foods are maintained in their frozen state;
- Chilled/refrigerated foods are kept at a temperature of between 0°C and 5°C;
- Dried and canned foods need not be cooled but are stored and transported at temperatures not exceeding 40°C.

Samples that are subjected to examination should be delivered to the food examiners as soon as possible. It is preferable to reach the laboratories within two hours and only in exceptional circumstances more than four hours. Food examiners will be properly notified if any delay that exceeds the four-hour duration is occurred (MAFF 1991).

In order to facilitate food examiners to determine the most appropriate examination and to interpret the results, officers are expected to supply the relevant information by completing a request form when the samples are submitted. Advice on the type of information is listed in the Code of Practice as:

- Name and authority of sampling officer;
- Sample number;
- Date, time and place of sampling;
- Description of sample including batch or lot number, canning code etc. and durability date (use by, best before, etc.);
- Reasons for sampling;

- Name of owner, manufacturer, importer, seller, buyer, as appropriate;
- Process and date of cooking (for cooked food - if known);
- Country of origin, conditions of storage in that country, transport conditions and transport time (if known);
- Conditions of storage at place of sampling;
- Other relevant storage factors, eg. condition of package, humidity, sanitation;
- Method of sampling;
- Conditions of storage and transport since sample taken;
- Clinical and epidemiological details (in case of suspected food poisoning).

However, in practical terms, it is unlikely that all of the above information will be included in the request forms (MAFF 1991).

4.4 Food Sampling Programmes

It would be a waste of time and resources to carry out routine sampling without firstly considering the objectives and carefully planning the sampling regime. A sampling and analytical protocol should be prepared in conjunction with the selected laboratory in order to ensure an agreed procedure and to encourage a uniform approach. Local authority sampling protocol is normally drawn up as a programme and presented in the form of a document or tables detailing the place, types and frequency of foodstuffs for sampling within a specific period of time (For example: monthly or yearly target). Different types of samples (official or informal, bacteriological or chemical) at local, regional, national or European levels will be

included in the food programmes. However, results of a national survey in Chapter 6 suggested that some Environmental Health Departments do not prepare yearly food sampling programme. Instead, reactive sampling is carried out either as a result of a complaint or if requested by other governmental bodies (For example: LACOTS).

Under the European requirement detailed in Article 14 of 89/397/EEC towards the submission of Statistical Returns, local authority sampling levels are closely monitored by MAFF and the DH through the quarterly returns. However, the level of sampling varies among U.K. local councils. Many local authorities considered that food sampling is a low profile activity, and prioritise their food safety enforcement activities mainly on the inspection of food premises instead. Therefore, these local councils undertake very little sampling. Others may carry out some proactive routine sampling, but the level appears to be relatively small and the programmes was not designed in a statistically validated fashion. Interviews with key officials from the local authorities and findings from the survey indicated that this was mainly due to the lack of staff and resources which prohibited a more structured sampling regime. Some local authorities, in conjunction with the regional or national microbiological forum, have been participating on the 'Shopping basket approach' where premises are selected randomly and a number of high risk foods on the shopping basket list are sampled. The list is changed when adequate data has been obtained (Widdows, Ribeiro and Brown 1996).

The Article 14 Working Party made reference to the World Health Organisation standard of 2.5 samples per 1,000 population for both chemical and bacteriological

sampling. It appears that the actual number of samples taken per head of population varies significantly across Europe and there is variation within the U.K. The Working Party recommended that local authorities should achieve a minimum level of 2.5 samples per 1,000 population for chemical sampling and 2 per 1,000 for bacteriological samples, but has not been taken up formally by central government (London Food Co-ordinating Group 1996). In Scotland, a national target rate of 3 samples per year per 1000 population has been recommended by the Convention of Scottish Local Authorities for chemical sampling, but there is no agreed national standard for microbiological sampling (Accounts Commission for Scotland 2000). Informally, Scottish local authorities also apply the same rate of 3 samples per year per 1000 population on microbiological sampling as well.

Since 1993-94, councils have been required by law to provide information on the performance of their duties, and to publish this information publicly each year. The Local Government Act 1992 places upon the Accounts Commission the duty each year to direct local authorities to publish such information. Comparisons of this information are based on the criteria of cost, economy, efficiency and effectiveness between the standards of performance achieved by: (i) different authorities in a financial year, and (ii) same authorities in different financial year. In order to decide what is 'good performance' or 'best practice', the Accounts Commission stated that further information would be required before any comparisons were made. For example, local factors may mean that a council with a performance which appears to be worse than that of another council has, in fact, performed better given the more difficult circumstances it faces (Accounts Commission for Scotland 2000). Table 4.1

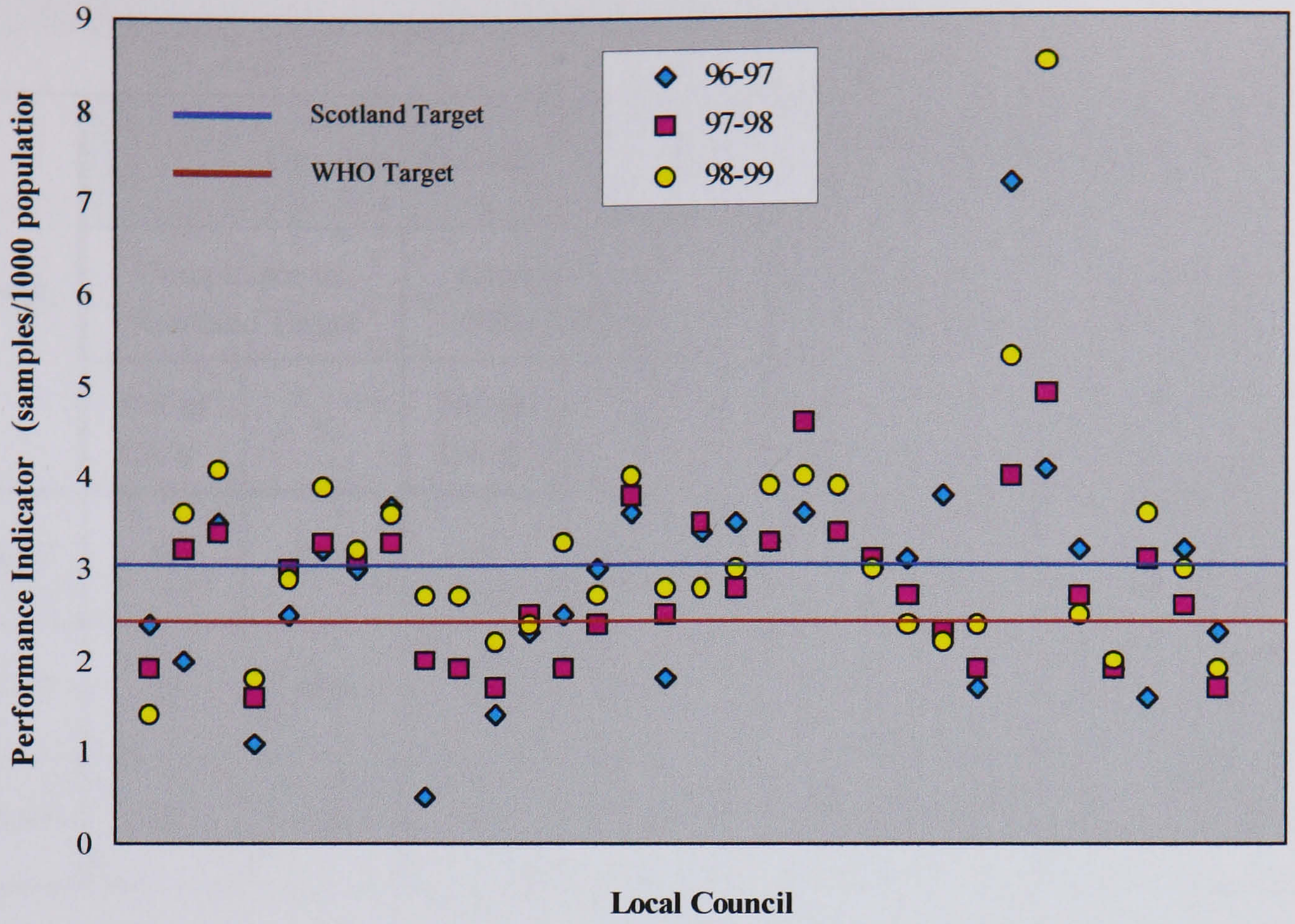
illustrates the performance indicators of 32 Scottish Unitary Councils' food sampling rates (number of samples per 1000 population per year) for both chemical and microbiological analysis between year the 96/97, 97/98 and 98/99. These figures are also shown in Graph 4.1(a) & (b) along with the lines of target rate. The percentage of local authorities meeting the Scotland or WHO sampling target rate is indicated in Table 4.2. Since target set for Scotland is higher than that of the WHO target rate, therefore it is not surprising to have a lower percentage of Scottish local authorities meeting the national rate. In fact, compliance to Scotland target remains at an average of 51.1%, whilst compliance to WHO target reached a higher mean value of 67.7%.

The International Commission on Microbiological Specifications for Foods (ICMSF) proposed microbiological criteria and devised 'Two-Class' and 'Three-Class' Sampling Plans for some commodities (Roberts, Hooper and Greenwood 1995). A Two-Class Plan is a simple way of deciding the acceptability of a food based on the presence or absence of pathogens. The decision-making process is defined by the number of sample units required for testing (n) and the maximum allowable number of sample units yielding unsatisfactory test results (c). For example, the presence of the organism or a count above the defined concentration denoted by m, which in a 2-Class Plan separates good quality from defective quality. A Three-Class Plan can be used for the situation where a proportion of sample units may be accepted whose test results fall between unequivocal acceptability and rejection, defined by the threshold value (m) and maximum value (M). Counts above m, which in a 3-Class Plan separates good quality from marginally acceptable quality, and up to and including M

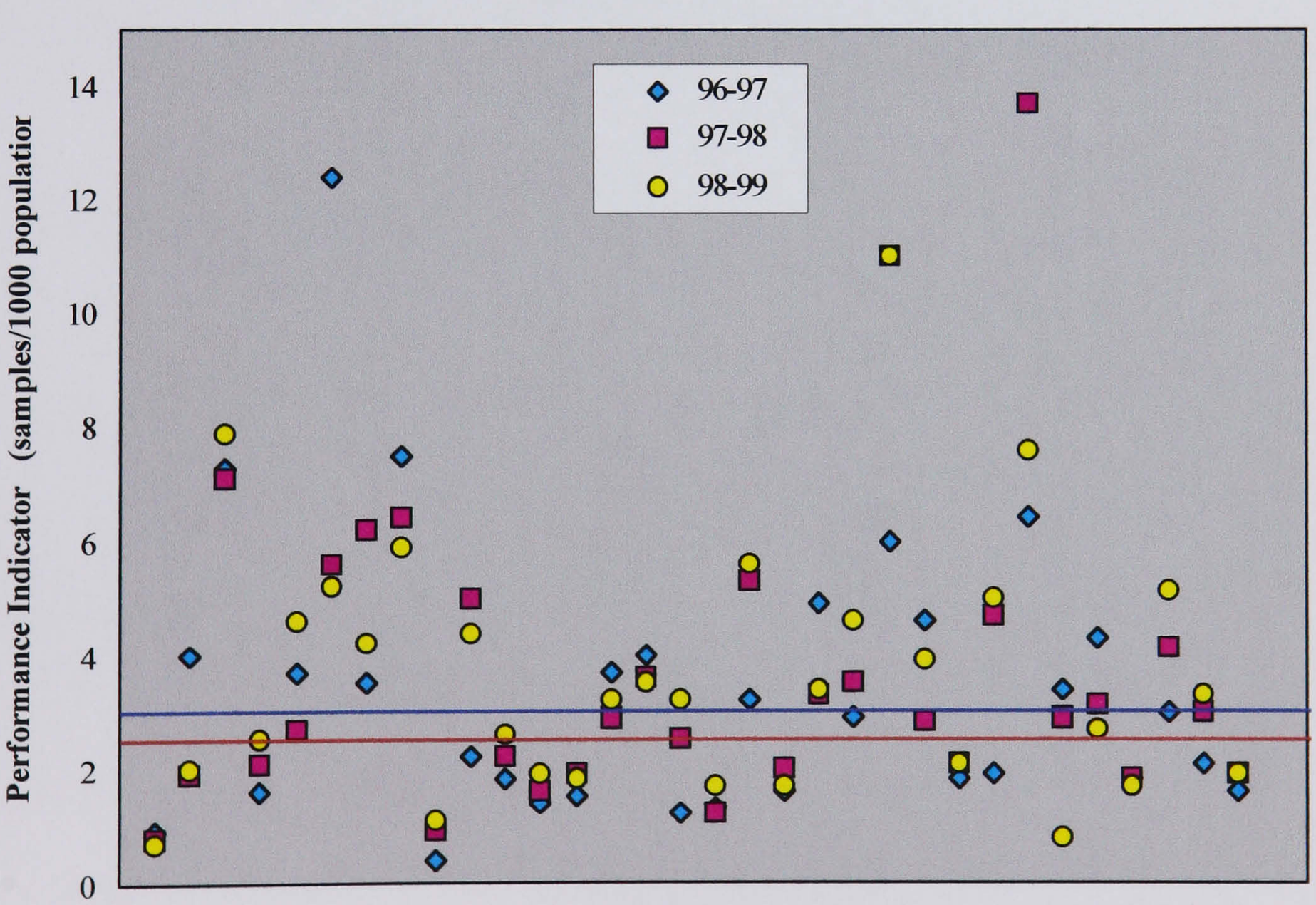
are undesirable but some can be accepted, the number acceptable being denoted by *c*. Again, in the 3-Class Plan both numbers, *n* and *c*, are used, from which it is possible to find the probability of acceptance (P_a) for a food lot of given microbiological quality. This scheme depends for acceptance or rejection not only on the proportion of 'defective' material (P_d) but also on the proportion of 'marginally acceptable' product (P_m). The stringency of the sampling plan depends upon *n* and *c*. The larger the value of *n* at a given value of *c*, the better the food quality must be to have the same chance of being passed. Conversely, for a given sample size *n*, if *c* is increased the plan becomes more lenient and will more often pass food lots of a given quality (ICMSF 1986). A more detailed explanation of calculating the probability of acceptance (P_a) will be discussed in Chapter 7. A full list of sampling plans and recommended microbiological limits for various food commodities are found in Appendix 7.

Scottish Councils	**Chemical Analysis** (samples / 1000 population)			**Microbiological Analysis** (samples / 1000 population)		
	96-97	97-98	98-99	96-97	97-98	98-99
Aberdeen City	2.4	1.9	1.4	0.9	0.8	0.7
Aberdeenshire	2.0	3.2	3.6	4.0	1.9	2.0
Angus	3.5	3.4	4.1	7.3	7.1	7.9
Argyll & Bute	1.1	1.6	1.8	1.6	2.1	2.5
Clackmannanshire	2.5	3.0	2.9	3.7	2.7	4.6
Dumfries & Galloway	3.2	3.3	3.9	12.4	5.6	5.2
Dundee City	3.0	3.1	3.2	3.5	6.2	4.2
East Ayrshire	3.7	3.3	3.6	7.5	6.4	5.9
East Dunbartonshire	0.5	2.0	2.7	0.4	0.9	1.1
East Lothian	2.7	1.9	2.7	2.2	5.0	4.4
East Renfrewshire	1.4	1.7	2.2	1.8	2.2	2.6
Edinburgh, City of	2.3	2.5	2.4	1.4	1.6	1.9
Falkirk	2.5	1.9	3.3	1.5	1.9	1.8
Fife	3.0	2.4	2.7	3.7	2.9	3.2
Glasgow City	3.6	3.8	4.0	4.0	3.6	3.5
Highland	1.8	2.5	2.8	1.2	2.5	3.2
Inverclyde	3.4	3.5	2.8	1.3	1.2	1.7
Midlothian	3.5	2.8	3.0	3.2	5.3	5.6
Moray	3.3	3.3	3.9	1.6	2.0	1.7
North Ayrshire	3.6	4.6	4.0	4.9	3.3	3.4
North Lanarkshire	3.9	3.4	3.9	2.9	3.5	4.6
Orkney Islands	3.0	3.1	3.0	6.0	11.0	11.0
Perth & Kinross	3.1	2.7	2.4	4.6	2.8	3.9
Renfrewshire	3.8	2.3	2.2	1.8	2.1	2.1
Scottish Borders	1.7	1.9	2.4	1.9	4.7	5.0
Shetland Islands	7.2	4.0	5.3	6.4	13.7	7.6
South Ayrshire	4.1	4.9	8.5	3.4	2.9	0.8
South Lanarkshire	3.2	2.7	2.5	4.3	3.1	2.7
Stirling	1.9	1.9	2.0	1.8	1.8	1.7
West Dunbartonshire	1.6	3.1	3.6	3.0	4.1	5.1
West Lothian	3.2	2.6	3.0	2.1	3.0	3.3
Western Isles	2.3	1.7	1.9	1.6	1.9	1.9

Table 4.1: Performance Indicators of Scottish Councils Food Sampling Activities



Graph 4.1(a): Performance Indicators of Scottish Councils on Chemical Analysis



Graph 4.1(b): Performance Indicators of Scottish Councils on Microbiological Analysis

Year	Chemical Analysis				Microbiological Analysis			
	Compliance to Scotland Target		Compliance to WHO Target		Compliance to Scotland Target		Compliance to WHO Target	
	No. of LA's	%	No. of LA's	%	No. of LA's	%	No. of LA's	%
96-97	18	56.3	21	65.6	16	50.0	17	53.1
97-98	15	46.9	21	65.6	17	53.1	20	62.5
98-99	16	50.0	23	71.9	14	43.8	21	65.6

Table 4.2: Level of Compliance to U.K. and WHO Targets on the Performance Indicator of Food Sampling Rate

4.5 Food Sampling Activities within the U.K. Network

It was described earlier with some details in Chapter Three the involvement of various organisational bodies that forms the backbone of Scotland's food co-ordination system as well as part of the whole U.K. food surveillance network. Although the majority of food sampling activities is undertaken at local level by the Environmental Health Departments, each of these bodies bears a significant role in:

- consideration of food safety and hygiene,
- co-ordination of food enforcement functions,
- initiation and participation of projects or surveys, or
- giving advice on the preparation of food law.

Each of these enforcement activities has a significant influence and input towards food sampling, and subsequently the design of the food programmes.

4.5.1 Sampling at Regional Level

On a regional basis, local authorities, food liaison groups and the public analysts work closely together on the design of the annual sampling programmes. Many surveys and projects are introduced at this level mainly due to complaints or topical concerns. The suggested surveys, once agreed, will be included in the liaison group surveillance programmes and carried out by the member authorities (SFLG 1995). In terms of microbiological surveillance, surveys are divided into two categories:

- organism-specific, e.g. *Salmonella enteritidis* ;
- commodity-specific, e.g. Total viable counts of sandwiches.

In comparison with chemical surveillance in which limits of many chemical contaminants are available, scientific evidence to support U.K. legal standards or guidelines for many specific pathogens in association with particular foodstuffs is in most case absent. Due to this fact, the decision on acceptance or rejection of the foodstuffs based on the results of analyses normally depends on the interpretations and expert opinions of the food examiners. Indeed, the absence of scientific proof made such decision exceedingly difficult and debatable. In practice, such interpretation has had to be based on personal experience of the food examiners working on a large number of such foods tested over many years (Gilbert 1992). Therefore, apart from the monitoring purpose, one of the main advantages of undertaking surveys is to aid the food examiners by compiling and comparing these results to determine a more accurate judgement towards the microbiological quality of foodstuffs under examination.

Several international organisations have attempted to establish microbiological criteria for foods. These include:

- European Union,
- World Health Organisation,
- International Commission on Microbiological Specifications for Foods,
- Codex Alimentarius Commission (Roberts, Hooper & Greenwood 1995).

Also, the Public Health Laboratory Service (PHLS) Food Surveillance Group has drawn up microbiological guidelines for some ready-to-eat foods sampled at point of sale, as shown in A.7.4 of Appendix 7 (Gilbert 1992). Some EU directives contain a mixture of microbiological standards and guidelines on some food, for example: milk

and milk products, fishery products, egg products, and live bivalve molluscs. Many of these are now implemented into U.K. food laws (Roberts, Hooper & Greenwood 1995).

4.5.2 Sampling at National Level

At national level, SFCC, LACOTS and Scottish Office contribute significantly towards the initiation of projects and surveys in Scotland, whilst the addition of MAFF and Department of Health concerns in a larger U.K. nationwide scale. Indeed, it is expected that the new Food Standards Agency will gradually take up the role of MAFF and DH. In Scotland, surveys are introduced each year through the liaison groups to all the Scottish local authorities, which are then included into their own food sampling programmes. Also, many projects are carried out by the SFCC through its Food Standards Sub-Committee (SFCC 1989).

Since LACOTS has extended its remit on food hygiene matters in Scotland, surveys normally initiated in the English and Welsh local authorities are now carried out across the Scottish border as well. For example: (i) cooked rice from restaurants, and (ii) take-aways and ice cream scoop rinse water from scoop ice cream retailers, caterers and mobile vendors, appeared in the Strathclyde Food Liaison Group 1995 Surveillance Programmes (SFLG 1995). In terms of food safety and hygiene activities, both SFCC and LACOTS have similar roles.

4.5.3 Sampling at European Level

At European level, the Scottish, Welsh and N. Irish Offices, Department of Health and MAFF have an important role on food co-ordination in the U.K. to other Member States and the rest of the European countries. Again, the new Food Standards Agency is expected to adopt the main central co-ordination in relation to food matters. In order to achieve a unified approach, it is necessary to combine the efforts of all governmental bodies at local, regional and national levels. As detailed in the Official Control of Foodstuffs Directive, Member States are recommended to participate in EC Co-ordinated Programme by taking food samples identified by the Commission and to report back the results of analyses (EU 1989). The EU does not specify the number of samples needed to be taken, and this is left for the Member States to determine (Kingcott 1995). To obtain a co-ordinated approach, local authorities discuss within their local liaison groups so that it may form part of their own sampling programmes. In Scotland, LACOTS co-ordinates with SFCC to make the necessary arrangements to provide the sampling and analysis protocols for the chemical analysis part of the Control Programme. With regard to the microbiological examination part of the programme, for which the Department of Health has responsibility for U.K. co-ordination, the SFCC was invited by the Scottish Office to extend the responsibility to co-ordinate this part of the programme in Scotland (see Figure 4.1). The completed forms will be returned to the Scottish Office and eventually submitted to the European Commission. The Commission welcomes comments or suggestions from the food authorities of the Member States on the selection of foodstuffs for testing and it will normally take three years to effect if it is

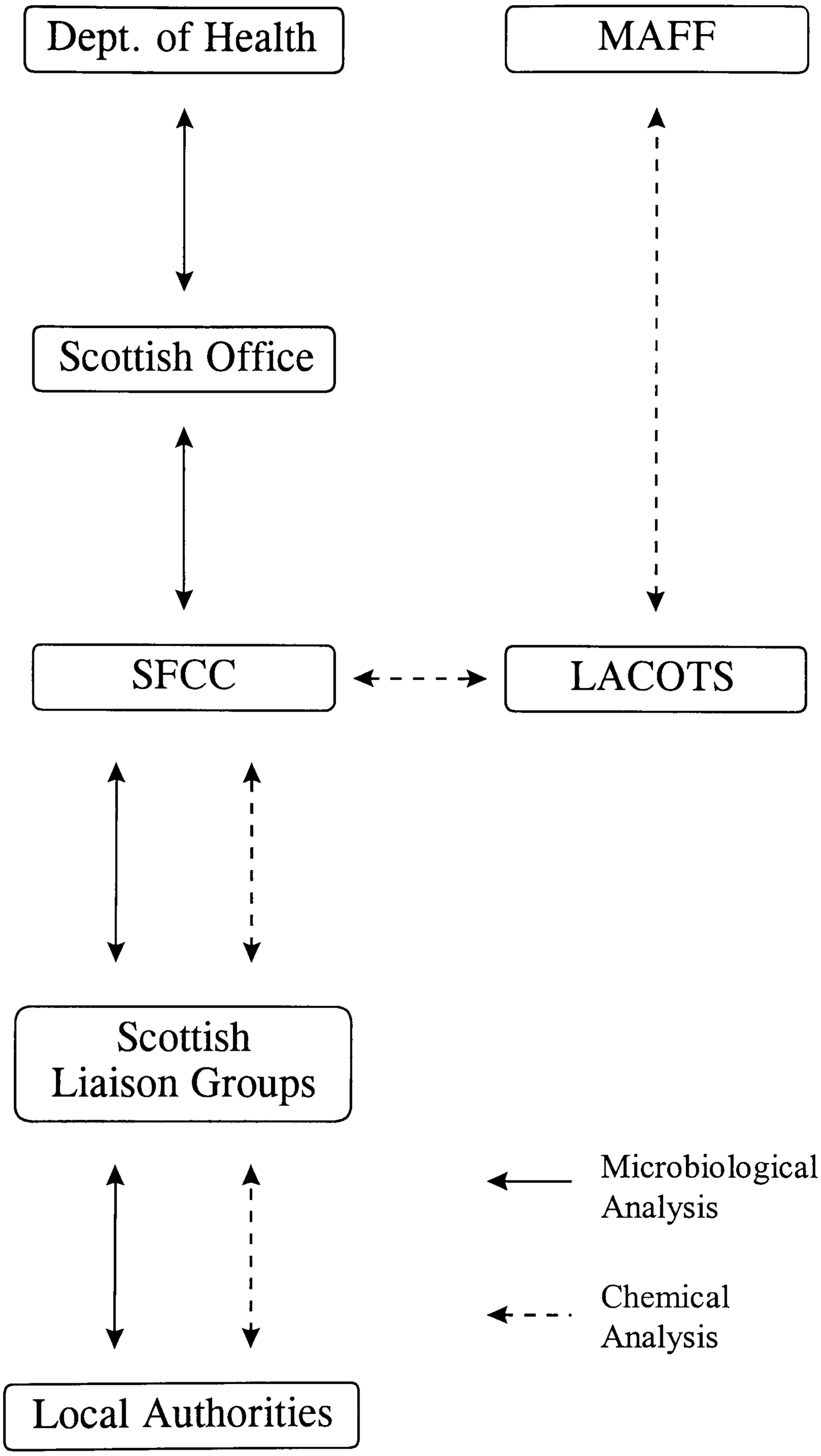


Figure 4.1: Co-ordination of the EU Food Programme under 89/397/EEC

Year	Directive	Food Control Programmes
1993	92/540/EEC	1. Adulteration of orange juice 2. Nitrates and nitrites in baby foods containing vegetables 3. Weight inspections for deep-frozen seafood 4. Microbiological tests on edible ices 5. Microbiological tests on ready-made foods
1994	94/175/EC	1. Aflatoxin B1 in products liable to contain aflatoxin B1, especially those intended for children 2. *Listeria monocytogenes* in meat-based pates, sold in the retail sector 3. Adulteration of frozen fish-based products 4. Adulteration of goat's and sheep's cheese
1995	95/77/EC	1. Adulteration of soluble coffee with non-bean material 2. *Listeria monocytogenes, Escherichia coli, and Aeromonas* in refrigerated salads and seasoned crudites 3. Botanic and geographical claims on honey, both community produced as well as imported from third countries 4. Temperature of quick frozen foodstuffs, sold in the retail sector
1996	96/290/EC	1. Microbiological assessment of dried and fermented ready-to-eat meat and meat products 2. Migration of plasticizers into foods 3. Temperature of chilled foods on display for sale 4. Benzo(a)pyrene in smoked pork products
1997	97/77/EC	1. Aflatoxins in spices (pepper, chilli and chilli powder, nutmeg, paprika powder) 2. Contamination of food products for persons suffering from food allergy or hypersensitivity
1998	98/133/EC	1. Aflatoxins in ground-nuts and pistachios
1999	1999/26/EC	1. Ochratoxin A in coffee 2. Additives in foodstuffs

Table 4.4: Commission Recommendations concerning the Co-ordinated Programme for the Official Control of Foodstuffs between 1993-99 (EU 1992-99)

accepted. A list of the recommendations concerning the EC co-ordinated programmes 1993-99 is shown in Table 4.4.

The Official Control of Foodstuffs Directive (89/397/EEC) also requires each Member State to complete the statistical returns and submit to the EU. In Scotland, the local authorities submit their Returns to SOAEFD on a quarterly basis. Before submitting these Returns to MAFF, each statistical form undergoes a manual checking process for any mathematical errors. This ensures consistency of approach in authorities' completion of the forms, and to raise with them any queries the Scottish Office may have on the information provided. Moreover, analyses of the returns may identify those authorities which appear to have either high or low inspection and/or sampling rates and to seek the reasons for this from those concerned. Every year when all four quarterly returns from each of the 32 local authorities are gathered and checked, the Scottish Office delivers the whole batch to MAFF. At this stage, MAFF holds all the summary returns covering England and Wales, Scotland and Northern Ireland. MAFF aggregates these returns to produce a single return for the U.K. and sends the final version to the European Commission in Brussels (see Figure 4.2). The numbers and results of official and informal samples in the U.K. and Scotland Returns between 1991-97 are listed in Table 4.5(a) and (b). Also, Graph 4.2(a) and (b) indicate the distribution of overall number of samples taken and the number of unsatisfactory samples between 1991 - 1997 in the U.K.

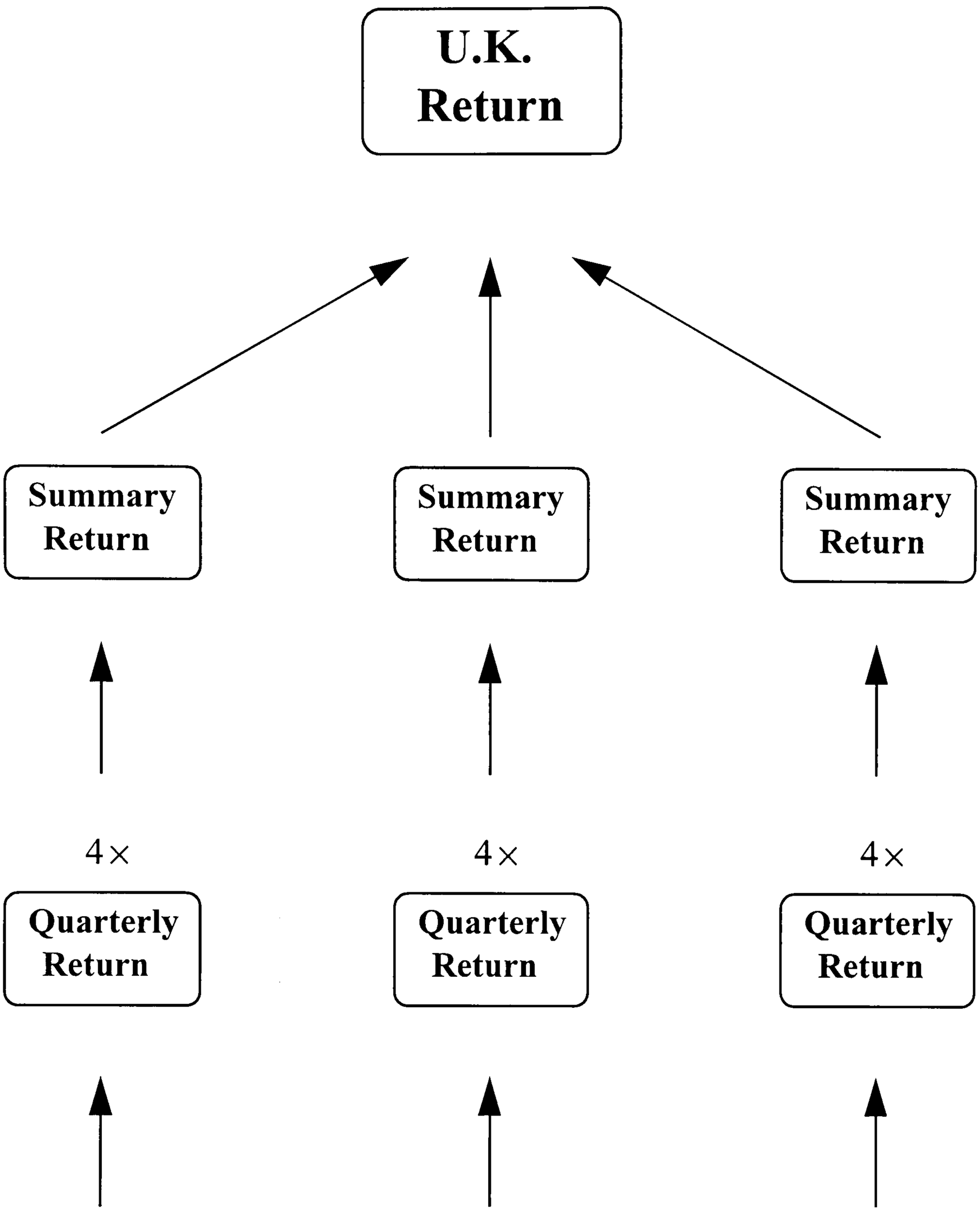


Figure 4.2: Aggregation of Local Authority Returns into a single U.K. Return

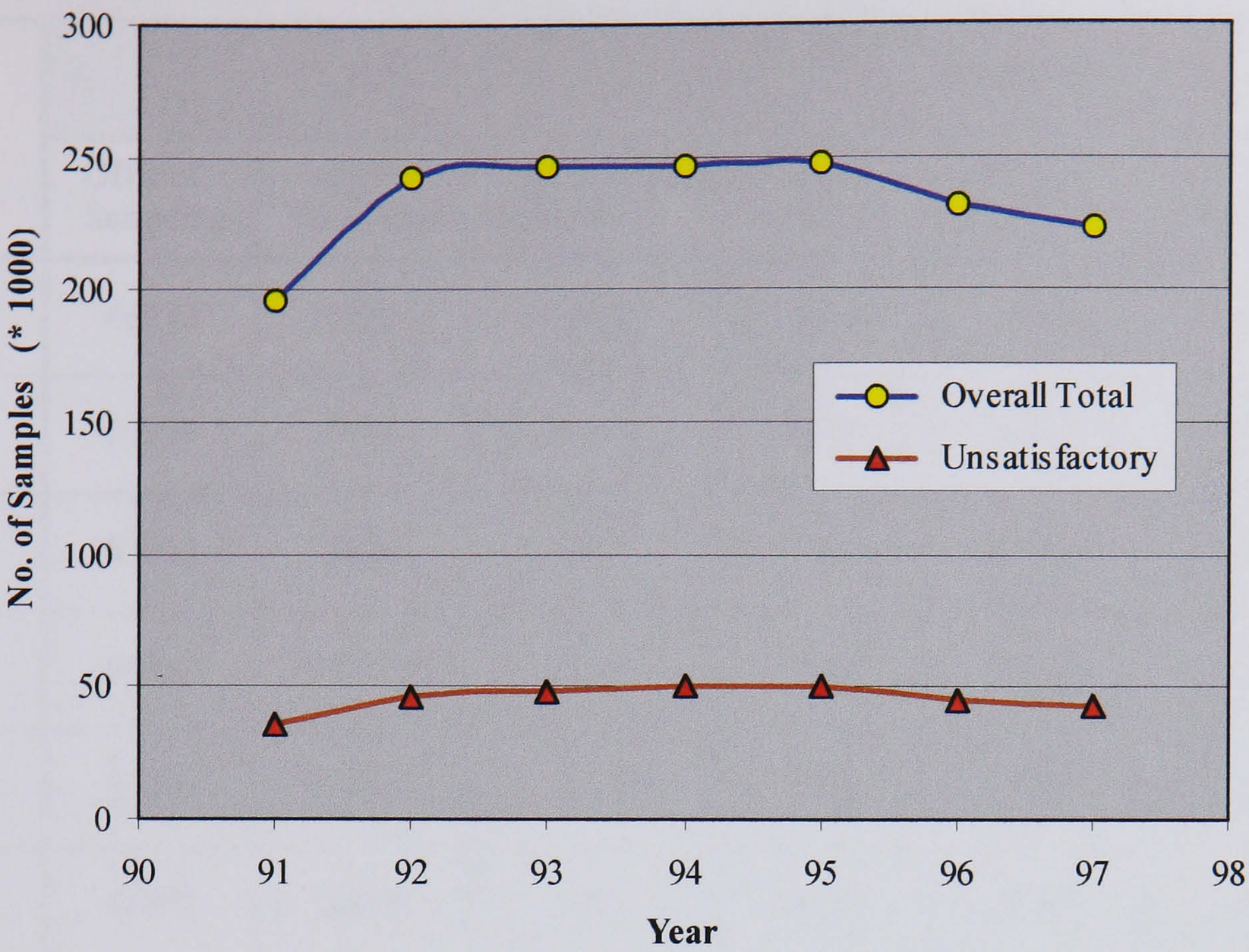
(Number of Local Authorities is based on January 1999 Figure supplied by MAFF)

Year	Sampling	U.K. Returns							
		Microbiological	Other	Composition	Label. & Present.	Total	Unsatisfactory	Overall Total	Overall Unsat.
1991	Official	Separation into Various Categories is not provided				46976	10648	196303	36121
	Informal	89601	10708	42412	21431	149327	25473		
1992	Official	Separation into Various Categories is not provided				65398	17533	241831	45834
	Informal	98958	11747	57244	31048	176433	28301		
1993	Official	Separation into Various Categories is not provided				67959	20204	246960	48438
	Informal	100853	13703	56767	32307	179001	28234		
1994	Official	Separation into Various Categories is not provided				65162	21154	246364	49828
	Informal	101040	10376	55715	37246	181202	28674		
1995	Official	Separation into Various Categories is not provided				63726	21642	247053	50477
	Informal	104638	11309	56753	31044	183327	28835		
1996	Official	Separation into Various Categories is not provided				62350	19035	231322	45471
	Informal	96834	11137	53025	31199	168972	26436		
1997	Official	Separation into Various Categories is not provided				65130	18718	223817	42944
	Informal	89405	9222	53045	29921	158687	24226		

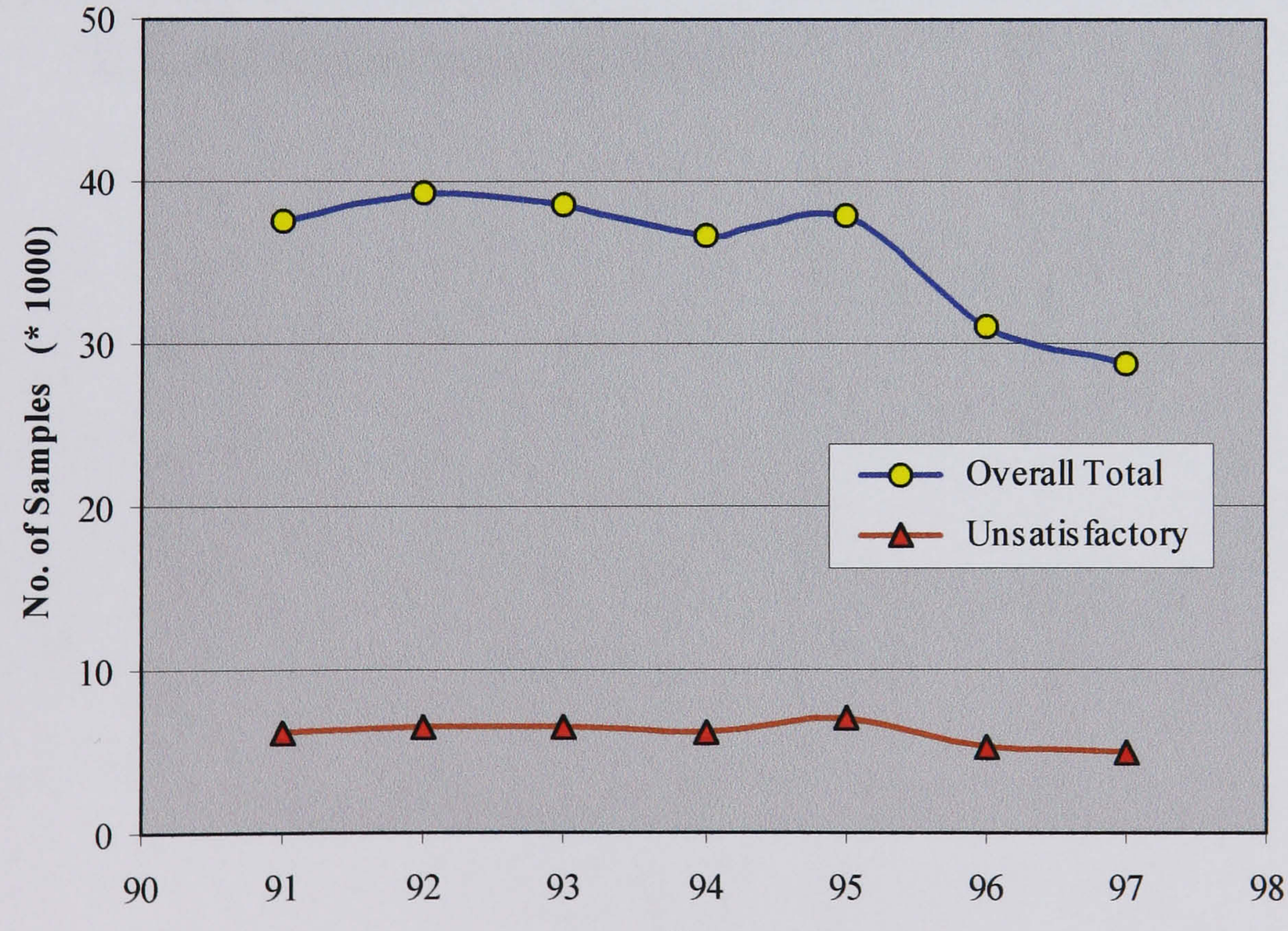
Table 4.5(a): The Numbers and Results of Official and Informal Samples in the U.K. Returns between 1991-97

Year	Sampling	Scotland Returns							
		Microbiological	Other	Composition	Label. & Present.	Total	Unsatisfactory	Overall Total	Overall Unsat.
1991	Official	Separation into Various Categories is not provided				2260	371	37562	6144
	Informal	19988	2518	12568	5346	35302	5773		
1992	Official	Separation into Various Categories is not provided				3008	711	39324	6543
	Informal	19846	2103	14558	7453	36316	5832		
1993	Official	Separation into Various Categories is not provided				2621	694	38574	6553
	Informal	19437	2858	14046	7264	35953	5859		
1994	Official	Separation into Various Categories is not provided				3060	861	36736	6139
	Informal	18958	2970	11791	7259	33676	5278		
1995	Official	Separation into Various Categories is not provided				3238	1181	37829	7008
	Informal	21024	2447	11059	7287	34591	5827		
1996	Official	Separation into Various Categories is not provided				2124	714	31121	5261
	Informal	16362	1594	11550	6965	28997	4547		
1997	Official	Separation into Various Categories is not provided				2304	791	28720	4930
	Informal	14426	1465	10294	5945	26416	4139		

Table 4.5(b): The Numbers and Results of Official and Informal Samples in the Scotland Returns between 1991-97



Graph 4.2(a): Variation of Overall Number of Samples Taken and the Number of Unsatisfactory Samples between 1991 - 1997 in the U.K.



Graph 4.2(b): Variation of Overall Number of Samples Taken and the Number of Unsatisfactory Samples between 1991 - 1997 in Scotland

Year	U.K.			Scotland		
	Official Sampling	Informal Sampling	% of Informal Sampling	Official Sampling	Informal Sampling	% of Informal Sampling
1991	46976	149327	76.1	2260	35302	94.0
1992	65398	176433	73.0	3008	36316	92.4
1993	67959	179001	72.5	2621	35953	93.2
1994	65162	181202	73.6	3060	33676	91.7
1995	63726	183327	74.2	3238	34591	91.4
1996	62350	168972	73.0	2124	28997	93.2
1997	65130	158687	70.9	2304	26416	92.0

Table 4.6: Comparison of the percentages of Informal Sampling undertaken in the U.K. and Scotland between 1991-97

4.6 Discussion

The majority of U.K. food sampling is undertaken by Environmental Health Departments as well as Trading Standards Departments in England and Wales as part of their food safety enforcement activity. Normally, food samples are procured for the purposes of local routine and investigational sampling as well as the participation of surveys or projects at various levels. As the food sampling system is different from other Member States of the European Union, U.K. samples can be categorised as either official or informal samples, depending on the purpose as to whether legal proceeding will be involved. Table 4.6 showed that over 70% of U.K. samples are collected informally, and Scotland has a higher percentage rate at over 90% mark. Indeed, informal sampling is preferred by the local authorities mainly because this is a less expensive option, since two officers are required to carry out official sampling. Due to the differences in the food sampling system, interpretation of what should be considered as a 'sample' created some debates in the European Commission towards the submission of statistical returns, which is discussed in detail in Chapter 5. According to Graph 4.2(a) and (b) where figures were extracted from the U.K. and Scottish summary returns between 1991-97, it was indicated that the overall number of samples taken by the local authorities in U.K. and Scotland were declining. In many cases, financial and time constraints may mean that less sampling was being carried out. Also, reorganisation of local authority structure by means of combination of a two-tier system to a single-tier system led to a reduction in the number of local councils. Consequently, this reduction had a side effect towards an overall decrease of U.K. sampling rate.

In order to plan the local sampling protocol carefully so that sampling at various levels will be included without duplication, it is important that local authorities design their food sampling programmes efficiently and effectively in an unified approach. However, the inconsistency of sampling rate among local authorities means that not every local authority carries out proactive random sampling, as suggested by many officials of the local authorities. Instead, reactive sampling in response to food or premises complaints is common. Therefore, it appears that not every Environmental Health Department prepares their food sampling programmes.

U.K. local councils have been required by law to publish the information on the performance of their duties publicly every year, and food sampling is one of the food safety enforcement duties. In Scotland, a national target rate of 3 samples per 1000 population per year has been recommended by COSLA for chemical sampling, but no agreed national standard for microbiological sampling has been set. WHO recommended a lower target rate of 2.5 samples per 1000 population per year for both chemical and microbiological sampling. Therefore, local authorities are under pressure to illustrate their fulfilment of duties and competence by meeting the national performance indicators. However, only about half of the Scottish local authorities were able to meet the national target between year 96/97 - 98/99.

There has been concern over the rationale behind these standards and it is doubtful whether food samples per 1,000 population is the most logical approach. It is suggested that a more realistic system would be sampling levels dependent on numbers and types of food premises, and in particular, food manufacturers,

importers, warehouses, wholesalers, packers and bottlers in individual local authority areas. Central government has started to investigate the adequacy of approach on the existing performance indicators. MAFF/DH Joint Food Safety and Standards Group (JFSSG) had raised interests to encourage research and development towards a scientific risk-based approach to food sampling. JFSSG stated in the Requirements Document 2000-01 that to ensure proper protection of the public the extent of random sampling must be soundly based on the severity of risk to the consumer rather than solely on the potential size of the population which may be affected (MAFF/DH 1999).

Also, International Commission on Microbiological Specifications for Foods (ICMSF) proposed microbiological criteria and devised 'Two-Class' and 'Three-Class' Sampling Plans for some food commodities. The decision-making process of both sampling plans is based on the number of sample units require for testing and the maximum allowable number of sample units yielding unsatisfactory test results. In particular, 'Three-Class' Sampling Plan can be able to differentiate between samples of good quality, marginally acceptable quality and unacceptable quality. Two-Class and Three-Class sampling plan can be found in both E.U. and the U.K. legislation. However, official from central government analytical service suggested that the proposed microbiological limits should only be treated as a reference, and not to be considered as U.K. legal standards. European Commission has not yet taken the lead in implementing or proposing many microbiological standards for various types of foodstuffs. Indeed, agreement from all fifteen Member States is not an easy

task, and the scientific work to determine agreed limits of pathogens on the wide ranges of foodstuffs would be extremely enormous.

Due to the complicated food co-ordination network in the U.K., local authorities strive to satisfy the sampling regime set at local, regional, national and European levels. Although every year many projects and surveys were initiated by the aforementioned organisations in the network both on a regional and/or national basis, local authorities might act reluctantly in participation to some of these surveys. It was because particular types of foodstuffs (For example: rice) might have been tested over many years, and considered to have no further benefits in repeating the same investigation again. On the other hand, participation of EC Co-ordinated Programmes has been successful and welcomed by the U.K. and other Member States. Topical concerns on any specific food contaminants, either chemical or microbiological nature, or food commodities were discussed among representatives of the Member States and agreed collectively. However, key officials from U.K. central and local governments both indicated different attitude towards the requirement of Official Control of Foodstuffs Directive (89/397/EEC). The submission of statistical returns had increased a lot of work along the U.K. food co-ordination network from local to central governmental levels. Considerable amount of time, effort and resources were necessary in order to fulfil the compliance to this requirement, but feedback from the European Commission was minimal. Questions had been raised by many U.K. governments at various levels towards the real purpose and benefit out of this EU requirement, or is it merely an example of EU bureaucracy over food control.

4.7 Conclusion

Due to the complexity of the U.K. multi-layered food co-ordination network, it would be difficult for the local authorities to carry out all types of sampling in an effective manner. Fundamentally, the design of a strategic, statistically validated food sampling programme for local authorities should be the way forward to accommodate and plan all types of sampling at various levels efficiently throughout the year. As figures indicated a decline in overall U.K. sampling, it is important that resources should be carefully planned and applied to this task so that the main purpose of food sampling would be achieved, and not simply an exercise to reflect local authority performance to the public. Indeed, one of the most fundamental but highly debatable discussions usually rest on what the appropriate numbers and types of samples should be in local authorities' annual food sampling programmes, and how these can be determined. Due to many factors and hindrances such as financial constraints or staff shortage, each local authority faces its own local problems towards the determination of sample sizes in the food programme if existed. Despite the limitation, it is important for local authorities to realise the significance of achieving representative samples, or else the results of samples would be completely meaningless and misleading.

Since the present national target rate on food sampling is based on the number of samples per 1000 head of population per year, future development towards a scientific risk-based approach would certainly improve the situation on the overall local sampling regime. However, interpretation and determination of 'risk' in

relation to food would be a big challenge, since case studies such as the Lanark blue cheese case (Allan 1995) had illustrated the complexity towards the argument of 'risk' and 'injurious' to human health. In any case, the concept and application of probability and statistics should not be omitted because the presence of uncertainty and variation is inevitable. Through the understanding of uncertainty and variation, biases and errors can be minimised to an acceptable level so that interpretation of sample results would be achieved with some confidence.

Chapter 5

Food Sampling in the E.U.

Chapter 5. Food Sampling in the E.U.

5.1 Introduction

The U.K., as a member of the European Union (EU), is obliged to implement the EU legislation agreed among the Member States. European legislation is aimed at creating a common market in goods so that products produced anywhere in the Union can be traded without undue restriction. The Official Control of Foodstuffs Directive (89/397/EEC) was adopted for this purpose of achieving a Single Market in foodstuffs, and it came into force on 1st April 1991. Article 14 of this Directive requires competent authorities of the Member States to draw up forward programmes which lay down the nature and frequency of inspections to be carried out regularly over a specific period. Each year Member State is expected to send necessary information on the implementation of the programmes during the previous year to the Commission, giving details on the criteria applied in drawing up these programmes, the number and type of inspections carried out and infringements established. Also, a recommendation concerning a co-ordinated programme of inspections will also be transmitted and carried out voluntarily by the Member States. (EU 1989). Thus the U.K. is required to submit the Statistical Returns to the European Commission on an annual basis. Concurrently, results of the Annual Recommended EU Co-ordinated Programme are collected and submitted to the European Commission. In order to comply with the requirement lay down in Article 14, a considerable amount of effort and resources towards the submission of Statistical Returns has been spent by the U.K. Government. With an estimate

population of 59.2 million based on 1998 figure (National Statistics 2000) and over 400 local authorities, there are indeed many organisational bodies located at local, regional and national levels that are working together to meet this requirement. However, comments returned from the EU on the performance of U.K. food inspection and sampling programmes appear to be minimal. For this reason, an investigation was undertaken to visit the European Commission (EC).

5.2 Method

After initial contact through written undertaking with Mr. E. Gaerner, Directorate General III E Unit E/1, in September 1996 requesting information on the Statistical Returns of the Member States, further inquiry was extended to the legal requirements under the Official Control of Foodstuffs Directive (89/397/EEC). An investigation, in part, was undertaken during November 1998 to visit the European Commission in Brussels and interviewed key members of the Commission who have major responsibilities on the enforcement of the Official Control of Foodstuffs Directive. A travelling scholarship was kindly awarded by the Royal Environmental Health Institute of Scotland (REHIS) to allow the research in Brussels to be carried out. Mr. Gaerner kindly agreed and arranged officials from DG III and DG XXIV who have direct involvement with the requirements to be interviewed. Those officials included:

- Mrs. C. Majewski, Directorate General III E (Industrial Affairs III - Consumer Goods Industries) Unit 1 (Foodstuffs - Legislation and Scientific and Technical Aspects),

- Mr. J.L. de Felipe, Directorate General XXIV,
- Mr. P. Dewevre, Directorate General XXIV, and
- Mr. V. Niemi, Directorate General VI

of the European Commission in Brussels, Belgium. Mrs. Majewski has direct responsibilities on food control legislation and policymaking, while Mr. Dewevre and Mr. de Felipe are both responsible for inspection and control visits. On the other hand, Mr. Niemi deals with veterinary control in Member States. Therefore, the objectives of the visit to the European Commission in Brussels are to:

(1) Investigate the main purpose and benefit of the requirements under the Official Control of Foodstuffs Directive (89/397/EEC),

(2) Establish what EU does with food sampling returns at present and plans for in the future,

(3) Discover any hindrances or limitations which prohibit appropriate feedback to Member States on the results of these Returns,

(4) Examine compliance of other EU countries and consistency of returns between countries,

(5) Discuss future plans of the EU towards food safety and hygiene in the content of achieving a Single Market in Europe.

5.3 Results

5.3.1 Submission of Statistical Returns

The submission of Statistical Returns began in 1991 following the enactment of the Official Control of Foodstuffs Directive. After the first submission, the Commission realised that effort put into sampling differed from one Member State to another. Also, the variation in the types of sample taken was greatly influenced by the tradition of each country. Intuitively based programmes appeared to be commonplace. For example, Greece was concerned that food related diseases are related primarily to chemical contaminants. The Commission had asked Member States to include certain categories of the sampling results in the Returns. However, inconsistencies were shown throughout the reports. It was later discovered that the Member States did not have the same understanding of what should be sampled within certain categories. For instance, some countries recorded the results of both raw and cooked meat under the same category while other Member States only sampled cooked meat in this category. Obviously, those reporting their results with both raw and cooked meat had higher bacterial counts and higher unsatisfactory rates. Translation also caused another problem. For example, the English word 'snack' may mean a snack food such as a packet of crisps in the U.K., but it was translated into 'chocolate biscuits' in France.

This problem was identified, and after a series of verbal discussions with the Member States, suggestions for improvement were proposed, but rectification of the

existing national statistics by Member States' central governments was not possible. It was because these returns reported local governments' work in this format and the information could not be refashioned by central governments. The underlying problem of the misunderstanding of the terminology actually remained at local level where the local government reporting systems were not uniform. Consequently, this prohibited an adequate analysis and comparison of statistics at central level. The European Commission decided to draw up guidelines in 1994 and eventually it was published in January 1996 (EU 1995).

Apart from the fact that a required format had not been correctly followed by several Member States and hindered the analysis of the statistics, the yearly submission of the Returns had also been affected by delays from some Member States. Through earlier contact by writing in October 1996 with Mr. Gaerner of Directorate General III (DGIII), it was shown that 13 Member States submitted the 1994 Returns but only 7 countries submitted the 1995 Returns. This was mainly due to administrative and/or technical reasons in certain Member States. In some countries where the population is relatively large, some delays were actually caused by the late submission of the statistics from local authorities to the central governments; while others with smaller populations like Luxembourg did not experience the same problem. In certain Member States, the lack of computerised reporting systems at some levels prolonged the process of submission. Mrs. Majewski of DGIII mentioned that political interference was another important factor that hindered harmonisation. For example, in France one aspect on their returns was not reported in each year as co-operation at national level was not achieved. Also, in Ireland there

was a period when their control officials went on strike and the Commission did not receive their Returns for two years. Nevertheless, all Member States eventually submitted returns, and prosecution using infraction procedure has never been applied.

When the statistics are collected, sorted and tabulated by the Commission, the overall results are compared and discussed among the Member States. Analyses such as the ratios of premises against inspections or sampling are commonly used to create a whole picture at European level. Under the Additional Measures Directive (93/99/EEC), Member States are visited by the appointed inspectors to monitor the equivalence and effectiveness of their food control systems, and the officials would take along with them the statistical returns during their visit. A set of questionnaires was devised for this purpose and the central governments were expected to acquire the necessary local knowledge to reflect their control at local level.

5.3.2 Recommended EU Co-ordinated Programme

The first co-ordinated programme of inspections provided for by Article 14(3) of Directive 89/397/EEC was carried out in 1993. Following discussions with the Member States, the programme was confined to a few groups of foodstuffs. Member States were recommended to take the samples and report back the results to the Commission. A list of the recommendations concerning the co-ordinated programmes is shown in Table 4.4 of Chapter 4. In order not to increase the financial burden to the administration of the Member States, sampling rates were not set but

the number of samples taken must be sufficient to provide an overview of the market in the foodstuffs concerned. Since the main purpose of the control programme is to assess how the control activities in the Member States are working and not specifically on the subject of scientific surveillance, it is not compulsory to use the recommended analysis methods. As it is not a legal requirement to carry out the control programme, the cost of insisting Member States to use the suggested methods simply means that control authorities would not participate. The industries aware of the EU co-ordinated programmes and they will know that the control authorities are all looking at the same problem, therefore the industries may tighten up their compliance with the food control regulations and stop adulterating their food products. In the main, this voluntary procedure has proved successful since the majority of the Member States are keen to participate and contribute to this annual programme.

5.3.3 Current Situation at the European Commission

Directorate General III E (Industrial Affairs III - Consumer Goods Industries) Unit 1 (Foodstuffs - Legislation and Scientific and Technical Aspects) (DGIII E/1) used to have responsibility for the Scientific Committee and all food control aspects. These included the control programme, assessment and analysis of the statistics and the control visits. However, in July 1997 the Unit was separated and some of the staff moved to Directorate General XXIV. The splitting up of DGIII E/1 was mainly due to the BSE Crisis. The Crisis indicated that the Commission needed to reorganise its work as conflicting roles had been perceived in DGVI. The criticism was that risk

assessment and Scientific Committee should not be put in the same Directorate General as risk management. Policymaking and risk management should be separated from the control and the Scientific Committee. It was felt that the policy makers could influence the decision of the Scientific Committee. Also, inspectors' independence had not been reached as it was possible that the inspectors would simply be told to carry out certain tasks. In order to make a clear separation between the responsibility of 'legislation' and 'inspection', it would be appropriate to put the inspectors into DGXXIV. For this reason, it also affected the staffing of DGIII E/1 on food control. For those who had the responsibility on food legislation would remain in DGIII while the others who had the duty on inspections and control visits would transfer to DGXXIV.

Because of the separation in DGIII E/1, the decision on the allocation of the main responsibilities on the control statistics and co-ordinated programmes has not yet been resolved. DGIII had made a proposal that the control programme might well be more suitable to be remained in DGIII, while the responsibility on the control statistics would better be done by the officials in DGXXIV. At the beginning of the first two years when the statistical returns were submitted to DGIII, the raw data were simply put together and handed back to Member States for discussion. These data were only available to the central control authorities of the Member States because it was not prepared in a comparable format and could have been misleading if it distributed more widely. As the Commission perceived the problems associated with the inaccuracies of data, guidelines were published in order to improve the situation and allow comparability of these statistics. Unfortunately, the separation of

DGIII E/1 in 1997 has left the responsibility of the statistical returns unassigned. This 'grey area' will hopefully be assigned to an appropriate DG in the near future. This means that the submitted returns which had already been subjected to refinement after the publication of the guidelines have not yet been fully analysed by the Commission, and therefore await distribution, discussion, and review.

5.3.4 Future Plans

Mrs. Majewski reflected her view that DGIII encourages Member States to concentrate on ensuring that food companies apply safe production methods and control their products through the application of HACCP system and good hygiene practices. In the future it is hoped that fewer samples will be taken for the 'hit or miss' type of food surveillance. Instead, sampling will be read for verification purposes and as part of specific projects and surveys. Regarding the development of microbiological criteria for foodstuffs, DGIII has not yet set any criteria for food products at retail level. Instead, some microbiological guidelines for a particular organism in a particular food have been produced. If it is concluded that this is the best way for controlling such a problem, the Commission may consider setting microbiological criteria in the future for products at retail level. Because of the partnership with other international organisations to maintain trade at global level, harmonisation of microbiological criteria for food product at European level has become a very difficult task. Therefore, although some Member States have set microbiological criteria in their own national legislation, the Commission has no intention at this stage to harmonise this area of food surveillance.

To further enhance the single market in foodstuffs within Europe, the Commission plans to consolidate all the general hygiene directives into one Directive. This includes the hygiene directives prepared in DGIII as well as in DGVI. However, there are many differences between these two sets of directives which complicate the process. Since all the hygiene directives are going to be coalesced, questions have been raised by the Member States for the reason of having a single hygiene directive but allowing many different control directives. Under this circumstance, the Commission may also have to consider changes to the control directives. If this is the case, minor changes to the existing control directives are inevitable, and this also applies to the Official Control of Foodstuffs Directive (89/397/EEC) too. Again, because of the difference in systems, plans towards the consolidation of the food control directives and the veterinary control directives have not yet fully developed.

5.4 Discussion

Despite the effort of producing the guidelines to harmonise the conditions for submission of statistics in order to reach an agreed explanation and understanding of the terminology, it is inevitable that there are still some confusing terms that are debatable over their meaning, for example, the definition of the word 'sample'. As detailed in the guidelines, 'sample' is defined as official sample taken in the course of official inspection procedures. If this were the case, U.K. officials would simply argue whether informal samples should also be included as 'EU samples' since the majority of samples are taken informally in the U.K. In other Member States like

Denmark, their sampling regimes are completely different. Irrespective of whether sampling is carried out officially or informally, the number of visits and samples taken are determined by the officers' judgement on the level of risk found in the food premises. Once the samples are procured and analysed, all the results can be used for prosecution if required depending on the severity of infringement. It is clear that the problem with the terminology is partly due to the difference in food control system applied in the Member States. This is why a Directive was adopted instead of a Regulation in order to take into account this difference in systems which exists.

Overall, the main problem due to the inaccuracies of data by variability was recognised, and guidelines were published to solve this problem. Mrs. Majewski also pointed out that the Commission realised some corruption still exists. The source of these inaccuracies is known since the data become more familiar to them. Unfortunately, the Commission has recently undergone internal reorganisation and improvement of the statistics has not yet been confirmed. Therefore, further development cannot be made until the statistics are properly examined. Once the allocation of responsibilities has been completed, the appropriate DG in charge of the returns will begin the analysis to identify further need for improvement. Also, another hindrance to the harmonisation is that some Member States refuse to use the recommended reporting form published in the guidelines since the procedures for collecting the inspection data may be different in these countries.

From the Commission's viewpoint, it is important that central governments of the Member States must have full knowledge on the performance of their local

authorities' food control work. Local governments reported back their inspection and sampling results to the centre as an evidence of their compliance with both National and European requirements. Assessment of central audit was then carried out by the Commission through the submission of statistical returns and control visits. Therefore, the Member States understand that there is a system where the statistics are being looked at. Central governments will communicate back to the local authorities concerning their performance and the Commission uses the statistics then to assess each central audit. Similarly, questions were often raised by the MEPs in the European Parliaments upon this issue. In order for the Single Market to work and have confidence in Member States' food law enforcement, the European Commission has the responsibility to ensure that the EU legislation is being applied by the Member States. Illustration of an adequate enforcement means that appropriate inspections and sampling must be carried out by the control officials of the Member States throughout the year, and the submission of the Statistical Returns is a piece of evidence of such enforcement. Mrs. Majewski explained that the Commission would like to see equivalence of control standards without it actually being exactly the same thing happening, however, the end results should all be the same. It is important for the Member States to illustrate their contribution to a European central idea for the completion of an internal market. For this reason, the submission of statistical returns is regarded as a statutory requirement.

5.5 Conclusion

Undoubtedly, it is an important issue for the Member States to illustrate the competence and transparency of their food control systems to the European Commission and other countries for the completion of a common market. It is equally important for each Member State to receive equivalent benefit out of this procedure. The comparison of previous data was not possible due to variability, and the underlying problem remains at local level where the reporting system is not uniform. The Commission is proactive by producing guidelines to rectify the situation. However, some Member States refuse to use the reporting forms published in the guidelines.

In order to allow proper comparison of this data, firstly it is important for the Commission and the Member States to make every effort to reach a firm agreement to use a common reporting system so that the statistics can be translated into meaningful information. Since the allocation of responsibility over the statistical returns will soon be confirmed, and it is possible that all the control directives may be consolidated into one directive in the future, it is the appropriate time for the Commission to fine-tune the existing guidelines for further improvement. The effectiveness of comparison will be determined by the design of the reporting system. Therefore, it is important that the design of the reporting system is based on a firm statistical foundation at European level. Once the statistical approach is achieved, comparison of Member States' performance can be done. Compliance cost assessment can be applied to evaluate whether this requirement is cost beneficial

both at national and European level. Also, articulation between local authorities, central governments and the European Commission must not be overlooked. Co-operation at all levels is required for successful data collection and analysis. Those who have poor submission rates must put more effort into this requirement. The need for the Commission to take into account special circumstances within Member States that may influence the submission of statistical returns should also be noted.

Chapter 6

National Survey on U.K. Food Sampling for Microbiological Examination and Chemical Analysis

Chapter 6. National Survey on U.K. Food Sampling for Microbiological Examination and Chemical Analysis

6.1 Introduction

Routine sampling of foodstuffs by local authorities at the point of sale has and continues to be an integral part of U.K. food surveillance activities. One of the main averred purposes of the programme is to identify potentially hazardous contaminants, either it is microbiological, physical or chemical in nature, before they present a risk to public health.

Considerable resource is spent on this task throughout the administrative layers of government but particularly within the local authority and analytical sectors. However epidemiological evidence indicates that whilst food surveillance by sampling continues apace food related illness exhibits an upward trend. This apparent contradiction highlights the essential weakness of current food sampling practices.

Thus the first and most basic scientific question must be to determine to what extent do current food sampling practices contribute to the overall programme of food surveillance and in particular to the prevention of foodborne illness. Since the majority of sampling activities is carried out at local level, therefore a survey was conducted to investigate the significance of local authority sampling regimes. The objectives of this survey was to:

(1) Investigate the purpose(s) of food sampling and subsequent analysis undertaken by the local authorities;

(2) Identify the criteria used for the decision of foodstuffs sampled;

(3) Profile the cost of food sampling and the number of food premises within the local areas, and to determine whether there is any connection between these two parameters that may exist;

(4) Examine the usefulness of results of analyses at different levels;

(5) Study the effectiveness and contribution of local authority food sampling programmes to the prevention of food-borne illness.

6.2 Methods

In order to achieve the above objectives for the investigation of U.K. food sampling, a national survey was carried out by means of a questionnaire sent to all U.K. local authorities. Since the intention was aimed at the sampling activities at local councils for microbiological examination and chemical analysis, therefore overall number of Environmental Health Departments in the U.K. was targeted as the total population where all local councils in England, Wales, Scotland and Northern Ireland were included. The addresses of the U.K. Environmental Health Departments were extracted from the Municipal Year Book 1998 Volume 1 and 2 (Clements 1998). A total of 439 questionnaires were sent by mail to the Environmental Health Departments located at District, Unitary or Borough Councils. Sampling for

composition and labelling were not included as an objective of the survey, therefore no questionnaires were sent to the Trading Standards Departments at District, County, Unitary or Borough Councils throughout U.K. A copy of the questionnaire can be found in A.8.1 of Appendix 8. Ideally, a pilot study should first be carried out to ensure that the questions were foolproof and be satisfactory in practice. After the questionnaires were sent out to all local authorities, it should be followed with reminders by writing to members of the samples explaining the importance of the survey in order to achieve a higher response rate (Owen and Jones 1986). Unfortunately, due to time and financial constraints, both pilot study and reminders had not been carried out. Instead, a similar national survey on local authority microbiological food sampling had been undertaken by LACOTS in 1995, and the results of LACOTS survey were used as a reference to the design of this survey (Cunningham 1995).

One of the main reasons for using postal enquiry was the great advantage of relatively low cost. The quality of the data derived from the questionnaire depended particularly on the selection of the sample and the drafting of the questions to be asked. Since the whole population was targeted, each local authority had an equal chance to be included as part of a survey and thus minimising the bias of misrepresentation of the population. Also, the design of the questionnaire was constructed in a way that not only would it cover the relevant questions to fulfil the objectives, it would also be easily understood. The type of question was open-ended, leaving the reply entirely to the respondent. In comparison with multiple-choice

question, open-ended question normally enhanced qualitative information to be obtained, although categorisation of data would be more difficult due to the ambiguity of answers (Owen and Jones 1986).

A total of seven questions were included in the survey in order to succeed the investigation for the aforementioned objectives. Due to many differences in the food control system between England and Wales, Scotland and Northern Ireland, results of the survey were also analysed separately according to the national boundaries. Since over 80% of local authorities are located in England and Wales, the overall U.K. results may not necessarily be the views of Scotland or Northern Ireland. Attempt was also made to categorise local authorities in terms of the number of food premises, but this information was not available and prohibited such analysis.

Question One posed the main inquisition towards the aims of food sampling and subsequent analysis undertaken by the U.K. local authorities. Results of the main aims were categorised into various statements. Since the majority of local authorities had suggested more than one aim, it was possible that the main aim could not be identified simply by observing the most important aim alone. Therefore, by using the score rating system which scaled from the score of five (A - most important aim) through to one (E - least important aim), the importance of each statement could be quantified and confirmed. Also, the most important aim (i.e. A – The Priority Aim) was analysed separately and compared with the results obtained from the score rating system to differentiate if there was any variation. Question Two investigated the

specific criteria used by the local authorities to determine which foodstuffs were sampled for testing. Answers for this question were separated into two groups depending on the testing of foodstuffs: chemical analysis and microbiological examination. In Question Three, the total cost of food sampling and subsequent analysis spent under the budget of Environmental Health Departments of the U.K. local authorities was examined. Again, the results were recorded in two separate groups under chemical analysis and microbiological examination. Under Question Four, investigation was extended to the total number of food premises located within each local authority in the United Kingdom. The results were categorised into groups scaled at an increment of 500 premises. In Question Five, usefulness of the results of analyses at local, national and European level were examined, and results at each level were complied into various statements for analysis. Question Six investigated the important issue as to whether local authorities considered their food sampling programme contributed significantly to the prevention of food-borne illness. Comments on either agreement or disagreement were tabulated and examined separately. Finally in Question Seven, local authorities were asked to express their view on whether current system of food sampling could be improved upon, and again the results were analysed separately according to agreement or disagreement.

6.3 Results

With 439 questionnaires sent out to the Environmental Health Departments of the local authorities located in England, Wales, Scotland and Northern Ireland, a total of 172 replies were received, and the number of returns represent 39.2% of the overall population. The distribution of returns is shown in Table 6.1 below:

Location	Column A	Column B	Column C	Column D
	Total no. of LA's targeted	No. of Replies	% (returns within national areas)	% (in terms of overall returns)
			C = (B ÷ A) × 100	D = (B ÷ 172) × 100
England	360	138	38.3%	80.2%
Wales	22	7	31.8%	4.1%
Scotland	32	18	56.3%	10.5%
N. Ireland	25	9	36.0%	5.2%
Total	439	172	39.2%	100%

Table 6.1: The Percentages of Returns from each National Area within the U.K.

Among these four National Areas, Scotland has a relatively higher return rate (56.3%) as compared to the others with the percentage lying at the thirtieth range.

Results from Question One indicated a wide range of answers on the main aims of food sampling and subsequent analysis. For this reason, these answers were sorted into ten statements:

Statement	Aim of food sampling and subsequent analysis:
1(1)	To monitor, assess and/or ensure the safety, standards, quality and hygiene of food
1(2)	To participate in routine inspection and/or sampling scheme
1(3)	To detect, identify or investigate problems, poor practice or high risk food where Environmental Health Officers raise concerns
1(4)	Legal requirements
1(5)	Food poisoning outbreaks / complaints
1(6)	Public protection
1(7)	Collection of data or information
1(8)	To give advice and/or education
1(9)	HACCP / risk assessments
1(10)	Others

From Table 6.2, the percentages of each statement calculated from 'The Priority Aim' and 'Score Rating System' were shown. Both sets of results indicated that Statement 1(1) (Monitoring, assessing and/or ensuring the safety, standards, quality and hygiene of food) was agreed by the local authorities as the most important aim of food sampling and subsequent analysis. However, a higher percentage of 39.0% from 'The Priority Aim' was obtained as compared to 24.7% from 'Score Rating System'.

Nevertheless, apart from Statement 1(1) and 1(2) with a relatively larger variation, the rest of each Statement tended to follow a similar pattern of proportion.

Also the results in Question One were complied and compared in relation to their national boundaries, and were illustrated in Tables 6.3 - 6.5. Since the number of replies in England and Wales constituted over 80% of the overall returns (see Table 6.1), percentages in Table 6.3 were almost identical to those in Table 6.2 as expected. While Scotland had peaks on Statement 1(1) and 1(4), returns of local authorities from Northern Ireland cast more vote on Statement 1(3) and 1(4).

U.K.													
Statement	The Priority Aim						Score Rating System						
	A	%	B	C	D	E	A×5	B×4	C×3	D×2	E×1	Total	%
1(1)	67	**39.0**	19	8	1	0	335	76	24	2	0	437	**24.7**
1(2)	16	**9.3**	27	23	13	6	80	108	69	26	6	289	**16.3**
1(3)	28	**16.3**	25	16	3	2	140	100	48	6	2	296	**16.7**
1(4)	21	**12.2**	26	9	1	0	105	104	27	2	0	238	**13.5**
1(5)	13	**7.6**	13	8	2	1	65	52	24	4	1	146	**8.3**
1(6)	6	**3.5**	1	1	0	0	30	4	3	0	0	37	**2.1**
1(7)	8	**4.7**	6	3	1	2	40	24	9	2	2	77	**4.4**
1(8)	3	**1.7**	7	2	1	0	15	28	6	2	0	51	**2.9**
1(9)	4	**2.3**	5	0	0	0	20	20	0	0	0	40	**2.3**
1(10)	6	**3.5**	17	11	13	1	30	68	33	26	1	158	**8.9**
	172	**100**	146	81	35	12	860	584	243	70	12	1769	**100**

Table 6.2: Percentages of Q.1 Statements on the Main Aims of U.K. Food Sampling

England & Wales													
Statement	The Priority Aim						Score Rating System						
	A	%	B	C	D	E	A×5	B×4	C×3	D×2	E×1	Total	%
1(1)	57	**39.3**	11	7	0	0	285	44	21	0	0	350	**23.6**
1(2)	16	**11.0**	24	19	11	5	80	96	57	22	5	260	**17.5**
1(3)	24	**16.6**	25	15	3	2	120	100	45	6	2	273	**18.4**
1(4)	14	**9.7**	19	6	1	0	70	76	18	2	0	166	**11.2**
1(5)	12	**8.3**	12	7	2	0	60	48	21	4	0	133	**9.0**
1(6)	3	**2.1**	0	1	0	0	15	0	3	0	0	18	**1.2**
1(7)	7	**4.8**	6	3	1	2	35	24	9	2	2	72	**4.9**
1(8)	3	**2.1**	7	2	1	0	15	28	6	2	0	51	**3.4**
1(9)	4	**2.8**	2	0	0	0	20	8	0	0	0	28	**1.9**
1(10)	5	**3.4**	14	9	12	1	25	56	27	24	1	133	**9.0**
	145	**100**	120	69	31	10	725	480	207	62	10	**1484**	**100**

Table 6.3: Percentages of Q.1 Statements on the Main Aims of England and Wales Food Sampling

Scotland													
Statement	The Priority Aim						Score Rating System						
	A	%	B	C	D	E	A×5	B×4	C×3	D×2	E×1	Total	%
1(1)	8	**44.4**	6	1	1	0	40	24	3	2	0	69	**39.4**
1(2)	0	**0**	1	3	1	1	0	4	9	2	1	16	**9.1**
1(3)	1	**5.6**	0	0	0	0	5	0	0	0	0	5	**2.9**
1(4)	4	**22.2**	5	2	0	0	20	20	6	0	0	46	**26.3**
1(5)	1	**5.6**	1	0	0	0	5	4	0	0	0	9	**5.1**
1(6)	2	**11.1**	0	0	0	0	10	0	0	0	0	10	**5.7**
1(7)	1	**5.6**	0	0	0	0	5	0	0	0	0	5	**2.9**
1(8)	0	**0**	0	0	0	0	0	0	0	0	0	0	**0**
1(9)	0	**0**	0	0	0	0	0	0	0	0	0	0	**0**
1(10)	1	**5.6**	2	0	1	0	5	8	0	2	0	15	**8.6**
	18	**100**	15	6	3	1	90	60	18	6	1	175	**100**

Table 6.4: Percentages of Q.1 Statements on the Main Aims of Scotland Food Sampling

Northern Ireland													
Statement	The Priority Aim						Score Rating System						
	A	%	B	C	D	E	A×5	B×4	C×3	D×2	E×1	Total	%
1(1)	2	**22.2**	2	0	0	0	10	8	0	0	0	18	**18.4**
1(2)	0	**0**	2	1	1	0	0	8	3	2	0	13	**13.3**
1(3)	3	**33.3**	0	1	0	0	15	0	3	0	0	18	**18.4**
1(4)	3	**33.3**	2	1	0	0	15	8	3	0	0	26	**26.5**
1(5)	0	**0**	0	1	0	1	0	0	3	0	1	4	**4.1**
1(6)	1	**11.1**	1	0	0	0	5	4	0	0	0	9	**9.2**
1(7)	0	**0**	0	0	0	0	0	0	0	0	0	0	**0**
1(8)	0	**0**	0	0	0	0	0	0	0	0	0	0	**0**
1(9)	0	**0**	0	0	0	0	0	0	0	0	0	0	**0**
1(10)	0	**0**	1	2	0	0	0	4	6	0	0	10	**10.2**
	9	**100**	8	6	1	1	45	32	18	2	1	98	**100**

Table 6.5: Percentages of Q.1 Statements on the Main Aims of Northern Ireland Food Sampling

For Question Two, the results were arranged into seven general statements for both chemical and microbiological testings:

Statements	Chemical Analysis	Microbiological Examination
2(0)	Not available / Responsibility of County Council (TSO)	Not available / Blank
2(1)	Complaints / Investigation of Food Poisoning or Illness	Same
2(2)	Local Manufacturing Products / Local Premises / Home Authority	Same
2(3)	Other food programmes at national, regional or local levels	Same
2(4)	Legal Requirement	Legal Standards and Advice / PHLS Guidelines
2(5)	Selected Chemicals targeted / Selected Food	Selected Pathogens targeted / Selected Food (high risk food or with previous problems, etc.)
2(6)	Others	Same

The proportion of U.K. specific sampling criteria for both chemical analysis and microbiological examination by the Environmental Health Departments of the U.K. local authorities were shown in Table 6.6. It was indicated clearly that there was no common trend between these two sets of results. In terms of criteria for chemical analysis, the majority of foodstuffs chosen for sampling were due to consumers' complaints or investigation of food poisoning incidents (Statement 2(1) – 31.4%). Also, 14.5% of local authorities considered that Home Authority Principle on the

testing of local produce (Statement 2(2)) were the second main criteria. However, 35.5% of overall replies (Statement 2(0)) indicated that either information regarding the sampling criteria was not available or sampling for chemical analysis was not carried out routinely as part of their duties and was normally done by Trading Standards Departments instead. On the other hand, results indicated that the main sampling criteria for microbiological examination shifted towards Statement 2(5) on selected foodstuffs or targeted pathogens at a percentage of 40.1%; while the second most important criteria rested on the participation of national, regional or local programmes.

Again, results of Question Two were also compared in accordance to the national boundaries. From Table 6.7 shown, the main sampling criteria for chemical analysis in England and Wales were the same as the U.K. one (Statement 2(1) - 36.6%). However, in Scotland and Northern Ireland results showed that local products and premises (Statement 2(2) - 72.2% and 66.7%) was the main factor which determined the choice of foodstuffs aimed at chemical testing. In terms of microbiological examination, all four national areas agreed that the main sampling criteria were based on the selected foodstuffs such as high-risk food or targeted pathogens (see Table 6.8).

Statements	Chemical Analysis		Microbiological Examination	
	No. of Replies	%	No. of Replies	%
2(0)	61	**35.5**	5	**2.9**
2(1)	54	**31.4**	16	**9.3**
2(2)	25	**14.5**	7	**4.1**
2(3)	10	**5.8**	48	**27.9**
2(4)	8	**4.7**	13	**7.6**
2(5)	5	**2.9**	69	**40.1**
2(6)	9	**5.2**	14	**8.1**
Total	172	**100**	172	**100**

Table 6.6: Percentages of Q.2 Statements on the Criteria used for the Determination of foodstuffs for sampling in the U.K.

Statements	Chemical Analysis					
	E&W	%	Scotland	%	N.I.	%
2(0)	61	**42.1**	0	**0**	0	**0**
2(1)	53	**36.6**	0	**0**	1	**11.1**
2(2)	6	**4.1**	13	**72.2**	6	**66.7**
2(3)	10	**6.9**	0	**0**	0	**0**
2(4)	6	**4.1**	2	**11.1**	0	**0**
2(5)	4	**2.8**	0	**0**	1	**11.1**
2(6)	5	**3.4**	3	**16.7**	1	**11.1**
Total	145	**100**	18	**100**	9	**100**

Table 6.7: Percentages of Q.2 Statements on the Criteria for Chemical Analysis in England and Wales, Scotland and Northern Ireland

Statements	Microbiological Examination					
	E&W	**%**	**Scotland**	**%**	**N.I.**	**%**
2(0)	5	**3.4**	0	**0**	0	**0**
2(1)	15	**10.3**	0	**0**	1	**11.1**
2(2)	2	**1.4**	5	**27.8**	0	**0**
2(3)	48	**33.1**	0	**0**	0	**0**
2(4)	11	**7.6**	2	**11.1**	0	**0**
2(5)	51	**35.2**	10	**55.6**	8	**88.9**
2(6)	13	**9.0**	1	**5.6**	0	**0**
Total	145	**100**	18	**100**	9	**100**

Table 6.8: Percentages of Q.2 Statements on the Criteria for Microbiological Examination in England and Wales, Scotland and Northern Ireland

In Question Three, only 82 local authorities (59 in England and Wales; 14 in Scotland; 9 in N. Ireland) out of the total 172 replies provided with answers specifying the annual cost of food sampling and its analysis. Among the 82 results, some of the information detailing the breakdown of cost by means of either chemical or microbiological testings was incomplete. As the difference in systems of local authorities between England and Wales, Scotland and N. Ireland described earlier in Chapter Three exist which directly influences budget setting for the Environmental Health Departments, therefore the profile of total annual cost on food sampling and subsequent analysis in each national area was examined separately. These profiles were illustrated in Tables 6.9 - 6.11.

While a free service for microbiological examination of foodstuffs is provided in England and Wales and Northern Ireland, local authorities in Scotland have to pay for this service through their own budgets. For this reason, Environmental Health Departments in Scotland have a different profile of sampling and analysis cost. In Table 6.10, the ratios of cost between chemical analysis and microbiological examination were shown. Out of twelve Scottish local authorities reported, only one local authority indicated that the budget for microbiological examination was higher than the one set for chemical analysis (i.e. Table 6.10: chemical / microbiological ratio < 1). The rest of the eleven local authorities reported that more money was actually spent on chemical analysis instead (i.e. Table 6.10: chemical / microbiological ratio > 1).

LA's	Chem. (£)	Micro. (£)	Both (£)
ENG 340	26,000	0	26,000
ENG 239	25,000	0	25,000
ENG 202	17,000	6,000	23,000
ENG 308			22,200
ENG 289			20,000
ENG 304			20,000
ENG 322	18,000	0	18,000
ENG 350	17,500	0	17,500
ENG 341			16,500
ENG 174	10,000	5,800	15,800
WAL 19	8,500	3,600	12,100
ENG 287	11,000	0	11,000
ENG 357	10,000	0	10,000
ENG 297			9,780
ENG 299	8,467	1,245	9,712
ENG 242	3,000	6,000	9,000
ENG 10			8,885
ENG 203	3,500	5,000	8,500
ENG 268			8,500
ENG 298			8,229
ENG 195	0	7,500	7,500
ENG 334			7,200
ENG 245			6,800
ENG 11	2,000	4,000	6,000
ENG 80	2,000	4,000	6,000
ENG 177	500	5,000	5,500
WAL 16	2,800	2,200	5,000
ENG 60	1,500	3,200	4,700
ENG 1	500	3,175	3,675
ENG 21			3,600

LA's	Chem. (£)	Micro. (£)	Both (£)
ENG 66	3,500	100	3,600
ENG 193	500	3,000	3,500
ENG 190			3,200
ENG 278	200	3,000	3,200
ENG 78	300	2,400	2,700
ENG 96			2,500
ENG 206	400	2,000	2,400
ENG 338	500	1,500	2,000
ENG 355			1,500
ENG 286			1,400
ENG 282			1,226
ENG 47	500	500	1,000
ENG 109	200	800	1,000
ENG 318	1,000	0	1,000
ENG 86			750
ENG 88	650	60	710
ENG 217	600	100	700
ENG 138	400	0	400
ENG 191			400
ENG 141	327	0	327
ENG 139	200	0	200
ENG 152	200	0	200
ENG 250	200	0	200
ENG 225	0	180	180
ENG 48	0	0	0
ENG 69	0	0	0
ENG 154	0	0	0
ENG 223	0	0	0
ENG 232	0	0	0
Mean			**6610**

Table 6.9: Total Annual Cost of Food Sampling and its Analysis in England & Wales

LA's	Chemical (£)	Microbiological (£)	Both (£)	Ratio (Chem / Micro)
SCO 14	180,000	43,000	223,000	4.19
SCO 28	163,000	15,500	178,500	10.52
SCO 12	104,900	23,700	128,600	4.43
SCO 7	88,000	8,000	96,000	11.00
SCO 8	65,000	17,000	82,000	3.82
SCO 6	30,000	35,000	65,000	0.86
SCO 23	51,000	12,000	63,000	4.25
SCO 3	35,460	27,213	62,673	1.30
SCO 9	40,000	12,000	52,000	3.33
SCO 31	37,500	9,800	47,300	3.83
SCO 19			32,000	-
SCO 25			30,050	-
SCO 29	11,000	3,000	14,000	3.67
SCO 32	3,500	3,000	6,500	1.17
Mean			**77,187**	**4.36**

Table 6.10: Total Annual Cost of Food Sampling and its Analysis in Scotland

LA's	Chemical (£)	Microbiological (£)	Both (£)
NI 9	0	0	24,500
NI 21	16,000	0	16,000
NI 23	15,000	1,000	16,000
NI 2	14,000	0	14,000
NI 6	13,400	0	13,400
NI 24	10,000	0	10,000
NI 3	0	0	9,000
NI 18	3,000	0	3,000
NI 8	0	0	1,500

Table 6.11: Total Annual Cost of Food Sampling and its Analysis in N. Ireland

For Question Four, results of the total number of food premises in each U.K. local authority were compiled and arranged into 17 groups from Group A to Q:

Group A:	Not Available	Group J:	4001 - 4500 premises
Group B:	1 - 500 premises	Group K:	4501 - 5000 premises
Group C:	501 - 1000 premises	Group L:	5001 - 5500 premises
Group D:	1001 - 1500 premises	Group M:	5501 - 6000 premises
Group E:	1501 - 2000 premises	Group N:	6001 - 6500 premises
Group F:	2001 - 2500 premises	Group O:	6501 - 7000 premises
Group G:	2501 - 3000 premises	Group P:	7001 - 7500 premises
Group H:	3001 - 3500 premises	Group Q:	7501 - 8000 premises
Group I:	3501 - 4000 premises		

It was shown in Table 6.12 that 38.4% of U.K. local authorities in survey had population of 501-1000 food premises (Cat. C) while a quarter of local authority returns had 1001-1500 food premises (Cat. D) within their catchment areas. Individually, England and Wales and Scotland were similar to the U.K. one, but N. Ireland had a slightly smaller number between 1-1000 food premises (Cat. B & C).

Investigation was extended to the variation of sampling and analysis cost (under the Environmental Health Departments' budgets) against the number of premises located within each local authority boundary, and the ratios were calculated and compared. As the local authorities' financial arrangement was different in England and Wales,

Scotland and N. Ireland, therefore each national profile was examined separately. From Table 6.13-6.15, the mean ratios in England and Wales, Scotland and N. Ireland were calculated to be £4.48/premises, £43.74/premises and £23.44/premises.

Cat.	No. of Premises in each LA	**U.K.**		**E&W**		**Scotland**		**N.I.**	
		LA's	%	LA's	%	LA's	%	LA's	%
A	N/A	3	1.7	2	1.4	1	5.6	0	0
B	1- 500	11	6.4	5	3.5	1	5.6	5	55.6
C	501-1000	66	38.4	58	40.0	4	22.2	4	44.4
D	1001-1500	43	25.0	37	25.5	6	33.3	0	0
E	1501-2000	18	10.5	17	11.7	1	5.6	0	0
F	2001-2500	11	6.4	11	7.6	0	0	0	0
G	2501-3000	9	5.2	7	4.8	2	11.1	0	0
H	3001-3500	3	1.7	2	1.4	1	5.6	0	0
I	3501-4000	0	0	0	0	0	0	0	0
J	4001-4500	1	0.6	1	0.7	0	0	0	0
K	4501-5000	4	2.3	2	1.4	2	11.1	0	0
L	5001-5500	1	0.6	1	0.7	0	0	0	0
M	5501-6000	1	0.6	1	0.7	0	0	0	0
N	6001-6500	0	0	0	0	0	0	0	0
O	6501-7000	0	0	0	0	0	0	0	0
P	7001-7500	0	0	0	0	0	0	0	0
Q	7501-8000	1	0.6	1	0.7	0	0	0	0
		172	100	145	100	18	100	9	100

Table 6.12: Breakdown of the number of food premises in U.K. Local Authorities

LA's	Cost (£)	Premises	Ratio
ENG 202	23,000	800	28.75
ENG 239	25,000	1,500	16.67
ENG 308	22,200	1,650	13.45
ENG 304	20,000	1,700	11.76
ENG 242	9,000	840	10.71
ENG 341	16,500	1,646	10.02
ENG 340	26,000	2,645	9.83
ENG 322	18,000	1,860	9.68
ENG 350	17,500	2,000	8.75
ENG 10	8,885	1,026	8.66
ENG 289	20,000	2,500	8.00
ENG 245	6,800	860	7.91
ENG 174	15,800	2,013	7.85
ENG 268	8,500	1,200	7.08
ENG 80	6,000	857	7.00
ENG 357	10,000	1,613	6.20
ENG 60	4,700	760	6.18
ENG 11	6,000	1,064	5.64
WAL 19	12,100	2,169	5.58
ENG 203	8,500	1,600	5.31
ENG 21	3,600	680	5.29
ENG 195	7,500	1,500	5.00
ENG 298	8,229	1,743	4.72
ENG 299	9,712	2,300	4.22
ENG 190	3,200	788	4.06
ENG 287	11,000	3,000	3.67
ENG 193	3,500	960	3.65
ENG 206	2,400	667	3.60
ENG 297	9,780	2,800	3.49
ENG 177	5,500	1,600	3.44
ENG 278	3,200	966	3.31
ENG 78	2,700	960	2.81
ENG 334	7,200	2,700	2.67
ENG 96	2,500	950	2.63
WAL 16	5,000	2,400	2.08
ENG 1	3,675	1,800	2.04
ENG 282	1,226	775	1.58
ENG 355	1,500	1,000	1.50
ENG 88	710	525	1.35
ENG 66	3,600	2,789	1.29
ENG 217	700	700	1.00
ENG 318	1,000	1,100	0.91
ENG 47	1,000	1,150	0.87
ENG 86	750	1,000	0.75
ENG 286	1,400	2,045	0.68
ENG 191	400	650	0.62
ENG 109	1,000	1,865	0.54
ENG 138	400	1,000	0.40
ENG 139	200	522	0.38
ENG 141	327	1,030	0.32
ENG 338	2,000	8,000	0.25
ENG 250	200	1,067	0.19
ENG 152	200	1,400	0.14
ENG 225	180	2,576	0.07
ENG 48	0	1,000	0
ENG 69	0	709	0
ENG 154	0	975	0
ENG 223	0	900	0
ENG 232	0	752	0
Mean			**4.48**

Table 6.13: Profile of the Ratio of Total Annual Cost for Food Sampling and its Analysis against the number of Premises in England and Wales

LA's	Cost (£)	Premises	Ratio (Cost / Premises)
SCO 9	52,000	633	82.15
SCO 7	96,000	1,277	75.18
SCO 14	223,000	3,200	69.69
SCO 3	62,673	925	67.75
SCO 28	178,500	2,693	66.28
SCO 8	82,000	1,328	61.75
SCO 31	47,300	1,265	37.39
SCO 23	63,000	2,000	31.50
SCO 19	32,000	1,201	26.64
SCO 12	128,600	5,000	25.72
SCO 6	65,000	2,747	23.66
SCO 25	30,050	1,440	20.87
SCO 32	6,500	500	13.00
SCO 29	14,000	1,300	10.77
Mean			**43.74**

Table 6.14: Profile of the Ratio of Total Annual Cost for Food Sampling and its Analysis against the number of Premises in Scotland

LA's	Cost (£)	Premises	Ratio (Cost / Premises)
NI 9	24,500	300	81.67
NI 6	13,400	320	41.88
NI 23	16,000	706	22.66
NI 2	14,000	700	20.00
NI 24	10,000	500	20.00
NI 21	16,000	900	17.78
NI 3	9,000	692	13.01
NI 18	3,000	327	9.17
NI 8	1,500	300	5.00
Mean			**25.69**

Table 6.15: Profile of the Ratio of Total Annual Cost for Food Sampling and its Analysis against the number of Premises in N. Ireland

For Question Five, results from the local authorities were complied into three groups: local, national and European levels, and each group was categorised into seven statements as shown below:

Statement	Local Level:
5A(0)	Blank / Not available
5A(1)	Education, Advice and Guidance
5A(2)	Ensure and improve food safety, standards, quality and hygiene
5A(3)	Identify and highlight specific problems and poor practice
5A(4)	Enforcement of legislation to ensure compliance with legislation and assist prosecution
5A(5)	Follow-up inspections which have poor results and/or complaints / confirm source of food poisoning and complaints
5A(6)	Feed in and compare with programmes, surveys or reports
5A(7)	Others

Statement	National Level:
5B(0)	Blank / Not available
5B(1)	Contribute to national surveys or co-ordinated programmes (eg. LACOTS , PHLS, MAFF, DH)
5B(2)	Build up statistical relevant database
5B(3)	Helps determine national guidelines and assess standards
5B(4)	Collaboration / comparison with other bodies' results (eg. other local authorities, liaison groups, microbiological food forum)

5B(5) Review and establish quality and standards of food

5B(6) Compliance with legislation

5B(7) Others

Statement European Level:

5C(0) Blank / Not available

5C(1) EU Programmes and surveys

5C(2) Produce statistics that contributes to data collection for comparison

5C(3) Other sampling programmes

5C(4) Ensure compliance with legislation

5C(5) Ensure and review quality & standards of food for surveillance purpose

5C(6) Determine food policies and/or limits

5C(7) Others

It was indicated in Table 6.16 that the majority of U.K. local authorities in the survey agreed that results of analyses at local level were mainly used for education, advice and guidance purposes (Statement 5A(1) - 19.8%) and for ensuring and improving the safety, standards and quality of foodstuffs (Statement 5A(2) - 16.3%). Comparison of the results at local level between England and Wales, Scotland and Northern Ireland showed a slightly different view. While England and Wales followed the same pattern as the U.K. results, Scottish data reflected that their results of analyses were mainly used for enforcement purpose to ensure that food premises comply with legislation (Statement 5A(4) - 22.2%) as well as for educational purposes (Statement 5A(1) - 16.7%). In Northern Ireland, replies on the usefulness of

sampling results was similar to those in Scotland, with a slightly higher percentage of Statement 5A(4) at 33.3%.

At national level, the U.K. figure indicated a sharp peak at Statement 5B(1), as shown in Table 6.17, whereby over half of the local authorities agreed that contribution to national surveys and co-ordinated programmes (eg. LACOTS, PHLS, MAFF or DH) was the main benefit from results of analyses. Individually, both England and Wales and Scotland had very similar pattern as the U.K. profile, but results from Northern Ireland showed that collaboration / comparison with other bodies' results (Statement 5B(4) - 44.4%) was the main use of sampling results at national level.

At European level, response from the U.K. local authorities was different compared to those at local and national levels. Results from Table 6.18 indicated that nearly half of the U.K. returns could not produce an answer to illustrate the usefulness of sampling results at European level (Statement 5C(0) - 47.1%), while 20.9% agreed that results of analyses contributed to EU Programmes and surveys (Statement 5C(1)). Although figures and patterns in England and Wales and N. Ireland were similar to the U.K. profile, returns from Scotland showed a different trend. Based on the Scottish samples, local authorities in Scotland believed that results of analyses were mainly used towards EU and other sampling programmes (Statement 5C(1) - 22.2% and Statement 5C(3) - 22.2%).

Statement 5A	Question 5A - Local Level							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	11	6.4	10	6.9	0	0	1	11.1
1	34	**19.8**	29	**20.0**	3	16.7	2	22.2
2	28	16.3	25	17.2	2	11.1	1	11.1
3	25	14.5	22	15.2	2	11.1	1	11.1
4	15	8.7	8	5.5	4	**22.2**	3	**33.3**
5	21	12.2	19	13.1	2	11.1	0	0
6	23	13.4	23	15.9	0	0	0	0
7	15	8.7	9	6.2	5	27.8	1	11.1
Total	172	100	145	100	18	100	9	100

Table 6.16: Percentages of Q.5A Statements on the Usefulness of the Results of Analyses at Local Level

Statement 5B	Question 5B - National Level							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	19	11.1	16	11.0	1	5.6	2	22.2
1	94	**54.7**	86	**59.3**	8	**44.4**	0	0
2	8	4.7	8	5.5	0	0	0	0
3	8	4.7	8	5.5	0	0	0	0
4	15	8.7	10	6.9	1	5.6	4	**44.4**
5	8	4.7	6	4.1	2	11.1	0	0
6	4	2.3	2	1.4	1	5.6	1	11.1
7	16	9.3	9	6.2	5	27.8	2	22.2
Total	172	100	145	100	18	100	9	100

Table 6.17: Percentages of Q.5B Statements on the Usefulness of the Results of Analyses at National Level

Statement 5C	Question 5C - European Level							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	81	**47.1**	75	**51.7**	2	11.1	4	**44.4**
1	36	20.9	30	20.7	4	**22.2**	2	22.2
2	10	5.8	8	5.5	1	5.6	1	11.1
3	11	6.4	7	4.8	4	**22.2**	0	0
4	5	2.9	2	1.4	3	16.7	0	0
5	7	4.1	4	2.8	3	16.7	0	0
6	5	2.9	4	2.8	1	5.6	0	0
7	17	9.9	15	10.3	0	0	2	22.2
Total	172	100	145	100	18	100	9	100

Table 6.18: Percentages of Q.5 Statements on the Usefulness of the Results of Analyses at European Level

For Question Six, results of survey from local authorities commenting on the contribution of their food sampling programmes were tabulated and presented in Table 6.19. 78 out of 172 U.K. local authorities (45.3%) believed that their food programmes contributed significantly to the prevention of food-borne illness, while 77 local authorities (44.8%) disagreed with this statement. The rest of 17 food authorities (9.9%) had different opinions and chose neither to agree nor disagree to Question Six. The overall count of agreement was almost the same as the count of disagreement. When each national area was examined separately, it was shown that Scotland (61.1%) and Northern Ireland (55.6%) had higher rates of agreement while England and Wales had relatively lower figure (42.8%) as compared to the U.K. percentage.

To further investigate the results of Question Six, comments on both agreement and disagreement were analysed separately. These results were categorised into various statements as shown below:

Statement	Agreement:
6A(0)	No comment
6A(1)	Identify trends and problems (including areas of concerns, problematic premises and hygiene failures)
6A(2)	Educational tool and advice
6A(3)	Improve and maintain standards and remedial work
6A(4)	Aid further enforcement
6A(5)	Others

Statement	Disagreement:
6B(0)	No comment
6B(1)	Either too little or not enough sampling done and therefore the number of samples were not considered to be representative
6B(2)	Food products have already sold to consumers before results of analyses given to officers; reactive sampling
6B(3)	Most results are satisfactory and no real local problems
6B(4)	Other approaches are more effective (eg. inspection, education)
6B(5)	Only used as an aid or tool
6B(6)	Existing sampling programme has minor contribution only (ie. it is not significant but helps highlight problems)
6B(7)	Others

Data shown in Table 6.20 reflected those who believed that food sampling programmes contributed significantly to the prevention of food-borne illness. Majority of the local authorities suggested that their programmes would identify trends and problems, especially food premises which had history of hygiene failures or areas of concerns (Statement 6A(1) - 43.6%). Others believed that the programmes functioned as a tool for educational or advisory purposes (Statement 6A(2) - 16.7%) as well as a way to maintain or improve standards of food hygiene (Statement 6A(3) - 16.7%). Individually, both England and Wales and Scotland agreed that identification of trends and problems was the main reason of their belief. In the case

of Northern Ireland, it appeared that sample size was simply too small to make any prediction.

On the other hand, Table 6.21 indicated the percentage of the local authorities which did not consider that their food sampling programmes contributed significantly to the prevention of food-borne illness. Nearly one fifth of the local authorities in this category considered that the amount of sampling carried out within their local areas was simply too little to be significant enough as the representation of the overall population (Statement 6B(1) - 18.2%). In England and Wales, so local authorities also believed that the hindrance of their sampling programmes towards the prevention of food-borne diseases was mainly due to small sample size. In terms of Scotland and Northern Ireland, figures provided were again too small to make any suitable comments on the most probable reason of disagreement.

Question 6	Food Sampling Programmes used by the Local Authorities contribute significantly to the Prevention of Food-borne Illness							
	U.K.		**E&W**		**Scotland**		**N. Ireland**	
	Count	%	Count	%	Count	%	Count	%
Agree	78	**45.3**	62	**42.8**	11	**61.1**	5	**55.6**
Disagree	77	**44.8**	70	**48.3**	4	**22.2**	3	**33.3**
Others	17	**9.9**	13	**9.0**	3	**16.7**	1	**11.1**
Total	172	100	145	100	18	100	9	100

Table 6.19: Percentages of Local Authorities Agreement towards the Belief of Food Sampling Programmes to the Prevention of Food-borne Illness

Statement 6A	Question 6A - Agree							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	6	7.7	3	4.8	2	18.2	1	**20**
1	34	**43.6**	27	**43.6**	6	**54.6**	1	**20**
2	13	16.7	12	19.4	0	0	1	**20**
3	13	16.7	10	16.1	2	18.2	1	**20**
4	3	3.9	3	4.8	0	0	0	0
5	9	11.5	7	11.3	1	9.1	1	**20**
Total	78	100	62	100	11	100	5	100

Table 6.20: Percentages of Q.6A Statements from the Local Authorities towards the belief of their Food Sampling Programmes to the Prevention of Food-borne Illness

Statement 6B	Question 6B - Disagree							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	13	16.9	13	**18.6**	0	0	0	0
1	14	**18.2**	13	**18.6**	1	25	0	0
2	10	13.0	7	10	2	**50**	1	**33.3**
3	7	9.1	7	10	0	0	0	0
4	5	6.5	5	7.1	0	0	0	0
5	8	10.4	8	11.4	0	0	0	0
6	9	11.7	8	11.4	0	0	1	**33.3**
7	11	14.3	9	12.9	1	25	1	**33.3**
Total	77	100	70	100	4	100	3	100

Table 6.21: Percentages of Q.6B Statements from the Local Authorities towards the disbelief of their Food Sampling Programmes to the Prevention of Food-borne Illness

Finally, Question Seven raised the important issue and the overall results were recorded in Table 6.22. While over three-quarters of the replies (78.5%) agreed that current system of food sampling could be improved upon, 14.5% disagreed with this statement, with 7% chose not to answer this question or had different opinions. When each national areas was examined individually, results from England and Wales and Northern Ireland were similar to the U.K. figures, but Scotland showed a different view. Apart from one undecided reply (5.6%) almost all Scottish returns (94.4%) indicated their belief that current system could be improved upon with virtually no disagreement to this question.

Again, comments on agreement or disagreement to Question Seven were examined, and the results were tabulated into several statements as listed below:

Statement	Agreement:
7A(0)	No comment
7A(1)	More time, staff and/or resources to allow more sampling to be undertaken
7A(2)	Better co-ordination on information and results
7A(3)	Better targeting and focussing on specific areas (eg. ready-made meals, problem areas, high risk premises, micro sampling)
7A(4)	More sampling and/or surveys at either local, regional or national level

7A(5)	Existing sampling programmes should be further developed and constantly reviewed; introduce new approach (eg. adopting shopping basket approach)
7A(6)	Incorporate sampling with other duties (eg. inspection)
7A(7)	Others

Statement	Disagreement:
7B(0)	No comment
7B(1)	Current situation is satisfactory
7B(2)	Resources constraints
7B(3)	Others

Table 6.23 indicated the percentages of 7A Statements of those who believed that existing system of food sampling could be improved upon. Nearly one-third of the local authorities in this category claimed that improvement of food sampling system would be achieved if more time, staff and/or resources were provided to allow more sampling to be undertaken (Statement 7A(1) - 31.9%). Again, results in England and Wales were very similar to the U.K. figures with the majority of count at Statement 7A(1), but Scotland and Northern Ireland had a more evenly distributed pattern of statement proportion.

In contrast, Table 6.24 recorded the proportion of 7B Statements which reflected those who did not believe that current food sampling system could be improved

upon. Majority of the local authorities had no further comments to support their choice (Statement 7B(0) - 44%), while others felt that either current situation was satisfactory (Statement 7B(1) - 16%) or resources constraints made improvement impossible (Statement 7B(2) - 16%). Individually, England and Wales showed very similar pattern as the U.K. percentages, but Scotland had no count on disagreement and only one count in Northern Ireland.

Question 7	Current System of Food Sampling could be Improved Upon							
	U.K.		**E&W**		**Scotland**		**N. Ireland**	
	Count	%	Count	%	Count	%	Count	%
Agree	135	**78.5**	111	**76.6**	17	**94.4**	7	**77.8**
Disagree	25	**14.5**	24	**16.6**	0	**0**	1	**11.1**
Others	12	**7**	10	**6.9**	1	**5.6**	1	**11.1**
Total	172	100	145	100	18	100	9	100

Table 6.22: Percentages of Local Authorities Agreement towards the Belief of Improvement of Current Food Sampling System

Statement 7A	Question 7A - Agree							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	15	11.1	10	9	4	**23.5**	1	14.3
1	43	**31.9**	41	**36.9**	1	5.9	1	14.3
2	13	9.6	9	8.1	3	17.7	1	14.3
3	15	11.1	12	10.8	2	11.8	1	14.3
4	9	6.7	6	5.4	2	11.8	1	14.3
5	17	12.6	15	13.5	2	11.8	0	0
6	5	3.7	4	3.6	1	5.9	0	0
7	18	13.3	14	12.6	2	11.8	2	**28.6**
Total	135	100	111	100	17	100	7	100

Table 6.23: Percentages of Q7A Statements of the Local Authorities towards the belief of Improvement of Current Food Sampling System

Statement 7B	Question 7B - Disagree							
	U.K.		E&W		Scotland		N. Ireland	
	Count	%	Count	%	Count	%	Count	%
0	11	**44.0**	10	**41.7**	0	0	1	**100**
1	4	16.0	4	16.7	0	0	0	0
2	4	16.0	4	16.7	0	0	0	0
3	6	24.0	6	25	0	0	0	0
Total	25	100	24	100	0	0	1	100

Table 6.24: Percentages of Q7B Statements of the Local Authorities towards the disbelief of Improvement of Current Food Sampling System

6.4 Discussion

Out of 439 questionnaires sent to the Environmental Health Departments within the U.K., a total of 172 returns was received. This was accounted to be 39.2% of the total population. In particular, more than half of the Scottish local authorities returned the questionnaires. According to Owen, a response rate of 20% of questionnaires returned without reminders is deemed marginally acceptable, while 40% can be considered as satisfactory (Owen 1986). However, a higher return rate should be targeted especially when statistical analysis is carried out on the results of the survey. Therefore based on the number of returns in this survey, the overall replies from the U.K. local Councils could be considered as the representative of the total population as a whole. Despite the achievement and advantage of postal enquiry, missing data due to non-response was a major source of error. It was very likely that a group who did not bother to return the questionnaire would differ in some important way from those who did take the time and trouble to fill it in. It might be possible that some Environmental Health Departments targeted their resources on other areas rather than on sampling and thus too embarrassed to reveal their sampling activities. Others might simply be too reluctant to complete and return the questionnaires.

Results from the questionnaire indicated clearly that monitoring, assessing and/or ensuring the safety, standards, quality and hygiene of foodstuffs was considered by the U.K. local authorities as the main aim of food sampling and subsequent analysis. Again, this was also proven through the Score Rating System. As a multi-functional

tool, food sampling also served for other purposes. This included other aims such as identification of problems or poor practices, participation of surveillance scheme, enforcement of legislation or used as an educational tool, etc.

In general, food samples are subjected to microbiological or chemical analysis in order to test for the quality or standards of foodstuffs within the batch. Results of analysis provide confirmation of either the presence of food contaminants (physical, chemical or microbiological) or contravention of food labelling and composition requirements. The decision for choosing any particular types of foodstuffs within the sampling programmes depended upon the criteria of food concerned or any specific issues targeted. It is important to note that U.K. local authority sampling arrangement differed nationally.

While all the Environmental Health Departments in U.K. local councils are responsible for food safety and hygiene issues, only those in Scotland and Northern Ireland also have the remit to cover food labelling and composition. In England and Wales, this task is dealt with by the Trading Standards Departments located at County Councils. Undoubtedly, this is a very important factor that influences local authorities' sampling regime. Due to this reason, over one-third of the replies indicated that sampling for chemical analysis was not available among their food safety activities. However, it was also recorded that some 31% of local authorities carried out chemical sampling mainly for the purpose of consumers' complaints or investigation of food poisoning incidents. Obviously, this was considered as reactive

sampling and was not included in the food programmes as part of routine sampling. Since Scotland and Northern Ireland have different local authority systems, the issue on chemical sampling in these countries was looked at separately. The majority of local authorities in both countries agreed that food products manufactured within local areas were the main criteria which determined the choice of foodstuffs aimed at chemical testing. Indeed, this is related to the recommendation from LACOTS on Home Authority Principle (MAFF, DH, SO and WO 1996).

In terms of microbiological examination, over 40% of local authorities suggested that selected pathogens or foodstuffs was the main criteria towards the choice in microbiological sampling programmes. It included food poisoning bacteria such as *E. coli*, *Salmonella spp.*, etc. or high risk food and food products manufactured or sold in problematic premises with history of contravention. This statement was also supported individually by all U.K. national areas. Also, a quarter of the replies agreed that other sampling programmes at national, regional or local levels had the influence on deciding the types of foodstuffs for microbiological food sampling. Local authorities are obliged to follow sampling programmes agreed in liaison group meetings, and these programmes often include sampling initiated at national or regional levels. Responsibility to comply with Official Control of Foodstuffs Directive exerts a lot of pressure both on central and local governments towards the submission of statistical returns. Local authorities must ensure that the sampling regimes reach a satisfactory level to show their competence in food safety enforcement. Under this arrangement, criteria for the type of foodstuffs aimed at

microbiological sampling were usually predetermined by European and national programmes, but this reflected the importance towards a co-ordinated approach in food sampling at central levels. On the other hand, Scotland and Northern Ireland disagreed that other sampling programmes would indeed affect their decision on microbiological sampling. In fact, no counts on this statement were recorded in Scotland and Northern Ireland but an indication of 33.1% in England and Wales. Such contrast emphasized the existence of free microbiological examination service provided by Public Health Laboratory Service (PHLS) to local authorities in England and Wales, while this service is not available in Scotland. English and Welsh Environmental Health Departments develop the protocols in association with their local Public Health Laboratories and local liaison groups and set up agreement with the laboratories on the quota of allocated samples for microbiological examination. Such programmes usually include criteria specified in other national or European sampling programmes (LACOTS, DH, MAFF, and EC) as well. However, Scottish local authorities do not receive the same treatment any more from the central government after 1994, and therefore the amount of samples examined will be directly related to the budget allowed. Under this circumstance, reduction on the number of samples is inevitable, and priorities will shift away from the participation of other sampling programmes when local issues have to be resolved.

Again, the comparison of total annual cost of food sampling and its analysis between England and Wales and Scotland further demonstrated the difference in expenditure on this particular area. While England and Wales had a mean value of approximately

£6,610 per local authority per year, the average figure in Scotland was actually over ten times the English and Welsh value. In fact, since the profile of sampling and analysis cost in England and Wales was incomplete, it was possible that its mean value might well be expected to go even lower, which meant that the difference between the comparison with Scotland would be even larger. The cost spent on chemical and microbiological testings in Scotland was examined separately, and statistical analysis suggested that 95% confidence limits for sample means on the chemical / microbiological ratio would fall between 2.53 and 6.20. Since the calculated mean based on 12 samples was 4.36 and this was merely an estimation of the true value, 95% confidence limits provided more information with a much better degree of certainty on where the true mean would lie. Undoubtedly, if the level of confidence were increased, the range would also be increased. The ratio indicated that resource spent on chemical sampling was between two to six times more than on microbiological sampling. This highlighted the difference in enforcement duties between U.K. national countries where food labelling and composition was also the interest of Scottish local authorities' food law enforcement activities.

Currently, central government measured local authorities' sampling performance based on population, and Environmental Health professionals suggested that it might well be more appropriate if the indicator aimed at the proportion of food premises instead. For this reason, a profile on the number of food premises within the U.K. local authorities was set up, and results indicated that over 60% of overall replies lie between 501-1500 food premises with only 18% of local councils had more than

2000 premises. Therefore, the majority of U.K. local authorities tended to have a relatively similar number of food premises within their catchment area. However, the financial arrangement on sampling and analysis cost directly controlled the number of samples taken. The variation of such cost against the number of premises located within each local authority boundary indicated that England and Wales had a ratio of £4.48/premises, while Scotland and N. Ireland had figures of £43.74/premises and £23.44/premises. Once again, the ratio in Scotland was nearly ten times the value in England and Wales, and this again reflected the higher expenditure of Scottish local authorities on food safety activities due to the absence of free scientific services.

Each year millions of pounds were spent on sampling and subsequent analysis which are usually undertaken by local authorities. The importance on the usefulness of analyses' results at all levels must not be overlooked, if so the purpose of sampling would be lost. In general, the view of Environmental Health Departments considering the usefulness of analyses' results at local level was diverse. It covered many aspects in similar proportions such as confirmation of food safety, identification of problems, compliance with legislation, comparison with other programmes, etc. However, among others almost one-fifth believed that these results were mainly used for educational and advisory purpose. As suggested by many EHOs through various interviews, prosecution is always the last resort in Environmental Health enforcement practice when dealing with problematic food premises, undoubtedly it would be advisable if sampling could be used as an educational tool to help assisting and improving the quality and standards of foodstuffs sold at these premises. But again

the effectiveness of analyses' results as an educational tool depends on the number and frequency of sampling for the detection of substandard foodstuffs. If the number of samples is not significant to the overall population, the probability of detecting any defective foodstuffs will be so low that this will simply become a 'hit or miss' type of sampling.

In terms of usefulness at national level, more than half of the replies suggested that result of analyses would contribute to national surveys or co-ordinated programmes. These surveys were usually initiated by LACOTS, PHLS, MAFF and DH. However, some local authorities expressed concerns that even though survey results were returned to the Environmental Health Departments, there had been no information given towards future national strategy on food safety based on these results. Therefore, even though the majority of local authorities realised that results of analyses would feed back through these national bodies for correlation, actual use of these findings was not always known to them. When investigation was extended to the European level, understanding on the usefulness of sampling results by U.K. local authorities declined rapidly. In fact, nearly half of the local authorities did not know how these results would be used for in Europe. Also, one-fifth replied that the results would contribute to EU control programmes and surveys, but again there was no mention on how these results would be interpreted and used to make future plans. Obviously, U.K. local authorities did not receive such information from the European Commission despite the compulsory submission of statistical returns under

89/397/EEC and the participation of EU co-ordinated programmes. This again reflected the lack of feedback from the Commission to their Member States.

Theoretically one of the main objectives of routine food sampling is to detect any presence of contaminated foodstuffs before it is being sold to consumers which, if successfully achieved, will contribute significantly to the prevention of food poisoning incidents. In order to fulfil the objective, food sampling programme is normally devised and used as a toolkit to assist local authorities to plan their sampling efficiently and effectively. However, in reality, the food programme may not serve desirably for the purpose as expected due to many confounding factors such as financial limitation. But again each programme used among local authorities will be different, and therefore its effectiveness has to be measured individually. Results of this survey indicated that 45% of replies believed that their programmes contributed significantly to the prevention of food-borne illness, while almost equal number of returns opposed to this belief. Those who attested to their food programmes were convinced by past evidence that problems had been identified where areas of concern and deteriorating standards were highlighted which might have led to food-borne illness if not dealt with. Potential food-borne outbreak scenarios could have occurred if the sampling programmes were absent and no routine sampling was undertaken. Others believed that the programmes would help improving and maintaining standards and remedial work, and could also be used as an educational tool to offer advice to food handlers. On the other hand, different opinion was also expressed by some local authorities in the survey towards the

disagreement of their sampling programmes that would contribute significantly to the prevention of food-borne illness. Many considered that there was too little sampling done or the amount of food samples taken in relation to volume of product sold was not significant enough to create an accurate picture of the food quality. In fact, most sampling was 'snapshot' taken and was not considered to be representative. Also some programmes were not extensive enough to cover a wide range of food premises. For example, some local authorities only sampled at retail outlets but did not target catering premises at all. Others reported that most of their sampling results were satisfactory and no real local problems were identified.

In many occasions, it was reported in the survey that during the course of routine food sampling substandard foodstuffs were identified and food poisoning incidents were prevented. However, some local authorities in the survey debated that overall number of food samples taken was simply too small to be representative of the total food population, and any detection of substandard foodstuffs was purely by chance, and therefore it was no reason to believe that the sampling programmes would contribute significantly to the prevention of food-borne illness. This might also be the main reason why some local authorities did not discover any problems through routine sampling. By means of food hygiene inspections, Environmental Health Departments would gain knowledge on the standards of local food premises. The majority of sampling activities would be concentrated on problematic premises and therefore the likelihood of detecting contaminated foodstuffs would be increased. On the contrary, selective sampling also means that other food premises might easily be

overlooked and the original concept of random sampling will be lost. Also, other possible influences that would affect local authority decision towards the contribution of their food programmes were also investigated.

Although less than half of the replies agreed with the contribution of their existing food programmes, over three-quarters believed that current system of food sampling could be improved upon. Among this category, nearly one-third of the local authorities reflected the view that a wider variety of foodstuffs at more frequent intervals would be sampled if more time, staff and resources were provided. As suggested by the local councils through the results of the survey that food sampling is considered to be a time consuming activity, and many local Environmental Health Departments attempted to reduce the amount of routine sampling in order to push the officers' time to achieve minimum inspection frequency instead. Obviously, the lack of resources was the major constraints to local authorities' food sampling. This was also the reason why some local authorities did not believe that food sampling could be improved upon. Based on the current financial climate, this group was not convinced that improvement on resource implications would be achieved. Others believed that a more co-ordinated approach through food groups responding to EU/national surveys was the best way forward whilst retaining the resources to tackle local food issues. Establishment of regional and national databases would avoid any duplication of sampling. Further development and regular review of the existing food sampling programmes would help identify any loopholes for rectification, for example, bias towards chemical sampling. New techniques such as the shopping

basket approach or LACOTS' sampling-questionnaires combination approach would provide a detailed database for comparison.

6.5 Conclusion

As supported by the majority of returns, it was concluded that the main aim of food sampling was to ensure that local-produced foods meet the required safety and standard level and would not cause any ill health. Based on this concept, sampling programmes were devised in order to fulfil this main aim. Due to the difference in local authority enforcement and financial arrangement, criteria of choosing samples for chemical and microbiological testing varied according to national boundaries. Obviously, the degree of food products manufactured or produced locally will be different among local areas. It is important that the types and frequency of foodstuffs included in each local authority sampling programmes must also be relevant to their own needs. Priority of European and national programmes often dictated which food will be sampled, and many local authorities expressed concerns to the appropriateness of these programmes. In particular, the participation of these programmes usually resulted with minimal feedback. Under this arrangement, the usefulness of this work is not always clear to local authorities towards the fulfilment of their aim.

Nowadays, food sampling does not only apply to end product testing, but it is also used as a tool for verification of HACCP systems. Clearly, end product testing is one

good way of preventing the occurrence of food poisoning incidents, and many local authorities had experienced successes of detecting substandard foodstuffs by this means. However, the main question was also raised on the effectiveness of food sampling to the prevention of food-borne diseases. In the main, one of the most fundamental but crucial determinants that decides and controls the usefulness of food sampling programmes is sample size. Obviously, the larger the sample size, the more accurate the estimation of the food quality will be. But in reality, this would not always be possible simply because of the limitation in resources and manpower. In many cases, local authorities struggled with their limited budgets and food law enforcement often competed with other local authority responsibilities for funding (James 1997), arrangement for analytical service was another hindrance. Therefore, it is important that local authorities were able to determine appropriate sample size for their programmes that would both be cost beneficial and at the same time is representative to the product volume. It is supported by over three-quarters of the returns that food programmes could be improved upon. Statistical approach to food sampling is the way forward to help determining suitable and meaningful sample size.

Chapter 7

Statistical Approach to Food Sampling

Chapter 7. Statistical Approach to Food Sampling

7.1 Introduction

Much of the earlier discussion was focussed on the examination of co-ordination network effectiveness and implementation of sampling for chemical and microbiological testing particularly at local level. As part of the routine food surveillance activities, application of food sampling programmes helped local authorities to plan and determine the types and frequency of sampling carried out over a specified period. However, in regard to food sampling two fundamental questions are often raised by the Environmental Health Professionals:

- What should be the appropriate sample size?
- What conclusions can be drawn from the analytical results?

To decide a representative sample from the food population within a limited budget and resources is an extremely difficult task faced by many local authorities. Coupled with the financial constraint is the lack of scientific evidence concerning many types of food contaminants. In particular, concentration of pathogens in foodstuffs that would lead to food poisoning incidents is one of the most debatable topics within food safety enforcement aspects. Solutions to these problems involve application of statistical concepts of population probability and sampling as well as the importance of standards setting. Concern was expressed by the governmental bodies that the introduction of statistical analysis would simply entail substantially more sampling than is currently done, and hence more cost because of its emphasis on statistical quality. For this reason, this Chapter aimed at critically analysing the meaning and

interpretation of food sampling based on statistical approach in order to examine how the standards could be met. The objectives were to:

(1) Identify possible confounding factors that might hinder the application of statistical theory to food sampling;

(2) Investigate the aspects of uncertainty and variation in the context of sampling;

(3) Analyse the theory and application of probability and statistics for the determination of statistically validated sample size in different situation;

(4) Study the important aspect of standards setting in relation to food sampling;

(5) Examine the relationship between cost and benefit and its method of analysis in the process of sampling.

7.2 Uncertainty and Variation

Since it is not feasible and practical to examine an entire lot or batch of food, this is why sampling is required so that results of analyses from the portion of the lot represented by the sample are used to draw conclusions about the whole. Acceptability or rejection of the lot is normally based on the levels of food contaminants presented in the sample. In order to control the problem of food contamination, some set of agreed requirements are imposed on those responsible for the contamination of food product in an effort to limit its effects on some vulnerable subject group. Ideally, the intention is to produce some optimal balance between a relevant measure of benefit and an appropriate assessment of cost. Such requirements

range from self-generated specifications by commercial organisations in support of their quality assurance regimes, to mandatory standards expressed in terms of some stated value that a contaminant level should not be exceeded and sanctions will be applied in the event of non-compliance. Selection of a standard, specification, or guideline for a particular application is a complicated process since great diversity exists among food products and operations by which they are processed and prepared.

Indeed, one of the crucial tasks is to determine an appropriate sample size which would be representative of the whole population. Application of statistical concepts indicated that there is an intimate relationship between the determination of sample size and standards setting (Barnett and O'Hagan 1997). Degree of leniency / stringency in standards setting is a major factor governing the design of sample size in statistical sampling programmes. Setting a standard is clearly a matter of understanding the effects of the contaminant in the subject. This understanding is often based merely on extrapolation of broad scientific results. In an extreme, for example, if a standard was set to an exceedingly stringent level that there was only a very little chance of meeting the requirement, then no matter how many samples were taken, the final result would be unlikely to comply with the requirement. On the contrary, an over-lenient standard would simply mean that almost every sample procured would be likely to pass the test. In both cases, sampling would become meaningless. Thus it is essential to understand both real-world effects of food contaminants and on the design of food sampling in order to determine how to set standards for control.

Unfortunately, it is inevitable that such real-world effects operate in various forms of uncertainty and variability that are often unpredictable in their behaviours and required to be expressed in terms of appropriate ways of defining and measuring uncertainty and variation. For example, the effect of a contaminant on a subject will vary for a number of reasons:

- Observation or measurement errors - inaccuracies in the measurement or observation process;
- Spatial or temporal effects - effects are not constant over space or time;
- Natural variability - intrinsic differences between one individual and another in their reactions to the contaminant stimulus (Barnett and O'Hagan 1997).

To understand relationships between a contaminant and the subject group in the face of such forms of uncertainty and variation requires probabilistic assessment of levels of uncertainty and statistical methods to infer and explain the relationships. In terms of microbiological contaminants, choice of sampling plan for a particular food or related product will depend on how well the microbiology of that food is understood.

7.2.1 Food Contaminant and Effect on Subject Group

In terms of effect on the subject group, the consequences of any particular level of food contaminant in the medium are inherently uncertain. Firstly, such uncertainty is mainly due to the limited scientific understanding of the mechanisms by which the food contaminant influences the effect. Also, there is uncertainty due to random

variation existed in several ways. There is natural variation between individuals in the subject groups in terms of their reaction to a given exposure to the contaminant. For example, if the concentration of *Staphylococcus aureus* exceeds 10,000 colony forming unit per gram in ready-to-eat food, then according to PHLS guidelines it is regarded as potentially hazardous and is very likely to cause food poisoning if consumed (Roberts, Hooper & Greenwood 1995). But the defence mechanism varies among each individual's immune system (Fox 1990) and therefore the likelihood of this enterotoxin selecting pathogen to cause food poisoning to every exposed individual also varies.

There is also variation in the levels of exposure that individuals in the subject group will receive. It is inevitable that such inherent randomness exists in a way that food contaminant may not spread evenly throughout the medium. One good example is the growth of *Listeria monocytogenes* in cheese (Ahmed and Steenson 1996). This pathogen multiplies inside 'pockets' and therefore it is difficult to determine whether the growth of this organism distributes uniformly throughout the cheese or not. Also, even if the dose of contaminant causing food poisoning were assumed to be known, the actual portion size (mass) of contaminated foodstuffs consumed by the individuals causing illness would be arduous to measure. Furthermore, to quantify the effect each individual will have to be measured, and there will add further uncertainty and variation introduced by any imprecision in the measurement process. This can be exemplified by chronic exposure to chemical contaminants by means of ingesting contaminated food and the long-term causes and health effects will be difficult to prove and measure.

7.2.2 Sample Variation and Uncertainty

In order to investigate the quality of the food lot (population), it is necessary to draw samples and test for compliance. However, concentrations of the contaminant will vary in time and throughout the medium at any location. Inevitably this leads to sample variation. Also, due to the ability of micro-organisms to grow and multiply rapidly when conditions of the environment become optimal, and so temperature is another crucial element added to this variation. Results of analyses by means of sample statistic are also influenced by sample size. Obviously, a relatively larger sample size is more likely to yield better results. For example, the calculated sample average is expected to be closer to the population mean if a larger sample size is chosen. In reality, even when the results of sampling is known in terms of relevant sample statistic, the true level of food contaminant at any given location will not be known. Such uncertainty is amplified by this variability within the standard. In other word, when the standard is set on the contaminant level and compliance test is carried out with that standard by reference to a sample statistic, then even if the test is passed the true contaminant level could be beyond the limit imposed by the standard. Therefore, variability exists not just within the standard but also beyond it.

As decision of acceptance is often based on the results of analyses, getting a true representative sample is by far one of the most important but difficult part of food sampling. Inevitably, there is uncertainty on the actual practice of choosing a representative sample. This is illustrated by a simple example shown in Figure 7.1.

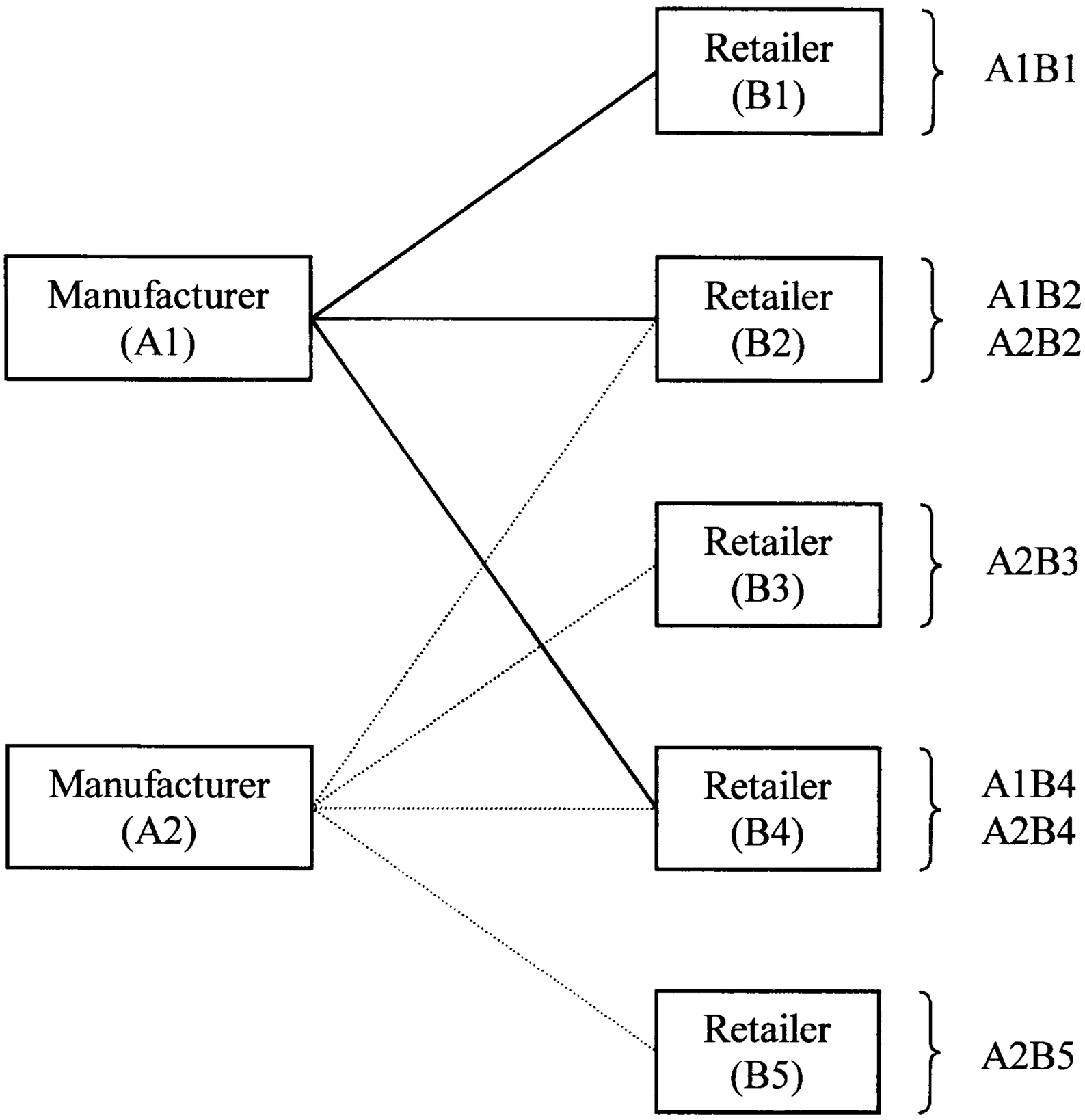


Figure 7.1: A Simple Food Products Distribution Model between a Manufacturer-Retailer Network

Assumed that there were two major food manufacturers (A1 and A2) located in one local authority area which supplied a single type of food product (Example: mince meat) to the local retailers. Manufacturer A1 supplied its product to Retailers B1, B2 and B4, while Manufacturer A2 supplied its product to Retailers B2, B3, B4 and B5. It was also assumed that there was only one type of stable food contaminant present in this food product. When Environmental Health Officers carried out routine food sampling activity at retail level, a total of seven possible samples could be taken from these five retail shops. However, in reality, this might only be five possible samples

because both Retailers B2 and B4 obtained the same type of product separately from Manufacturers A1 and A2, and this is possible that sampling officers would simply treat these two individual products as a single generic type. Within the choice of five product samples, there were four combinations:

Combination	Outcomes	A1	A2
1	A1B1, A1B2, A2B3, A1B4, A2B5	3	2
2	A1B1, A1B2, A2B3, A2B4, A2B5	2	3
3	A1B1, A2B2, A2B3, A1B4, A2B5	2	3
4	A1B1, A2B2, A2B3, A2B4, A2B5	1	4

If one sample was taken from each of the five retail shops, it would simply be perceived as five individual samples. However, it is important to note that these samples were originated from either Manufacturers A1 or A2. Assuming that the place of production of these food products was known, then indeed, in a statistical mind, it should not be counted as five samples but rather two samples instead. It was because the samples taken from the retailer shops would be exactly the same as those taken either from Manufacturers A1 or A2. Combination 1-4 indicated the frequency of sample duplication originated from either Manufacturer A1 or A2.

It is illustrated through this simple model the existence of uncertainty of obtaining a representative sample due to the uncertainty about the place of origin of the samples. In an instance when samples of Combination 4 were selected, then four out of five samples would actually be produced from Manufacturer A2. Unsurprisingly, results

of analyses would simply bias towards the produce from this manufacturer, and these samples would not be a good representative of the population. Also when sampling was extended to the production level, samples taken from the Manufacturers A1 and A2 would be identical to those taken from Retailers B1-B5. In many cases, these samples would be mistaken, treated and recorded as individual samples whilst the truth was simply a matter of unintentional sample duplication. This argument only holds when food contaminant is stable and stay unchanged in the medium at any location. When food contaminant was microbiological in nature, variation in time and temperature might lead to bacterial multiplication at point of sale. In such case, it might be inappropriate to consider that samples from both production and retail levels be treated the same due to the possibility of variation in microbiological quality for human consumption. Overall, sample variation is complicated by the uncertainty of obtaining a true representative sample from the lot. Measurement error further compounds these uncertainties.

7.2.3 Other Causes of Uncertainty and Variability

In addition to the uncertainty and variation which exists among samples and over the way food contaminant influences the effect, often the effect will have other causes in which no control is exerted. Even if it is effective in reducing changes in the effect due to the contaminant, adverse changes may arise from many other causes. For example, a renewal licence has been issued jointly to Isotron PLC, Swindon to irradiate herbs and spices. Food irradiation has the potential to offer benefits in reducing the risk from harmful micro-organisms such as *Salmonella*, while helping

to prevent food spoilage and waste (MAFF 1998). The reactive ions produced in food by irradiation injure or destroy micro-organisms immediately by changing the structure of cell membranes and affecting metabolic enzyme activity. A more important effect is the disruption of DNA and RNA molecules in cell nuclei where the DNA double-helix fails to unwind and the micro-organisms cannot reproduce by cell division (Fellows 1988). In general, the smaller and simpler the organism, the higher the dose of radiation that is needed to destroy it. Irradiation doses up to the overall average maximum dose of 10 kGy is permitted in the U.K., and this dose of radiation will only have pasteurising effect on food where most vegetative cells of pathogenic organisms will be destroyed but not spores (Hobbs & Roberts 1997). However, if food irradiation were applied to heavily contaminated foodstuffs, even though the average maximum dose would successfully destroy both spoilage and pathogenic micro-organisms, the spores would not be killed. In such case, not only a valuable indicator of unwholesomeness was removed, it would be possible that a change of microflora in food might allow spores to germinate and multiply rapidly when the conditions became favourable. Also, the destruction of toxin-producing bacteria after food has been contaminated with toxins is indeed a health hazard since toxins are most resistant to be denatured.

7.3 Representation of Uncertainty

As the uncertainties were recognised, and then it is important to introduce representation of uncertainty in a formalised expression, which normally involves the notions of chance, randomness, risk, hazard and unpredictability. The concept of probability formed the basis for expressing uncertainty and also as the basis on which statistical methods for analysing sample data have been developed. In the face of uncertainty and variation, the application of statistical models and methods helps to stretch understanding through ambiguity, and to derive cost-effective and defensible actions in such circumstances. Also, in order to understand the principles of sampling, it is absolutely necessary to understand the meaning and theory of probability.

7.3.1 Probability

Probability is a measure associated with an event A based on the information B, denoted by $P(A \mid B)$ but generally abbreviated to $P(A)$, which takes a value such that $0 \leq P(A) \leq 1$. It is the quantitative expression of the chance that an event will occur (Everitt 1999).

There are generally three approaches to probability:-

(i) A priori approach;

(ii) Empirical approach;

(iii) Subjective approach (Owen & Jones 1986).

For the purpose of this research, majority of the applications is based on a priori and empirical approaches to probability. In a priori approach, it is assumed that both the possible outcomes of a test and the weight of probability of each outcome in proportion to its likelihood are known before the test is performed. In the case of empirical approach, it is the approach where estimation of probability is feasible only if sampling is undertaken.

7.3.2 Probability Distribution

In many cases, estimation of probability only concerns a single event, but representation of uncertainty is more often required concerning the value of an uncertain quantity (or variable). Probability can also be used to estimate for all values in the feasible range. Since the relative frequency distribution of a variable gives the possible values of the variable and the proportion of times each value occurs, so when the estimation of probability is plotted against the value of each variable will produce the probability distribution (Weiss 1999). In other word, probability distribution can be expressed as:

- In a discrete random variable - a mathematical formula that gives the probability of each value of the variable (Example: Binomial distribution and Poisson distribution),
- In a continuous random variable - a curve described by a mathematical formula which specifies, by way of areas under the curve, the probability that the variable falls within a particular interval (Example: Normal distribution and Exponential distribution) (Everitt 1999).

7.3.3 Binomial Distribution

Binomial distribution, also known as Bernoulli distribution, is the most important and most widely used discrete probability distribution. It is the simplest way to classify a population with or without a certain property (attribute). The distribution of the number of 'successes', X, in a series of n-independent Bernoulli trials where the probability of success at each trial is p and the probability of failure is $q = 1 - p$ (Everitt 1999). A simple formula can be used to obtain binomial probabilities:

$$\mathrm{P}(X = r) = \frac{n!}{r!(n-r)!}\, p^r\, (1-p)^{n-r}, \qquad r = 0, 1, 2, \ldots\ldots, n$$

where X denotes the total number of successes in n Bernoulli trials with success probability p. Respectively, the mean and standard deviation of a binomial random variable with parameters n and p can be calculated to be:

$$\text{Mean } \mu = n\,p$$

$$\text{Standard Deviation } \sigma = \sqrt{n\,p\,(1-p)}$$

In a large finite population that has a specified attribute, it is usually impractical and often impossible to determine the population proportion directly. Therefore, in practice, sampling is undertaken to estimate the population proportion based on the sample statistic. However, the exact probability distribution of X depends on whether the sampling is done with or without replacement. If sampling is done with replacement, then the sampling process constitutes Bernoulli trials, and the random variable X has the binomial distribution with parameters n (sample size) and p

(population proportion). In reality, sampling is commonly done without replacement. However, in practice, this can usually be approximated by binomial distribution. This is because there is little difference between sampling with and without replacement if sample size does not exceed 5% of the population size (Weiss 1999).

The application of Binomial distribution is well exemplified by the Two-Class Attributes Plan proposed by the International Commission on Microbiological Specifications for Foods (ICMSF). As described in Chapter Four, the decision-making process of a Two-Class Attributes Plan is defined by n and c (ICMSF 1986). Suppose the true probability of contaminated items in a food lot (p) was 20%, and a 2-Class Sampling Plan with $n = 10$ and $c = 2$ was applied. The probability of acceptance (P_a) would be 0.68. This meant that on 68 of every 100 occasions when a sample of several sample units was taken from a 20% defective lot, it was expected that two or fewer of the ten tests showing the presence of the organism and thus calling for acceptance; while on 32 of every 100 occasions there would be three or more positives, calling for non-acceptance. Figures 7.2 illustrated the probability distribution of one binomial distribution histograms of sample size 10 at various proportions (p).

On the other hand, Three-Class Attribute Plan was also recommended by ICMSF. This method yields additional quality information by identifying three categories of quality: good, marginal or bad (ICMSF 1986). In fact, 3-Class Attribute Plan is developed from Trinomial (or trivariate hypergeometric) Distribution (Bray, Lyon and Burr 1973), and it is defined by n, c_1 and c_2; and the lot quality is defined by any

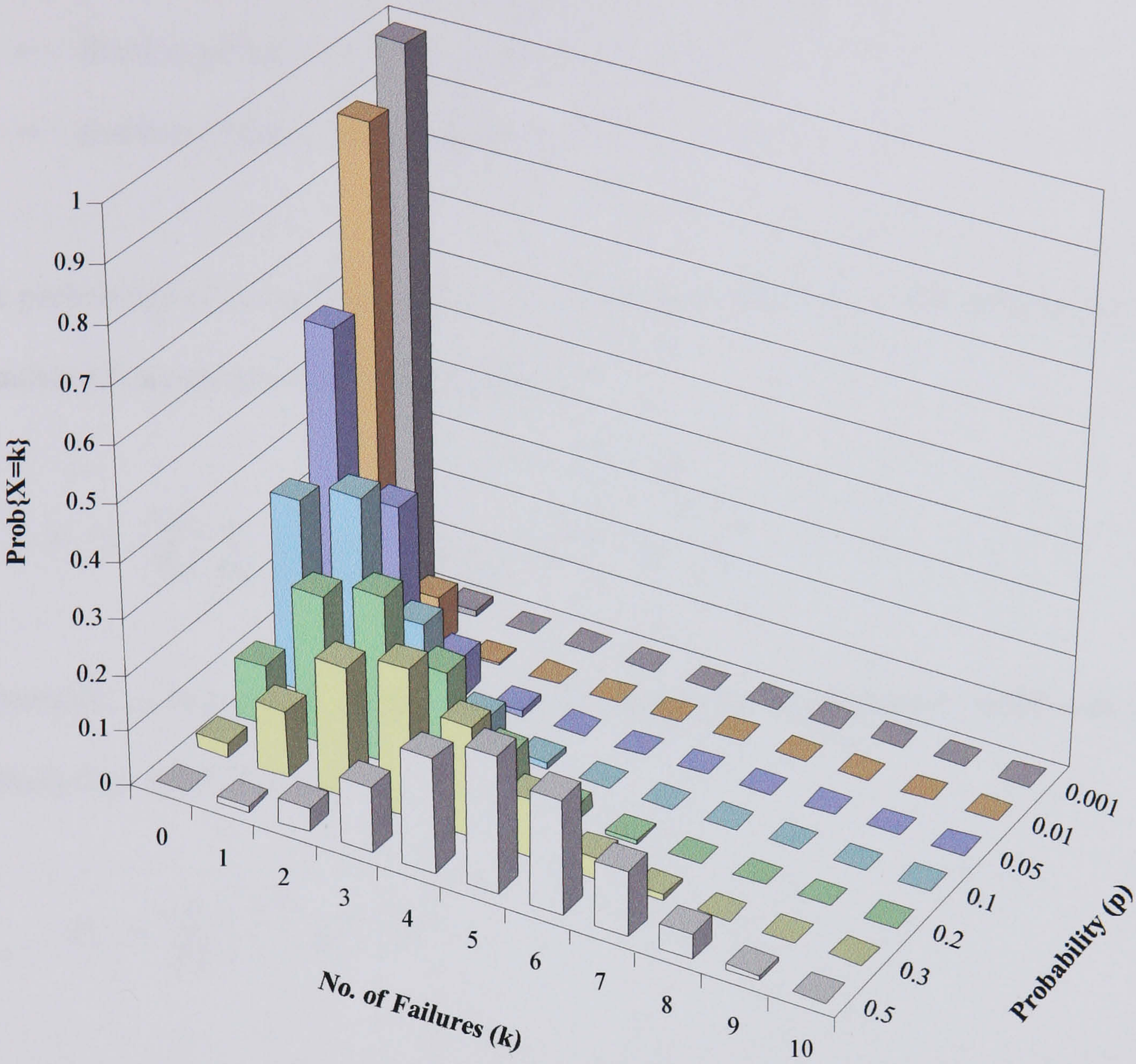


Figure 7.2: Probability Distributions of Binomial Histograms at various sample proportion (p) when sample size $n = 10$

c_1 = maximum allowable number for the sum of marginal quality and bad quality items in the sample

c_2 = maximum allowable number of bad quality items in the sample

p_0 = fraction of items of good quality in the lot = $1 - p_1 - p_2$

p_1 = fraction of items of marginal quality in the lot

p_2 = fraction of items of bad quality in the lot

The probability of acceptance (P_a) of the food lot on the basis of the sample can be calculated from the equation shown below:

$$P_a = \sum_{i=0}^{c_1 - j} \sum_{j=0}^{c_2} \frac{n!}{i!\ j!\ (n-i-j)!}\ p_0^{\,n-i-j}\ p_1^{\,i}\ p_2^{\,j}$$

In practice, c_2 is often set at zero (i.e. no allowance for any defective units) and the formula then simplifies to:

$$P_a = \sum_{i=0}^{c} \binom{n}{i}\ p_0^{\,n-i}\ p_1^{\,i}$$

This partial sum is of exactly the same form as that for a binomial distribution, but it is not in general binomial because $p_0 + p_1$ is not generally unity. For example, a food lot had 20% marginal quality (p_1) & 10% defective quality (p_2), and when a 3-Class Sampling Plan with $n = 10$ and $c = 2$ was applied, the probability of acceptance (P_a) would be 0.21. On the basis of the particular values decided upon for m and M, only 21 lots out of 100 of that quality will be accepted, because these lots have no defective counts and two or fewer marginally acceptable counts out of the 10 samples chosen from the lot. The other lots will all be rejected.

7.3.4 Normal Distribution

Normal distribution is the most important continuous probability distribution in statistics which is frequently applied to make statistical inferences such as estimating parameters and conducting hypothesis tests. For a normally distributed variable, the percentage of all possible observations that lie within any specified range equals the corresponding area under its associated normal curve. This statement is also true approximately for a variable that is approximately normally distributed (Freedman, Pisani and Purves 1998). When sample units of a sample are taken, then decision has to be made as to whether a variable is normally distributed, or at least approximately normally distributed. Normality can be assessed by means of normal probability plot. Linear relationship between normal scores against observed values indicated the variable is normally distributed.

Both binomial and normal distributions are considered to be the most important types of probability distributions used to express random variables. In many occasions, measurement of uncertain variables in the work of food sampling is based on representation of binomial distribution. However, if the sample size is large, normal distribution can be used as an approximation to the binomial distribution. Statisticians consider that a large sample is a sample which has more than thirty items (Owen & Jones 1986).

7.4 Statistical Sampling Theory and Inferences

The concept of sampling is central to the study of statistics, and the main reason of food sampling is to try to learn something about the population from which the sample was drawn. Obviously, the sample taken is likely to form only a fraction of the population, and any conclusion drawn about the population is subject to error. In more complicated situations, bias has to be taken into account as well.

$$\text{Estimate} = \text{Parameter} + \text{Bias} + \text{Chance Error}$$

Bias is known as non-sampling error where it just simply means any kind of systemic error in an estimate (Freedman, Pisani and Purves 1998). On the other hand, chance error is often called sampling error where it is the error resulting from using a sample to estimate a population characteristic. Before attempting to quantify the scale of sampling errors, analysis will be limited in three ways: (i) it must be confined to large samples (i.e. $n \geq 30$), (ii) it must be confined to simple random samples, (iii) it must be confined to infinite or very large populations.

7.4.1 Sampling Distribution of the Mean and Proportion

In practice, the population (i.e. food lot) is usually very large and it is not feasible to obtain the sampling distribution of all sample means. Instead, this can be determined, or at least approximated, by means of mathematical formulae. Then the sampling distribution of the sample mean can be used to make inferences about a population mean based on the mean of a sample from the population. Due to the fact that

standard deviation of sample mean ($\sigma_{\bar{x}}$) determines the amount of sampling error to be expected when a population mean is estimated by a sample mean, it is often referred to as the standard error of the sample mean (*SE*). Therefore, the standard error of sample mean is:

$$SE \text{ for mean (with replacement)} = \sigma_{\bar{x}} = \frac{\sigma}{\sqrt{n}}$$

Even when sampling is done without replacement from a finite population, as long as sample size is 5% or less of the population size, approximation is acceptable. However, based on the important Central Limit Theorem, the variable $\bar{x}$ is approximately normally distributed regardless of the distribution of the variable under consideration as long as sample size is relatively large (i.e. $n \geq 30$). The approximation becomes better with increasing sample size. (Owen & Jones 1986).

In the situations when results of sample are presented in percentage form, then the sampling distribution of the proportion can be derived from the same way as the sampling distribution of the mean, since a proportion can always be regarded as a mean. The standard error of sample proportions is:

$$SE \text{ of the Proportions} = \sigma_{\hat{p}} = \sqrt{\frac{p(1-p)}{n}}$$

This is just like the standard error of sample mean where the larger the sample size (n) the smaller will be the standard error (Owen & Jones 1986).

7.4.2 Confidence Intervals for One Population Mean and Proportion

Due to the existence of sampling error, sample mean can not simply be expected to be the same as population mean, but merely a point estimate of μ based on the sample. Therefore, it is important to evaluate the accuracy of the estimate, and this is done by means of confidence-interval estimate for μ. Firstly, z-interval procedure is used when σ is known. The confidence intervals (C.I.) for the mean is:

$$100(1-\alpha)\%\ \text{C.I. for mean} = \bar{x} \pm z_{\alpha/2} \cdot \frac{\sigma}{\sqrt{n}}$$

where n is the sample size, and $\bar{x}$ is computed from the sample data. C.I. is exact for normal populations and is approximately correct for large samples from non-normal populations. Also, the z-interval procedure is robust to moderate violations of the normality assumption (Weiss 1999).

Secondly, t-interval procedure is used when σ is unknown. The confidence intervals for the mean is:

$$100(1-\alpha)\%\ \text{C.I. for mean}\ (\text{df}=n-1) = \bar{x} \pm t_{\alpha/2} \cdot \frac{s}{\sqrt{n}}$$

where n is the sample size, s is the sample standard deviation and df is the degree of freedom. Again, C.I. is exact for normal populations and is approximately correct for large samples from non-normal populations. The t-interval procedure is also robust to moderate violations of the normality assumption.

On the other hand, *z*-interval procedure is applied for obtaining C.I. for the population proportion. In this case, confidence intervals for population proportion is:

$$100(1-\alpha)\%\ \text{C.I. for proportion} \;=\; \hat{p} \pm z_{\alpha/2} \cdot \sqrt{\frac{\hat{p}(1-\hat{p})}{n}}$$

where n is the sample size and $\hat{p} = x / n$ is the sample proportion. In a situation where sample size is small and preliminary data analyses indicate either the presence of outliers or that the variable under consideration is far from normally distributed, then neither the *z*-interval procedure nor the *t*-interval procedure is appropriate. Instead, non-parametric method should be used (Weiss 1999).

7.4.3 Precision and Margin of Error

The confidence level $(1 - \alpha)$ of a confidence interval for a population mean (μ) indicates the confidence of the estimate in which μ actually lies in the confidence interval; and the length of the confidence interval indicates the precision of the estimate. Long confidence intervals signify poor precision, whereas short confidence intervals indicate good precision. For a fixed sample size, a decrease in confidence level (C.L.) yields a smaller *z*-score and leads to a decrease in length of the confidence interval, and therefore increases the precision, and vice-versa. However, a decrease in C.L. reduces the length of C.I. and increases the precision. In order to improve the precision, it is necessary to decrease the length of the confidence interval. However, if the precision is to be improved by reducing the length of confidence interval but without affecting the confidence level, this can be accomplished by decreasing the margin of error (E).

$$\text{Margin of Error, } E = z_{\alpha/2} \cdot \frac{\sigma}{\sqrt{n}}$$

Both σ and the z-score are fixed terms (as it is stated early that the confidence level should not be affected), this leaves the sample size, n, that can be varied. Therefore, by increasing n, E will be lowered.

In the case when dealing with sample proportion instead of sample mean, the margin of error in estimating a population proportion by a sample proportion is:

$$\text{Margin of Error, } E = z_{\alpha/2} \cdot \sqrt{\frac{\hat{p}\,(1 - \hat{p})}{n}}$$

Again, the margin of error is equal to half the length of the confidence interval. It represents the precision with which a sample proportion ($\hat{p}$) estimates the population proportion (p) at the specified confidence level.

7.4.4 Determination of Sample Size

One way of determining the required sample size is to first specify E and C.I. in advance so that the specifications can be met. The required sample size for a (1 - α)-level C.I. for mean with a specified E is:

$$\text{Required Sample Size, } n = \left(\frac{z_{\alpha/2} \cdot \sigma}{E} \right)^2$$

However, in practice, σ is usually unknown. In this case, s can be used as estimation in place of σ by taking a preliminary large sample (i.e. $n \geq 30$).

Similar analysis can be used to find the required sample size for sample proportion. The sample size required for a (1 - α)- level C.I. for population proportion (p) with a specified E is:

$$\text{Required Sample Size, } n = \hat{p}\ (1 - \hat{p}) \left(\frac{z_{\alpha/2}}{E} \right)^2$$

Again $\hat{p}$ exists as an unknown parameter. In practice, there are two ways to estimate $\hat{p}$. Firstly, since the largest possible value of $\hat{p}\ (1-\hat{p})$ is 0.25 when $\hat{p} = 0.5$, therefore the most conservative approach for determining n is to use that value in the above equation. Then a (1 - α)-level C.I. for p at most E can be obtained is:

$$\text{Required Sample Size, } n = 0.25 \left(\frac{z_{\alpha/2}}{E} \right)^2$$

On the other hand, because food sampling is time-consuming and expensive, it is usually best not to take a larger sample than necessary. If an educated guess ($\hat{p}_g$) for the observed value of $\hat{p}$ can be made, for example, from a previous study or theoretical considerations, then that guess can be used to obtain a more realistic sample size. In this case, the equation will be:

$$\text{Required Sample Size, } n = \hat{p}_g\ (1 - \hat{p}_g) \left(\frac{z_{\alpha/2}}{E} \right)^2$$

In real situation, the probability of some members in a population which possess a certain attribute (for example: level of pathogens above stated requirement) may be low, and there is a major concern when determining an appropriate n since E can be affected significantly by n. In order to further investigate the relationship between these two variables, graphs of E were plotted against n with various $\hat{p}$ based on 68%, 95% and 99.7% C.I. for population proportion. The variation of $\hat{p}$ and $\sqrt{\hat{p}\ (1-\hat{p})}$ of the standard errors indicated in Table 7.1 can be used as the generic values for the calculation of E under different n and z-scores. Since the application of normal approximation requires that sample size should be large (i.e. $n \geq 30$), therefore n were selected between 30 to 300 with sample proportions ($\hat{p}$) from 0.5 to 0.001 plotted on the same graph. Using the same procedure, three separate graphs were plotted with C.I. set at 68%, 95% and 99.7%. However, in order to ensure that normal approximation is reasonably good (i.e. near normal), there are certain criteria in which n should comply to. In fact, there are different opinions among statisticians regarding such criteria. Kottegoda and Rosso stated that for a large sample size of over 30 with both np and $n(1 - p)$ greater than 5, then sampling distribution is very

$\hat{p}$	$\sqrt{\hat{p}(1-\hat{p})}$	$\hat{p}$	$\sqrt{\hat{p}(1-\hat{p})}$
0.5	0.5	0.05	0.218
0.45	0.497	0.04	0.196
0.4	0.49	0.03	0.171
0.35	0.477	0.02	0.14
0.3	0.458	0.01	0.099
0.25	0.433	0.009	0.094
0.2	0.4	0.008	0.089
0.15	0.357	0.007	0.083
0.13	0.336	0.006	0.077
0.1	0.3	0.005	0.071
0.09	0.286	0.004	0.063
0.08	0.271	0.003	0.055
0.07	0.255	0.002	0.045
0.06	0.237	0.001	0.032

Table 7.1: The Variation of $\sqrt{\hat{p}(1-\hat{p})}$ and $\hat{p}$

nearly normal (Kottegoda & Rosso 1997). Weiss described a commonly-used rule of thumb for good normal approximation to be np and $n(1 - p)$ both greater or equal to 10. Another theory also mentioned by Weiss is the criterion which is $np(1 - p) \geq 25$ (Weiss 1999). Ross believed that normal approximation will be quite good for values of n satisfying $np(1 - p) \geq 10$ (Ross 1987). The four different criteria suggested were:

- Normal Approximation Criterion 1: $np(1 - p) \geq 25$
- Normal Approximation Criterion 2: $np(1 - p) \geq 10$
- Normal Approximation Criterion 3: $n\ (1 - p) \geq 10$
- Normal Approximation Criterion 4: $n\ (1 - p) > 5$

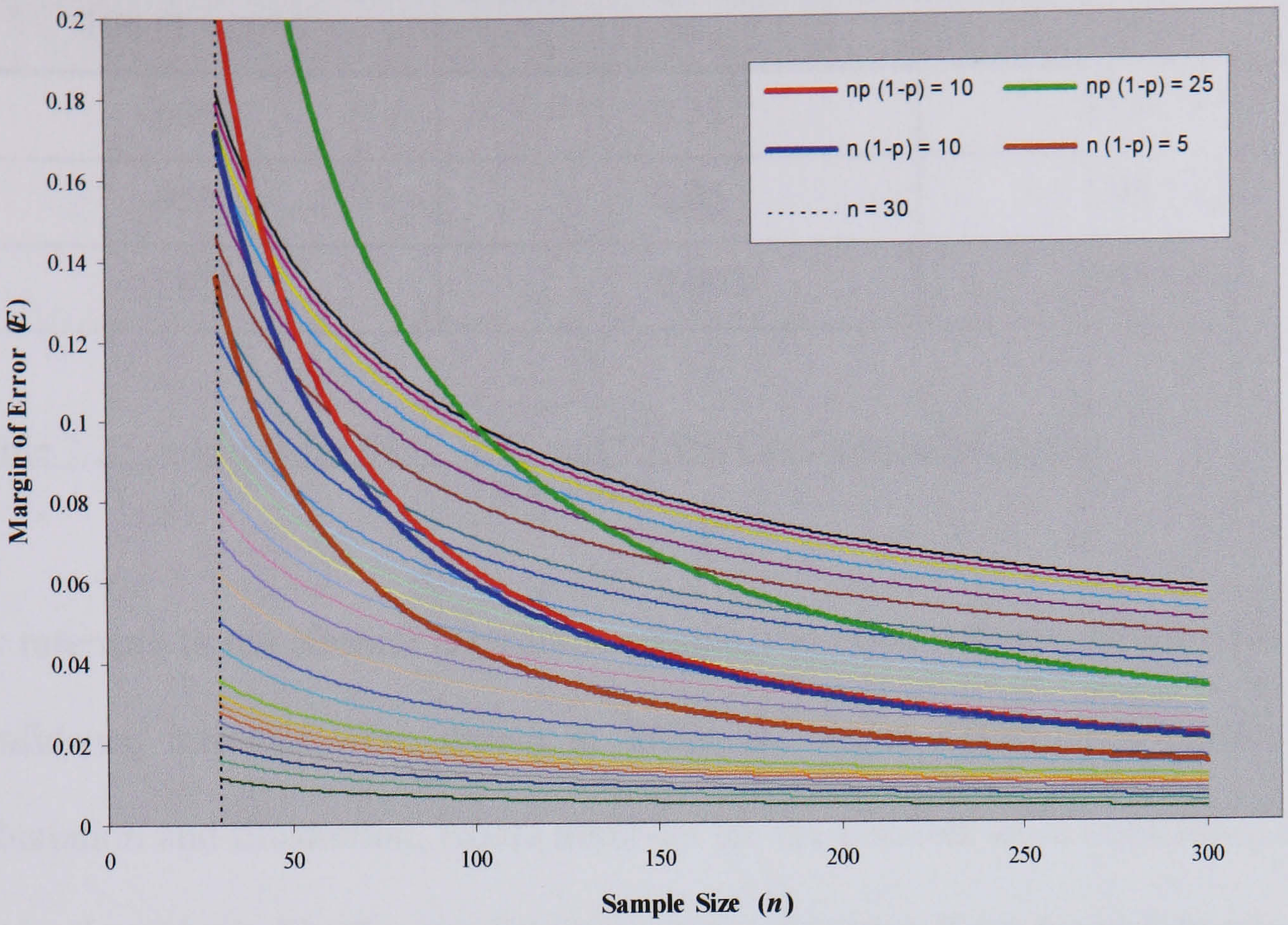
A simple analysis was carried out in order to distinguish and determine a suitable criterion that would be implemented for the purpose of this research. In Graph 7.1, margin of errors was plotted against sample sizes with different sample proportions based on 95% confidence interval equation. Overlapping the curves were the lines that indicated the boundaries of the four criteria. Graph 7.2 illustrated the areas of boundaries in which sample sizes chosen within each specific area would satisfy the criteria for near normality. It was clearly shown in Graph 7.2 that Criterion 1 tended to be more stringent (represented by green area: A), while Criterion 4 appeared to be more lenient (represented by all areas: A + B + C + D). In order to optimise the situation, Criterion 2: $np(1 - p) \geq 10$ (represented by green and red areas: A + B) was adopted for this research so that a reasonable area was chosen as the requirement for near normality.

Based on the requirement under Criterion 2, Graph 7.3 - 7.5 were plotted at different C.I.'s. The equation that satisfied good normal approximation was calculated using the method of simultaneous equations for Equations 1(a) and 1(b) as shown below:

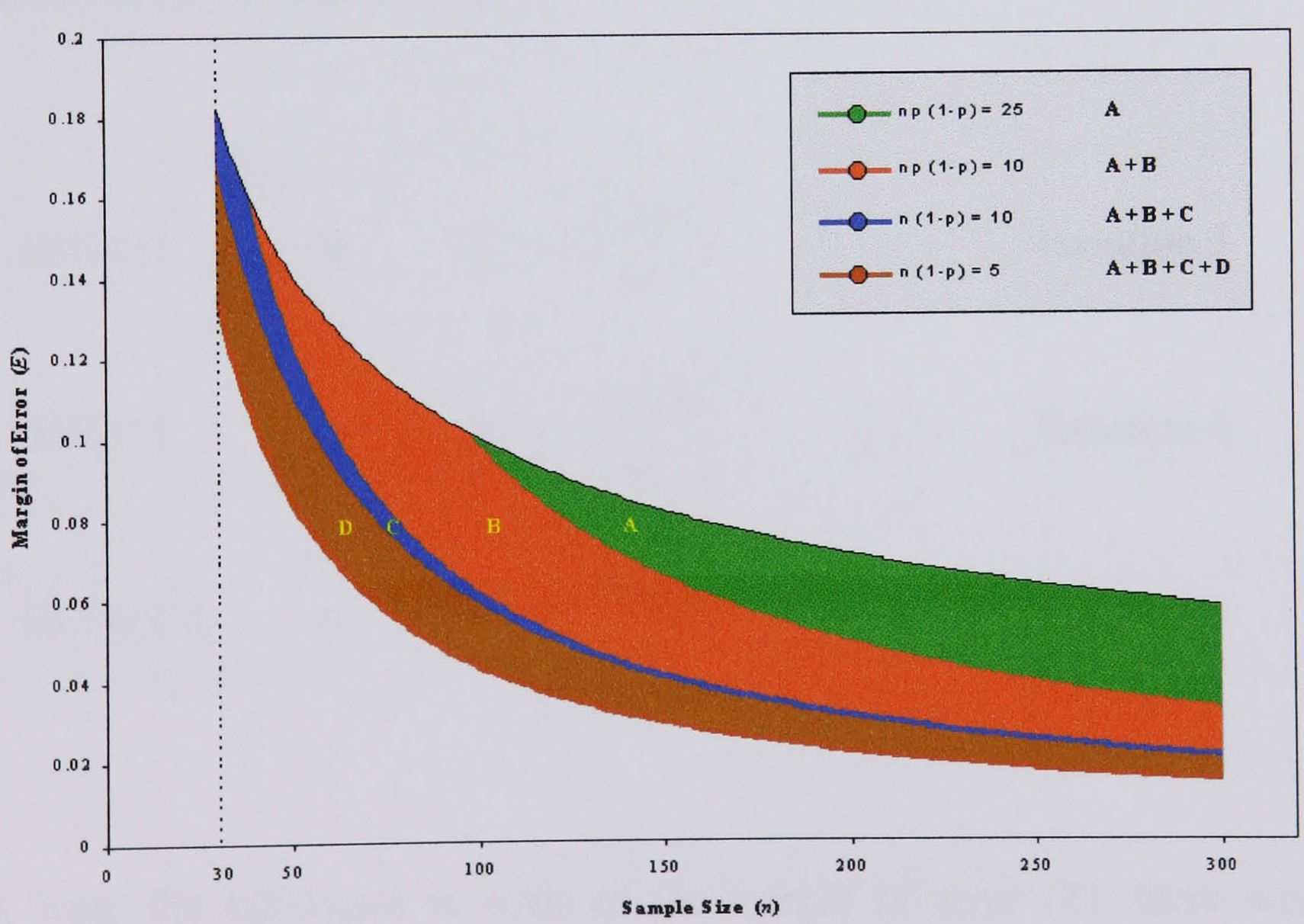
$$\Rightarrow \quad \begin{cases} E = z_{\alpha/2}\sqrt{\dfrac{p(1-p)}{n}} & \text{----- Equation 1(a)} \\ np(1-p) = 10 & \text{----- Equation 1(b)} \end{cases}$$

$$\Rightarrow \quad \frac{n E^2}{(z_{\alpha/2})^2} = \frac{10}{n}$$

$$\Rightarrow \quad E = \frac{\sqrt{10}\,(z_{\alpha/2})}{n} \qquad \text{----- Equation 2}$$



Graph 7.1: Indication of the lines of boundaries that satisfied the four criteria



Graph 7.2: Illustration of the areas of boundaries that satisfied the four criteria

100 (1 - α)%	α	$z_{\alpha/2}$
68%	0.32	0.99 (1)
95%	0.05	1.96 (2)
99.7%	0.003	2.97 (3)

Table 7.2: z-scores for 68%, 95% and 99.7% Confidence Intervals

By referring to the Normal Distribution Table, the exact *z*-scores for the above three confidence intervals were shown in Table 7.2 above. However, for the ease of calculation and illustration, whole numbers for the *z*-scores were used instead of the decimal numbers. Finally, substituting $z_{\alpha/2}$ into Equation 2 produced Equation 3 to 5 shown below. These equations were plotted in Graph 7.3 - 7.5 and compared. The sample sizes (n) satisfying good normal approximation for each confidence interval was enclosed in the shaded areas.

$$68\%\ \text{C.I.} \quad \Rightarrow \quad E = \frac{3.162}{n} \qquad \text{--------} \quad \text{Equation 3}$$

$$95\%\ \text{C.I.} \quad \Rightarrow \quad E = \frac{6.325}{n} \qquad \text{--------} \quad \text{Equation 4}$$

$$99.7\%\ \text{C.I.} \quad \Rightarrow \quad E = \frac{9.487}{n} \qquad \text{--------} \quad \text{Equation 5}$$

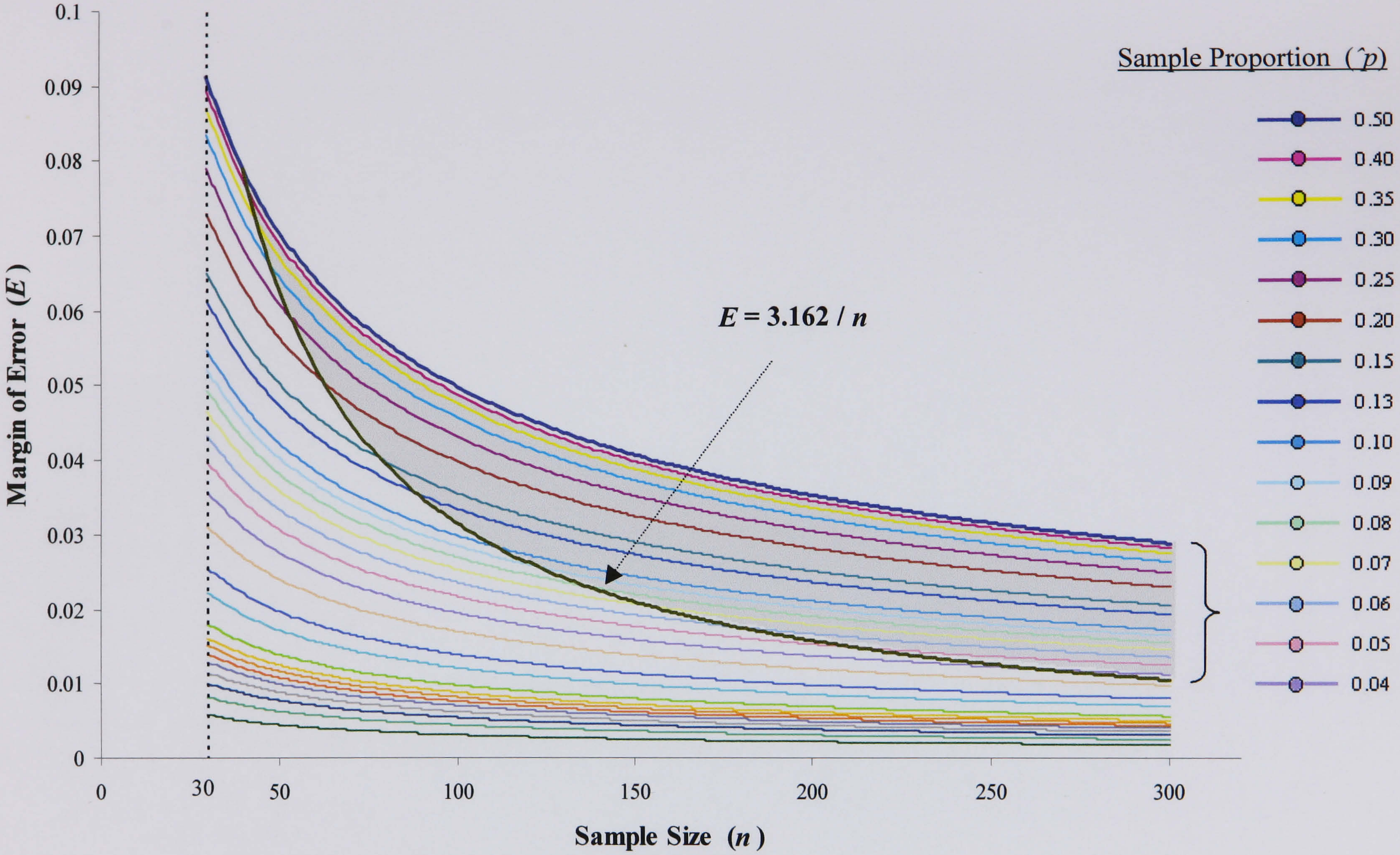
Apart from the difference in scale of the margin of error (E), there were many features in which all three graphs behaved in common. More lines with lower sample proportion ($\hat{p}$) were excluded from the shaded area when sample size (n) decreased.

This exclusion became more apparent when n was less than 100. For example, when n = 300, $\hat{p} < 0.04$ were excluded; when n = 200, $\hat{p} < 0.05$ were excluded; and when n = 100, $\hat{p} < 0.1$ were excluded. For those with relatively larger $\hat{p}$, the negative gradient was very steep when n < 50. For those with relatively smaller $\hat{p}$ and/or larger n, the gradient gradually dropped and approached zero gradient. Negative gradient reflected that smaller sample size (n) had greater margin of error (E); and a decrease in gradient occurred when n became larger, resulting with smaller E. Intersections between the line for good normal approximation and the curves of various sample proportions represented the minimum sample sizes to achieve good normal approximation. Co-ordinates of intersection points were obtained from Graph 7.3-7.5. Since standard error ($SE = \sqrt{[\, p\,(1-p) / n\,]}$) for all three curves was the same, the only difference was the z-score ($z_{\alpha/2}$) which represented the number of SE at different confidence levels. Therefore, margin of error (E) for 95% C.I. would be twice as much as 68% C.I., and E for 99.7% C.I. would be three times as much as 68% C.I. Table 7.3 indicated the minimum sample sizes and corresponding margin of errors for different C.I.'s.

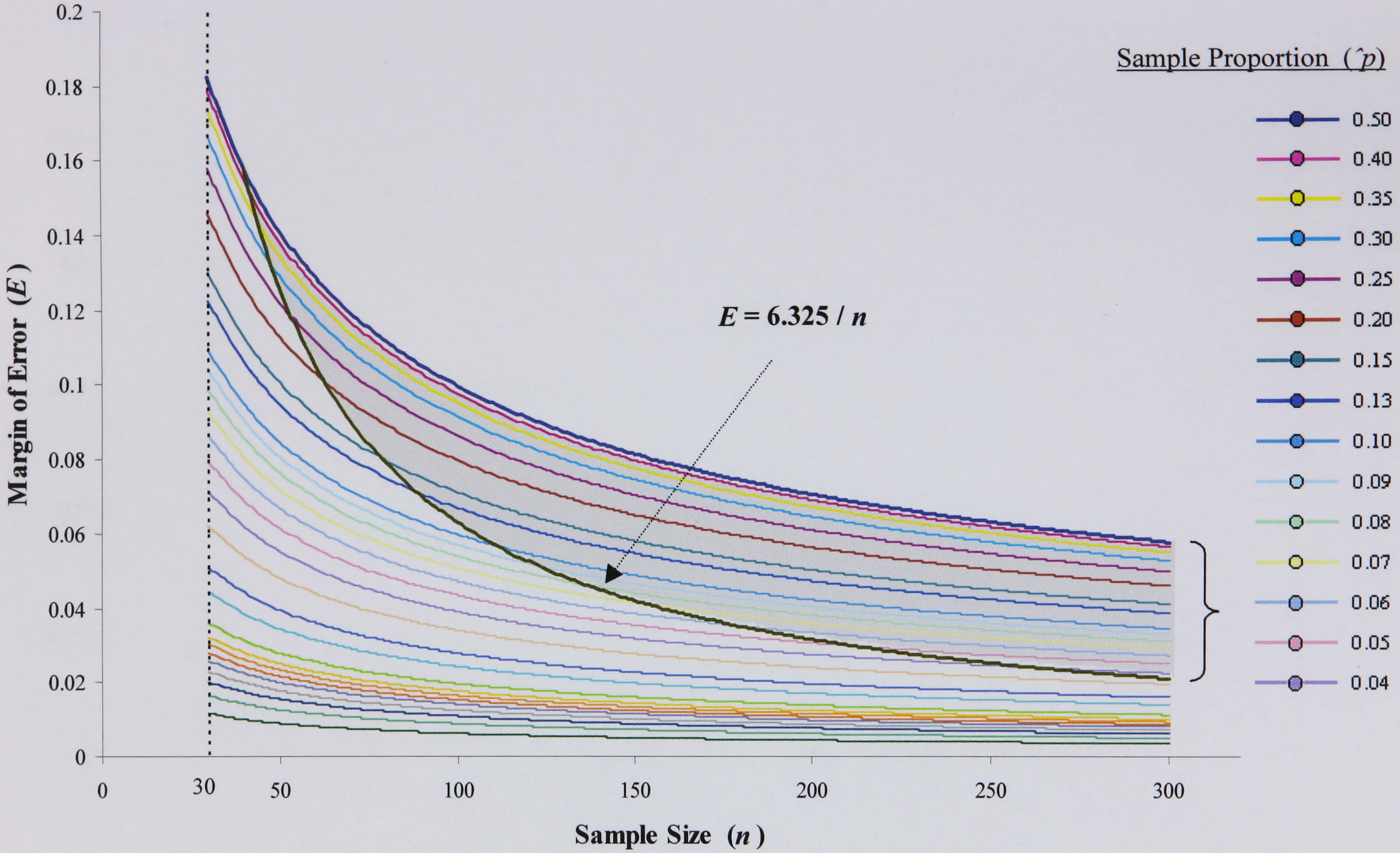
Taking 95% confidence level as a marker, the ratio of margin of error against sample proportion ($E/\hat{p}$) was shown in Table 7.4(a) in order to illustrate the scale of sampling error in comparison with its sample proportion under minimum sample size (n_{min}) for good normal approximation. To further illustrate the above relationship, n_{min} was doubled and a new set of E and corresponding $E/\hat{p}$ ratio were obtained in Table 7.4(b). The two sets of ratios were plotted against their sample proportions in Graph 7.6. Results from Graph 7.6 indicated that both lines were near linear, but the

line with a larger sample size had a lower $E/\hat{p}$ ratio and a smaller negative gradient than the other line.

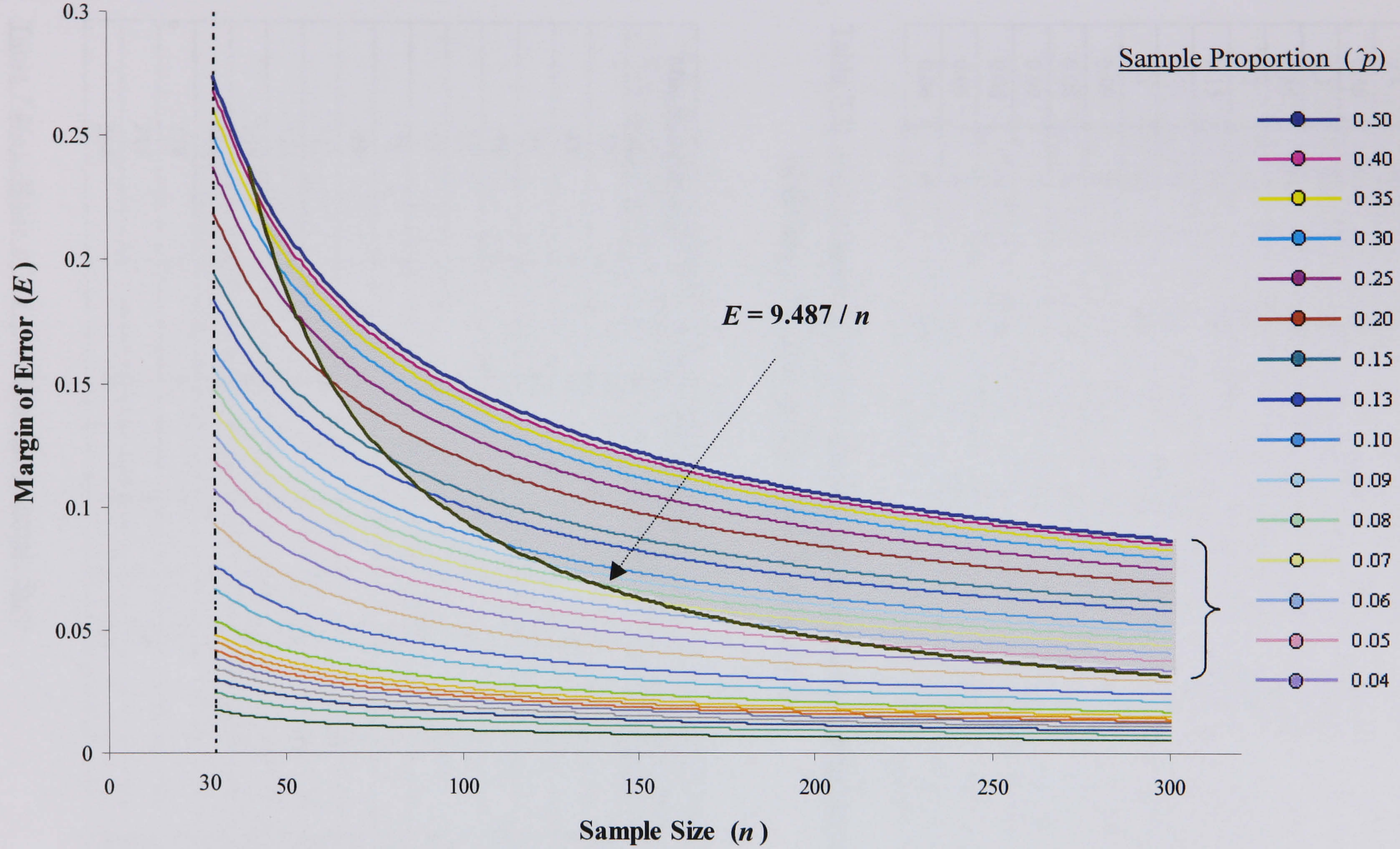
All three shaded areas each from Graph 7.3 – 7.5 were put together in Graph 7.7 and compared. Firstly, the blue area for 1 *SE* appeared to be the smallest, while the red area for 3 *SE* was the largest. Secondly, area for 2 *SE* overlapped area for 1 *SE* and was represented by the green shade; while area for 3 *SE* overlapped area for 2 *SE* and was represented by the brown area. There was no overlap between areas of 1 *SE* and 3 *SE*, but this might be possible when n became exceedingly large. Thirdly, area for 3 *SE* had larger values of margin of errors (E) with steeper negative gradient than the other two.



Graph 7.3: Illustration of Suitable Sample Size at 68% C.I. that satisfied Good Normal Approximation



Graph 7.4: Illustration of Suitable Sample Size at 95% C.I. that satisfied Good Normal Approximation



Graph 7.5: Illustration of Suitable Sample Size at 99.7% C.I. that satisfied Good Normal Approximation

Proportion ($\hat{p}$)		Min. Sample Size (n)	Margin of Error (E) (%)		
d.p.	%		68% C.L.	95% C.L.	99.7% C.L.
0.5	50	40	7.9	15.8	23.7
0.4	40	42	7.6	15.1	22.7
0.35	35	44	7.2	14.4	21.6
0.3	30	48	6.6	13.2	19.8
0.25	25	53	6.0	11.9	17.9
0.2	20	62	5.1	10.2	15.3
0.15	15	78	4.1	8.1	12.2
0.13	13	89	3.6	7.1	10.7
0.1	10	111	2.9	5.7	8.6
0.09	9	123	2.6	5.2	7.8
0.08	8	138	2.3	4.6	6.9
0.07	7	154	2.1	4.1	6.2
0.06	6	178	1.8	3.6	5.4
0.05	5	211	1.5	3.0	4.5
0.04	4	264	1.2	2.4	3.6

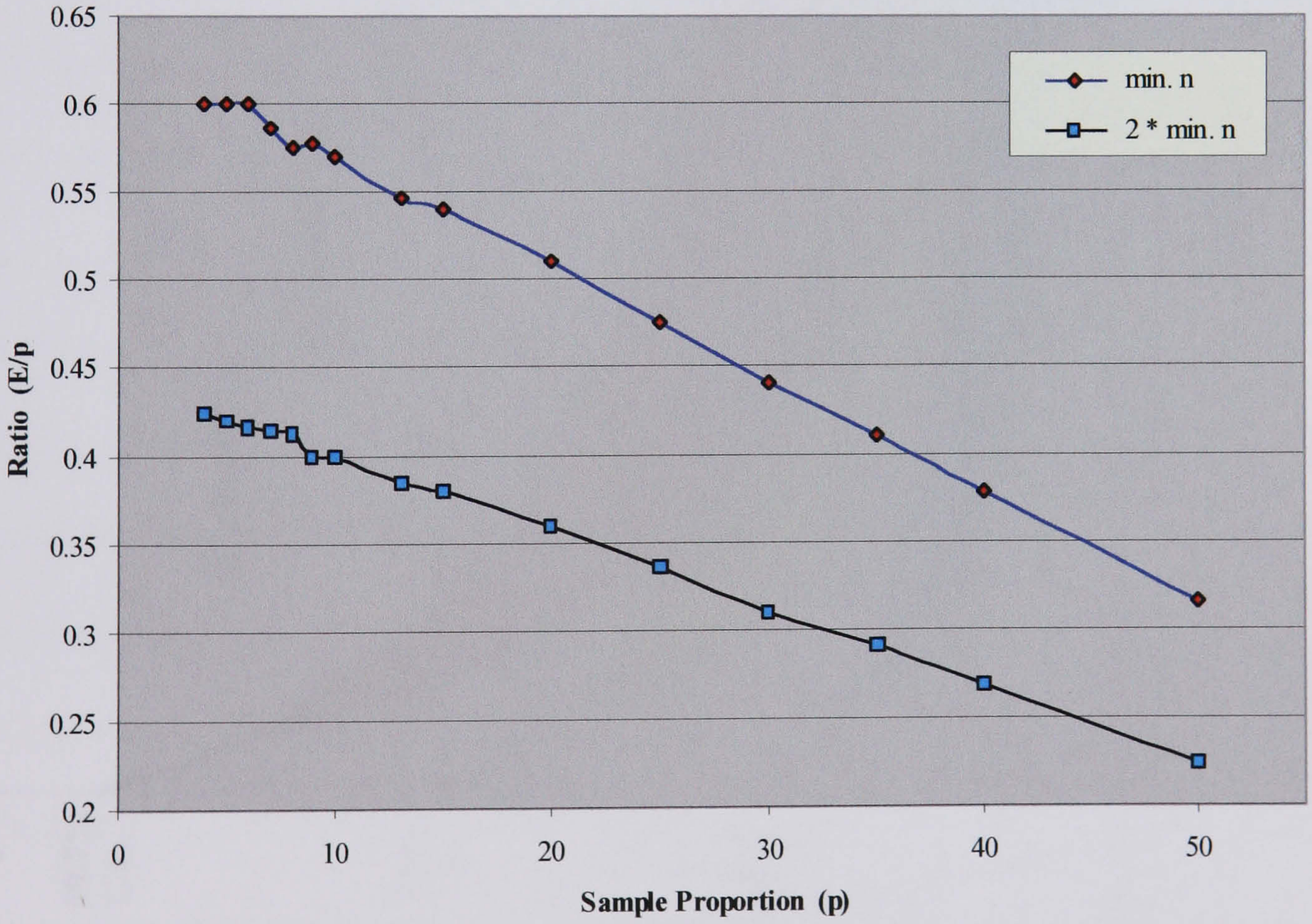
Table 7.3: Indication of minimum Sample Sizes and corresponding Margin of Errors of different C.I.'s for good Normal Approximation

Min. Sample Size (n_{min})	95% Confidence Intervals (%)		Ratio (E / $\hat{p}$)
	$\hat{p}$	Margin of Error (E)	
40	50	± 15.8	0.316
42	40	± 15.1	0.378
44	35	± 14.4	0.411
48	30	± 13.2	0.440
53	25	± 11.9	0.476
62	20	± 10.2	0.510
78	15	± 8.1	0.540
89	13	± 7.1	0.546
111	10	± 5.7	0.570
123	9	± 5.2	0.578
138	8	± 4.6	0.575
154	7	± 4.1	0.586
178	6	± 3.6	0.600
211	5	± 3.0	0.600
264	4	± 2.4	0.600

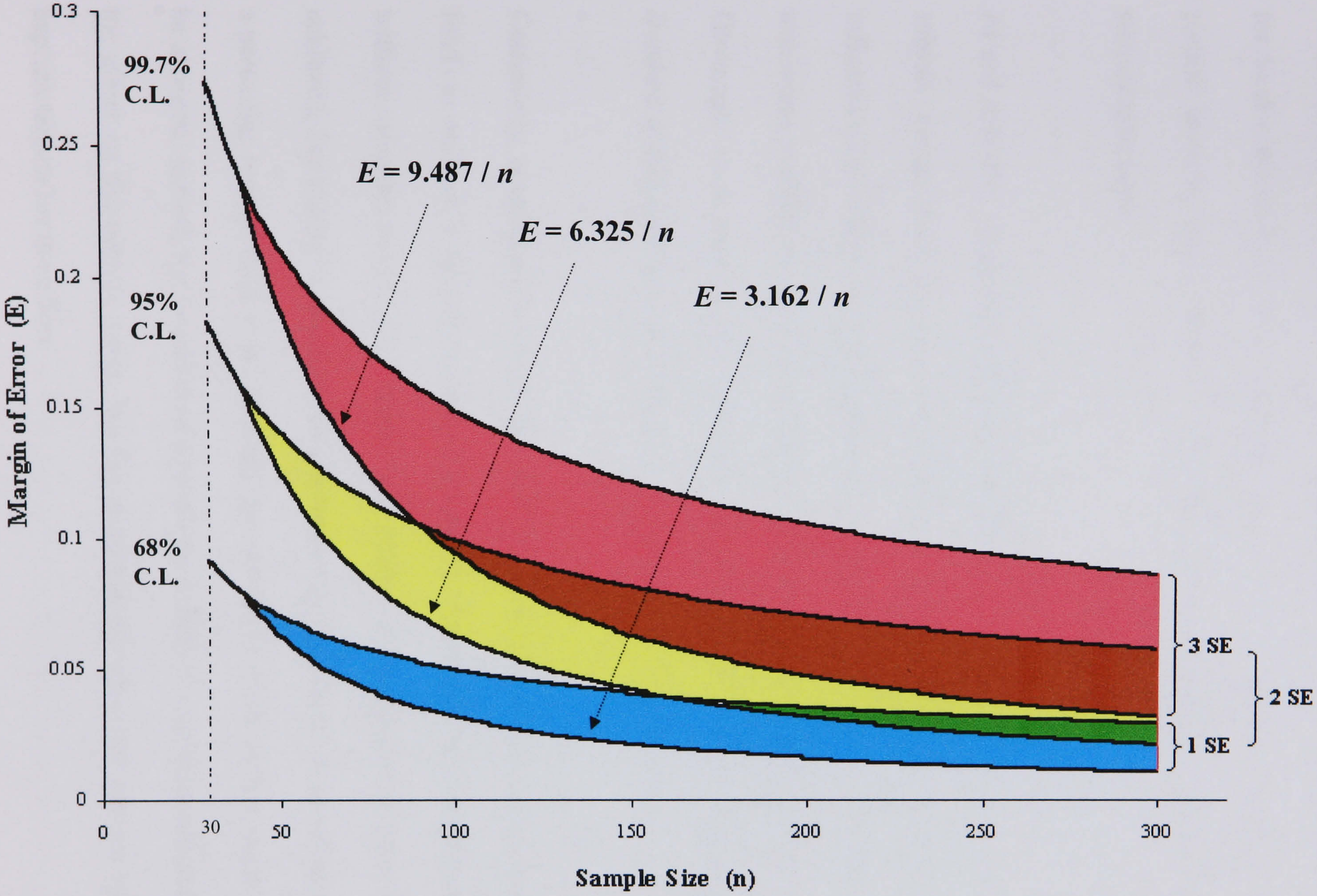
Table 7.4(a): Ratio of E / $\hat{p}$ at minimum Sample Size

$2 \times n_{min}$	95% Confidence Intervals (%)		Ratio (E / $\hat{p}$)
	$\hat{p}$	Margin of Error (E)	
80	50	± 11.2	0.224
84	40	± 10.7	0.268
88	35	± 10.2	0.291
96	30	± 9.3	0.310
106	25	± 8.4	0.336
124	20	± 7.2	0.360
156	15	± 5.7	0.380
178	13	± 5.0	0.385
222	10	± 4.0	0.400
246	9	± 3.6	0.400
276	8	± 3.3	0.413
308	7	± 2.9	0.414
356	6	± 2.5	0.417
422	5	± 2.1	0.420
528	4	± 1.7	0.425

Table 7.4(b): Ratio of E / $\hat{p}$ at 2 × minimum Sample Size



Graph 7.6: Comparison of E / $\hat{p}$ Ratio at different Sample Size



Graph 7.7: Overlap of Shaded Areas at 68%, 95% and 99.7% C.L. satisfying Good Normal Approximation

7.5 Statistical Concept of Standards Setting

Having discussed in detail on the subject of uncertainty and its representation as well as the important theory of statistical food sampling involving the determination of sample size, attention is now focussed on the statistical concept of standards setting for food contaminants. By examining the concept of standard setting, the overall picture towards the purpose of sampling can be reviewed unambiguously in a statistical manner.

At one extreme, a standard might be set to place a limit on the level of effect on a subject group, without actual reference to any contaminant which causes or influences that effect. For example, this can be a limit that only allows a certain maximum number of food poisoning cases to occur on elderly people every year. Obviously such standard is not applicable on the subject of food control, and standard of this kind has never been used in relation to food in practice.

Commonly, a standard is set on the level of food contaminant in the medium (i.e. food) at each of a specified class of locations. Often this is a target which is set without reference to the measures that will need to be introduced in order for it to be achieved. For example, when a limit of controlling a chemical or a pathogen is set on a particular type of food, it is often that no mention is given on how such level is to be attained. Indeed, the intention of controlling or limiting the contaminant will limit the effect on the subject group, but the standards are often set without reference to explicit targets for the effect.

When the standard is set on locations which represent the places where food contaminant enters the medium (i.e. food), the control measures are often more explicit. For example, this may be the control of mastitis in the flock in order to prevent the possibilities of *Listeria monocytogenes* in milk and cheese (Ahmed and Steenson 1996), or it may be a control of a process in a food manufacturer so that no chemicals from leaks in machinery can contaminate food products. Although the control measures may be clearer, the link to effect may be more complex. The standard may be set at locations where contamination arises, but the interest is in reducing contaminant levels at other, more general locations, representing thereby an extra step between the standard and the effect.

A standard may be set on a specific sample statistic. One of the main advantages of this type of standard is that compliance to the standard can be determined clearly. However, compliance to a standard which refers to the level of contaminant in a location cannot usually be determined precisely because the level in the whole location can not simply be measured. As mentioned earlier, it is inevitable that compliance testing requires the use of a sample statistic. It is possible that sample statistic is subject to error, either the standard may be met over the whole location but a poor sample leads to it failing the test; or the standard may not be met over the whole location but a lucky sample leads to it passing the test.

Whichever the kinds of standard is used, there is a link between the standard and the effect on the subject group. Concurrently, there is another link between the standard and the specific actions needed to achieve the standard. Both of these links are

crucial because each link represent one side of the cost-benefit balance. The cost of setting standards lies in the actions needed to achieve the standards, and the benefit lies in achieving improvements in effect. While quantification of these two sides is particularly difficult, it is generally true that setting the standard at a more stringent level will improve the effect on the subject group, but will cost more to achieve.

Barnett and O'Hagan suggested the chain of causality in which the standard could be set at any point on the chain from cost to benefit, as shown in Figure 7.3 below.

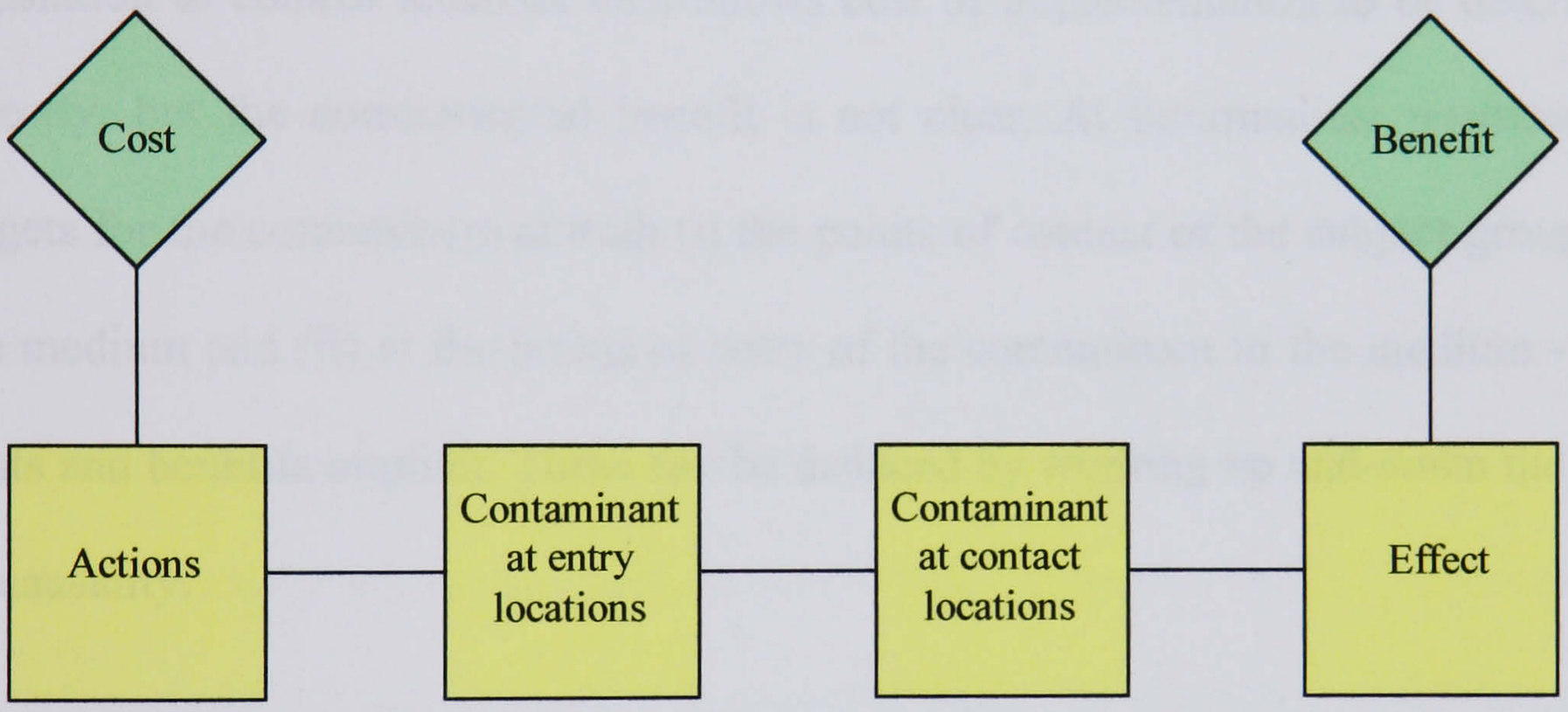


Figure 7.3: Chain of Causality from Cost to Benefit (Barnett and O'Hagan 1997)

A target might be set at any of the four positions in Figure 7.3:- in consideration of the contaminant effect; the contaminant presence at contact locations; the contaminant presence at entry locations; or the actions in relation to the contaminant. It was indicated by Barnett and O'Hagan that the diagram should be viewed in a schematic sense, where in practice there are generally many positions along the line

from actions to effect at which a standard may be set. In addition, the costs and benefits were placed at opposite ends of the line. The cost arises from the costs of modifying the actions of the contaminator by introducing more effective contamination control technology in order to meet the standard. The benefits arise from improvements in the effects on the subject group. When a target is set for the effect (For example: to ensure that no food poisoning will occur to consumer from products sold at retail), a direct benefit can be achieved; but the necessary practical steps to achieve the target and consequent costs are unspecified. On the other end, a target set for the actions which lead to the contamination (For example: setting up of legislation to control fertilizer use) allows cost of implementation to be determined directly; but the consequential benefit is not clear. At intermediate positions, the targets for the contaminant at both (i) the points of contact of the subject group with the medium and (ii) at the points of entry of the contaminant to the medium - leave costs and benefits implicit. These can be deduced by working up and down the chain of causality.

However, it is important to note that causality is not deterministic. As mentioned in Section 7.3 on the sources of uncertainty and variation, natural variability of foodstuffs and between individuals of the subject group will combine with scientific uncertainty about the processes involved and with any measurement errors, so that there will be uncertainty either about the changes which would result at any point in the chain from changes at the preceding point or in the assessment of sample data. No matter which position along the chain of causality is chosen for the position of a standard, there will be uncertainty about either the cost or the benefit or both.

7.5.1 Ideal and Realizable Standards

First of all, it is considered that the aims of setting standards will typically be concerned with the improved effects on the subject group (For example: to prevent harm to consumers from a chemical or microbiological contaminant). In fact, expression of these aims may be vague. In contrast, objectives of setting standards represent specific achievements that would act as precise and verifiable indicators of progress towards an aim. In other word, standards can be understood as objectives, but strictly speaking objectives imply that standard should be verifiable. Yet a standard which demands, for instance, that the concentration of a chemical contaminant for one food type in retail shops should not exceed some limit, is not verifiable. Indeed, the concentration of chemical contaminant in all retail shops cannot be measured at any one time, still less continuously over a period of time. The standard can be tested by sampling, but this does not objectively verify the standard. Random variation between sample items and measurement errors implies random variation in sample statistics, and a consequent degree of uncertainty over whether or not the standard is being satisfied.

Therefore, a standard which is expressed in such a way that it can be determined without uncertainty whether it is satisfied at any location is called a realizable standard. On the other hand, a standard which is not realizable is known as an ideal standard. Any standard which is set on the level of contaminant throughout a location or over a period of time will typically be ideal because it is not possible to measure the level at all points in a location, or to measure most contaminants at even a single

point continuously over time. Although the level of contaminant at a location cannot be verified objectively by sampling, but if the standard is set only in terms of the sample then it may become realizable. It is clearly objectively verifiable whether this standard holds, but this is no longer a standard for the level of contaminant in the whole medium at that location.

Referring back to the chain of causality in Figure 7.3, it is possible to set realizable standards along the chain in terms of sample statistics, as shown in Figure 7.4 below:

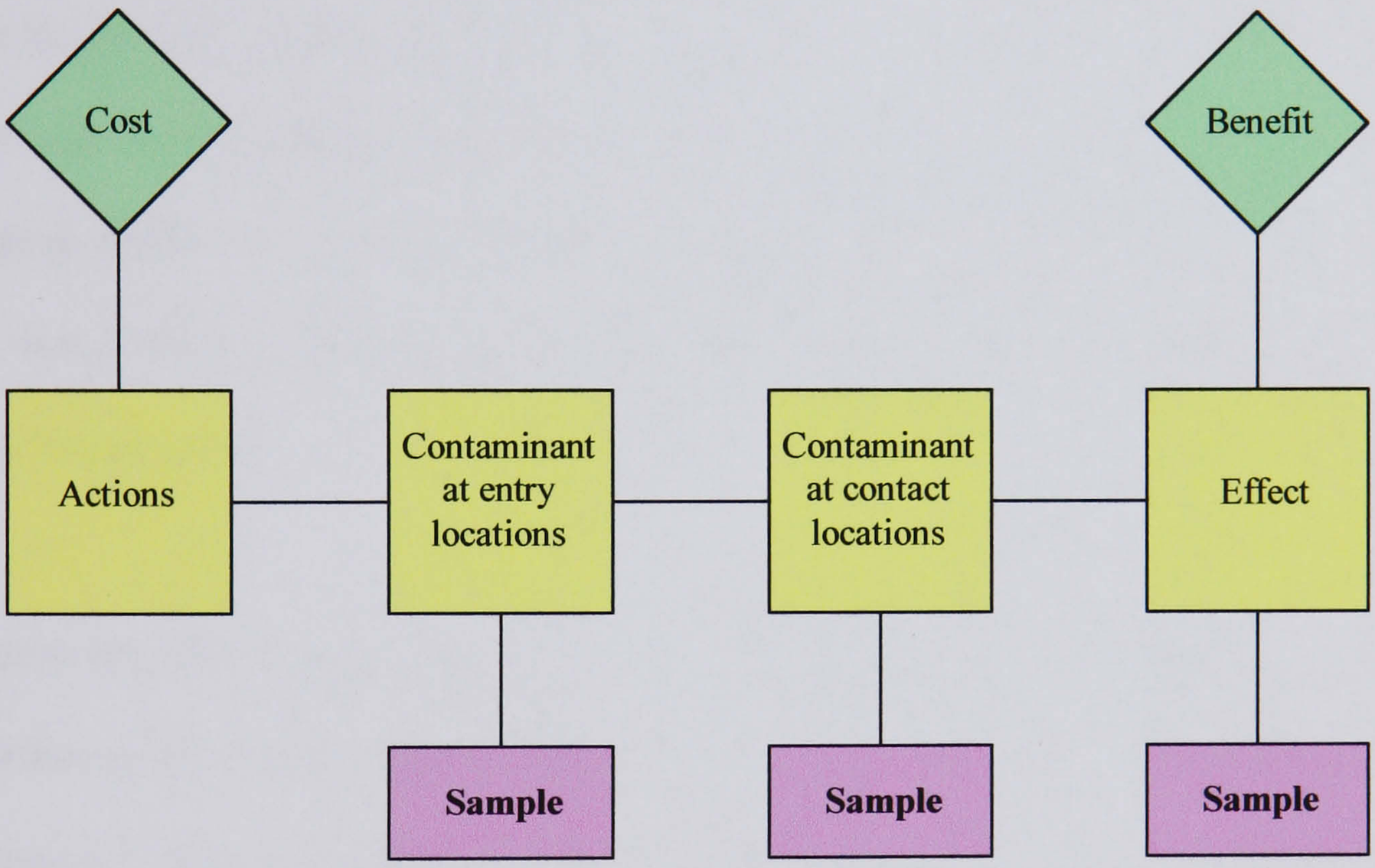


Figure 7.4: Cost-Benefit Chain with Verifiable Objectives

where sample can be taken at labelled positions and standards can typically be framed in realizable terms. Besides the possibility of a realizable standard being based on the results of sampling food contaminant levels (either at contact locations

or at entry locations) or on sampling effects (in the subject group), standards on actions causing food contamination are typically objectively verifiable and hence constitute realizable standards. Whereas, standards on contaminant levels in the whole of the medium at a location, or on effects in the whole subject group, are typically ideal.

Realizable standard has the main advantage that there is no uncertainty towards compliance, but placing a standard on a sample will mean more uncertainty over the benefit arising from the standard, because the standard is moved a further step away from the benefit. Instead, ideal standard will give less uncertainty about benefits, but there will be uncertainty over compliance with it. Therefore, application of ideal standard would be completely useless if compliance to the standard would not be met, unless there is some system to ensure that compliance is met at any location in some formal sense.

Suppose an ideal standard is set on cooked rice which required that the level of *Bacillus cereus* should not exceed 10^5 cfu/g, as indicated by PHLS guidelines for ready-to-eat food as unacceptable and potentially hazardous (Roberts, Hooper and Greenwood 1995). The location is at retail level or catering outlets, and the standard is set on 'contact' locations where the medium polluted by this food contaminant is in contact with the subject group. However, it is still not entirely clear what such a standard would mean because the level of *Bacillus cereus* will vary over time due to variation. In fact, it would be common to set the standard in terms of average level to control the total level of *Bacillus cereus* over a period of time, but it would also be of

concern about a single location selling cooked rice with very high level of *Bacillus cereus*. So a standard might be set to limit both the average (at a baseline level) and the maximum (at a critical threshold).

The level X of food contaminant at any location will typically vary over time, and will often vary from point to point within the location. Any standard for X should recognise this variation. So X can be considered as a random quantity with a probability distribution such that $P(X \leq x)$ is the probability that X does not exceed some value x, in the sense that X does not exceed x over this proportion of time (and/or space). For a single sample unit taken at a random time and/or point, this is represented in terms of the probability distribution of the level of contaminant in that single sample unit.

Suppose Figure 7.5 might be the distribution of *Bacillus cereus* in cooked rice where:

x_a - is the average level of *Bacillus cereus* (i.e. the mean of the probability distribution);

x_m - the maximum level so that $P(X > x_m) = 0$; and

x_p - the level in which contamination exceeds x_p only a proportion of the time (example: 5%) so that $P(X > x_p) = 0.05$ (i.e. x_p is the upper 5% point of the distribution, or 95th percentile).

Any feature of the relevant probability distribution might be made the subject of an ideal standard. The maximum will generally be a poor choice. Firstly, it is because

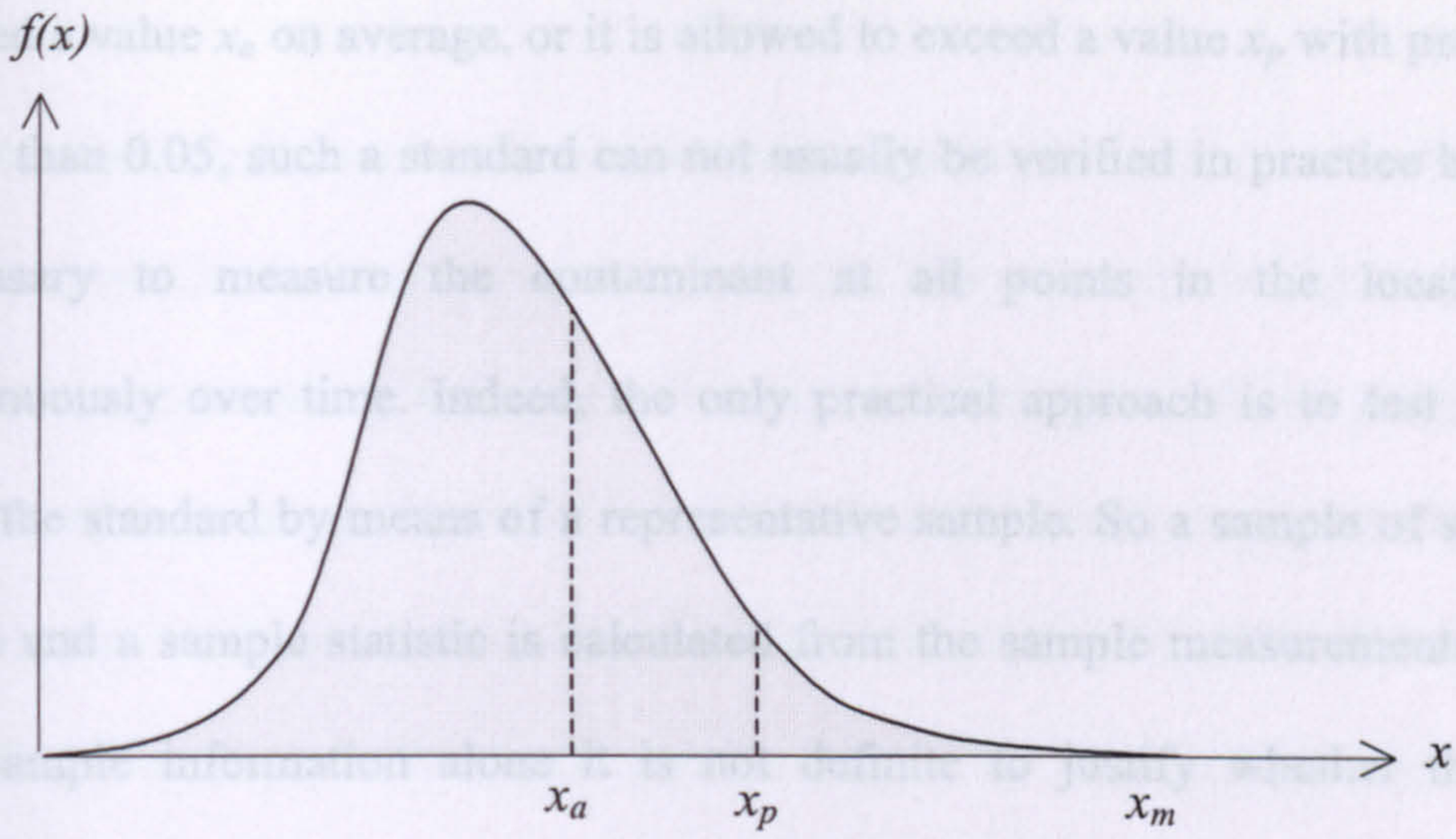


Figure 7.5: Example of Distribution of *Bacillus cereus* in Cooked Rice

such level will often not be well defined since no theoretical upper limit exists; secondly, it is inherently difficult to control in most applications. Instead, it is comparatively more appropriate to use a suitable upper percentile. In fact, the choice of feature to control will depend on the context and the nature of contaminant-effect relationship. For a contaminant whose effects have a threshold form (For example: many species of pathogens which can cause acute food poisoning symptoms by ingesting a high level in a single occasion, but may not cause illness at lower level), some suitably high percentile which lies below the threshold will limit the frequency at which the level goes over the threshold. On the other hand, a standard for a contaminant whose effects are cumulative (For example: chemical contaminants of carcinogenic nature which can seriously damage the health of people after exposure for a long period of time, but do not show any illness at a short period), controlling the average level will be more appropriate.

When an ideal standard indicates that the true level of contaminant X should not exceed a value x_a on average, or it is allowed to exceed a value x_p with probability no more than 0.05, such a standard can not usually be verified in practice because it is necessary to measure the contaminant at all points in the location and/or continuously over time. Indeed, the only practical approach is to test compliance with the standard by means of a representative sample. So a sample of some size is taken and a sample statistic is calculated from the sample measurements. But from the sample information alone it is not definite to justify whether this location complies with the standard, and the use of a sample introduces further uncertainty. For instance, if the sample average exceeds x_a, this does not necessarily mean that the location fails. The true average of X might well be below x_a and by chance that the sample average has turned out to be above x_a. Equally, if the sample average is below x_a, this does not necessarily mean that the true average of X is below x_a; or if more or less than 5% of sample units have measurements above x_p then the same does not necessarily hold for the true distribution of X. This is why the introduction of statistical inference in Section 7.4 is so important in order to predict and determine the distribution of X based on a sample. Implementation of statistical inference requires a criterion to be properly defined, based on a suitable sample statistic, in order to declare whether a location passes or fails the test of compliance. But declaring a location to have passed or failed the test does not absolutely prove that it is or is not complaint. There will always be some uncertainty existing in sampling.

7.5.2 Statistically Verifiable Ideal Standards

An ideal standard is not verifiable, whereas a realizable standard is verifiable (i.e. it can be determined without uncertainty whether it is satisfied). In order to use an ideal standard, it is necessary to implement some operational procedure by taking samples in order to test statistically whether it is satisfied. However, statistical testing is itself a process of verification which seems to make an ideal standard verifiable, the use of sampling technique still exists with a degree of uncertainty. Therefore, clear distinction is needed to contrast the difference between a statistically verifiable (ideal) standard and an exactly verifiable (realizable) standard.

It is extremely important to note that a large and well-planned sample is capable of much more accurate verification than a small or badly planned sample, as discussed in details in Section 7.4.4. Suppose an ideal standard asserts that the average value of level X of a contaminant should not exceed a limit x_a. From a sample, it is not possible to claim that the true average has any specific value, but it is possible to state the confidence interval which lies between some limits x_1 and x_2 with prescribed probability. A poor sample (in terms of size, design or execution) can still produce confidence limits, but x_1 and x_2 will be much further apart than they would be if calculated from a good sample. In such case, using a poor sample increases the chance of straddling the standard. Such a result would be inconclusive because the outcome fails to demonstrate that the true average is genuinely below or above x_a with sufficiently high probability. Therefore, the quality of statistical verification will depend on the quality of the sampling and of the statistical techniques used to

process the sample measurements. Essentially, this involves use of an appropriate model to reflect what is truly known about the mechanisms of contaminant effects and about the factors governing uncertainty and variation.

Based on the statistical theory, setting an ideal standard without also setting a standard for its statistical verification will leave such standard open to abuse by those claiming compliance on the basis of inadequate statistical procedures. In order to combine these two components into a single standard, the concept of a statistically verifiable ideal standard was introduced. Basically, a statistically verifiable ideal standard comprises two parts:

(i) an ideal standard - which should acknowledge variation and uncertainty;

(ii) a standard for statistical verification of the ideal standard - which will typically be expressed as a level of assurance of compliance with the ideal standard that must be demonstrated (Barnett and O'Hagan 1997).

A statistically verifiable ideal standard must also be flexible. However, many current standards tend to be designed as ideal standards with prescriptive compliance criterion. One of the advantages in being more prescriptive is that statistical verification can be reduced to a simple look-up table for numbers of samples that may be allowed to have concentration exceeds x_p.

Since an ideal standard must be formulated in a way which properly acknowledges natural variation, so the compliance criterion must be statistically based because objective verification is not possible for ideal standards. So a statistically verifiable

ideal standard may be thought of as a combination of an ideal standard with a compliance criterion, both of which give proper recognition to uncertainty and variation and linked to ensure a guaranteed level of assurance that a required condition holds. Again, an ideal standard alone has no real beneficial use without the companion of a compliance criterion, and the verification which can be achieved by any compliance criterion must be statistically based. The look-up table is a very good compliance criterion because the quality of statistical verification which it affords has been thought through carefully. However, such a standard prescribes a specific compliance criterion, whereas a statistically verifiable ideal standard is more flexible. In fact, a statistically verifiable ideal standard specifies the quality of statistical verification required, but does not specify the procedure by which that is to be achieved. This is left open for circumstance, and possibly to negotiation. In particular, it allows advantage to be taken of improvements over time in technology and statistical techniques, without needing to change the standard. Such improvements might allow the statistical verification criterion to be met more economically, for example by taking fewer samples, whereas an ideal standard with a prescriptive compliance criterion would continue to demand the same sampling effort.

In comparison with a realizable standard based on sampling, it is clear that it is much preferable to apply statistically verifiable ideal standard. Firstly, it is because the realizable standard suffers from the same drawback of over-prescriptiveness as an ideal standard with a conventional compliance criterion. Secondly, a realizable standard is moved further away from the benefits, as shown in Figure 7.4. The

benefits are less certain, and there is even no explicit understanding of how the sample-based standard controls the contaminant level in the medium as a whole.

7.6 Cost and Benefit Analysis

After introducing the concepts of ideal, realizable and statistically verifiable ideal standards for the purpose of standard setting, subject is now turned to the consideration of costs and benefits from setting standards for the control of food contaminants. Obviously the set up and maintenance of standards involves costs, and the compliance of such standards should yield benefits. For instance, if an ideal standard is to specify that the 95^{th} percentile for the distribution of a contaminant concentration should not exceed x, then an important question to raise is on how the level x should be chosen. Barnett and O'Hagan suggested that the quantitative levels for standards could only be set by balancing cost against benefit, and by doing so will entail understanding the various links in the chain from cost to benefit in Figure 7.9 (Barnett and O'Hagan 1997).

According to Barnett, a formal analysis of costs and benefits is a simple application of statistical decision theory in principle. It is considered that the possible standards can be reckoned as a set of possible decisions. In order to compare cost and benefit, both must be measured on the same scale and in the same units. In principle, both cost and benefit are expressed on the scale of utilities. In practice, these may not be easily measured and quantified. For example, if the benefit is in lives saved from

food-borne diseases, and the cost in sterling pounds, then the process of converting these to utilities is equivalent to placing a monetary value on a life. Assuming that utilities can be assigned, then the theory allows for uncertainty about the cost and benefit associated with a given decision. Such uncertainty implies a distribution of the cost utility and a distribution of the benefit utility, and hence a distribution of the conjoint cost-benefit utility. The mean of this overall distribution is calculated, and this defines the value of a decision.

Although this theoretical cost-benefit analysis based on the assignment of utilities was proposed, the difficulty of implementation and execution as well as the inevitable controversy over the assignment of utilities makes such analyses highly disputatious. Despite the drawback, such an approach has its own advantages. Firstly, any imprecise evaluation between the analyses of cost and benefit will be consistent along the chain, thereby any actual decision made will carry the same imponderable measures. Secondly, the decision analysis focuses the discussion on exactly what assignments of utilities must be made, and subject to those determines an optimal decision on objective scientific principles.

7.7 Discussion

The main purpose of carrying out food sampling is to try to learn some information about the food lot since it is not practically possible to examine the entire population. Unfortunately, it is inevitable that sampling is subjected to both uncertainty and variation. It is very important that these must be taken into account within the sampling regime, or else the sampling results would be open to errors and lose the accuracy and significance. Consequently, failure to acknowledge uncertainty and variation will lead to erroneous decisions being made from these inaccurate results.

Not only do the measurement errors in the process of sampling and analysis lead to inaccuracies, uncertainty due to the limited scientific understanding of many food contaminants and their effect on the subject group is another major factor that must not be overlooked. Coupled with the above ambiguity, the situation is worsened by inevitable sample variation. In the context of food sampling, this is undoubtedly the most important item which is necessary to be addressed in greater detail. It was illustrated earlier that sample variation is due to intrinsic and extrinsic factors. In addition, microbiological contaminants have the ability to grow and multiply which even more complicate the variation in sample if time and temperature has not been properly controlled. This problem can be difficult to overcome particularly in rural areas where long distance between place of sampling and testing laboratories exists. This may equally apply to chemical contaminants that are volatile and unstable by nature.

In the main, uncertainty and variation of sampling mainly comprises of bias and chance error. While bias belongs to the group of non-sampling error which is any kind of systemic error that exists in the estimate, chance error is often referred to as the sampling error. Representation and quantification of sampling errors requires the concept of probability and statistical analysis. By means of probability distribution graphs, the values of an uncertain variable can be estimated in the feasible range. Indeed, a type of distribution, known as the binomial distribution, is considered to be one of the most important and widely used discrete probability distribution in the field of statistics. Due to its binomial property, many sampling models and plans such as the 2-Class Sampling Plan proposed by ICMSF are based on this important theory. Besides the simplicity of applying this distribution, it is inevitable that cumbersome calculation is involved when sample size becomes very large. Fortunately, normal distribution can be used as an approximation to binomial distribution if sample size is large (i.e. $n \geq 30$). Like binomial distribution, normal distribution is a very important continuous probability distribution in statistics which is frequently applied to make statistical inferences. Its symmetrical mesokurtic curve and the ease of obtaining the areas under the standard normal curve that represents possible observation makes estimation of uncertainty much simpler and feasible.

In order to examine the magnitude of sampling error, a different type of probability distribution called the sampling distribution is required to reflect the level of accuracy of the samples. Due to the very important theory of Central Limit Theorem, even if the distribution of the variable itself is non-normal, the mean of the sample mean is approximately normally distributed provided that the sample size is large.

Since sample mean is merely a point estimate of the population mean based on the sample, this important property allows standard error for mean to be estimated simply by normal approximation. Commonly, evaluation of the accuracy of estimate is presented in terms of confidence intervals. Under different situations, separate procedures for obtaining confidence intervals are required, depending on the availability of population standard deviation or population proportion. The precision of the estimate is indicated by the width of the confidence interval. However, if the precision is required to be improved but without affecting the confidence level, then the margin of error must be decreased instead. In order to do so, it is necessary to increase the sample size.

To overcome the problem of sample variation and achieve a higher confidence in estimating the population mean, the determinant rests on sample size. Ideally, a relatively larger sample size is more likely to yield a better result; but in practice, this is often hindered by financial and resource constraints. In fact, there is no way the true level of food contaminant at any location can be known by sampling, unless the entire food lot is tested. But by means of statistical analysis, such variation can be quantified and a degree of confidence in which the true level lies can be obtained and justified. Therefore, it is aimed at selecting a minimum sample size to reduce the cost but at the same time obtaining a good estimate of the population mean value. Indeed, determination of appropriate sample size creates a lot of debates. In Section 7.4.4, a model was developed to examine the behaviour of margin of error (E) under different sample size and sample proportion. In order to assure good normal approximation, the model was based on Criterion 2 for values of n satisfying $np(1\text{-}p) \geq 10$. The main

purpose of this model was to test the precision of the estimate from the level of E at each of their sample proportions ($\hat{p}$). The main reason for choosing confidence intervals at 68%, 95% and 99.7% was because those intervals represented one, two and three standard errors. Apart from the fact that it was good for illustrative purpose as well as ease for calculation (since E for both 95% and 99.7% C.I. are multiple of E for 68% C.I.), 95% confidence intervals is often used by statisticians to estimate population mean from a sample. It is because this particular C.I. has a good level of confidence and a statistically acceptable margin of error.

In Graph 7.3 - 7.5, margins of error (E) of various sample proportions from 0.5 to 0.001 were plotted against the sample size ranging from 30 to 300. The shaded areas represented the sample sizes which can achieve good normal approximation at each of their designated sample proportions. Values under the unshaded areas indicated that even though application of normal approximation is feasible, estimation of population proportion would not be desirable and sufficiently accurate, unless prior knowledge confirmed that the mean of sample proportions was normally distributed. It was shown from these graphs that when sample proportion ($\hat{p}$) was less than 0.04, good normal approximation would not be attained. With a much larger sample size, it was possible that a lower sample proportion might be included, but in practice larger n is very difficult to achieve. Also, any further increase of n would not significantly reduce the margin of error since the curves tended to be horizontal. Overall, examination of the curves indicated that the accomplishment of good normal approximation required a relatively larger sample size, but any major increase in n for very small $\hat{p}$ would not help to include those curves in the shaded areas.

In fact, the main interest was to examine how the smallest possible sample size could be obtained and at the same time be able to achieve reasonably precise estimate of the population proportion. Based on this model, only those with $\hat{p} \geq 0.04$ (4%) enclosed in the shaded areas would be included for good estimation. The minimum sample sizes (n) and their corresponding margins of error (E) at different confidence levels for each of the sample proportions ($\hat{p}$) were listed in Table 7.3 in Section 7.4.4. As the level of sample proportion decreased, sample size increased rapidly. 95% confidence level was chosen as a marker and the ratio between margin of error and its corresponding sample proportion was examined. Obviously, the smaller the ratio, the narrower the width of the confidence intervals and consequently the more precise the estimation of population proportion would be. It was clearly shown in Table 7.4(a) that the margins of error were relatively large in comparison with their sample proportions. For example: for $\hat{p}$ at 6%, 5% and 4%, the size of E was 60% of $\hat{p}$; while $\hat{p}$ at 10% had a 57% ratio. The only way to reduce the margin of error but keeping the same level of confidence was to increase the sample size. Table 7.4(b) indicated that by doubling the sample size, there was a clear reduction in the margin of error. Such reduction was illustrated in Graph 7.6 by means of a near straight line at a lower $E/\hat{p}$ ratio as compared to the other line at a higher ratio.

The relationship between sample size, confidence level and margin of error was again highlighted in Graph 7.7. If the sample size were fixed, an increase in confidence level would inevitably lead to an increase in margin of error. At higher level of confidence, margin of error was also larger due to the bigger value of z-score, but a small increase in sample size from n_{min} would produce a greater

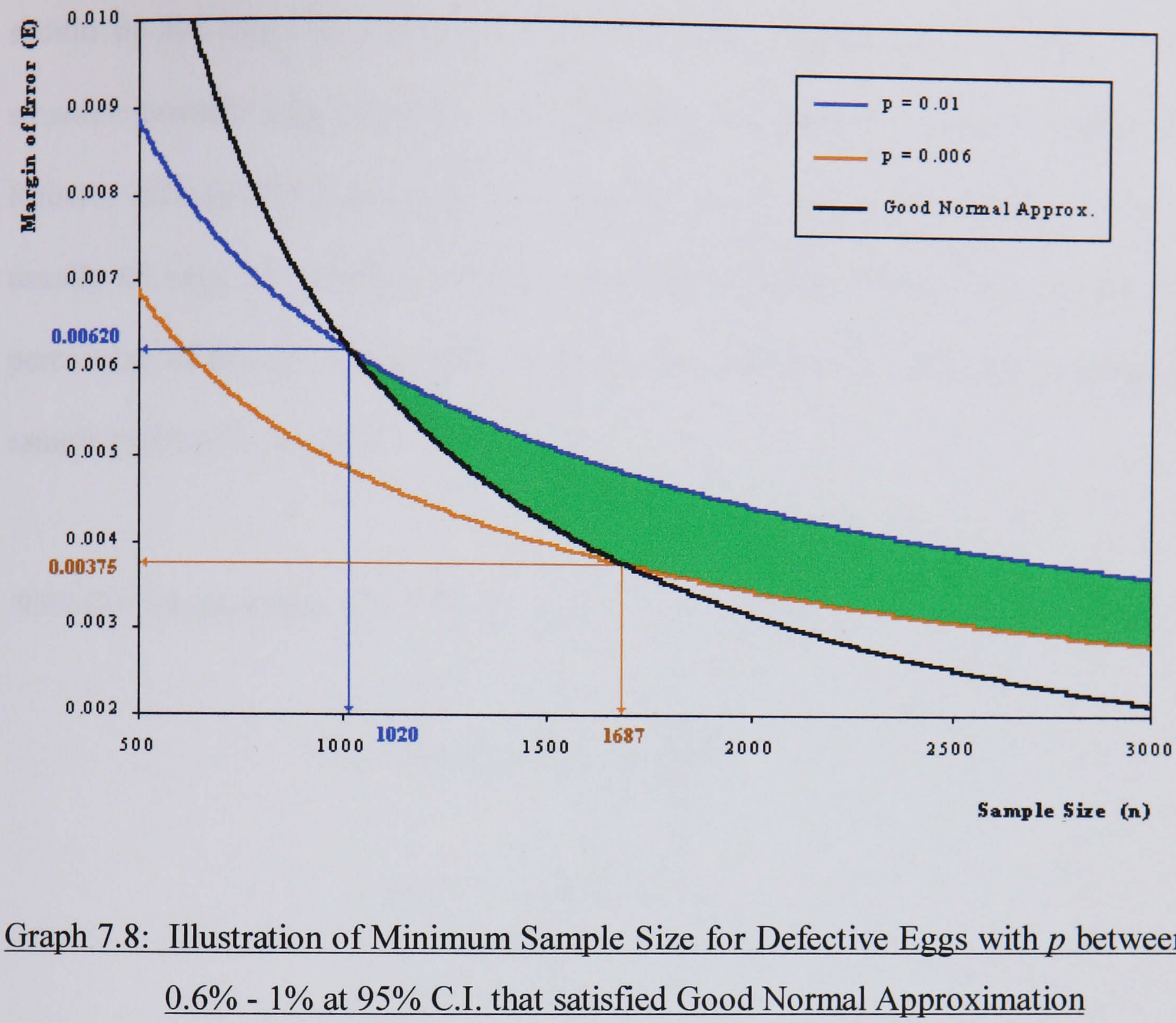
reduction of E than the others at lower confidence levels. Obviously, the ideal situation was to maintain a high level of confidence with a smaller margin of error. Therefore, the only way to achieve this goal was to increase the sample size to a desirable level.

However, one main problem was that curves with small sample proportions were excluded from good normal approximation unless sample size were very large. This could be argued that a sample size of 30 or above would satisfy the minimum requirement of normal approximation to sampling distribution. Strictly speaking, such statement might well not be considered as entirely untrue, but the main point was to obtain a reasonably good estimate of sampling error and confidence intervals through normal approximation from the sampling distribution graph in order to predict whether such sample would be a representative of the population. If the criterion for good normal approximation was not met, then such prediction might be inaccurate. Even if it was assumed that normal approximation was met, small sample proportion had many others problems for proper statistical analysis. As shown in Table 7.4(a) and (b), a decrease in sample proportion caused a significant increase in $E/\hat{p}$ ratio. It is important to note that it is the $E/\hat{p}$ ratio that is crucial to determine whether such sample is statistically acceptable or not. In order to control the $E/\hat{p}$ ratio and shorten the width of the intervals, a substantially large sample size would be required.

This problem can be well illustrated by real scenario of low detection rate of infected eggs due to contamination with *Salmonella enteritidis* phage type 4. The incidence of

this organism causing food poisoning had risen since 1987 with cases and outbreaks throughout the U.K., in parts of the USA and also in Europe where poultry and eggs are the common vehicles (Hobbs and Roberts 1997). Poultry are known to be major reservoirs of *Salmonellae* and the shells of hens' eggs may be contaminated through contact with faeces in the cloaca or in the nest or battery. In flocks infected with *Salmonella enteritidis* phage type 4, it has been shown that the infection can be transmitted via the ovary. The use of hen's eggs in lightly cooked or uncooked foods such as mousse and custards has given rise to many reported cases and outbreaks of *Salmonella enteritidis* phage type 4 food poisoning. Even one infected egg may contaminate batches of liquid egg broken out in bulk for freezing or drying. Fragments of shell and the hands of those breaking out the eggs may contaminate the equipment and the mix. Surveys of eggs, both home-produced from retail shops and imported, showed a variable proportion to be contaminated with this pathogen (Hobbs and Roberts 1997). North indicated that where *Salmonellae* are present in egg-laying flocks, only a very small number of eggs (approximately 1%) might be infected (North, Duguid and Sheard 1996). Also, it was stated by Sprenger that through some research approximately 0.6% of eggs laid by an infected flock might be contaminated (Sprenger 1993).

Assuming that the percentage of defective eggs sold in the U.K. was between 0.6% - 1%, in order to met good normal approximation the minimum sample size would be a value between 1020 - 1687 under 95% confidence level, as shown in Graph 7.8. Within the area coloured green in Graph 7.8 was the possible choice of n and corresponding E which satisfied the above criterion. In such case, the margin of error



Graph 7.8: Illustration of Minimum Sample Size for Defective Eggs with *p* between 0.6% - 1% at 95% C.I. that satisfied Good Normal Approximation

for $p = 1\%$ would be 0.620% and E for $p = 0.6\%$ would be 0.375%. Therefore, where n were at their minimum that satisfied good normal approximation, the 95% confidence intervals for $p = 1\%$ and $p = 0.6\%$ would be:

- $1\% \pm 0.620\%$, $E/\hat{p}$ ratio = 62.0% where $n = 1020$
- $0.6\% \pm 0.375\%$, $E/\hat{p}$ ratio = 62.5% where $n = 1687$.

From the above figures, normal approximation was satisfied only when sample size was elevated to four digit figures. Also, it was clearly shown that the level of sampling errors was undesirably high, with $E/\hat{p}$ ratio at 62.0% or above. This means that if the margin of errors were required to be lowered, it would be necessary to

further increase the sample size to an even greater level. Having identified what should be the required minimum sample size for eggs in the U.K., the current situation towards egg sampling was examined and compared. Firstly, Hobbs and Roberts indicated that the sampling rate for imported eggs from all countries is usually 60 eggs per 360,000 or lorry load (Hobbs and Roberts 1997). Suppose the percentage of infected eggs in the batch was 1%, then 95% confidence intervals for sample proportion would be:

$$95\%\ \text{C.I. for proportion} = 0.01 \pm 1.96 \sqrt{\frac{(0.01)(1-0.01)}{60}}$$

$$= 0.01 \pm 1.96 \sqrt{\frac{0.0099}{60}}$$

$$= 0.01 \pm 1.96\ (0.0128)$$

$$= 0.01 \pm 0.0252$$

$$\text{In Percentage Form} = \underline{1\% \pm 2.5\%}$$

Without even extend to the consideration for good normal approximation, the 95% confidence intervals above did not make much sense at all in terms of statistical deduction. The margin of error was 2.5 times greater than the sample proportion, and the lower limit stretched beyond zero. It is interesting to note that 1% of defective items in a sample of 60 would not expect more than one infected egg to be present in this sample (in fact, only 0.6 of an egg was expected to be present in the sample if such sample was a true representative of the batch). If a test compliance was set at $c = 0$, then a detection of one defective egg would simply fail the test. However, the main point should be focussed on how confident a sample of 60 eggs would

represent the batch. With a margin of error which is 2.5 times greater than its sample proportion, the decision based on such sample statistic would be questionable. In this case, an unacceptable batch would easily pass the test.

Secondly, Table 7.5 presented the sampling activities of egg and egg products in 19 former Scottish District Councils between 1991-94. This information was extracted from the Scottish Quarterly Returns gathered by the Scottish Office under the requirement of Official Control of Foodstuffs Directive (Scottish Office 1991-94). Figures under official sampling were total number of samples for all purposes (i.e. testing for microbiological or other contamination, composition, or labelling) at a quarterly basis. Figures under informal sampling were numbers of samples solely for the testing of microbiological contamination. The sample size ranged from 1 to 19 at a three-month period. Also, food sampling programmes for the year 1994 and 1995 kindly supplied by several Scottish local authorities for this research has shown that the annual target for egg and egg products sampling ranged between the value of 3 to 6, and the total number of samples taken were below 9 per annum. Again, due to the small sample size, the accuracy of the sample in representing the batch would be debatable, since the margin of error would be expected to go even larger.

Through the detailed discussion on statistical theory of food sampling between population and sample proportion, sample size, confidence level and precision, it is most important to understand how this concept can be used and benefited in real life. Indeed, the reason for food sampling and subsequent analysis is to collect some information about the foodstuffs sold in food premises whether compliance of agreed

Quarterly Returns	1991								1992								1993								1994							
	Official				Informal				Official				Informal				Official				Informal				Official				Informal			
Scot. LA's	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th
LA 01																								1					1	1		3
LA 02																																
LA 03					1																									1		
LA 04																													2			5
LA 05				1		2		1										3					1	3								
LA 06																								3								3
LA 07														1	1								1									
LA 08						1									4						2	2		1					2	2		
LA 09								1					1								2	11								1		
LA 10							2						1								1											3
LA 11					1	2	5						1	19	8	12					6	10	5	12					7	4	3	8
LA 12		1													2	1								2					2			5
LA 13							2																						3			5
LA 14																																
LA 15		1						1															4									
LA 16								2					1		4						1		5	3								
LA 17					4	1																										
LA 18						2	2					1		1							1								3	2		
LA 19						3	1		1					1								1	3	1						2		
Scotland	5				60				4				116				12				125				10				124			
U.K.	1018				5728				959				3592				817				2495				933				1884			

Table 7.5:Quarterly Returns of Scottish Official & Informal Samples on Egg & Egg Products between 1991-94 (Scottish Office 91-94)

requirement is met. Such requirement may be set as legal standards, specifications or even guidelines; and sampling may be carried out routinely for the investigation of microbiological, chemical or physical contamination presented in food, as well as trading standard requirement on food labelling and composition. On the contrary, if no such limits existed, then sampling of food would be meaningless. Specifically, the absence of many standards for microbiological and chemical contaminants due to the lack of scientific evidence make enforcement of food law very difficult. The Food Safety Act 1990 clearly states that it is an offence to sell any food which fails to comply with food safety requirements if it is unfit for human consumption or rendered injurious to health, etc., but in real terms without the support of scientific evidence it is highly debatable in court to prove that any suspected food may cause ill health when consumed. Classic example included the case study of Clydesdale District Council against Humphrey Errington t/a H.J. Errington & Co. where failure to condemn the 44 batches of Lanark Blue Cheese was mainly due to the lack of scientific proof to justify the presence of *Listeria monocytogenes* serotype 3a in food would cause ill health (Allan 1995).

In Section 7.5, standards setting based on statistical concept was discussed in some detail. Commonly, some U.K. microbiological or chemical standards belong to the category of ideal standard. This is the standard in which it can not be verified in a way that it can be determined without uncertainty whether such standard is satisfied at any location due to the existence of uncertainty and variation along the chain of causality. For example, Tetrachloroethylene in Olive Oil Regulations 1989 which requires that olive oils and olive-pomace oils with tetrachloroethylene content of

more than 0.1mg/kg may not be offered for retail sale is an ideal standard (MAFF 1998). Obviously, the concentration of tetra-chloroethylene in olive oils in all retail shops cannot be measured at any one time or even continuously over a period of time. Instead, the practical way is to procure samples and test for compliance, but again this does not objectively verify the standard due to sampling variation and uncertainty. Therefore, application of ideal standard would be completely meaningless if compliance to the standard would not be met, unless there is some formal system to ensure that compliance is fulfilled.

On the other hand, another type of standard which is verifiable is known as realizable standard. Typically, if the standard is set on the sample itself then it is realizable. For instance, the Two-Class and Three-Class Sampling Plan suggested by ICMSF on various types of foodstuffs are examples of realizable standards. Undoubtedly, it is clearly verifiable whether the standards holds or not from the results of analyses on the sample units, but then this is not a standard for the level of contaminant in the whole medium at a particular location.

Due to the limitation existed in both ideal and realizable standards, the concept of statistically verifiable ideal standard was introduced. Basically, it is a standard which comprises an ideal standard and a standard for statistical verification of the ideal standard, both of which give proper recognition to uncertainty and variation with a guaranteed level of assurance that a required condition holds. Also, a statistically verifiable ideal standard must be flexible. Although the quality of statistical verification required is specified, the procedure by which that is to be achieved is left

open so that further improvement may be allowed without needing to change the standard. As mentioned before, Example Two is an ideal standard with a prescriptive compliance criterion rather than a statistically verifiable ideal standard due to the lack of flexibility. Another illustration similar to Example Two can be found in the Dairy Products (Hygiene) (Scotland) Regulation 1995, in which the standards for raw cows' milk intended for the manufacture of any milk-based product (made with raw milk) which has not undergone any heat-treatment during its manufacture is:

(a) Plate count at 30°C/ml $\leq 1 \times 10^5$, & Somatic cell count/ml $\leq 4 \times 10^5$;

(b) *Staphylococcus aureus* / ml: $n = 5$, $c = 2$, $m = 500$ cfu/ml, $M = 2000$ cfu/ml

(Scottish Office 1995).

The compliance criterion is based on the 3-Class Sampling Plan which again is considered to be more prescriptive. It specifies how many samples are permitted to have concentrations within m and M for a total number of samples (obviously no samples are allowed to have concentrations exceeds M).

7.8 Conclusion

In comparison, taking a food sample is easy enough, but to ensure that the sample taken is a true representative of its food lot may not be so simple and obvious. Therefore, it is extremely important that officers need to plan their sampling carefully so that the samples taken are representatives of their batches. All of the aforementioned uncertainty and variation must be considered prior to procurement. Relevant information regarding the types and origin of foodstuffs collected, the nature of food contaminants subjected to analysis, time and location, sample size (in relation to the history of contravention for the estimation of the probability of defective items in the food lot), etc. must be clearly recognised.

One of the main difficulties is the detection of food contaminants at low levels, especially those which have severe hazard to human health. No matter how low the probability of defective food units in the whole batch, it is very important not to overlook this issue. In particular, pathogens such as *Escherichia coli* O157 or *Clostridium botulinum* can spread and multiply rapidly, and lead to fatal incidents even at low level. The development of the statistical model has indicated that a very large sample size would be required if sample proportion was low. However, current practice reflected that very large sample size could not be adapted in local authority food sampling programmes. Indeed, when sample size is so small that normal approximation can not be met, then there is no confidence at all to justify the accuracy of the sample statistics. This was illustrated clearly in the example on egg or egg products sampling. The intention was not to question why local authorities did

not take more samples on egg or egg products among other types of foodstuffs. Indeed, egg was chosen merely for illustrative purpose, but the big question was: what information can be obtained based on the results of these samples, and how accurate will this information be. How would a sampling rate of one egg per month be of any actual benefit for the representation of eggs sold in the food premises within the local area. Indeed, this is simply trying to find a needle in a haystack. This is why the implementation of statistical analysis for verification is needed to reflect what should be the correct procedure so that there would be at least some confidence about the sample statistics.

It is common to find that control of some food contaminants was simply based on either ideal or realizable standards, followed by some kind of sampling without even realised or justified whether such standards had been correctly complied with or not. Through the understanding of statistically validated sampling in relation to sample size and the probability of defective items in the food lot, then compliance criterion for statistical verification of the ideal standard can be determined, which allows statistically verifiable ideal standard to be set up. In setting up such standard, the limitation of low sample proportion can be taken into account by adjusting the sample size and confidence level to suit the needs. Also, it can be used to determine the feasibility and accuracy towards the appropriateness of standard setting. However, due to the lack of scientific evidence to ascertain the maximum level of many food contaminants that would lead to foodborne illness, setting up a statistically verifiable ideal standard becomes a very difficult task. Another very important aspect is the balance of cost against benefit in standard setting.

Comparison between cost and benefit must be measured in the same scale and in the same units. If a standard requires that a very large sample size is needed for the detection of a particular food contaminant in a certain type of food, then the high cost of sampling and subsequent analysis should be compared with the actual benefit out from reducing such contaminant. As discussed earlier, the chain of causality where such standard should be set would determine the ratio between cost and benefit.

Chapter 8

Discussion / Conclusion

Chapter 8. Discussion / Conclusion

Many people conceived of food sampling as simply a matter of procuring some food units and subjected for testing. Environmental Health professionals realised that there were some underlying problems existed within the sampling regime, in particular, the use of small sample size, but this subject was repeatedly being avoided or omitted. Indeed, food sampling is a very complicated issue that inevitably involves much uncertainty and variation. Often these uncertainties and variations are not so obvious and easy to understand and predict. Also, there are many other problems which exist outwith the activity of food sampling itself.

First of all, it is very clear that the U.K. food surveillance network is far too complex. The three-way food co-ordination system covering England and Wales, Scotland and Northern Ireland indicated a lack of uniformity and varying quality of enforcement practice, particularly at local level. Fragmentation and lack of co-ordination between bodies involved in food policy and in the monitoring and control of food safety meant that duplication of food sampling is inevitable under scarce resources. Scottish Environmental Health Departments face even more hardship towards their sampling due to the absence of free analytical services and additional responsibility on food labelling and composition. The setup of the new Food Standards Agency is aimed at targeting the loopholes in order to regain public confidence on U.K. food safety. The majority of sampling is undertaken by the local authorities, in which the sampling programmes, if they exist, cover food samples at local, regional, national and European levels. Since this new independent body acts as one-stop shop over all

matters related to food, it would be ideal if the Food Agency would take the lead to revise the existing U.K. sampling regime and co-ordination network so that duplication of sampling can be avoided at all levels and by many local authorities. The Agency must recognise the importance of local knowledge possessed by the Environmental Health Departments through routine inspection and sampling, and this information is invaluable towards the design of the food programmes. Most importantly, sampling should be planned in a unified approach in order to monitor, predict and control the occurrence of food poisoning outbreaks in an efficient and effective manner.

As a member of the European Union, the legal requirement detailed in the EU Directives placed an important role towards U.K. food law enforcement. The introduction of the Food Safety Act 1990 aimed at facilitating harmonisation of EU Directives into U.K. food laws in order to achieve a single market in foodstuffs. One of the main European legislation concerning food sampling activity is specified in Article 14 of the Official Control of Foodstuffs Directive (89/397/EEC), in which all Member States are required to submit statistical returns detailing the performance and results of yearly inspection and sampling to the European Commission. In the EU point of view, the main reason for submitting the food reports is to act as evidence of their compliance with both national and European requirements. Assessment of central audit was then carried out by the Commission through the submission of statistical returns and control visits in order to succeed the completion of a common market. However, feedback from the Commission towards the submission of statistical returns was minimal. It is understood that this problem was

largely due to the inconsistency of reporting system from the Member States which prohibited proper analysis. Also, European Commission was undergoing internal reorganisation between 1998, and allocation of responsibilities on the control statistics and co-ordinated programmes has not yet been resolved. Indeed, it is an extremely difficult task to achieve equivalence of control standards since each country has its own system and interpretation, but the end results should be the same. Any decision at European level has an impact towards the sampling regime among the Member States. The amount of time, effort and resources spent by the U.K. on this task was uncountable in order to prove to the Commission the competence in U.K. food standards and hygiene enforcement. The Commission should also provide constructive comments and contrasts on the performance among Member States through proper analysis of these statistics so that improvement can be made.

Apart from satisfying the demand at European level, national concern on food sampling activity must not be overlooked. Currently, the standard of measuring sampling levels is based on the number of samples per 1,000 head of population per year. National target rate for Scotland is 3 samples per 1000 population per year for chemical sampling, but there is no agreed national standard for microbiological sampling. In England and Wales, the standards set by WHO of 2.5 samples per 1,000 population per year for both chemical and bacteriological sampling are used. Results showed that approximately half of the Scottish local authorities were able to meet the national performance indicator. In fact, the overall number of sampling in the U.K. is decreasing, and Scotland had a sharp drop in number after the reorganisation of local authorities in 1996. Indeed, such decline in sample numbers is not surprising due to

the reduction in the number of local authorities throughout the U.K. Also, there has been a reduction in sampling from manufacturers / producers in some local authorities on the basis that premises which are approved under vertical legislation should have their own sampling programmes. Whatever the outcome of future government consideration on this issue, an increased level of food sampling will be required than is currently the case. Local authorities should critically examine their sampling requirements based on local need. In order to achieve maximum effectiveness and the best use of scarce resources, local authorities should ensure that proactive routine sampling, other than for reactive duties such as complaints, food poisoning and port health and home authority duties, is carried out in conjunction with the liaison groups and LACOTS and/or SFCC. To avoid duplication of work, proposed sampling projects should be cleared initially through the relevant bodies to ensure that other departments are not proposing to carry out similar surveys. To ensure effective distribution and share of information, it would be efficient if results of surveys or projects are submitted to relevant Food Panel of LACOTS or SFCC.

For the purpose of this research, a national survey was carried out in order to further investigate the activity of food sampling at local level. The majority of Environmental Health Departments located in local councils suggested that the main aim of food sampling and subsequent analysis was to monitor and ensure the standards and safety of foodstuffs sold in their areas. Over 40% agreed that selected pathogens or targeted foodstuffs was the main criteria used to determine the types of foodstuffs sampled for microbiological examination. In terms of sampling for chemical analysis, different enforcement systems among U.K. national areas have diverse

opinions. In England and Wales where food labelling and composition is normally carried out by the Trading Standards Departments, most local Environmental Health Departments would only take reactive samples for the purpose of consumers' complaints and food poisoning investigation. In Scotland, this task is also the responsibility of the Environmental Health Departments, and the majority indicated that food products manufactured in local areas was the main criteria for chemical sampling. The cost premises ratio spent on food sampling and analysis showed that Scotland was ten times higher than that in England and Wales. It is not surprising to expect such a high figure since Scottish local authorities have to carry the heavy burden towards the cost of analyses. In terms of usefulness of analyses' results at local level, local authorities had different views towards many aspects, but indication for educational purpose had a higher proportion among others. At national level, contribution to national surveys was believed to be the main use. However, at European level, about half of the local authorities did not know how their results would be used in Europe. Although one-fifth indicated that results would contribute to EU control programmes, no further information was supplied by the European Commission. 45% of U.K. local authorities believed that their food sampling programmes contributed significantly to the prevention of food-borne illness, while equal proportion disagreed with this statement. However, three-quarters of local councils trusted that the current system of food sampling could be improved upon, in particular, if more time, staff and resources were available to increase the frequency of sampling.

Through the results of the national survey, it was clearly shown that U.K. local authorities were eager and prepared to advance their sampling regime. Indeed, the aims and objectives of sampling were unambiguous towards the protection of public health. However, there were many different opinions and criticisms, both positive and negative in attitude, towards the whole rationale in local authority sampling. Concerns had been expressed on the compliance sampling initiated by upper levels, and by doing so many were not convinced the real benefits. Through past experience, problems had been identified during the course of inspection and sampling and led to the prevention of food-borne diseases, yet the number of food poisoning incidents showed an upward trend. Indeed, evidence was given in the survey that some food poisoning incidents were prevented due to routine sampling; however, based on yearly programmes on the frequency of sampling, should more food poisoning incidents be prevented? Again, nearly half of the replies believed that existing food sampling programmes did not contribute significantly to the prevention of food-borne illness. Many suggested that either there was too little sampling done or the number of samples taken was insignificant to the overall food volume, so that the true quality of food lot could not be properly identified. In many cases, it is inevitable that results of sampled food did not prove the original hypothesis, for example: results of analyses from badly handled food appeared to be satisfactory, and vice versa. This problem was mainly due to the lack of funding towards food sampling, and local authorities were handicapped by financial constraints. With additional support on staff and resources, it was believed that the current food sampling regime could be improved. In the main, local authorities reckoned that the turning point for improvement depended on the wider variety of foodstuffs sampled

and an increase in number of samples taken. In such case, what should the appropriate sample size be in order to reflect the true quality of food lot?

It is very clear that the fundamental concept of sampling was not comprehended by the food control authorities. Indeed, the main reason for food sampling and subsequent analysis is to collect some information about the food lot since it is not practically possible to examine the entire population. Based on the results of analyses, some decision for acceptance or rejection whether the food lot complies with the agreed requirement will be made. Unfortunately, through the course of sampling, the presence of uncertainty and variation is inevitable. However, sampling errors can be represented and quantified through the concept of probability and statistical analysis, therefore a degree of confidence where the true level of sample mean lies can be obtained and justified. Through the properties and application of binomial and normal distributions in sampling distribution graphs where the level of sample accuracy can be reflected, the close relationship between confidence level, sample size, margin of error and precision were identified and understood. It was shown that good precision and small margin of error depend on the sample size in order to achieve good estimation of population mean or proportion. To further examine the behaviour of margin of error (E) under different sample size and sample proportion, a model was developed where good normal approximation was based on values of n satisfying $np(1\text{-}p) \geq 10$. The purpose was to test the precision of the estimate from the level of E at each of their sample proportions ($\hat{p}$). Also, the model would allow the smallest possible sample size under various proportions to be obtained which at the same time satisfying good normal approximation. Results

indicated that with a sample size between 30-300, sample proportion less than 4% would not be included in good estimation. Through the real example: *Salmonella enteritidis* in eggs, it was proved that the detection of food contaminants at low levels required a very large sample in order to obtain good estimation. But in reality, local authority sampling regimes had never even reach the minimum requirement. In fact, the majority of local authority routine sampling was 'hit or miss' type, with no statistical validation whatsoever. It is understood that local budget on food sampling is very limited and scarce, which prohibit an increase in sampling. But by sampling, say, several eggs in a three-month period, how can the accuracy and benefit be justified. If the same procedure were repeated over other sampling programmes by all the U.K. local authorities, the amount of time, effort and resources would be considerably significant. There could be argued that some potential food poisoning incidents were detected and prevented through existing sampling regime; but in a logical approach if the programmes were planned in a statistical manner, food poisoning incidents would have been reduced to a much lower level at the first place. In the main, the importance of sample size must not be overlooked in the existing sampling programmes, or else effort and resources would well be spent on different areas in order to effectively prevent the occurrence of food-borne illness. In fact, one of the most effective ways to prevent food poisoning through business is the adoption of 'hazard analysis' approach to food production and sampling has its role in this system. To determine a suitable sample size of any specific food contaminants in any particular food type, estimation of possible food contaminant levels in the lot (i.e. population proportion of defective items) would provide a clear picture of what n should be for good approximation. Due to the fact that there are numerous food

contaminants among large variety of foodstuffs, further research on the determination of critical levels for both chemical and microbiological food contaminants hazardous to health is absolutely necessary in order to improve the current situation. Without the existence of food standards agreed among the enforcing bodies, sampling itself is completely meaningless. In general, it is understood that large sample size is not feasible due to the high cost, but small sample size would lead to erroneous conclusions. If local authorities considered undertaking routine sampling at a regional basis, such high cost might be split. Some local authorities suggested that those with a relatively high number of food manufacturing premises within their area should be taking significantly more samples than those with fewer such premises. In any case, central government support towards sampling and analysis cost is vital to the success of efficient and effective food sampling programme, and consequently lead to the prevention of food-borne illness. Alternatively, a requirement can be placed on food premises to undertake their own routine sampling, and Environmental Health Officers from the councils will then carry out local audits on the samples' results in a regular basis. In this arrangement, high cost of obtaining sufficiently large sample size under local authorities' sampling budgets can be avoided. However, integrity of the true representative samples submitted for analysis would be questionable. Also, the financial burden for the cost of food and analysis will simply shift to the owners of the food premises and will give rise to financial consequences.

Indeed, one of the reasons for sampling is to ensure that foodstuffs for human consumption comply with the legal standard so that it will not cause ill health. In

other words, sampling requires the existence of standards, or else there is no need to sample. Commonly, many U.K. Regulations belong to ideal standards while the ICMSF sampling plans are examples of realizable standards. Due to the limitation existed in both standards, the concept of statistically verifiable ideal standard was introduced. It is a standard which comprises an ideal standard and a standard for statistical verification of the ideal standard and it must be flexible in nature. Through the detailed analysis on the concept of food sampling, knowledge on determining appropriate sample size can be applied to the design of a flexible compliance criterion in the statistically verifiable ideal standard so that compliance to such standard can be justified with confidence. However, the absence of many limits made the design of the standard very difficult.

Finally, it is advised that both local and central government should make every effort to ensure that the design of food sampling programmes used by the local authorities are statistically validated so that some degree of confidence can be obtained from the sampling results in order to avoid incorrect and fallacious conclusions. Initial financial support to local sampling is inevitable, but the reduction of overall food poisoning incidents will ultimately compensate the cost and fulfil the promise on public health. The design of statistically validated sampling programmes should be incorporated in the statistically verifiable ideal standards so that verification on whether the compliance to legal requirement is met or not can be justified. However, the lack of many microbiological and chemical limits becomes an obstacle. It is advised that the European Commission should take the lead in this area in order to achieve a Europe-wide unified approach to food standards. Further research is

required to extend the investigation of statistical analysis to the food contaminants in various types of foodstuffs. Also, detailed examination on cost benefit analysis along the chain of causality is necessary to develop best practice on U.K. food sampling regime.

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Appendices

Appendix 1

Codes of Practice - Food Safety Act 1990

A.1 Codes of Practice - Food Safety Act 1990

No. 1	:	Responsibility for Enforcement of the Food Safety Act 1990
No. 2	:	Legal Matters
No. 3	:	Inspection Procedures - General
No. 4	:	Inspection, Detention and Seizure of Suspected Food
No. 5 (Revised)	:	The Use of Improvement Notices
No. 6	:	Prohibition Procedures
No. 7	:	Sampling for Analysis or Examination
No. 8 (Revised)	:	Food Standards Inspections
No. 9	:	Food Hygiene Inspections
No.10	:	Enforcement of the Temperature Control Requirements of Food Hygiene Regulations
No.11	:	Enforcement of the Food Premises (Registration) Regulations
No.12	:	Division of Enforcement Responsibilities for the Quick Frozen Foodstuffs Regulations 1990
No.13	:	Enforcement of the Food Safety Act 1990 in relation to Crown Premises
No.14	:	Enforcement of the Food Safety (Live Bivalve Molluscs and Other Shellfish) Regulations 1992
No.15	:	Enforcement of the Food Safety (Fishery Products) Regs. 1992
No.16	:	Enforcement of the Food Safety Act 1990 in relation to the Food Hazard Warning System
No.17	:	Enforcement of the Meat Products (Hygiene) Regulations 1994
No.18	:	Enforcement of the Dairy Products (Hygiene) Regulations 1995 and the Dairy Products (Hygiene)(Scotland) Regulations 1995
No.19	:	Qualifications & Experience of Authorised Officers & Experts
No.20	:	Exchange of Information between Member States of the EU on Routine Food Control Matters

Appendix 2

Scottish Local Authority Appointment for the Analytical Services provided by the four Public Analysts

A.2.1 Glasgow Scientific Services

Argyll and Bute Council

City of Glasgow Council

West Dunbartonshire Council

Dumfries and Galloway Council

East Ayrshire Council

East Dunbartonshire Council

East Renfrewshire Council

Inverclyde Council

North Ayrshire Council

North Lanarkshire Council

Renfrewshire Council

South Ayrshire Council

South Lanarkshire Council

Clackmannanshire Council

Falkirk Council

Stirling Council

Western Isles Island Council

A.2.2 Edinburgh Scientific Services

City of Edinburgh Council

East Lothian Council

Midlothian Council

West Lothian Council

Scottish Borders Council

Orkney Islands Council

Shetlands Islands Council

A.2.3 Aberdeen Scientific Services

Aberdeen City Council

Aberdeenshire Council

Moray Council

Highland Council

A.2.4 Dundee Scientific Services

Dundee City Council

Angus City Council

Perth and Kinross Council

Fife Council

Appendix 3

PHLS - 49 Public Health Laboratories in England and Wales

A.3.1 East Laboratory Group

(a) Cambridge
(b) Chelmsford
(c) Ipswich
(d) Luton
(e) Norwich
(f) Oxford
(g) Peterborough
(h) Reading
(i) Whipps Cross

A.3.2 Midlands Laboratory Group

(a) Birmingham
(b) Coventry
(c) Shrewsbury
(d) Stoke

A.3.3 North Laboratory Group

(a) Carlisle
(b) Hull
(c) Leeds
(d) Middlesbrough
(e) Newcastle

A.3.4 North West Laboratory Group

(a) Chester
(b) Liverpool
(c) Manchester
(d) Preston

A.3.5 South West Laboratory Group

(a) Bristol
(b) Exeter
(c) Gloucester
(d) Hereford
(e) Plymouth
(f) Taunton
(g) Truro

A.3.6 Thames Laboratory Group

(a) Ashford
(b) Brighton
(c) Central Middlesex
(d) Dulwich / Kings
(e) Surrey

A.3.7 Trent Laboratory Group

(a) Leicester
(b) Lincoln
(c) Nottingham
(d) Sheffield

A.3.8 Wales Laboratory Group

(a) Bangor
(b) Cardiff
(c) Carmarthen
(d) Rhyl
(e) Swansea

A.3.9 Wessex Laboratory Group

(a) Dorchester
(b) Poole
(c) Portsmouth
(d) Salisbury
(e) Southampton

Appendix 4

Structure of Local Liaison Groups in Scotland

A.4.1 North of Scotland Liaison Group

(a) Aberdeenshire
(b) City of Aberdeen
(c) Highland
(d) Moray
(e) Orkney
(f) Shetland

A.4.2 Central Liaison Group

(a) Clackmannanshire
(b) Falkirk
(c) Stirling

A.4.3 Western Scotland Liaison Group

(a) Argyll and Bute
(b) City of Glasgow
(c) West Dunbartonshire
(d) Dumfries and Galloway
(e) East Ayrshire
(f) East Dunbartonshire
(g) East Renfrewshire
(h) Inverclyde
(i) North Ayrshire
(j) North Lanarkshire
(k) Renfrewshire
(l) South Ayrshire
(m) South Lanarkshire
(n) Western Isles

A.4.4 Fife and Tayside Liaison Group

(a) Angus
(b) City of Dundee
(c) Fife
(d) Perthshire & Kinross

A.4.5 Lothian & Borders Liaison Group

(a) Scottish Borders
(b) City of Edinburgh
(c) East Lothian
(d) Midlothian
(e) West Lothian

Appendix 5

Qualifications for Authorised Officers of the Food Authorities

A.5.1 Food Hygiene

1. (a) Certificate of Registration of the Environmental Health Officers Registration Boards;
   (b) The Institute of Environmental Health Officers Diploma in Environmental Health (or its antecedents); or
   (c) The Diploma in Environmental Health awarded by the Royal Environmental Health Institute of Scotland (or its antecedents);

2. In respect of the inspection of food premises only: a Certificate in Food Premises Inspection issued by one of the following:-
   (a) The Environmental Health Officers Registration Board (EHORB),
   (b) The Scottish Food Safety Officers Registration Board (SFSORB), or
   (c) The Institute of Food Science and Technology (IFST).

A.5.2 Food Standards

1. Diploma in Trading Standards or its antecedents;

2. (a) Certificate of Registration of the Environmental Health Officers Registration Board;
   (b) The Institute of Environmental Health Officers Diploma in Environmental Health (or its antecedents); or
   (c) The Diploma in Environmental Health awarded by the Royal Environmental Health Institute of Scotland (or its antecedents);

3. Diploma in Consumer Affairs or its antecedents, provided it includes Paper Four of Part II of the Diploma which relates to Food and Agricultural Standards;

4. A certificate in Food Standards Inspections issued by the Scottish Food Safety Officers Registration Board.

Appendix 6

Formal Samples for Chemical Analysis

which may consider best be left in Unopened Containers

A.6 Formal Samples for Chemical Analysis which may consider best be left in Unopened Containers

1. Food containing evanescent ingredients, eg. soft drinks containing Vitamin C;

2. Food containing volatile substances, eg. chloroform, alcohol;

3. Product where it may not be possible to ensure that each ingredient is divided equally between the three parts, eg. products where there is a declaration of added water, meat products with lumps of meat, fruit cocktail, yoghurts with fruit;

4. Products which are difficult to extract from the container and where there is a possibility of a considerable quantity of the food remaining in the container, eg. salad cream, sauces, treacle;

5. Food packed in aerosols;

6. Aerated food, eg. carbonated soft drinks;

7. Products in hermetically sealed containers, eg. meat pastes, jams;

8. Products where it is necessary to have an unopened container in order to carry out a particular test, eg. condensed milk where there is a statement that the contents are equivalent to a quantity of whole milk.

Appendix 7

ICMSF Plan Stringency, Sampling Plans and

Recommended Microbiological Limits; and

PHLS Microbiological Guidelines for some Ready-To-Eat Foods

A.7.1 Plan Stringency (case) in relation to degree of health hazard and conditions of use

Type of hazard	Conditions in which food is expected to be handled and consumed after sampling, in the usual course of events		
	Reduce degree of hazard	Cause no change in hazard	May increase hazard
No direct health hazard Utility (e.g. general contamination, reduced shelf-life, and spoilage)	Case 1	Case 2	Case 3
Health hazard			
Low, indirect (indicator)	Case 4	Case 5	Case 6
Moderate, direct, limited spread	Case 7	Case 8	Case 9
Moderate, direct, potentially extensive spread	Case 10	Case 11	Case 12
Severe, direct	Case 13	Case 14	Case 15

A.7.2 Suggested sampling plans for combinations of degrees of health and conditions of use

Degree of concern relative to utility and health hazard	Conditions in which food is expected to be handled and consumed after sampling, in the usual course of events		
	Conditions reduce degree of concern	Conditions cause no change in concern	Conditions may increase concern
No direct health hazard	*Increase shelf-life*	*No change*	*Reduce shelf-life*
Utility (e.g. shelf-life, and spoilage)	Case 1 3-class n=5, c=3	Case 2 3-class n=5, c=2	Case 3 3-class n=5, c=1
Health hazard	*Reduce hazard*	*No change*	*Increase hazard*
Low, indirect (indicator)	Case 4 3-class n=5, c=3	Case 5 3-class n=5, c=2	Case 6 3-class n=5, c=1
Moderate, direct, limited spread	Case 7 3-class n=5, c=2	Case 8 3-class n=5, c=1	Case 9 3-class n=10, c=1
Moderate, direct, potentially extensive spread	Case 10 2-class n=5, c=0	Case 11 2-class n=10, c=0	Case 12 2-class n=20, c=0
Severe, direct	Case 13 2-class n=15, c=0	Case 14 2-class n=30, c=0	Case 15 2-class n=60, c=0

A.7.3 ICMSF Sampling Plans and Recommended Microbiological Limits for some food commodities

Product	Test	Case	Plan Class	n	c	Limit / cm^2 or g	
						m	M
Raw meats							
Carcass meat, before chilling	APC	1	3	5	3	10^5	10^6
Carcass meat, chilled	APC	1	3	5	3	10^6	10^7
Edible offal, chilled	APC	1	3	5	3	10^6	10^7
Carcass meat, frozen	APC	1	3	5	3	$5*10^5$	10^7
Boneless meat, frozen (beef, veal, pork, mutton)	APC	1	3	5	3	$5*10^5$	10^7
Comminuted meat, frozen	APC	1	3	5	3	10^6	10^7
Edible offal, frozen	APC	1	3	5	3	$5*10^5$	10^7
Processed meats							
Dried blood	{ Staph. aureus	8	3	5	1	10^2	10^4
Plasma	{ C. perfringens	8	3	5	1	10^2	10^4
Gelatin	{ Salmonella	11	2	10	0	0	
Roast beef	Salmonella	12	2	20	0	0	
Pate	Salmonella	12	2	20	0	0	
Poultry & poultry products							
Cooked poultry meat, frozen; To be reheated before eating (eg. prepared frozen meals)	Staph. aureus	8	3	5	1	10^3	10^4
	Salmonella	10	2	5	0	0	
Cooked poultry meat, frozen, Ready-to-eat (eg. turkey rolls)	Staph. aureus	8	3	5	1	10^3	10^4
		9	3	10	1	10^3	10^4
	Salmonella	11	2	10	0	0	
Cured and/or smoked poultry meat	Staph. aureus	9	3	10	1	10^3	10^4
	Salmonella	11	2	10	0	0	
Dehydrated poultry products	Salmonella	11	2	10	0	0	
Raw chicken (fresh or frozen), during processing	APC	1	3	5	3	$5*10^5$	10^7
Milk & milk products							
Dried milk	APC	2	3	5	2	$3*10^4$	$3*10^5$
	Coliforms	5	3	5	1	10	10^2
	Salmonella - normal routine	10	2	5	0	0	
		11	2	10	0	0	
		12	2	20	0	0	
	Salmonella - for high-risk population	10	2	15	0	0	-
		11	2	30	0	0	-
		12	2	60	0	0	-
Cheese, 'hard' & 'semi-soft' types	Staph. aureus	8	2	5	0	10^4	-

Product	Test	Case	Plan Class	n	c	Limit / cm^2 or g	
						m	M
Eggs & egg products							
Pasteurised liquid, frozen, & dried egg products	APC	2	3	5	2	$5*10^4$	10^6
	Coliforms	5	3	5	2	10	10^3
	Salmonella - normal routine	10	2	5	0	0	-
		11	2	10	0	0	-
		12	2	20	0	0	-
	Salmonella - for high-risk population	10	2	15	0	0	-
		11	2	30	0	0	-
		12	2	60	0	0	-
Fish & shellfish							
Fresh & frozen fish & cold-smoked	APC	1	3	5	3	$5*10^5$	10^7
	E. coli	4	3	5	3	11	500
	Salmonella	10	2	5	0	0	-
	V. parahaemolyticus	7	3	5	2	10^2	10^3
	Staph. aureus	7	3	5	2	10^3	10^4
Pre-cooked breaded fish	APC	2	3	5	2	$5*10^5$	10^7
	E. coli	5	3	5	2	11	500
	Staph. aureus	8	3	5	1	10^3	10^4
Frozen raw crustaceans	APC	1	3	5	3	10^6	10^7
	E. coli	4	3	5	3	11	500
	Salmonella	10	2	5	0	0	-
	V. parahaemolyticus	8	3	5	1	10^2	10^3
	Staph. aureus	7	3	5	2	10^3	10^4
Frozen cooked crustaceans	APC	2	3	5	2	$5*10^5$	10^7
	E. coli	5	3	5	2	11	500
	Staph. aureus	8	2	5	0	10^3	-
	Salmonella	11	2	10	0	0	-
	V. parahaemolyticus	8	3	5	1	10^2	10^3
Cooked, chilled, & frozen crabmeat	APC	2	3	5	2	10^5	10^6
	E. coli	6	3	5	1	11	500
	Staph. aureus	9	2	5	0	10^3	-
	V. parahaemolyticus	9	3	10	1	10^2	10^3
Fresh & frozen bivalve moluscs	APC	3	2	5	0	$5*10^5$	-
	E. coli	6	2	5	0	16	-
	Salmonella	12	2	20	0	0	-
	V. parahaemolyticus	9	3	10	1	10^2	10^3
Vegetables, fruits & nuts							
Frozen vegetables & fruits (pH>4.5)	E. coli	5	3	5	2	10^2	10^3
Dried vegetables	E. coli	5	3	5	2	10^2	10^3
Coconut (desiccated)	Salmonella						
growth not anticipated		11	2	10	0	0	-
growth anticipated		12	2	20	0	0	-
Yeast	Salmonella	12	2	20	0	0	-

Product	Test	Case	Plan Class	n	c	Limit / cm^2 or g	
						m	M
Cereals & cereal products							
Cereals	Moulds	5	3	5	2	10^2-10^4	10^5
Soya flours, concentrates, & isolates	Moulds	5	3	5	2	10^2-10^4	10^5
	Salmonella	10	2	5	0	0	-
Frozen bakery products (ready to eat) with low-acid or high a_w fillings or toppings	Staph. aureus	9	3	5	1	10^2	10^4
	Salmonella	12	2	20	0	0	-
Frozen bakery products (to be cooked) with low-acid or high a_w fillings or toppings (eg. meat pies, pizzas)	Staph. aureus	8	3	5	1	10^2	10^4
	Salmonella	10	2	5	0	0	-
Frozen entrees containing rice or corn flour as a main ingredient	B. cereus	8	3	5	1	10^3	10^4
Frozen & dried products	Staph. aureus	8	3	5	1	10^2	10^4
	Salmonella	10	2	5	0	0	-
Fats & oils							
Peanut butter & other nut butters:							
Consumed without heating or other treatment to destroy microbes	Salmonella	11	2	10	0	0	-
Used as ingredient in high-moisture food	Salmonella	12	2	20	0	0	-
Sugar, cocoa, chocolate & confectionery							
Cocoa	Salmonella	11	2	10	0	0	
Chocolate & other confectionery	Salmonella	11	2	10	0	0	
Formulated foods							
Coated or filled, dried shelf-stable biscuits	Coliforms	5	3	5	2	10	10^2
	Salmonella	11	2	30	0	0	-
Dried & instant products requiring reconstitution	APC	6	3	5	1	10^4	10^5
	Coliforms	6	3	5	1	10	10^2
	Salmonella	12	2	60	0	0	-
Dried products requiring heating to boiling before consumption	APC	4	3	5	3	10^5	10^6
	Coliforms	4	3	5	3	10	10^2
	Salmonella	10	2	15	0	0	-
Natural mineral waters, other bottled waters, process waters, & ice							
Non-carbonated natural mineral waters (eaux plates) & bottled non-carbonated waters, not classified as mineral waters	Coliforms	5	2	5	0	0	-
	Pseudomonas aeruginosa	8	2	5	0	0	-
Carbonated waters (natural mineral or other bottled waters)	pH		2	5	0	3.5	-

A.7.4 PHLS Microbiological Guidelines for some Ready-To-Eat Foods

Criterion	Food	Microbiological Quality (cfu/g, unless otherwise stated)			
		A	**B**	**C**	**D**
Aerobic plate count (30°C; 48-72 hr)	(1) Cooked pies, pasties, quiches, etc.; confectionery products without dairy cream	$<10^3$	10^3 - 10^5	$>10^5$	
	(2) Cooked meats	$<10^4$	10^4 - 10^6	$>10^6$	
	(3) Sandwiches with salad	$<10^4$	10^4 - 10^7	$>10^7$	
	(4) Sandwiches with salad; cooked seafoods; confectionery products with dairy cream; prepared mixed salads	$<10^5$	10^5 - 10^8	$>10^8$	
Salmonella spp.	(1) - (4)	not detected in 25g			present in 25g
L. monocytogenes		not detected in 25g	present in 25g -$<10^2$		
E. coli		<20	20 - $< 10^2$	10^2 - 10^4	$>10^4$
S. aureus		<20	20 - $< 10^2$	10^2 - 10^4	$>10^4$
C. perfringens		<200	200 - $< 10^3$	10^3 - 10^4	$>10^4$
B. cereus & other Bacillus spp.		<200	200 - $< 10^4$	10^4 - 10^5	$>10^5$
V. parahaemolyticus	Seafoods	not detected in 25g			present in 25g
Campylobacter spp. (thermotolerant)	Cooked poultry	not detected in 25g			present in 25g

A - Satisfactory

B - Fairly Satisfactory

C - Unsatisfactory

D - Unacceptable - potentially hazardous

Appendix 8

Results of National Survey on U.K. Food Sampling

for Microbiological Examination and Chemical Analysis

A.8.1 Questionnaire

National Survey

THE UNIVERSITY OF STRATHCLYDE IN GLASGOW

UK FOOD SAMPLING FOR MICROBIOLOGICAL EXAMINATION & CHEMICAL ANALYSIS

Questionnaire completed by: _____

Position: _____

Telephone No. : _____

Fax No. : _____

Please complete and return this questionnaire to:

Raymond Wong
Environmental Health
University of Strathclyde
John Anderson Building
107 Rottenrow
Glasgow G4 0NG

It is much appreciated if you could kindly answer the questions by filling in the blanks.

Q.1 What are the main aims of food sampling and subsequent analysis undertaken by your Local Authority?

Most Important: .....

.....

.....

.....

Least Important: .....

Q.2 What specific criteria do you use to choose which foodstuffs are sampled for?

Chemical Analysis: .....

.....

.....

Microbiological Examination: .....

.....

.....

Q.3 What is the total annual cost of food sampling and its analysis?

Chemical: .....

Microbiological: .....

Q.4 What is the total number of food premises within your local authority?

.....

.....

Q.5 What are your results of analyses used for:

At Local Level: .....

.....

At National Level: .....

.....

At European Level: .....

.....

Q.6 Do you think that the food sampling programme used by your local authority contributes significantly to the prevention of food-borne illness?

☐ Yes ☐ No

Please comment: .....

.....

.....

.....

.....

Q.7 Do you think that your current system of food sampling could be improved upon?

☐ Yes ☐ No

Please comment: .....

.....

.....

.....

Please use space provided overleaf on page 3 for any additional information you may wish to provide.

Many thanks for completing this questionnaire.

Additional Information

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Environmental Health
University of Strathclyde

A.8.2 Results of Question One

A.8.2.1 Allocation of Statements from U.K. Replies

LA's	Question One				
	MI				LI
	A	B	C	D	E
1	1	3	0	0	0
2	3	2	0	0	0
3	1	8	2	2	7
4	1	10	4	10	0
5	1	1	10	0	0
6	4	4	2	0	0
7	7	8	0	0	0
8	3	4	7	0	0
9	7	4	0	0	0
10	1	1	0	0	0
11	5	10	1	2	0
12	3	2	0	0	0
13	1	4	0	0	0
14	1	10	0	0	0
15	10	5	2	10	0
16	1	3	0	0	0
17	2	0	0	0	0
18	1	4	0	0	0
19	9	2	0	0	0
20	5	2	0	0	0
21	5	2	2	2	0
22	7	2	10	0	0
23	2	7	10	0	0
24	4	0	0	0	0
25	1	2	3	4	0
26	3	3	0	0	0
27	1	7	0	0	0
28	3	3	5	2	0
29	1	9	0	0	0
30	9	3	0	0	0
31	1	5	2	0	0
32	5	0	0	0	0
33	2	5	4	8	0
34	3	2	0	0	0
35	1	4	0	0	0
36	1	0	0	0	0
37	1	3	3	2	0
38	2	3	10	0	0
39	3	2	2	0	0
40	5	4	3	2	0
41	4	0	0	0	0
42	1	0	0	0	0
43	1	4	0	0	0
44	1	8	0	0	0
45	1	0	0	0	0
46	3	8	4	0	0
47	8	10	3	0	0
48	3	3	0	0	0
49	1	1	4	3	10
50	1	0	0	0	0
51	7	10	7	3	0
52	1	4	1	10	0
53	1	10	0	0	0
54	1	0	0	0	0
55	1	4	3	0	0
56	3	3	1	10	2
57	5	2	2	0	0
58	3	0	0	0	0

LA's	Question One				
	MI				LI
	A	B	C	D	E
59	1	2	0	0	0
60	6	4	1	2	7
61	4	2	10	0	0
62	3	0	0	0	0
63	1	0	0	0	0
64	3	3	3	10	0
65	1	1	1	0	0
66	1	0	0	0	0
67	10	3	8	7	2
68	4	1	10	0	0
69	5	3	2	0	0
70	4	10	0	0	0
71	1	3	3	10	0
72	3	3	3	3	0
73	1	3	2	0	0
74	7	8	10	0	0
75	10	1	2	0	0
76	8	7	5	0	0
77	5	0	0	0	0
78	1	1	4	0	0
79	1	5	2	0	0
80	2	0	0	0	0
81	1	0	0	0	0
82	5	2	0	0	0
83	2	5	2	0	0
84	2	0	0	0	0
85	4	3	3	0	0
86	1	8	0	0	0
87	3	2	0	0	0
88	2	7	3	10	2
89	1	7	0	0	0
90	6	5	0	0	0
91	9	4	0	0	0
92	1	10	10	0	0
93	3	10	0	0	0
94	1	3	3	10	0
95	3	0	0	0	0
96	1	4	5	2	0
97	1	2	0	0	0
98	1	3	2	0	0
99	1	2	2	0	0
100	2	10	6	0	0
101	7	3	2	0	0
102	2	5	0	0	0
103	10	10	1	2	0
104	3	8	0	0	0
105	1	9	0	0	0
106	2	5	1	0	0
107	8	4	3	0	0
108	1	0	0	0	0
109	4	3	0	0	0
110	4	2	3	0	0
111	5	1	5	2	0
112	3	10	0	0	0
113	1	3	0	0	0
114	4	2	2	2	0
115	2	0	0	0	0
116	1	2	0	0	0

LA's	Question One				
	MI				LI
	A	B	C	D	E
117	2	4	0	0	0
118	4	5	0	10	2
119	6	2	0	0	0
120	4	5	3	10	3
121	10	10	2	5	0
122	5	1	0	0	0
123	2	5	0	0	0
124	1	1	10	5	3
125	2	4	5	0	0
126	5	2	8	0	0
127	9	4	5	10	2
128	3	3	0	0	0
129	3	4	2	0	0
130	1	3	0	0	0
131	3	2	0	0	0
132	1	4	4	0	0
133	1	1	3	0	0
134	4	0	0	0	0
135	4	7	0	0	0
136	3	5	2	0	0
137	1	2	0	0	0
138	2	3	7	0	0
139	3	6	5	0	0
140	4	1	4	0	0
141	4	2	10	0	0
142	3	1	2	0	0
143	3	2	0	0	0
144	6	4	10	0	0
145	1	4	0	0	0
146	4	10	3	2	5
147	1	0	0	0	0
148	4	5	2	2	0
149	1	2	4	0	0
150	1	10	0	0	0
151	4	0	0	0	0
152	4	0	0	0	0
153	6	4	0	0	0
154	4	1	0	0	0
155	1	10	0	0	0
156	7	1	0	0	0
157	10	1	4	0	0
158	1	4	0	0	0
159	1	4	0	0	0
160	1	1	1	1	0
161	6	4	0	0	0
162	1	1	0	0	0
163	3	4	2	0	0
164	1	0	0	0	0
165	5	1	2	10	2
166	1	10	0	0	0
167	7	0	0	0	0
168	1	0	0	0	0
169	3	3	0	0	0
170	1	2	5	10	0
171	1	0	0	0	0
172	1	0	0	0	0

MI Most Important Aim
LI Least Important Aim

A.8.2.2 Allocation of Statements from England & Wales Replies

LA's	Question One				
	MI				LI
	1(1)	1(2)	1(3)	1(4)	1(5)
1	1	3	0	0	0
2	3	2	0	0	0
3	1	8	2	2	7
4	1	10	4	10	0
5	1	1	10	0	0
6	4	4	2	0	0
7	7	8	0	0	0
8	3	4	7	0	0
9	7	4	0	0	0
10	1	1	0	0	0
11	5	10	1	2	0
12	3	2	0	0	0
13	1	4	0	0	0
14	1	10	0	0	0
15	10	5	2	10	0
16	1	3	0	0	0
17	2	0	0	0	0
18	1	4	0	0	0
19	9	2	0	0	0
20	5	2	0	0	0
21	5	2	2	2	0
22	7	2	10	0	0
23	2	7	10	0	0
24	4	0	0	0	0
25	1	2	3	4	0
26	3	3	0	0	0
27	1	7	0	0	0
28	3	3	5	2	0
29	1	9	0	0	0
30	9	3	0	0	0
31	1	5	2	0	0
32	5	0	0	0	0
33	2	5	4	8	0
34	3	2	0	0	0
35	1	4	0	0	0
36	1	0	0	0	0
37	1	3	3	2	0
38	2	3	10	0	0
39	3	2	2	0	0
40	5	4	3	2	0
41	4	0	0	0	0
42	1	0	0	0	0
43	1	4	0	0	0
44	1	8	0	0	0
45	1	0	0	0	0
46	3	8	4	0	0
47	8	10	3	0	0
48	3	3	0	0	0
49	1	1	4	3	10

LA's	Question One				
	MI				LI
	1(1)	1(2)	1(3)	1(4)	1(5)
50	1	0	0	0	0
51	7	10	7	3	0
52	1	4	1	10	0
53	1	10	0	0	0
54	1	0	0	0	0
55	1	4	3	0	0
56	3	3	1	10	2
57	5	2	2	0	0
58	3	0	0	0	0
59	1	2	0	0	0
60	6	4	1	2	7
61	4	2	10	0	0
62	3	0	0	0	0
63	1	0	0	0	0
64	3	3	3	10	0
65	1	1	1	0	0
66	1	0	0	0	0
67	10	3	8	7	2
68	4	1	10	0	0
69	5	3	2	0	0
70	4	10	0	0	0
71	1	3	3	10	0
72	3	3	3	3	0
73	1	3	2	0	0
74	7	8	10	0	0
75	10	1	2	0	0
76	8	7	5	0	0
77	5	0	0	0	0
78	1	1	4	0	0
79	1	5	2	0	0
80	2	0	0	0	0
81	1	0	0	0	0
82	5	2	0	0	0
83	2	5	2	0	0
84	2	0	0	0	0
85	4	3	3	0	0
86	1	8	0	0	0
87	3	2	0	0	0
88	2	7	3	10	2
89	1	7	0	0	0
90	6	5	0	0	0
91	9	4	0	0	0
92	1	10	10	0	0
93	3	10	0	0	0
94	1	3	3	10	0
95	3	0	0	0	0
96	1	4	5	2	0
97	1	2	0	0	0
98	1	3	2	0	0

LA's	Question One				
	MI				LI
	1(1)	1(2)	1(3)	1(4)	1(5)
99	1	2	2	0	0
100	2	10	6	0	0
101	7	3	2	0	0
102	2	5	0	0	0
103	10	10	1	2	0
104	3	8	0	0	0
105	1	9	0	0	0
106	2	5	1	0	0
107	8	4	3	0	0
108	1	0	0	0	0
109	4	3	0	0	0
110	4	2	3	0	0
111	5	1	5	2	0
112	3	10	0	0	0
113	1	3	0	0	0
114	4	2	2	2	0
115	2	0	0	0	0
116	1	2	0	0	0
117	2	4	0	0	0
118	4	5	0	10	2
119	6	2	0	0	0
120	4	5	3	10	3
121	10	10	2	5	0
122	5	1	0	0	0
123	2	5	0	0	0
124	1	1	10	5	3
125	2	4	5	0	0
126	5	2	8	0	0
127	9	4	5	10	2
128	3	3	0	0	0
129	3	4	2	0	0
130	1	3	0	0	0
131	3	2	0	0	0
132	1	4	4	0	0
133	1	1	3	0	0
134	4	0	0	0	0
135	4	7	0	0	0
136	3	5	2	0	0
137	1	2	0	0	0
138	2	3	7	0	0
166	1	10	0	0	0
167	7	0	0	0	0
168	1	0	0	0	0
169	3	3	0	0	0
170	1	2	5	10	0
171	1	0	0	0	0
172	1	0	0	0	0

MI Most Important Aim

LI Least Important Aim

A.8.2.3 Allocation of Statements from Scotland Replies

LA's	Question One				
	MI				LI
	1(1)	1(2)	1(3)	1(4)	1(5)
148	1	3	0	0	0
149	3	2	0	0	0
150	1	8	2	2	7
151	1	10	4	10	0
152	1	1	10	0	0
153	4	4	2	0	0
154	7	8	0	0	0
155	3	4	7	0	0
156	7	4	0	0	0
157	1	1	0	0	0
158	5	10	1	2	0
159	3	2	0	0	0
160	1	4	0	0	0
161	1	10	0	0	0
162	10	5	2	10	0
163	1	3	0	0	0
164	2	0	0	0	0
165	1	4	0	0	0

MI Most Important Aim
LI Least Important Aim

A.8.2.4 Allocation of Statements from Northern Ireland Replies

Number of Reply	Question One				
	MI				LI
	1(1)	1(2)	1(3)	1(4)	1(5)
139	3	6	5	0	0
140	4	1	4	0	0
141	4	2	10	0	0
142	3	1	2	0	0
143	3	2	0	0	0
144	6	4	10	0	0
145	1	4	0	0	0
146	4	10	3	2	5
147	1	0	0	0	0

MI Most Important Aim
LI Least Important Aim

A.8.3 Results of Question Two

LA's	Question Two	
	Chem.	Micro.
1	4	3
2	0	0
3	1	5
4	1	3
5	0	3
6	1	5
7	0	3
8	0	4
9	2	6
10	1	6
11	0	5
12	0	6
13	0	5
14	0	3
15	1	5
16	0	3
17	0	3
18	1	3
19	1	6
20	0	0
21	1	5
22	0	3
23	2	3
24	5	5
25	3	1
26	0	5
27	1	6
28	1	6
29	0	3
30	1	1
31	1	4
32	0	5
33	3	3
34	1	1
35	0	5
36	1	3
37	0	3
38	0	3
39	0	5
40	1	1
41	3	3
42	0	5
43	4	4
44	0	3
45	4	4
46	0	5
47	0	5
48	1	5
49	1	3
50	0	3
51	1	4
52	0	5
53	0	5
54	0	5
55	0	3
56	6	3
57	1	3
58	1	5

LA's	Question Two	
	Chem.	Micro.
59	1	5
60	1	5
61	1	5
62	1	2
63	0	3
64	0	5
65	0	3
66	0	3
67	6	3
68	0	5
69	1	3
70	0	5
71	1	5
72	3	0
73	1	5
74	0	5
75	1	3
76	1	3
77	0	0
78	3	3
79	0	3
80	3	3
81	1	3
82	0	3
83	0	4
84	1	3
85	1	5
86	0	3
87	3	3
88	3	5
89	1	4
90	1	1
91	0	6
92	1	1
93	0	3
94	0	3
95	5	5
96	1	4
97	5	5
98	0	5
99	0	4
100	0	3
101	0	6
102	0	0
103	0	5
104	0	3
105	1	3
106	0	3
107	1	3
108	0	5
109	1	1
110	1	1
111	0	1
112	1	5
113	1	6
114	1	5
115	6	5
116	2	5

LA's	Question Two	
	Chem.	Micro.
117	1	6
118	4	5
119	3	3
120	6	5
121	6	6
122	0	6
123	1	1
124	3	3
125	1	1
126	1	1
127	0	5
128	0	3
129	0	5
130	1	5
131	1	4
132	5	5
133	2	1
134	2	2
135	1	1
136	1	1
137	0	5
138	2	5
139	2	5
140	2	5
141	5	5
142	1	1
143	2	5
144	6	5
145	2	5
146	2	5
147	2	5
148	2	5
149	2	5
150	2	2
151	2	2
152	2	5
153	4	5
154	4	5
155	6	6
156	6	2
157	2	4
158	2	5
159	2	5
160	2	2
161	2	5
162	2	4
163	6	5
164	2	2
165	2	5
166	4	6
167	4	4
168	0	5
169	0	5
170	1	3
171	1	5
172	0	5

A.8.4 Results of Question Three

LA's	Question 3: Cost		
	Chem.	Micro.	Total
1	500	3175	3675
2	-	2200	
3	-	0	-
4	-	-	-
5	B	B	8885
6	2000	4000	6000
7	?	0	-
8	0	?	-
9	?	0	-
10	-	-	-
11	B	B	3600
12	-	24000	
13	?	0	-
14	?	5000	
15	?	?	-
16	?	?	-
17	?	0	-
18	500	500	1000
19	-	0	-
20	-	-	-
21	-	0	-
22	-	1200	
23	3000	-	
24	-	1400	
25	1500	3200	4700
26	-	?	-
27	?	?	-
28	3500	100	3600
29	?	?	-
30	-	0	-
31	1000	?	
32	-	1000	
33	300	2400	2700
34	2000	4000	6000
35	-	3000	
36	?	0	
37	?	1000	
38	B	B	750
39	?	5500	
40	650	60	710
41	-	4500	
42	-	500	
43	-	6000	
44		4500	
45	B	B	2500
46	?	0	-
47	?	?	-
48	200	800	1000
49	?	?	-
50	?	-	-
51	?	-	
52	?	-	-
53	-	9700	
54	-	420	
55	-	1800	
56	400	0	400
57	200	0	200
58	327	0	327

LA's	Question 3: Cost		
	Chem.	Micro.	Total
59	?	6000	
60	-	1200	
61	200	0	200
62	-	0	-
63	-	300	
64	?	?	-
65	-	1200	
66	-	?	-
67	10000	5800	15800
68	-	0	-
69	500	5000	5500
70	-	?	-
71	-	-	-
72	B	B	3200
73	B	B	400
74	500	3000	3500
75	-	0	-
76	-	7500	7500
77	1600	See Q.1	
78	17000	6000	23000
79	3500	5000	8500
80	?	400	
81	400	2000	2400
82	-	0	-
83	-	2500	
84	600	100	700
85	-	-	-
86	-	0	-
87	?	1000	
88	-	180	
89	-	0	-
90	-	-	-
91	-	0	-
92	25000	0	25000
93	-	4000	
94		2140	
95	3000	6000	9000
96	B	B	6800
97	2500	2500	5000
98	-	400	
99	?	?	
100	-	10000	
101	-	8000	
102	0	?	
103	-	3000	
104	?	0	
105	B	B	8500
106	-	4159	
107	200	3000	3200
108	-	2000	
109	B	B	1226
110	?	5000	
111	?	?	-
112	B	B	1400
113	11000	0	11000
114	-	?	-
115	B	B	20000
116	B	B	9780

LA's	Question 3: Cost		
	Chem.	Micro.	Total
117	B	B	8229
118	8467	1245	9712
119	B	B	20000
120	15000	?	
121	B	B	22200
122	1750	?	
123	1000	0	1000
124	18000	0	18000
125	-	0	-
126	?	?	-
127	?	0	-
128	B	B	7200
129	?	?	-
130	500	1500	2000
131	26000	0	26000
132	B	B	16500
133			
134	17500	0	17500
135	?	?	-
136	B	B	1500
137	-	3300	
138	10000	0	10000
139	14000	0	14000
140	B	B	9000
141	13400	0	13400
142	B	B	1500
143	B	B	24500
144	3000	-	3000
145	16000	0	16000
146	15000	1000	16000
147	10000	0	10000
148	35460	27213	62673
149	30000	35000	65000
150	88000	8000	96000
151	65000	17000	82000
152	40000	12000	52000
153	104900	23700	128600
154	180000	43000	223000
155	?	?	-
156	?	2000	
157	B	B	32000
158	51000	12000	63000
159	?	10000	
160	B	B	30050
161	163000	15500	178500
162	11000	3000	14000
163	?	?	-
164	37500	9800	47300
165	3500	3000	6500
166	-	-	-
167			
168	-	19516	
169	?	500	
170	2800	2200	
171	?	?	-
172	8500	3600	12100

A.8.5 Results of Question Four

LA's	Question 4	
	Premises	Cat.
1	1800	E
2	1197	D
3		A
4	820	C
5	1026	D
6	1064	D
7	692	C
8	1300	D
9	5000	K
10	800	C
11	680	C
12	2200	F
13	1300	D
14	1797	E
15	1140	D
16	1354	D
17	880	C
18	1150	D
19	1000	C
20		A
21	900	C
22	450	B
23	1700	E
24	1012	D
25	760	C
26	1100	D
27	650	C
28	2789	G
29	1449	D
30	709	C
31	839	C
32	1234	D
33	960	C
34	857	C
35	1000	C
36	1100	D
37	850	C
38	1000	C
39	1000	C
40	525	C
41	800	C
42	1000	C
43	878	C
44	1402	D
45	950	C
46	400	B
47	983	C
48	1865	E
49	1227	D
50	800	C
51	700	C
52	770	C
53	1130	D
54	1500	D
55	600	C
56	1000	C
57	522	C
58	1030	D

LA's	Question 4	
	Premises	Cat.
59	1000	C
60	1224	D
61	1400	D
62	975	C
63	3200	H
64	5500	L
65	832	C
66	1462	D
67	2013	F
68	1526	E
69	1600	E
70	860	C
71	850	C
72	788	C
73	650	C
74	960	C
75	936	C
76	1500	D
77	930	C
78	800	C
79	1600	E
80	875	C
81	667	C
82	1250	D
83	1200	D
84	700	C
85	727	C
86	900	C
87	347	B
88	2576	G
89	1400	D
90	752	C
91	1000	C
92	1500	D
93	1850	E
94	510	C
95	840	C
96	860	C
97	1067	D
98	570	C
99	1400	D
100	1250	D
101	715	C
102	1800	E
103	1400	D
104	1000	C
105	1200	D
106	957	C
107	966	C
108	460	B
109	775	C
110	1200	D
111	1200	D
112	2045	F
113	3000	G
114	2300	F
115	2500	F
116	2800	G

LA's	Question 4	
	Premises	Cat.
117	1743	E
118	2300	F
119	1700	E
120	1450	D
121	1650	E
122	1450	D
123	1100	D
124	1860	E
125	5625	M
126	2566	G
127	3150	H
128	2700	G
129	4734	K
130	8000	Q
131	2645	G
132	1646	E
133	4500	J
134	2000	E
135	2400	F
136	1000	C
137	500	B
138	1613	E
139	700	C
140	692	C
141	320	B
142	300	B
143	300	B
144	327	B
145	900	C
146	706	C
147	500	B
148	925	C
149	2747	G
150	1277	D
151	1328	D
152	633	C
153	5000	K
154	3200	H
155	5000	K
156	750	C
157	1201	D
158	2000	E
159		A
160	1440	D
161	2693	G
162	1300	D
163	772	C
164	1265	D
165	500	B
166	1250	D
167	1977	E
168	2063	F
169	629	C
170	2400	F
171	2027	F
172	2169	F

A.8.6 Results of Question Five

LA's	Question 5		
	Local	Nat.	Euro.
1	3	1	0
2	2	0	0
3	1	1	0
4	2	1	1
5	2	1	1
6	4	1	1
7	1	2	2
8	4	4	1
9	2	7	2
10	1	5	5
11	5	7	7
12	6	2	2
13	2	1	0
14	2	1	0
15	2	0	7
16	3	7	1
17	1	7	1
18	1	1	3
19	5	3	6
20	0	0	0
21	1	4	0
22	2	4	2
23	7	1	0
24	2	1	0
25	2	1	1
26	3	1	3
27	1	3	0
28	5	1	0
29	3	1	0
30	7	1	1
31	1	1	0
32	6	1	0
33	5	1	0
34	6	1	3
35	6	1	1
36	4	1	0
37	6	1	0
38	3	5	1
39	6	1	3
40	4	1	3
41	7	0	0
42	3	0	0
43	2	1	1
44	2	1	0
45	1	1	1
46	0	0	0
47	1	7	0
48	5	4	0
49	2	1	0
50	1	1	0
51	1	1	1
52	6	1	1
53	7	1	0
54	5	1	0
55	6	1	1
56	6	1	7
57	5	1	2
58	6	1	0

LA's	Question 5		
	Local	Nat.	Euro.
59	2	1	2
60	1	1	0
61	1	5	0
62	3	1	0
63	1	1	5
64	4	7	0
65	6	1	1
66	2	1	0
67	7	5	0
68	0	0	7
69	6	1	0
70	4	1	0
71	3	0	0
72	7	1	0
73	3	1	0
74	6	1	0
75	1	1	0
76	1	2	0
77	0	0	0
78	0	0	0
79	6	0	0
80	0	1	0
81	1	1	1
82	5	1	1
83	6	1	0
84	0	1	0
85	5	3	6
86	3	1	0
87	6	1	1
88	5	1	2
89	6	1	0
90	6	1	0
91	1	4	6
92	1	1	0
93	3	1	0
94	7	1	1
95	0	0	0
96	4	3	6
97	5	7	7
98	5	1	0
99	5	5	7
100	2	0	0
101	1	2	7
102	0	1	0
103	0	0	0
104	3	5	7
105	2	2	2
106	2	1	0
107	1	1	1
108	2	0	0
109	1	2	0
110	3	1	0
111	5	1	0
112	5	1	5
113	1	3	0
114	5	1	7
115	3	4	3
116	2	1	0

LA's	Question 5		
	Local	Nat.	Euro.
117	5	1	0
118	6	0	0
119	1	4	3
120	7	7	0
121	6	1	7
122	5	1	1
123	3	1	0
124	5	4	7
125	6	3	0
126	1	1	7
127	3	1	1
128	1	1	7
129	2	1	0
130	6	1	7
131	3	1	0
132	2	7	1
133	3	1	1
134	4	6	4
135	7	6	5
136	3	1	1
137	1	1	0
138	6	1	1
139	3	4	2
140	2	7	7
141	4	4	0
142	7	4	0
143	1	0	1
144	0	0	0
145	4	7	7
146	4	6	1
147	1	4	0
148	1	7	1
149	7	7	6
150	2	5	5
151	4	6	4
152	3	1	1
153	5	1	3
154	4	1	3
155	7	7	1
156	5	4	4
157	1	1	0
158	7	7	1
159	4	5	5
160	2	1	2
161	7	0	0
162	7	1	3
163	4	1	3
164	1	7	5
165	3	1	4
166	2	4	1
167	2	3	7
168	3	1	0
169	3	4	0
170	1	2	4
171	2	2	1
172	3	3	1

A.8.7 Results of Question Six

Question 6: **YES**			
LA's	Stat.	LA's	Stat.
1	1	99	3
2	5	101	3
3	1	102	1
7	2	103	1
12	1	104	1
13	1	107	3
14	4	108	1
16	3	109	1
18	2	111	1
27	0	118	2
28	3	122	1
33	5	124	1
34	1	127	5
36	1	129	1
42	1	130	3
44	5	131	1
45	0	134	4
46	2	135	2
47	2	136	5
50	2	138	3
51	1	139	1
52	3	143	3
54	1	144	0
55	1	146	5
59	1	147	2
62	1	148	3
64	1	151	0
65	2	152	1
67	2	153	1
68	1	154	5
69	3	156	0
72	1	159	1
82	3	161	3
83	2	162	1
84	1	163	1
87	0	165	1
89	2	166	5
96	2	167	5
97	4	172	1

Question 6: **NO**			
LA's	Stat.	LA's	Stat.
5	1	79	0
6	0	80	7
8	1	81	5
9	2	85	4
10	3	86	3
15	2	88	1
17	0	90	0
21	7	91	1
22	0	93	6
23	7	98	7
24	0	105	7
25	4	106	0
26	0	110	2
29	3	112	5
30	5	113	0
31	5	114	0
32	7	115	3
35	6	117	6
37	1	119	7
38	0	120	5
39	2	121	2
40	2	123	1
41	7	125	1
43	5	126	7
48	4	132	5
49	2	133	1
53	6	137	5
56	0	141	2
57	1	142	6
58	4	145	7
60	1	150	2
61	3	157	1
63	6	160	7
66	1	164	2
70	6	168	0
71	1	169	3
74	1	170	3
75	6	171	6
76	4		

Question 6: **OTHERS**	
LA's	Statement
4	Others
11	Others
19	Others
20	Others
73	Others
77	Others
78	Others
92	Others
94	Others
95	Others
100	Others
116	Others
128	Others
140	Others
149	Others
155	Others
158	Others

A.8.8 Results of Question Seven

Question 7: **YES**							
LA's	Stat.	LA's	Stat.	LA's	Stat.	LA's	Stat.
1	1	54	1	109	1	156	0
2	1	55	4	110	5	157	7
4	1	57	7	111	1	158	6
5	2	58	3	112	1	159	2
6	0	59	1	114	1	160	1
8	7	60	7	115	1	161	0
9	2	61	5	116	7	162	2
10	4	63	0	117	0	163	3
12	1	64	1	118	5	164	0
13	4	66	3	119	3	165	4
14	5	67	5	120	3	166	1
15	1	68	5	121	4	167	5
16	1	69	1	122	1	168	6
17	1	72	0	123	1	169	1
21	3	73	4	125	3	172	1
23	2	74	5	126	1		
24	7	75	3	127	2		
25	7	76	5	128	1		
26	1	77	1	129	1		
27	0	78	2	132	1		
28	3	79	1	133	1		
30	3	80	1	134	0		
31	4	81	5	135	1		
32	7	83	7	136	5		
33	3	84	2	137	5		
34	5	85	0	138	2		
36	1	88	2	139	0		
37	1	89	7	141	2		
38	1	90	0	142	7		
39	6	92	5	143	7		
41	6	95	3	145	3		
43	2	96	1	146	4		
46	0	97	1	147	1		
47	7	98	6	148	5		
48	7	99	1	149	5		
49	1	101	1	150	2		
50	7	103	7	151	0		
51	1	104	1	152	4		
52	7	105	0	153	3		
53	3	107	5	154	7		

Question 7: **NO**	
LA's	Statement
3	0
7	0
11	1
18	2
19	3
22	0
29	2
35	1
40	2
42	0
45	0
62	3
65	2
70	0
82	1
86	3
91	3
93	1
102	0
108	3
113	0
124	0
144	0
170	3
171	0

Question 7: **Others**	
LA's	Statement
20	Others
44	Others
56	Others
71	Others
87	Others
94	Others
100	Others
106	Others
130	Others
131	Others
140	Others
155	Others

Appendix 9

Terminology

A.9 Terminology

Food contaminant:

This term will mean the substance(s) whose presence in the foodstuffs is of concern. The term might refer to a food contaminant of physical (Example: sharp nail, broken glass, etc.), chemical (Example: lead, chloropropham, etc.) or microbiological (Example: *E. coli, Salmonella spp.,* etc.) nature.

Medium:

Concern will relate to the presence of food contaminant in some medium. In this context, the term generally applies to what it is considered under the Food Safety Act 1990 as food for human consumption.

Location:

This term will refer to a specific instance of the medium to which sampling will be carried out. So the location of sampling for the testing of food quality might be an individual food manufacturer or any chosen food premises.

Sample and sample unit:

To test or monitor the level of food contaminant at a location, it is not normally possible to measure the level in the whole location, so that the usual process is to take samples. However, statisticians use the word 'sample' for the group of units which is withdrawn to estimate the character of a population, while food examiners

would call any one these units a 'sample'. In order to minimise the confusion, a sample unit is defined as an individual sample of the medium at a location, taken at some point within the location, and at some point in time. A sample will be a collection of sample units taken according to some defined scheme or strategy for sampling (Barnett and O'Hagan 1997).

Effective Sample:

An effective sample of the population consists only of those sample units that are actually examined. For example, if ten sample units are drawn, but only three are examined, then the sample size of the sampling plan is three and not ten.

Lot:

Ideally a lot is a quantity of food or food units produced and handled under uniform conditions. This implies that there is homogeneity within a lot, but rarely happens in practice. In most instances the levels and distributions of food contaminants within the food lot is heterogeneous. In another word, a lot should be composed of food produced with as little variation as possible for a given process or commodity. Because of the uncertainties in identifying a lot, therefore it is acceptable in statistical sense that it is a collection of units of a product.

Sample Statistic:

This term will refer to the result of any calculation based on measurements on the sample units in a sample. The measurements made on the sample units may often be

concentrations of the food contaminants. Such measurements may be used to calculate the mean or standard deviation, or to count how many sample units have measurements over some legal limits, or to calculate the range of measurement values in the sample.

Subject Group:

This term refers to those individuals on whom the effect of the food contaminant is the basis of concern and the motivation for setting standards. The subject group may be a collection of people such as the general population or some specific group such as the YOPI group (young, old, pregnant or immuno-compromised). A group of special interest, perhaps because of its high susceptibility to the contaminant or its high degree of contact with the medium, may be called a 'critical group'. For example, those people who choose to consume the Japanese Fugu fish are highly susceptible to be poisoned by the deadly tetrodotoxin than the rest of the population.

Effect:

This term will mean some measure of the condition of a subject group that is or expected to be affected by the food contaminant. For example, exposure to *Bacillus cereus* emetic toxin associated with rice dishes leads to food poisoning characterised by nausea and vomiting with occasional diarrhoea (Shinagawa 1990). In a relative measure, the effect is a decrease in the well-being of the subject group. In severe case, such effect could be fatal (Example: neurotoxin produced by *Clostridium botulinum*).

Microbiological Criterion:

This term, as defined by the International Commission on Microbiological Specifications for Foods, consists of -

(i) a statement of food to which the criterion applied;

(ii) a statement of the food contaminant(s) of concern;

(iii) the analytical method(s) to be used for its (their) detection and/or enumeration;

(iv) the sample to be taken from a lot of food or from a source of concern;

(v) the microbiological limit(s) appropriate to the product (ICMSF 1986).

In general, there are three types of microbiological criterion:

(a) Microbiological Standard - a mandatory criterion which is enforceable by the regulatory agency having jurisdiction.

(b) Microbiological Specification - a criterion which is applied as a condition of acceptance of a food by a food manufacturer or a public or private agency.

(c) Microbiological Guideline - a criterion which is used by a manufacturer or regulatory agency to monitor a food process or system and usually serves as an advisory tool.

Sampling Plan:

It is a procedure for withdrawing a sample, carrying out analysis of appropriate sample units, and making appropriate decisions based on an agreed criterion. A sampling plan should include all the points of a microbiological criterion.