

Strategic Developmental Review of Health Board Food Control Laboratories



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Foreword



Good food is important for our well-being. Without it, there is a real threat of disease as well as a threat to our prosperity.

People are now very interested in the quality and safety of food. This is partly due to food scares as well as a developing international food market.

The Department of Health and Children has ten food safety laboratories and although but one element in the wider food safety analytical service framework, these laboratories play a key role in protecting the public's health, by analysing the microbiological and chemical content of food so that it is safe to eat. In recent years there has been serious investment in these laboratories so that the country now has a highly professional and enthusiastic workforce committed to food safety.

Constant watchfulness is needed to protect the public from foodborne disease. We have learned that food related problems can suddenly appear and cause major problems. With this in mind the Department commissioned this report by **safefood** to help with ensuring the on-going development of services to protect the public. A Strategy Review Group was set up and members were greatly helped by the input from staff and users of laboratory services.

The Group sought to address two particular concerns: the need to secure an on-going high quality and responsive service as well as the need for fast and responsive communication between different laboratories. The Group was also aware of the need that our recommendations should produce an efficient and cost-effective solution.

The report recommends the concept of a single laboratory service on several sites, with advice on the processes and structures that would assist its delivery. The Group considers that these recommendations will result in a more public health focused analytical service in which the public can have confidence.

It has been a personal pleasure for me to have worked with members of the Strategy Review Group. Their commitment to the task was exemplary and I thank them for their hard work and for their contribution to the final consensus. We are also grateful to Mr. Noel Usher and his senior colleagues in the Department of Health and Children, whose willingness to facilitate our work was both generous and open. We were provided with an excellent and dedicated secretariat from **safefood** – Ms Sinead Guckian, Dr. Gary A. Kearney and Dr. Thomas Quigley.

Dr Mary O'Mahony
Chairperson
Strategy Review Group
July 2004

1. Executive Summary

1.1 Introduction and findings

The Official¹ Food Safety laboratories have a critical role in ensuring food safety and public health for the whole population of the Republic of Ireland. These public health laboratories are made up of 7 microbiological testing laboratories and 3 chemical or Public Analyst's laboratories. The laboratories are regionally based and offer an accredited (INAB) service to 10 health boards thus spanning the country. The role of the laboratories is to test food for compliance with the relevant legislation and guidelines, identify food-borne hazards and disease outbreaks, provide essential risk assessment information for national and international needs, provide a food testing service for consumers and a water testing service on a national basis. They also participate in dedicated National and EU surveys under the auspices of the Food Safety Authority of Ireland (FSAI).

There has been significant investment and development in food-related public health protection in Ireland in recent years. However, there are still a number of issues that have the potential to impact on these laboratories in delivering a fully effective public health service in a cost efficient manner. Building on what has been achieved to date, this strategic review identifies those issues to be addressed in order to ensure (1) a cost effective national co-ordinated food safety laboratory service, (2) that future laboratory service needs are accounted for in the delivery of their Public Health role, and (3) that this Service meets both national and international requirements and standards.

In a country that depends on its agri-food industry, consumer and international confidence is crucial. This confidence is built by access to validated independent and impartial evidence of the safety of the food supply chain. A responsive and nationally focused food safety laboratory service is key to providing such reassurance.

The Official Food Safety Laboratories have for the past 5 years formally collaborated as a group in conjunction with the FSAI and the Environmental Health Service to provide a service that is focussed on national needs and aligned with EU legislation. The laboratories have also liaised closely with the Department of Health and Children and **safefood**, the Food Safety Promotion Board. However further structured facilitation would allow the laboratories to combine their efforts in an even more coordinated and cohesive way.

SINGLE LABORATORY SERVICE

To provide a new fully co-ordinated and cost effective national laboratory Service, **we recommend that the laboratories be combined into a unified but multi-sited integrated Food Safety Laboratory Service (FSLs) that provides a microbiological and chemical food analytical service.**

MANAGEMENT

Individual laboratories will continue to be managed locally but the operational control and direction of the Food Safety Laboratory Service would reside with the Health Service Executive (HSE). Operational control and direction residing within HSE is critical to the success of the integrated Service. Such control would ensure that the appropriate strategic development of the FSLs takes place, that local and regional health offices would exercise accountable resource management and maintain an adequate laboratory

¹ European Communities Official Control of Foodstuffs (Approved Laboratories) Order, S.I. 95 of 1998

service that is capable of meeting food standard requirements and demands resulting from outbreaks and emergencies.

The HSE will require stakeholder and expert advice on the strategic direction of the FSLs.

We recommend that a permanent Food Safety Laboratory Advisory Committee (FSLAC) be established to advise and work with the HSE on the policy and operational direction of the FSLs that will be implemented via a HSE senior scientific laboratory co-ordinator. This advisory committee will also advise on international linkages as well as future developments of the FSLs.

To allow for operational direction within HSE and to secure development **we strongly recommend that the above-mentioned senior scientific laboratory coordinator be appointed by the HSE.**

This laboratory coordinator, which would be a senior scientific post, would have an overall coordination role to ensure the delivery of a cohesive and accountable service. The appointment of a senior scientist who understands the food safety and administrative issues would provide a robust mechanism to ensure that transparent accountable systems are in place while driving forward **national standards, specifications and outputs.**

It is anticipated in the reformed health service that new Regional Health Offices and the National Hospital Office will administer the individual laboratories. Some laboratories may have difficulty in accessing HSE-allocated funding for food testing in this structure. However in order **to achieve the new unified single Service we recommend that an internal HSE protocol between the three pillars of the new Health Service Executive be established.**

FUNDING

There has been in recent years a considerable investment in the laboratory services. However, we identified a number of issues relating to funding, such as inconsistencies between Health Board funding management, ineffective budgetary mechanisms and the insufficient dissemination of budgetary information. To ensure value for money **we recommend that the FSLs has a ring-fenced budget with transparent accountability, that the laboratory managers be informed of their annual allocations at the start of the year and that appropriate financial management systems be implemented. Local and Regional Health Offices should provide details of annual operational plans and financial provisions for their food laboratory service and it is necessary to develop guidelines in relation to private work as conducted by the FSLs.**

LEGISLATION

The FSLs must also continue to support the enforcement of food law through working effectively with the Environmental Health Service and the FSAI, meeting requirements of new food law, and be proactive by introducing appropriate monitoring to comply with new legislation. Laboratories working at the coalface of enforcement would be in a position to provide advice and expertise in the preparation of such legislation. **Therefore we recommend that the FSLs continues to be consulted and have an input in the preparation and implementation of relevant legislation.**

In order to provide a quality national laboratory service **we recommend that the FSLs continues to be supported to maintain and develop mandatory accreditation to internationally agreed standards.**

FACILITIES AND STAFFING

The Department of Health and Children (DoHC) has made significant investment in the staffing and equipping of laboratories in recent years. However, the standard of laboratory accommodation varies significantly. **We recommend that laboratory accommodation be reviewed by the HSE including the requirement for containment level 3 facilities.**

To develop and deliver this quality service, staff training and development is critical. Generally training provision varies and can be limited. Training and staff development should include management development, health and safety understanding, IT skills and ongoing technical training. **We therefore recommend that the FSLs establish a robust training framework with a dedicated annual training budget that is operational at local level.**

It is important to ensure that there is an attractive career structure in place for laboratory staff. There are anomalies in grading and access currently within the FSLs and we recommend that **staffing anomalies of the FSLs as a whole be reviewed as a priority. We also recommend that the filling of approved vacancies be expedited appropriately. A new promotional grade of 'Senior Executive Analytical Chemist' should be introduced into the Service's PALS.**

RANGE OF SERVICE

The range, appropriateness and amount of work undertaken by laboratories were considered. We recommend **that standard national protocols be developed specifying the parameters to be tested, that the analytical activities of the FSLs be continually reviewed to account for risk based analysis, that rapid screening techniques be introduced where appropriate, and that the export certification process be reviewed.**

To ensure that the FSLs is as effective as possible there must be close collaboration between the laboratories and clients. Our examination of the laboratories has highlighted certain cross-functional weaknesses including food sample selection and prioritisation. **We recommend that these issues be reviewed to ensure they are risk based and optimally selected.**

The ability of the FSLs to effectively and rapidly respond to food alerts and emergencies is of paramount importance but this is currently fragmented nationally. **We recommend therefore that laboratory operational times be expanded to provide a more client focused service and that an out of hours Service-wide agreement be put in place together with appropriate access to reference facilities.**

One of the key areas in which the cost effectiveness of the FSLs could be maximised is in the rationalisation of specialisations so that centres of expertise could be established. **We therefore recommend that specialised testing capacities be further developed within the FSLs.**

An effective way to provide an ongoing, robust and rapid response to food alerts and emergencies is to develop an adequately resourced capability for R&D. **We recommend that the FSLs be facilitated to develop an adequately resourced capability for developmental applied research.**

There is also a need to introduce an international dimension to Ireland's scientific endeavours. Laboratory staff members have insufficient participation in EU technical working groups. The level of interaction between Irish and European laboratories is low. **We recommend that the FSLs be facilitated to develop close international cooperation and interaction.**

INFORMATION SHARING

The collection, collation and analysis of laboratory data is necessary in order to ensure that resources are allocated to the most appropriate areas of food-related public health significance and to assure Irish consumers of the safety and hygiene of the food supply. The current arrangements for access to test data are not ideal. **We recommend that appropriate electronic data management systems be quickly established to ensure data management and timely transfer for public health and food control purposes.** It is also important to ensure that there are clear and effective communication pathways, both internally and externally, to the multi-sited FSLs. Information sharing and exchange is critical to the development of a well co-ordinated network. **We recommend national surveys be strengthened, that laboratory information be readily accessible and that as a priority it continues to be integrated in a timely manner with human and animal disease surveillance data.** This will in turn, facilitate and strengthen future advice given by the Food Safety Laboratory Advisory Committee (FSLAC) and the policy-making and operational direction by the HSE.

We believe that these recommendations will result in a better-coordinated and therefore more effective national food laboratory service for Ireland. Critical to the provision of a fully integrated and coherent Food Safety Laboratory Service has to be central control and operational direction by the HSE, taking account of advice from the FSLAC.

The 16 recommendations from this strategic review are listed hereafter in section 1.2. These recommendations are not listed under their terms of reference but have been prioritised.

1.2 Recommendations

Single Service

Recommendation: We recommend that the Public Analysts' Laboratories and the Official Food Microbiology Laboratories be integrated as a new single official HSE Food Safety Laboratory Service (FSLs) (*Recommendation 1*);

Management of the FSLs in the reformed health Service

Recommendation: We recommend

- the establishment of a HSE Food Safety Laboratory Advisory Committee (FSLAC) to provide, national strategic planning advice to the HSE with regard to the Service (*Recommendation 16*);
- the appointment of a senior scientific coordinator within the HSE with overall responsibility for ensuring the co ordination of the Food Safety Laboratory Service taking account of national strategy planning advice (*Recommendation 16*);
- that the Food Safety Laboratory Service develop nationally agreed laboratory standards and specifications (*Recommendation 16*);
- an internal HSE protocol between the three pillars of the Health Service Executive be established (*Recommendation 16*);

Funding

Recommendation: We recommend that

- the Food Safety Laboratory Service have a ring-fenced budget with transparent accountability to ensure a value for money service (*Recommendation 10*);

- the laboratory managers be informed of their annual allocations at year begin (*Recommendation 10*);
- financial management systems be implemented to provide detailed information with regard to the analytical activities of the Food Safety Laboratory Service (*Recommendation 10*);
- national guidelines be developed governing involvement of the HSE Food Safety Laboratory Service in 'private work' (*Recommendation 10*);
- local and regional health offices include in their annual service plans to the HSE details of operational plans and financial provisions for their Food Safety Laboratory Service (*Recommendation 10*);

Laboratory Facilities

Recommendation: We recommend that

- laboratory accommodation be reviewed to meet the current and future service requirements including the requirement for containment level 3 facilities (*Recommendation 8*);
- the Food Safety Laboratory Service consider the common procurement of consumables (*Recommendation 8*);

Strategic Planning

Recommendation: We recommend that the Food Safety Laboratory Service and stakeholders develop a structured strategic approach to operational planning which would encompass annual business plan cycles. (*Recommendation 11*);

Legislation

Recommendation: We recommend that

- the HSE Food Safety Laboratory Service (FSLs) and stakeholders continue to be consulted and have an input in the preparation of relevant legislation (*Recommendation 2*);
- the Food Safety Laboratory Service be supported to maintain and develop their accreditation to relevant international standards (*Recommendation 2*);

Information Sharing

Recommendation: We recommend that appropriate electronic data management systems be established for the Food Safety Laboratory Service to ensure management and timely transfer of surveillance data for public health and food control purposes. (*Recommendation 14*);

Staffing

Recommendation: We recommend that

- the filling of all approved vacancies should be prioritised and expedited appropriately (*Recommendation 9*);
- a new promotional grade of 'Senior Executive Analytical Chemist' should be introduced into the Service's PALs (*Recommendation 9*);
- the staffing anomalies of the Food Safety Laboratory Service as a whole be reviewed as a priority (*Recommendation 9*);

Training

Recommendation: We recommend that the Food Safety Laboratory Service

- establish a robust training framework to develop expertise and address future public health considerations (*Recommendation 5*);
- have a dedicated annual training budget that is operational at local level (*Recommendation 5*);

Analytical Activities

Recommendation: We recommend that

- the analytical activities of the Food Safety Laboratory Service be continually reviewed to ensure that the service addresses emerging pathogens and contaminants of public health significance (*Recommendation 7*);
- rapid screening technologies be introduced for core work where appropriate (*Recommendation 7*);
- standard national protocols, specifying the parameters to be tested, be developed for the Food Safety Laboratory Service (*Recommendation 7*);
- the export certification process be reviewed (*Recommendation 7*);

Surveys

Recommendation: We recommend that

- the systematic planning of national surveys be strengthened amongst stakeholders (*Recommendation 6*);
- that information from national surveys continue to be aligned with human and animal disease surveillance data (*Recommendation 6*);

Specialisations

Recommendation: We recommend that the Food Safety Laboratory Service continue to develop specialised testing capacities on a nationally co-ordinated basis (*Recommendation 3*);

Applied Research and Development

Recommendation: We recommend that the Food Safety Laboratory Service develop a capability for developmental applied research on a nationally co-ordinated basis (*Recommendation 4*);

Sampling

Recommendation: We recommend that

- sampling criteria be based on risk priorities (*Recommendation 12*);
- the sampling selection point mechanism should be optimised to ensure cost effectiveness (*Recommendation 12*);

Scientific Co-Operation

Recommendation: We recommend that the Food Safety Laboratory Service develop close cooperation and interaction with official laboratory agencies and research institutions across the EU (*Recommendation 15*);

Accessibility

Recommendation: We recommend that

- laboratory operational times be expanded to provide a more client focused and risk-based service delivery (*Recommendation 13*);
- a Food Safety Laboratory Service wide agreement for an out of hours service be put in place (*Recommendation 13*);
- appropriate access to reference facilities for organism and toxin detection be provided (*Recommendation 13*).

2. Background to the Review

2.1 Introduction

Good food is important for our health and well being. The public relies on the State to ensure that the food we eat is safe and does not cause illness or death. Over the past decades, there has been a dramatic increase in the importance of food safety with an emphasis on the necessity of comprehensive food safety controls. Food scares, media coverage and the developing international food market have resulted in the consumer giving food safety unprecedented attention. Consumers rely on the providers of food and on the State to ensure that checks are in place for their protection and well being.

In Ireland, there are many laboratories involved in food safety monitoring, surveillance, analysis and research. Some operate directly or are under the aegis of government departments, others are managed by local authorities, some by health boards, others are privately owned or within institutes of higher education, and other laboratory establishments are funded or run by various national agencies.

However, there are ten officially approved² Health Board food safety laboratories in Ireland. Their role³ is to conduct a wide range of tests to ensure that food complies with national regulations and guidelines and is safe for public consumption. They are all accredited (INAB) to ISO/IEC 17025 standard and all hold service contracts with the Food Safety Authority of Ireland via their health boards.

The Department of Health and Children (DoHC) set up a Strategy Review Group to review the official health board accredited laboratory services and to propose a strategy for their development. The DoHC requested that **safefood** act as secretariat and coordinator to this group. This report outlines the main findings of the review, and the group's subsequent recommendations.

In this chapter, we will outline the importance of food safety and introduce the ten food safety laboratories. We will then present the rationale behind this review, introduce the Strategy Review Group and its Terms of Reference.

² European Communities Official Control of Foodstuffs (Approved Laboratories) Order, S.I. 95 of 1998

³ European Communities, Official Control of Foodstuffs Regulations, S.I. 85 of 1998

2.2 The importance of food safety

Today, as always, food is important. The combination of increasing public interest in the quality of food and the increasing complexity of the food chain has emphasised the importance of food safety.

We need to ensure that the food we eat is safe. Thus it is necessary to conduct microbiological examinations and chemical analysis of food on retail sale and at other points along the food chain. We need to:

- monitor indicator organisms in food and identify pathogens;
- verify that foods comply with their label descriptions and claims;
- verify that foods comply with statutory compositional standards;
- ensure that foods do not contain harmful levels of metals, chemicals or natural toxicants.

2.3 The Official Health Board Food Safety Laboratory Services

There are ten statutory designated official Health Board Food Safety Laboratories located on nine sites in Ireland⁴. Their statutory role is to test food to ensure that it complies with national guidelines and legislation. Their objective is to prevent risks to public health and to protect consumer interests.

There are three Public Analyst's Laboratories (PALs), based in Cork, Galway and Dublin. There are seven Official Food Microbiology Laboratories (OFMLs), with two laboratories in Dublin (one is part of the Dublin PAL) and others in Waterford, Cork, Limerick, Galway and Sligo.

The PALs carry out chemical testing of food, while the OFMLs carry out microbiological examination of food. The Dublin PAL uniquely has both chemical and microbiology scopes. All laboratories are designated as approved official food safety laboratories according to legislation⁵. The laboratories carry out analysis on a wide range of foodstuffs and waters, submitted primarily by the Health Board Environmental Health Service (EHS), but also by consumers, hospitals, other agencies and companies.

2.4 The Rationale behind the Review

Following the introduction of a wide range of EU food control legislation, the DoHC has made significant investment in the development of the laboratory Services in recent years. This investment includes increased staffing, resources for accreditation, new specialised equipment and instrumentation, and a number of new laboratory facilities. This has resulted in an enhanced capability to accommodate an increased number of samples, achieve greater outputs and provide a wider range of analytical services.

The food safety arena is constantly changing, with new developments and priorities. Many protective mechanisms have been and continue to be put in place to protect consumer health and to provide accurate, up-to-date information to consumers. In the last five years, new agencies like the Food Safety Authority of Ireland, **safefood** - the Food Safety Promotion Board, and the European Food Safety Authority have been established, and the laboratories must consider the most effective methods of working with national agencies. It is also difficult to predict what food safety episodes will occur in the future, as emerging food-borne hazards and diseases continue to challenge the food safety services.

⁴ Contact information for the ten laboratories can be found under Appendix 8.1.

⁵ European Communities Official Control of Foodstuffs (Approved Laboratories) Order, S.I. 95 of 1998

To ensure that these enhanced laboratory services can continue to deliver a high-quality, highly responsive and adaptive food safety service within this constantly changing arena, the DoHC considered it both prudent and necessary to review the services.

Furthermore, in the context of the commissioning of the recent Hanley, Brennan and Prospectus reports, and in light of the current Health Service reforms, Mr Michéal Martin, Minister for Health and Children, considered it both timely and opportune to commission this developmental review.

2.5 The Strategy Review Group

Under the chairpersonship of Dr Mary O'Mahony (Director of Local and Regional Services, Health Protection Agency, UK), the DoHC set up a Strategy Review Group⁶, made up of representatives from the laboratories, the DoHC, health board administration, health board departments of public health and the Food Safety Authority of Ireland. The DoHC requested that **safefood**, the Food Safety Promotion Board, act as the secretariat and coordinator to this group.



Back: Dr. Des Feely, Dr. Eleanor McNamara, Dr. Bernard Hegarty, Ms. Lil Manley, Ms. Siobhan Mc Evoy, Ms. Helen Cowman **Front:** Dr. Margaret Fitzgerald, Dr. Mary O' Mahony (Chairperson), Mr. Kevin Moyles

The Strategy Review Group met on six occasions between January 2003 and February 2004.

2.6 Terms of Reference

The DoHC presented the Strategy Review Group with the following Terms of Reference:

'To consider the operations of the Public Analyst's Laboratory and Food Microbiology Laboratory Services in the Republic of Ireland and propose a cost effective strategy for the development of the laboratory services in view of their food safety and food law responsibilities'

The Terms of Reference were elaborated by the DoHC to:

- 1 consider the legislation with regard to the functions and responsibilities of laboratories;
- 2 review the current position with regard to legislative obligations, accreditation, laboratory specialisations, research activities, staff training, survey work and laboratory capacities;
- 3 review the facilities and resources of the laboratories;
- 4 identify the needs of food safety agencies in terms of their laboratory requirements;
- 5 examine the factors which influence the effectiveness of the present arrangements and to recommend measures to improve them;
- 6 assess current arrangements for rapid access to laboratory test data;
- 7 report on collaboration between laboratories and the need for enhanced scientific co-operation and laboratory linkages.

⁶ Members of the Strategy Review Group can be found under Appendix 8.2.

3. Methodology

3.1 Introduction

In this chapter, we will outline the methods used to gather the information required to complete the review process and make our recommendations. We divided the review process into two broad strands; information gathering and consultation. This chapter will outline the methods we employed to collate information within each of these strands.

3.2 Information gathering

We collated both quantitative and qualitative information to identify the main issues pertaining to the Terms of Reference and to assess the current position of the laboratory services. We carried out the following exercises to obtain laboratory perceptions and attitudes, and to identify opportunities for development.

3.2.1 BASELINE DATA SURVEY

In order to make recommendations on the development of the services, we needed current, accurate information on issues relevant to the Terms of Reference. We compiled a detailed, comprehensive questionnaire and sent this to all laboratory managers, all of whom responded.

3.2.2 EU FOOD SAFETY LABORATORY MODELS

In formulating a future strategy, we decided that it would be useful to obtain an overview of some comparable European food control systems from a laboratory perspective⁷. We wanted to understand how they were organised, both procedurally and structurally, in relation to our Terms of Reference.

The Danish Veterinary and Food Administration hosted a two-day visit for a delegation of the Public Analyst's staff, Food Safety Authority of Ireland (FSAI) and the secretariat in June 2003. The group obtained both a regional and national perspective by visiting the national food safety headquarters in Morkhoj, and a regional laboratory in Flasketorvet.

A delegation of Official Food Microbiology Laboratory staff, FSAI and the secretariat visited the Inspectorate for Health Protection and Veterinary Public Health in Eindhoven in The Netherlands.

3.2.3 LABORATORY VISITS

The group visited the Galway OFML and the Galway PAL in June 2003. This gave us the opportunity to meet laboratory staff, to view the facilities and to get an overview of the type of work they were carrying out.

3.2.4 ADDITIONAL INFORMATION

The group also requested additional information on the water testing activities of the laboratories, current applications for extensions to facilities, and the export certification work of PALs.

⁷ A list of the laboratory staff members who participated in these visits is in Appendix 8.3.

3.3 Consultation

The group considered it essential that all laboratory directors and staff would be kept up to date on the activities of the review, and that their opinions on current activities and the future development of their service would be included in its considerations. We employed the following consultation exercises to ensure that this happened:

3.3.1 PRE-REVIEW BRIEFINGS

The secretariat travelled to all ten laboratories, and gave briefings to all laboratory directors and senior staff.

3.3.2 STRATEGY REVIEW SUBGROUPS

The varied scope of the Terms of Reference meant that there were many elements to consider. We created three subgroups⁸ to cover the subject areas of microbiology, chemistry and organisational matters.

These subgroups included members of the Strategic Review Group, senior laboratory personnel and scientists with specialisations in particular areas. Their remit was to work on specific aspects of the Terms of Reference and other issues identified by the group, and to produce recommendations. The technical subgroups dealt with issues specific to each service, while the organisational subgroup addressed issues common to both.

Each subgroup met twice, and we held six meetings over a seven-week period. Each subgroup produced draft recommendations for the Strategy Review Group to consider.

3.3.3 SUBMISSIONS FROM STAKEHOLDERS

In February 2003, we sent consultation letters to organisations with an interest in the review, asking for written submissions on the Terms of Reference⁹. All laboratories provided submissions to the secretariat, both individually and in collaboration with each other. In all, we received twenty responses. The secretariat collated all recommendations and issues, and presented these to the Group for consideration.

3.3.4 LABORATORY FORUM

We held a one-day Laboratory Forum in Dublin on Friday 11 July 2003 for members of laboratory staff. The Principal Officer of the Food Unit in the DoHC, members of the Strategy Review Group and personnel from the Environmental Health Service (EHS) nominated by the Health Board CEO Group attended the Forum. The purpose of this forum was to give attendees an opportunity to contribute to the review. The secretariat collated all recommendations and issues, and presented these to the group for consideration.

⁸ The membership of each subgroup is detailed in Appendix 8.4

⁹ Invited Stakeholders Consultation List is available in Appendix 8.5

4. Food Safety – Protecting Public Health

4.1 Introduction

Food safety has emerged as a major consumer issue in Europe in the last decade. We have briefly introduced the topic of food safety and its importance to public health. However, in order to understand the environment in which the laboratories work and to establish the context for this report, we will now provide a detailed analysis of food safety in the modern world, and its implications for the work of the laboratories.

We will begin by outlining the importance of food safety by highlighting recent food scares and the implications of these food-borne diseases. We will then discuss the factors that can impact on food safety, including new technologies, deliberate contamination, new diseases and chemical contaminants.

We will then put these food-associated health risks into a business context, by looking at the food trade globally, across Europe and in Ireland, and its impact on the safety of food.

Following this overview, we will look at the consumer's perspective. We will explain the changing demands of the consumer, highlight the impact that food scares have had on consumer confidence, and discuss the consumer's increased interest in labelling and traceability.

This will lead us to discuss the various responses to food safety from an international, European and Irish perspective.

The Irish government has recently implemented a major reorganisation in the way in which the Irish health system is structured and managed. In this last section, we will consider food safety in the era of the Health Service Reform.

4.2 What are the risks?

4.2.1 RECENT FOOD SAFETY ISSUES

Microbiological, chemical or physical hazards can cause food-borne illnesses. Recent food scares around the world have damaged consumer confidence in the safety of their food supply, and in the ability of the regulatory agencies to monitor the agri-food industry.

- 1994, the US: *Salmonella Enteritidis* in ice cream led to 224,000 falling ill.
- 1996 in Scotland, an outbreak of food poisoning involving *E. coli* O157 was responsible for the death of 17 people and made 496 others ill.
- In 1996, Bovine Spongiform Encephalopathy (BSE) and its link to variant Creutzfeldt-Jacob disease (vCJD) created widespread unease about meat products and the safety of the food chain. The significant health and economic consequences of BSE were felt across Europe and beyond.
- 2000, in Japan; the contamination of milk with the *S. aureus* toxin led to 14,500 falling ill.
- 2000 in Walkerton, Canada; the contamination of the water supply by *Escherichia coli* O157:H7 affected 2,000 people, and six children died.

Large-scale outbreaks have also occurred in Ireland. In 2000, *Salmonella Typhimurium* in a cooked ham product caused illness in 78 people, 27 of whom were hospitalised. In another outbreak in 2000, 125 people became ill after consuming shellfish contaminated with a Norwalk-like virus.

The chemical contamination of food has also had far-reaching effects:

- 1981, Spain; the case of toxic vegetable rape-seed oil led to 800 deaths, and affected 20,000 people.
- 1998, India; toxic mustard seed oil led to over 60 deaths.
- 1999, Belgium; dioxin contamination of food products through PCB-contaminated feed led to widespread trade disruption, the loss of hundreds of millions of Euros for Belgian food producers and the resignation of government ministers. Years of investigation may be required before we can know the effects of this dioxin exposure on public health.

Other recent food contamination cases include aflatoxins in pistachio nuts, benzene in some soft drinks, benzopyrenes in primrose oils, and the contamination of feed in The Netherlands in May 2002 when a hormone (medroxyprogesterone acetate) was inadvertently incorporated into compound feed.

A large number of additional sporadic cases occur, many of which not only fail to reach media headlines but also fail to reach our reporting systems.

4.2.2 INCIDENCE AND IMPLICATIONS OF FOOD-BORNE DISEASES

Food-borne diseases are an enormous global health problem. Millions of people fall ill and many die as a result of eating unsafe food¹⁰. The true number of food-borne diseases is difficult to evaluate. In many instances, only a small proportion of cases actually come to the notice of health authorities, and even fewer are investigated. Even in industrialised countries, it is believed that less than 10% of cases are reported.

The 'Acute Gastroenteritis in Ireland, North and South' 2003 study found that acute gastroenteritis is an important public health problem causing a large burden of illness in the community. In any four-week period, 4.5% of people suffered from acute gastroenteritis from a variety of causes including food-borne diseases. It has been estimated that on the island of Ireland there occurs about 8800 new episodes of acute gastroenteritis per day or 3.2 million new episodes per year. Food-borne disease not only significantly affects health and well-being, but also has economic consequences for individuals, families, communities, businesses and countries. These diseases impose a substantial burden on healthcare systems and markedly reduce economic productivity, as indicated by over 15 million working days lost in Ireland each year through acute gastroenteritis.

As we saw in section 4.2.1, chemicals are a significant source of food-borne illness, although their effects are often difficult to link with a particular food. Chemical contamination of food can affect health after a single exposure or, more often, after long-term exposure. However, the health consequences of exposure to chemicals in food are often inadequately understood. While assessments of the risks associated with exposure to pesticides, veterinary drugs and food additives are usually supported by extensive information, less data are available on the toxicology of some contaminants in food.

¹⁰ WHO global strategy for food safety: safer food for better health

4.3 Factors that impact on food safety

4.3.1 NEW TECHNOLOGIES

The introduction of new food production technologies, such as genetic engineering, the irradiation of food and modified atmosphere packaging, can be used to increase agricultural production, extend shelf-life or make food safer.

The usefulness and safety of GMOs must be demonstrated if they are to be accepted by consumers

Biotechnology (the application of biological knowledge and techniques to develop products), offers major challenges and opportunities for the future. Public health can benefit enormously from biotechnology's potential to increase the nutrient content of foods, decrease their allergenicity and improve the efficiency of food production. However, their usefulness and safety must be demonstrated if they are to be accepted by consumers. A major area of concern to many consumers is the introduction of Genetically Modified Organisms (GMOs) into the food chain. Consumers have expressed their concerns over a wide range of issues such as safety to public health, the potential damage to the environment, the disruption of ecosystems and their ethical or moral objections.

The impact on public health of new types of foods, foods containing functional ingredients such as prebiotics or probiotics or new packaging materials will need to be monitored as an integral part of food safety control. For example, a potentially carcinogenic chemical, semicarbazide, was recently found at very low levels in baby foods and other foods packaged in glass jars and bottles and sealed with lids containing plastic gaskets.

4.3.2 BIO-TERRORISM

The possibility of deliberate contamination of the food supply due to bio-terrorist attacks has become a global consideration, and many countries have recently formulated strategies to manage such a crisis.

4.3.3 NEW DISEASES, NEW CHALLENGES

Emerging food-borne diseases will continue to challenge food safety services. In the future, increased surveillance of animal feed and human foodstuffs may identify previously unknown chemical or microbiological contaminants, or establish clearer links between specific contaminants and human health.

New food-borne pathogens are emerging, old food-borne pathogens are showing up in new foods, and multi drug-resistant strains of micro-organisms are increasing. We consider some food-borne diseases as emerging, even when we already recognise them, because they have recently become more common. Most countries with systems for reporting cases of food-borne illnesses have documented increases over the past few decades in the incidence of diseases caused by some micro-organisms in food, including pathogens such as *Campylobacter jejuni* and parasites such as *cryptosporidium*, *cyclospora* and trematodes.

The emergence of new pathogens, and pathogens not previously associated with food, is a major public health concern. Examples include *E. coli* O157 and *Salmonella* Typhimurium DT104, which has developed resistance to five commonly prescribed antibiotics and is a major concern in many countries because of its rapid spread during the 1990s.

Chemical contaminants in food include natural toxicants such as mycotoxins and marine toxins, environmental contaminants such as mercury, lead, radionuclides and dioxins, and naturally - occurring chemicals in plants, such as glycoalkaloids in potatoes. Food additives and nutrients such as vitamins and essential minerals are used to increase or improve the food supply, but assurance must first be obtained that these uses are safe. The EU White Paper on Food Safety refers to the need for national surveillance and control systems, analytical support, and setting limits for new and existing contaminants.

4.3.4 THE CHANGING DEMANDS OF THE CONSUMER

The globalisation of the food trade may be of benefit to consumers, as it may provide a wider variety of high-quality foods that are accessible and affordable. However, changing food habits can result in a changing pattern of food-borne illnesses. Consumers demand a wider variety of foods than in the past, including foods that are not in season and often eaten away from home. In fact, greater numbers of people are consuming foods prepared in restaurants, canteens and fast-food outlets, meaning food for many is prepared by a few and can therefore be the source of major food-borne disease outbreaks.

Demographic profiles are altering. Increasing numbers of elderly people are more susceptible to micro-organisms in food. A greater life expectancy, with increasing numbers of immunocompromised people, means that there is a larger vulnerable population for whom unsafe food is a serious threat. There has also been an increase in the demand for internationally traded foods and, as a result, there are greater requirements for the transportation, storage and preparation of food.

To meet the consumer's growing demand, we import an ever-increasing proportion of our food¹¹. As a result, we may be exposed to pathogens not commonly found in Ireland. In addition, changes in eating patterns and the increasing interval between the processing and consumption of foods, may all contribute to the increased incidences of food-borne illness attributed to microbiological organisms.

Food safety must be addressed along the entire food chain by measures based on sound scientific information at both national and international levels.

4.4 The food trade

4.4.1 THE GLOBAL FOOD MARKET

In 1999, more than 1,500 farms in Europe received dioxin-contaminated feed from a single source over a two-week period

The global integration and consolidation of agricultural and food industries, and the globalisation of the food trade, have changed the patterns of food production, processing, distribution and preparation. This presents new challenges to food safety. The array of new food products, coupled with mass production and distribution of foods, has the potential to produce scattered, nationwide outbreaks of illness.

Food-borne disease outbreaks do not recognise international boundaries. Food and feed is distributed over increasing distances, creating the conditions necessary for widespread outbreaks of food-borne illness. Appropriate controls are also necessary to prevent any contaminants in animal feed reaching

¹¹ Compendium of Irish Agricultural Statistics, Department of Agriculture and Food, 2004

the human food chain. In 1999, more than 1,500 farms in Europe received dioxin-contaminated feed from a single source over a two-week period. Food produced from animals given this contaminated fodder found its way onto every continent within weeks. All these changes may lead to situations in which a single source of contamination can have widespread, even global consequences. The international spread of meat and bone meal prepared from cattle affected by BSE is a high profile example, as outlined in section 4.2.1.

Enhanced food control measures may be necessary to monitor potential increased levels of food imports. These food safety requirements have to be compatible with provisions of World Trade Organisation (WTO) agreements. The WTO Sanitary and Phytosanitary Agreement recognises each country's right to establish its own level of protection, but does not allow 'arbitrary and unjustifiable' variation in the levels of protection if this variation results in trade discrimination.

4.4.2 THE EUROPEAN FOOD MARKET

The EU Official Control of Foodstuffs Directive (89/397/EEC), while prioritising health protection, notes that the protection of fair trade and the provision of consumer information are valid aspects of food control. The Regulation on General Food Law (178/2002) also stresses the protection of consumers' interests, and states that food regulations apply to foods exported from the EU.

4.4.3 THE IRISH FOOD MARKET

Ireland is traded the world over as 'The Food Island', and so it is of national importance that we maintain good food safety practices at all stages of the Irish food production chain. The food and agriculture sectors are the largest indigenous industries and vital for the country's economy. In 2002, the Irish agri-food sector accounted for approximately 10% of GDP and over 40,000 jobs, with output of the order of €16 billion¹². Over 70% of Irish food and drink exports go to markets within Europe, and eight of the top ten Irish-owned exporting companies are involved in the food sector. An effective food control-monitoring infrastructure provides the necessary reassurances of safe food to consumers at home and abroad.

4.5 The consumer's perspective

4.5.1 CONSUMER CONFIDENCE

European consumers realise that the trade in food and farm products is international, and can see the network of international trade that underlies the food industry and brings products to their supermarket shelves. Yet the incidents of food scares have led to a fall in consumer confidence in the safety of the food supply, and a demand for transparent processes.

4.5.2 FOOD LABELLING AND TRACEABILITY 'FROM FARM TO FORK'

Food labelling is the key source of information by which the consumer can determine which food to buy by reference to value for money, composition, nutritional content, and in some cases the method by which the foodstuff was produced/processed. It also allows consumers who wish to avoid certain foods, whether for health, ethical or environmental reasons, to make an informed choice. Food labelling must therefore serve its primary purpose of informing the consumer and is a key element in building consumer confidence in a food. There is already a considerable bank of EU labelling legislation in place and there are more proposals being considered which will provide further protection to the consumer.

¹² Source: Department of Agriculture and Food

Consumers need to be confident that food businesses have put their health before any other consideration

While labelling and traceability have different objectives, they complement one another particularly if the information on the label of a food provides for the identity and history of the product to be traced.

Consumers are showing a greater interest in how and where their food is produced, and are seeking reassurances as to its safety. The traceability of food from ‘farm to fork’ is of huge importance to consumers, and they need to be confident that food businesses have put the consumer’s health before any other consideration.

Ensuring good traceability will facilitate the quicker identification and resolution of problems. Testing methodologies are currently available to facilitate easier trace-back, and a food-testing service should help to provide consumer protection by generating information on the safety and quality of food.

4.6 Responses to food safety risks

4.6.1 THE INTERNATIONAL RESPONSE

National governments and other non-governmental organisations have recognised that food safety is an essential public health function. Controlling the risks in food safety presents big challenges, and demands coordinated methods of risk assessment, risk management and risk communication. As a result, there are many international groups and stakeholders helping to develop policies to promote the safety of food.

The World Health Organization (WHO) is a key player in the international coordination of food safety. The WHO issued a global strategy for food safety in 2002, outlining the action needed to reduce food-borne illness. In addition, the WHO and the Food and Agriculture Organisation of the United Nations (FAO), through their subsidiary body, the Codex Alimentarius Commission (Codex), develops safe standards for food in order to protect the health of consumers and ensure fair practices in the food trade. Recent international agreements have put even further emphasis on the importance of Codex guidelines and recommendations, and the WHO uses these as the international references for food safety.

International focus on food safety will continue to increase in the coming decades, with further globalisation of the world food supply and a growing understanding of food safety risks to human health.

4.6.2 THE EUROPEAN RESPONSE

The EU Commission issued its ‘White Paper on Food Safety’ in January 2000, to restore consumer confidence in Europe’s ability to guarantee food safety and quality. This announced a comprehensive package of eighty-four measures, the cornerstone of which was the Regulation on General Food Law (Regulation 178/2002) and the establishment of an independent European Food Safety Authority (EFSA). The EU formally established EFSA in January 2002 with the primary responsibility of providing independent scientific advice on all matters with a direct or indirect impact on food safety. It is also responsible for communicating directly with consumers on relevant food safety matters.

The speed with which the community institutions and the member states adopted this complex and comprehensive regulation reflects the exceptionally high importance attached to food safety. The EU is seeking greater harmonisation in food-borne disease surveillance. Both the Republic of Ireland and other Member States will have to ensure that they have the processes in place to meet

these requirements. With the establishment of EFSA, it is anticipated that more proactive food safety measures are taken by Member states in the future. EFSA has indicated that it will seek greater information on all aspects of food-borne illness.

The European Commission wants more frequent and effective checks on foodstuffs. It will require member states to set pathogen reduction targets and to increase reporting to the EU. This will require better data collection and more detailed data analysis from member states. Under Regulation (EC) No. 882/2004 of the European Parliament and of the Council the Commission obliges member states to have effective food control systems in place:

‘(competent authorities)...must have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that the official controls and control duties can be carried out efficiently and effectively.’¹³

The official laboratory services need to be in a strong position to comply with the new legislation and any new specific requirements, including staff training, increased control of food imports of non-animal origin and the designation of laboratories as National Reference Laboratories.

4.6.3 THE IRISH RESPONSE

Over the past decade, there has been considerable investment in the food safety system. The Department of Health and Children (DoHC) has invested significantly in the health board Environmental Health Service and food safety laboratories. Other government departments, including the Department of Agriculture and Food and the Department of Communications, Marine and Natural Resources have also enhanced their food safety activities.

The Food Safety Authority of Ireland (FSAI) was established under the Food Safety Authority of Ireland Act, 1998. The Act was enacted in July 1998 and came into effect on 01 January 1999. The FSAI was one of the first national food safety agencies in Europe and is a statutory, independent and science-based body, dedicated to protecting public health and consumer interests in the area of food safety and hygiene. It comes under the aegis of the Minister for Health and Children. The principal function of the FSAI is to take all reasonable steps to ensure that food produced, distributed or marketed in the State meets the highest standards of food safety and hygiene reasonably available and to ensure that food complies with legal requirements, or where appropriate with recognised codes of good practice. The Authority has national responsibility for co-ordinating the enforcement of food safety legislation in Ireland. Through the mechanism of a service contract model, the FSAI focuses on bringing together the various regulatory units that are responsible for monitoring different components of the food chain.

In 1999, the laboratories in conjunction with the FSAI established a programme of quarterly national liaison meetings of Official Food Microbiology Laboratories (OFML) and Public Analyst’s Laboratories (PAL) which has helped to assist and co-ordinate at a national level;

- the planning of national annual and regional sampling programmes;
- data transfer;
- the development of the national food surveillance database;
- standardisation of laboratory reporting of results;
- responses to emerging food safety issues and legislative developments.

¹³ Proposal for a Regulation of the European Parliament and of the Council on Official Feed and Food Controls (Article 4)

The FSAI also meets regularly with the ten health boards, including the Environmental Health Service (EHS) and relevant OFML/PAL representatives to discuss issues covered by the service contract including development of and feedback on surveillance topics, regional sampling issues, and out-of-hours cover for food control. In 2002, FSAI started joint national meetings between the EHS and laboratory groups to address issues of joint concern, such as data capture, sampling selection criteria, sampling mechanisms, and the development of national surveillance programmes.

safefood, the Food Safety Promotion Board, was established as one of six cross-border implementation bodies, set up under the terms of the Belfast Peace Agreement in 1999. The Board's governing legislation is the British-Irish Agreement Act 1999 and the North-South Co-operation (Implementation Bodies) Northern Ireland Order 1999. Conducting its work on an all-island basis, the Chief Executive reports directly to the North South Ministerial Council (NSMC). **safefood** is tasked with the promotion of and research into food safety and has a general remit to act as an independent source of scientific advice. Additionally, **safefood** works in partnership with laboratories to promote scientific co-operation, communication and linkages between food safety laboratories, in part, through the provision of a bi-monthly laboratory newsletter and hosting regional and national food safety workshops and seminars. It provides co-operative programmes, incl. staff training, inter-laboratory staff exchanges and facilitates joint laboratory collaborative projects. **safefood** is also tasked with developing cost effective facilities for specialised laboratory testing on the Island of Ireland.

4.7 Food safety in the era of reform

4.7.1 THE HEALTH SERVICE REFORM

Drawing on international best practice, the national Health Strategy and the Brennan¹⁴, Prospectus¹⁵ and Hanley Reports¹⁶, the government has decided to implement a major reorganisation in the way in which the Irish health system is structured and managed.

The government has developed the Health Service Reform Programme¹⁷ around major priorities, in order to create a more rational, accountable and responsive health service with a clear national focus on service delivery and executive management. These priorities include the need:

- for a national focus on service delivery and executive management of the system;
- to reduce the fragmentation of the current system and to make it more manageable;
- for clear accountability throughout the system;
- for better budgeting and service planning arrangements;
- for continuous quality improvement and external appraisal;
- for robust information gathering and analysis capabilities;
- to preserve and build on the strengths of the existing system.

The new health service structure will involve a major rationalisation of the existing health service agencies, and will include the abolition of existing health boards, authorities and other agencies. The reform programme will reorganise the DoHC, and will separate executive and non-executive functions.

¹⁴ Brennan Commission on Financial Management and Control Systems in the Health Service, January 2003.

¹⁵ Prospectus Audit of Structures and Functions in the Health System, 2003.

¹⁶ Hanley Report of the National Task Force on Medical Staffing, 2003.

¹⁷ The Health Service Reform Programme Booklet, DoHC, June 2003.

The most appropriate decision-making level will have clear accountability for spending, and key decision makers will be fully involved in planning, management and control processes. In addition, there will be performance-measurement processes that are consistent with recognised international best practice. These will help to develop strong service planning and evidence-based funding processes, and to establish links between service delivery and evaluation.

The programme will establish a national agency, the Health Service Executive (HSE), which will be external to the DoHC and will manage the health service as a single national entity. Accountable to the Minister for the executive management of the health service, the HSE will deliver services specified by the Department within a budget. The HSE will assume responsibility for all of the functions of the existing health boards and the Eastern Regional Health Authority.

The service provided by the HSE will be based on three service pillars:

1. **The National Hospitals Office (NHO)** will be responsible for the centralised planning, coordination and management of acute hospital services nationally.
2. **The Primary, Community and Continuing Care Directorate (PCCCD)** will be responsible for managing and delivering non-hospital services at local and regional levels across the country. A network of four Regional Health Offices (RHOs) will deliver non-acute services, including food safety, supported by the existing Community Services Area structures (Local Health Offices). The RHOs will act as regional offices of the HSE, and will be responsible for regional planning, commissioning and funding all non-acute services.
3. **The National Shared Services Centre (NSSC)** will have a remit for the provision of shared services across the wider health system. The use of shared services will be mandatory for statutory agencies.

The establishment of the **Health Information and Quality Authority (HIQA)** will ensure that quality of care is promoted throughout the system, and that services are based on evidence-supported best practice. The implementation of all of the components of the Health Service Reform Programme will take approximately 18 to 24 months. The government has established an interim board of the HSE.

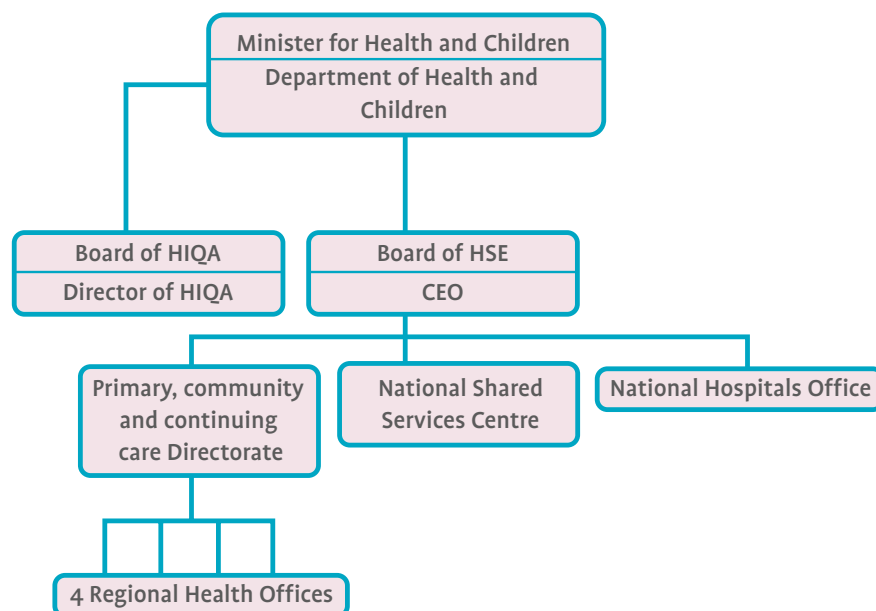


Figure 4.1: The proposed restructured Health Service

4.7.2 IMPLICATIONS FOR THE MANAGEMENT OF FOOD SAFETY

Policy for both food safety and the associated Laboratory Services will remain with the DoHC. However, the HSE and two of its pillars, the PCCCD with its subsidiary RHOs, and the NHO, will carry out the executive function previously carried out by health boards.

The HSE and the PCCCD will manage and assume responsibility for food safety and the laboratory services. However, food laboratories are in different settings, so it is likely that under the future management structure, different HSE pillars will administer different service laboratories. Based on existing structures, we expect that three RHOs will separately administer the three PALs, as well as two of the non-hospital based OFMLs and the NHO will administer those OFMLs situated in a hospital environment.

The implications of the Health Service Reform for our findings and recommendations are discussed in chapter 6.

4.8 Conclusion

The nature and extent of these current and potential future risks to food safety have been identified and, against this complex and concerning background, many countries are reviewing the effectiveness of their food safety control systems in order to protect public health and participate in global food trade. Food safety legislation has become increasingly stringent. This legislation will continue to evolve along with the establishment of independent food safety authorities in many countries. There will be a greater emphasis on risk-analysis in order to obtain better scientific knowledge of food-borne illness and its causes. This will provide a preventive basis for regulatory measures for food safety at both national and international levels.

The increased incidence of food-borne disease due to microbiological hazards is the result of many factors, all associated with our fast-changing world. The coming decades will see new challenges, only some of which can be predicted now.

In the protection of public health, food-borne disease surveillance is a vital element that permits outbreaks to be identified, disease trends to be tracked, new and emerging diseases to be identified, and the impact of food safety control measures to be evaluated.

A food supply that is adequate in quantity, quality, accessibility and safety is a prerequisite for achieving and maintaining the health of Ireland's population. A food safety service operating to international standards of best practice is central to the protection of public health and is a key component of an effective and integrated food control system.

5. Findings of the Strategy Review Group

5.1 Introduction

In order for the Strategy Review Group to meet the requirements of the Terms of Reference for this project successfully, a substantive body of research was undertaken. Chapter 3 outlined how we collated the information needed for this project. In this chapter, we will present the findings of our research, which will lead into our recommendations to answer the requirements of the Terms of Reference.

The findings in this chapter are based on current structures and processes, which are subject to change due to the Health Service Reform, as outlined in section 4.7. However, we have developed our subsequent recommendations to take into account the proposed changes and aims of the reform.

We begin by reviewing the current provision by health boards of food safety in Ireland, the frameworks, structures and funding of the current food safety laboratories. We then review the laboratories' resources, in terms of their facilities, equipment and human resources.

Following this review of resources, we look at the accreditation requirements for laboratories, before conducting a detailed review of the types of analytical activities the laboratories actually perform.

We then move on to review the methods used to report and communicate information and data, both internally around the laboratories and externally to other stakeholders.

Finally, we review the laboratories' responsibilities in an emergency situation or outbreak and their ability to respond to it.

5.2 The provision of food safety in Ireland

5.2.1 CURRENT RESPONSIBILITY FOR FOOD CONTROL

Overall responsibility for food safety policy in Ireland falls to the Department of Health and Children (DoHC), the Department of Agriculture and Food (DAF) and the Department of Communications, Marine and Natural Resources (DCMNR). Responsibility for food legislation enforcement falls to the Food Safety Authority of Ireland (FSAI). In this report, we will deal with health board food safety activities. There are ten health boards in Ireland¹⁸, and each has responsibilities for food control for a number of counties. All health boards report to the DoHC and have service contracts with the FSAI.

This service contract allows for the provision of a food control service, which incorporates an Environmental Health Service (EHS) and the food safety laboratories.

The EHS inspects the retail and catering sectors of the food industry and, for foods of non-animal origin, the wholesale, manufacturing and distribution sectors. Besides regulating the registration of premises manufacturing and serving food and monitoring hygiene controls, the EHS carries out sampling of food products, deal with food complaints and investigates food-borne outbreaks for

¹⁸ Southern, South Eastern, North Western, North Eastern, Mid-Western, Midland, Western and the Eastern Regional Health Authority (Northern Area, East Coast Area and South Western Area Health Boards).

health boards. The EHS submits food samples to laboratories for chemical and microbiological analysis. Within health boards, routine day-to-day infectious disease control is the responsibility of the Senior Area Medical Officers (SAMO) in each community care area who report to the Specialist in Public Health Medicine (SPHM) with responsibility for infectious disease. The SPHM is involved in the investigation of outbreaks of infectious diseases at regional level, incl. food borne cases, and is also responsible for epidemiological investigation of cases.

5.2.2 THE LEGISLATIVE FRAMEWORK

The Food Safety Authority of Ireland (FSAI) Act 1998 confers executive responsibility for food law enforcement to the FSAI. Health boards, as agents of the FSAI through service contracts, are responsible for the enforcement of this legislation. Official health board laboratories provide an agreed level of food control analytical services, through service contracts with the FSAI that largely dictate their food control activities.

The European Communities, Official Control of Foodstuffs Regulations, S.I. 85 of 1998, is the key Irish legislative framework governing food control¹⁹. This legislation affirms ‘sampling and analysis’ as food control operations, and deals with both inspection issues and with a number of laboratory issues, including official laboratories and standards.

The European Communities Official Control of Foodstuffs (Approved Laboratories) Order, S.I. 95 of 1998, designates official health board food control laboratories, as approved laboratories²⁰. In addition, the European Communities Official Control of Foodstuffs (Approved Examiners) Order, S.I. 465 of 1998, gives statutory recognition to people qualifying as ‘Approved Food Examiners’. Among others, this Order includes as Approved Examiners:

- Public Analysts
- Deputy Public Analysts
- Executive Analytical Chemists
- Consultant Microbiologists
- Chief Laboratory Technologists.

The statutory role of laboratories is to test food for compliance with a range of diverse but protective legislative controls put in place to protect consumer health and interests. For example, Public Analyst’s Laboratories (PALs) monitor for the presence of contaminants, residues, additives, nutrients and so on in foodstuffs, while Official Food Microbiology Laboratories (OFMLs) monitor for a range of pathogens and indicator organisms according to agreed guidelines. Schedule 1 of the Service Contract between each health board and FSAI²¹ lists this legislation. The Health and Safety and Welfare at Work Act further governs the functions of laboratories.

5.2.3 THE FOOD SAFETY LABORATORY SERVICES

There are ten laboratories, located on nine sites²². Three PALs carry out chemical testing, and seven OFMLs conduct microbiological examinations (one OFML is located within the Dublin PAL). The relevant health boards administer the laboratories where they are located. Figure 5.1 shows the locations of the ten laboratories across Ireland.

¹⁹ S.I. 85 of 1998, is derived from EU legislation governing food control and official laboratories (EU Directives 89/397/EEC and 93/99/EEC).

²⁰ This order also places the Radiological Protection Institute of Ireland (RPII) as an Official Food Control Laboratory. This laboratory undertakes specialised monitoring of radiological activity in foodstuffs and in a wide range of environmental matrices. The RPII is not included within the scope of this review.

²¹ Legislation enforced by Health Board Laboratories is available under Appendix 8.6.

²² Contact information for the ten laboratories can be found under Appendix 8.1.

According to legislation all laboratories are designated as Official Food Safety/Surveillance laboratories²³. Their statutory role is to test food for compliance with the relevant national guidelines and legislation to prevent risks to public health and to protect consumer interests. The laboratories carry out chemical and microbiological analysis on a wide range of foodstuffs and waters, submitted primarily by the EHS but also by consumers, hospitals, other agencies and companies. All food laboratories also participate in outbreak incidences, national and EU alerts, and EU programmes as required.

A laboratory 'Approved Examiner' will notify the EHS and the FSAI of details of all submitted food samples including those that fail to comply with the relevant standards, legislation or guidelines, and those considered unfit for human consumption. These food products can be recalled, detained or withdrawn from the market. A range of enforcement action can be taken, ranging from advice to prosecution.

There is no national coordinating mechanism for the operational management of laboratories, and operational and budgetary systems vary from health board to health board.

The three regulatory PALs are each headed up by a Public Analyst. All PALs report to the General Manager of Community Services on administrative issues within their respective health board. Five of the OFMLs are linked to their clinical microbiological counterpart laboratories in hospitals. Of the remaining two, one Dublin OFML is part of the Dublin PAL and the Cork OFML is a stand-alone facility, separate from the clinical microbiology laboratory in Cork University Hospital. Consultant Medical Microbiologists are directors of six OFMLs, while the Public Analyst heads up the Dublin OFML in the Dublin PAL. The core operational hours for the laboratories are Monday to Friday from 9am to 5pm.

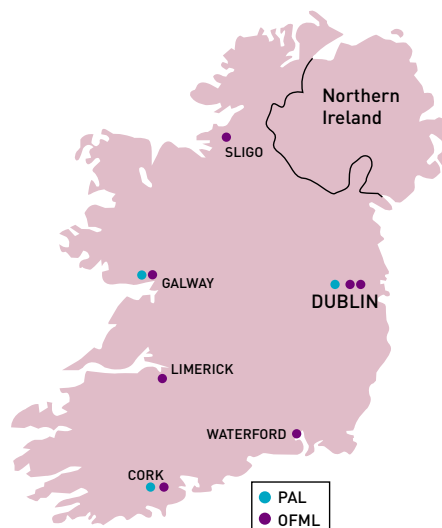


Figure 5.1: Location of OFMLs & PALs

²³ European Communities Official Control of Foodstuffs (Approved Laboratories) Order, S.I. 95 of 1998

The following table provides a national breakdown of the Health Boards, counties and laboratories:

Table 5.1: A national breakdown of health boards, counties and laboratories

Official Food Control Laboratories	Health Boards served	Counties served	Population (est. 2002)
Galway PAL, Galway OFML, Sligo OFML and Limerick OFML	Western	Galway, Mayo and Roscommon	380,297
	North-Western	Donegal, Leitrim and Sligo	221,574
	Mid-Western	Clare, Limerick and Tipperary (NR)	339,591
			Subtotal: 941,462
Cork PAL, Cork OFML and Waterford OFML	Southern	Cork and Kerry	580,356
	South-Eastern	Carlow, Kilkenny, Tipperary (SR), Waterford and Wexford	423,616
			Subtotal: 1,003,972
Dublin PAL and OFML, and Dublin Public Health (SWAHB) OFML	ERHA	Dublin, Kildare and Wicklow	1401,441
	Midland	Laois, Longford, Offaly and Westmeath	225,363
	North-Eastern	Cavan, Louth, Meath and Monaghan	344,965
			Subtotal: 1,971,769
			TOTAL 3,917,203

(Source: Central Statistics Office - 2002 census)

5.2.4 THE STRUCTURE AND FUNCTIONS OF THE LABORATORY SERVICES

5.2.4.1 OFFICIAL FOOD MICROBIOLOGY LABORATORIES

OFMLs perform accredited testing of food samples for a broad range of food-borne pathogens and indicator organisms, carry out surveys and related research, participate in the investigation and control of outbreaks, and provide independent expert clinical and technical advice. The type of analysis they perform depends on the particular food, the background of the sample and the specific pathogen of interest. All OFMLs undertake, to varying degrees, microbiological analysis of water. In addition, it is required under the FSAI service contract that OFMLs perform testing of waters as part of the management of a food outbreak incident. Figure 5.2 shows the general structure of an OFML.

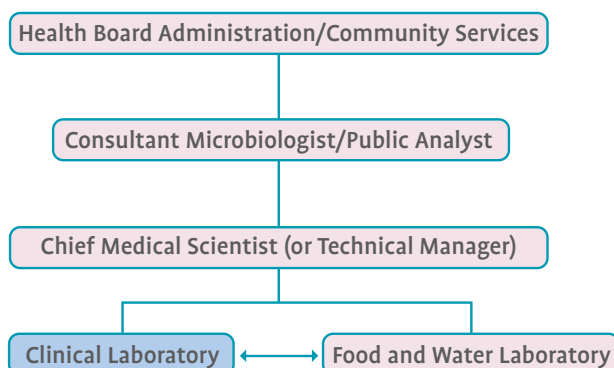


Figure 5.2: General structure of an Official Food Microbiology Laboratory²⁴

²⁴ This structure is broadly descriptive, and structures may vary between laboratories.

5.2.4.2 PUBLIC ANALYST'S LABORATORIES

PALs carry out chemical analysis, along with physical tests and microscopic examination, on a wide range of foodstuffs. The tests that the PALs carry out depend on the particular food, statutory provisions and historic problems with the food. PALs participate as appropriate in EU food alerts and emergencies and also provide expert and technical advice. All three PALs carry out food export certification work.

All three laboratories have separate and distinct water and effluent testing sections, and provide a service for some sanitary authorities, consumers and health boards (EHS and Haemodialysis Units). The Galway PAL has a drugs section that carries out work for the Irish Medicines Board, and has a toxicology service for health board pathologists in this region. They perform other miscellaneous testing, including food-export certification work, air pollution monitoring and Road Traffic Act testing.

The Dublin laboratory also provides a microbiological food and water testing service, and is designated as an OFML for microbiological testing. The Dublin PAL carries out metal analysis on clinical samples from hospitals and doctors throughout the state. Figure 5.3 shows the general structure of a PAL.

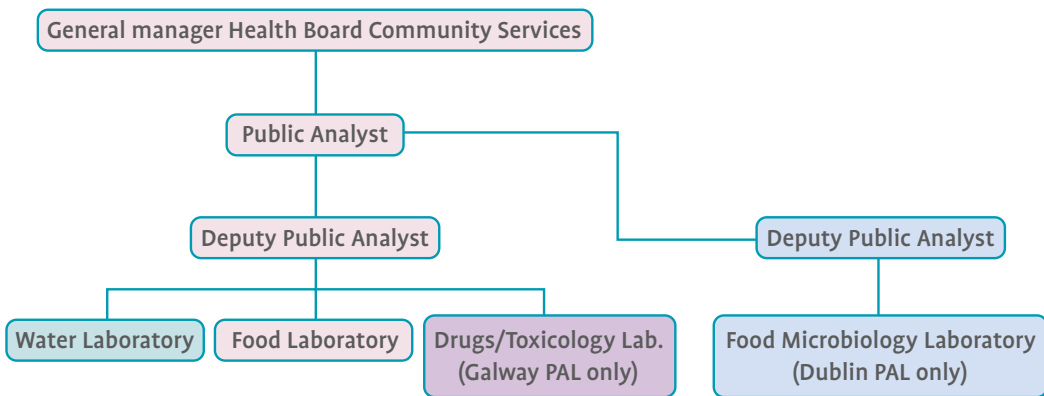


Figure 5.3: General structure of a Public Analyst's Laboratory²⁵

5.2.5 CURRENT FUNDING FOR FOOD CONTROL

The Department of Health and Children (DoHC) allocates ring-fenced funding to health boards for food control, which is divided between the EHS and the laboratories. The health board community services or the hospital administration manages these budgets, and they are generally not managed by the food laboratories.

For the five OFMLs attached to clinical laboratories, funding comes through the acute hospitals. The other two OFMLs and PALs receive funding through health board community services.

There are generally two types of funding for each laboratory:

- **Core funding:** this comprises the pay and non pay budgets allocated by the DoHC. Core funding has been calculated based on the previous year's expenditure and on Health Board Service Plans sent to the DoHC. Some health boards do not include food control laboratories in these service plans.
- **Developmental funding:** this is allocated annually by the DoHC to each health board. This method of funding may include payments for a specific purpose.

²⁵ This structure is broadly descriptive, and structures may vary between laboratories.

- Some laboratories secure additional external funding from food agencies and other sources.

All three PALs provided us with their core and developmental funding details. Due to financial systems at health board level, it was difficult for some OFMLs to provide budgetary information. Some health boards had difficulty supplying accurate 2002 pay and non-pay budgetary information, while one Board was unable to supply their laboratory's non-pay budget. However, in table 5.2 we have provided the budgetary figures submitted by laboratories for this review, with percentage breakdowns of each budget in Figure 5.4a and 5.4b:

	PAL Budget 2002	OFML Budget 2002²⁶
Non-Pay Budget	€2,386,466	€1,568,371 ²⁷
Pay Budget	€4,074,239	€3,206,706
Extra External Funding	€60,000	€213,000
Developmental Funding	€374,000	€540,000
Total	€6,894,705	€5,528,077

Source: Laboratory Directors

Table 5.2: 2002 Budget of PALs & OFMLs

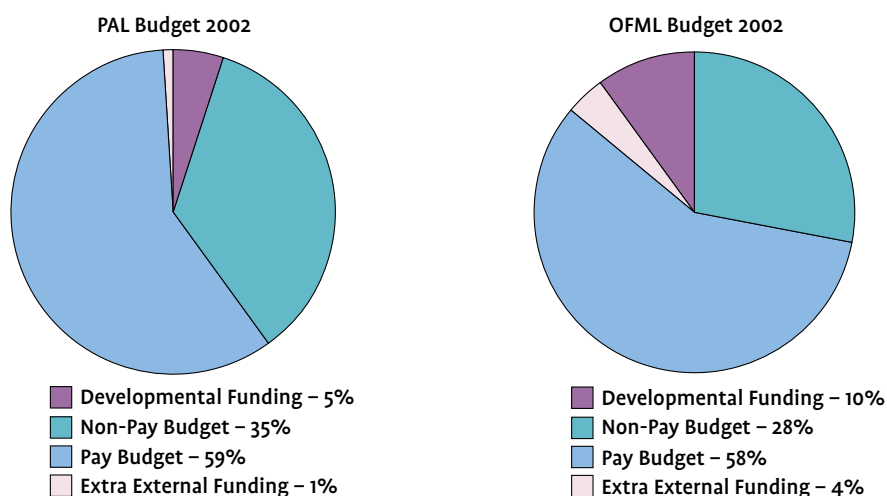


Figure 5.4a: % Breakdown of PALs 2002 budget

Figure 5.4b: % Breakdown of OFMLs 2002 budget

The health boards have applied the allocation of DoHC ring-fenced funding variably to different laboratories. The budgetary information available and actual funding mechanisms for laboratory allocations differ from health board to health board.

The level of budgetary information supplied to laboratories and the timeliness of this information varies greatly between different health boards. Some boards do not inform laboratories of their allotted annual budget, and 'allocate funding' on a piece-wise basis throughout the year rather than give budgets. Most laboratory managers do not receive either budgetary information before the start of the financial year, or ongoing budgetary accounts of laboratory expenditure throughout the year.

²⁶ These figures are for six of the seven OFMLs; the seventh OFML is included in the PAL budget.

²⁷ This figure includes five of the OFML non-pay budgets.

In addition, for a few laboratories, there appears to be a lack of transparency in the actual funding mechanism within their health boards. This is a major adverse factor in the effective management of these laboratories. Under these constraints, laboratory managers cannot plan adequately and cost effectively, as they are unable to manage their service financially. This ultimately leads to difficulties in accountability and cost efficiency.

All PALs engage in export certification as agreed with DoHC and FSAI, and private contract work on a fee-paying basis. For some laboratories, any revenue earned is passed directly to their respective health board. Some laboratories have difficulty in obtaining external research or work grants, as any income secured is not ring-fenced for the laboratory's future use by the relevant board.

All laboratories carry out other non-food analytical testing, such as water testing, for health boards, local authorities and others. These costs were included in the overall budgets provided. However, it is not possible to make clear budgetary distinctions between food and non-food activities with the financial management systems employed by most boards. In particular, the non-pay budget includes some clinical activity cost centres for some OFMLs situated in hospitals. In addition, the budgetary allocations for OFML food microbiological testing in the Dublin PAL are contained within the overall Dublin PAL budget.

For the reasons we have identified above, it is not possible to provide fully accurate costs for any laboratory's food activities alone. Due to these limitations, it was not possible for us to assess the cost effectiveness of the current food safety laboratory services.

5.3. Laboratory resources

5.3.1 FACILITIES

5.3.1.1 GENERAL LABORATORY ACCOMMODATION

In the mid to late 1990s, the DoHC funded the provision of new facilities in response to the advent of new EU legislation. Cork and Galway PALs and Cork OFML moved into new purpose-built establishments within hospital complexes, which are easily accessible and have scope for expansion. The Dublin PAL moved into Sir Patrick Duns Hospital. This facility has no scope for expansion as it is a listed building, and a planning brief for a new laboratory has been submitted.

The food analytical work areas for most OFMLs located in clinical hospital environments are in a number of small rooms adjacent to the clinical laboratory. Some facilities are inadequate. There is considerable overcrowding and, in some instances, food and clinical microbiology staff have to share ancillary equipment and facilities. There is a lack of media preparation, office and storage space, with a number of laboratories having to use their corridors as storage areas. In recent years, significant investment in laboratories has enhanced their capability to accommodate an increased number of samples. However, for many laboratories there has not been a proportionate increase in laboratory accommodation relative to the increased staff numbers and samples.

Seven laboratories are currently in the process of seeking new laboratory accommodation or extensions to their existing premises. Some of the OFML applications have been made as part of a wider public health microbiology laboratory application. Submissions have included requests for additional or new facilities such as:

- Containment Level 3 (CL3) facilities;
- media preparation areas;
- general laboratory analytical areas;
- store rooms;
- offices;
- cold rooms;
- record storage and;
- completely new laboratory facilities.

Most applications are at the proposal consideration, design, planning permission or tendering stage at either health board or department level. Some developments have been included as part of the National Development Plan and other projects may be resourced directly by individual health boards. However, in recent times, due to the current uncertain economic climate, some projects have been shelved, while others are in doubt or are still awaiting approval by health boards.

5.3.1.2 CONTAINMENT LEVEL 3 (CL3) FACILITIES

Most OFML laboratories are operating in Containment Level 2 facilities. A number of laboratories are currently in the process of seeking new laboratory accommodation and extensions to existing premises to accommodate Containment Level 3 (CL3) facilities to meet current standards. The Dublin Public Health (SWAHB) OFML has a CL3 facility to handle Biological Group 3 pathogens such as VTEC. The remaining OFMLs do not have CL3 facilities.

5.3.1.3 REFERENCE FACILITIES

The Dublin Public Health (SWAHB) OFML offers a national VTEC diagnostic service. This laboratory also serves as the National Designated Laboratory for diagnosis of bacterial bioterrorism pathogens.

OFMLs also avail of the services of the interim Salmonella Reference Laboratory in the Clinical Science Institute in Galway. The Waterford OFML offers a Listeria typing service. The OFMLs use the Laboratory of Enteric Pathogens in Colindale and the Health Protection Agency, UK, for typing and other reference work to varying degrees. However, in the context of EU legislation, no PAL or OFML is currently a reference laboratory.

5.3.2 TECHNICAL EQUIPMENT

In recent years, the DoHC has made significant investment in the provision of specialised equipment and instrumentation. Developmental Funding allocations have been the main facilitator of this development of analytical services and the expansion of test portfolios.

Laboratories have introduced many new food analytical technologies, which are more sensitive and allow rapid testing, into routine operations in recent years. These include ELISA, PCR and other DNA-based assays.

New equipment requires increased levels of reagents and consumables, which considerably increase laboratory costs. Laboratories individually purchase many similar reagents and consumables, but there is no central service procurement policy or mechanism for the purchase of generic consumables. The use of the common procurement system operated by Health Board Regional Materials Managers has not been fully explored.

5.3.3 HUMAN RESOURCES

Laboratories have a variety of staffing groups, from medical, technical and scientific to administrative and support personnel.

5.3.3.1 PALS – GRADES, RESPONSIBILITIES AND QUALIFICATIONS

There are two grades of scientific and technical laboratory staff in the PALS: the chemist grade and the technician grade. The chemist grade consists of the Public Analyst (PA), Deputy Public Analyst (DPA) and the Executive Analytical Chemist (EAC), who are all appointed as 'Approved Examiners' according to S.I. 465 of 1998. The technician grades consist of a Chief Technician, Senior Laboratory Technician and Laboratory Technician.

The PA is the Laboratory Director who has overall responsibility for the running of the laboratory, and reports to the Health Board General Manager (Community Services) on administrative issues. The DPA assists the PA with regard to the management of PAL operational activities, advises on strategic planning and deputises for the PA as appropriate. An EAC is in charge of each section of the laboratory, including food, water and other specialist sections such as toxicology. In the food laboratory, EACs have responsibility for subsections of the food laboratory. All Laboratory Technicians report to and are supervised by EACs or PA/DPA.

- PAs, DPAs and EACs hold a first- or second-class BSc (Hons) degree, and have at least five years' experience, although most have postgraduate degrees such as PhDs.
- Senior Grades and Chief Laboratory technicians have a minimum of a National Diploma or an equivalent qualification, and a minimum of five years' experience. Some also have additional degree level qualifications.

- Technicians have a minimum of a National Certificate in Science (Chemistry or Biology) awarded by the NCEA, and at least three years' experience. Most also have National Diploma qualifications and some have additional degree level qualifications.

EACs have been appointed as Approved Food Examiners and have operational responsibilities for accreditation, food liaison meetings, applied research and development, and an increased supervisory role. Some EACs are also supervising other EACs within the food laboratory. A request for a new promotional grade of Senior Executive Analytical Chemist has been lodged with the Health Service Employers Agency (HSEA). Table 5.3 outlines the numbers and grades of PAL staff, and figure 5.5 provides the general staff structure²⁸ (food only):

PALs	
Grade	Number of Food Staff (WTE)²⁹
Public Analyst	2.3
Deputy Public Analyst	2.3
Executive Analytical Chemist	20.5
Chief Laboratory Technician	1.3
Senior Laboratory Technician	4.5
Laboratory Technician	34
Administration/Clerical	6
Total	70.9

Table 5.3: Numbers & grades of Public Analyst's Laboratory staff

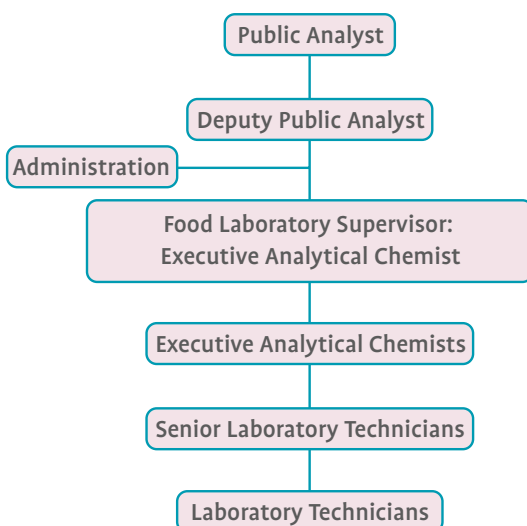


Figure 5.5: General staff structure of Public Analyst's Laboratory

²⁸ There are some structural differences between the three PALs.

²⁹ These staff numbers are on a Whole Time Equivalence (WTE) basis for food work only, and were supplied by laboratory directors.

5.3.3.2 PAL REMUNERATION

There are two issues regarding remuneration within the PALs. Firstly, a 'Branch E Certificate Allowance' is a salary scale sanctioned by the DoHC for individuals possessing the qualification of Mastership in Chemical Analysis (MChemA) from the Royal Society of Chemistry in the UK. No one in the service currently possesses this certificate. This qualification seems outdated, considering that most chemists now have a MSc. or PhD. This issue is currently under review within the DoHC.

The second remuneration anomaly concerns the pay relativity between EACs and laboratory technicians in PALs. A recent review of the clinical medical laboratory scientist structure resulted in salary increases for technicians within PALs, which affected their relativity with EACs. This issue needs to be considered in the context of national wage agreements.

5.3.3.3 OFMLs – GRADES, RESPONSIBILITIES AND QUALIFICATIONS

The technical and scientific staff of the five OFMLs located in a clinical setting varies, but generally includes a Chief, a Senior and Basic Grade Medical Scientists. All staff report to the Consultant Microbiologist, who is a medical doctor and laboratory director.

The Chief, Senior and Basic Grade Medical Scientists have honours degrees in Medical Laboratory Science, and some hold postgraduate degrees. They are members of the Academy of Medical Laboratory Science.

The Consultant Microbiologist and some senior scientific staff have a dual mandate, with duties in both the clinical and food microbiology laboratories. The responsibilities of Consultant Microbiologists cover a wide range of advisory and diagnostic services, and food, water and clinical activities within their own health boards.

In the two remaining OFMLs, the Dublin PAL has the same staffing grades as the chemistry section, with a Deputy Public Analyst in charge. The Cork OFML has a Technologist (equivalent to Senior Medical Scientist I), Senior, and Laboratory Technicians who also report to a Consultant Microbiologist. In general, technician grades in the latter laboratory have food science qualifications. As detailed in S.I. 465 of 1998, Consultant Microbiologists and Chief Laboratory Technologists are 'Approved Examiners'. Table 5.4 outlines the numbers and grades of OFML staff:

OFML	Grade	Number of Food Staff (WTE) ³⁰
Dublin, Waterford, Limerick, Galway and Sligo ^v	Consultant Microbiologist	1.6
	Chief Medical Scientist	1.33
	Senior Medical Scientist	13.8
	Medical Scientist ⁱ	30.5
	Other ⁱⁱ	0.53
	Administration	2.6
	Support staff ⁱⁱⁱ	6.65
		Subtotal: 57.01
Cork ^{iv}	Consultant Microbiologist	0.4
	Technologist	1
	Senior Laboratory Technician	3.6
	Laboratory Technician	9.5
	Administration	1.6
	Support staff ⁱⁱⁱ	1
		Subtotal: 17.1
Dublin PAL ^v	Deputy Public Analyst	1
	Executive Analytical Chemist	1
	Senior Laboratory Technician	1.75
	Laboratory Technician	5
	Administration	0.5
		Subtotal: 9.25
		TOTAL: 83.36
<p>i - includes trainees ii - includes laboratory manager and molecular biologist iii - includes laboratory assistants, aides and cleaners iv - Laboratory Director: Consultant Microbiologist v - Laboratory Director: Public Analyst Source: Laboratory Directors</p>		

Table 5.4: Levels & grades of Official Food Microbiology Laboratory staff

³⁰ These staff numbers are on a Whole Time Equivalence (WTE) basis for food work only, and were supplied by laboratory directors.

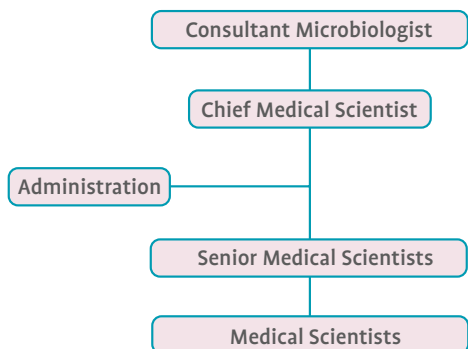


Figure 5.6a: The general staff structure of an OFML attached to clinical laboratories

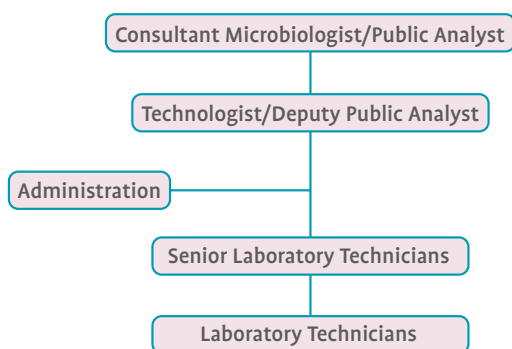


Figure 5.6b: The general staff structure of Cork OFML and Dublin PAL OFML ³¹

Within the seven OFMLs, there are three different staffing structures and associated qualifications. This has led to certain inequities and limitations in the development of the service. In particular, senior laboratory technicians with food science qualifications who work outside the clinical environment, and who are not members of the Academy of Medical Laboratory Science, cannot progress beyond the fifth point of the Senior Medical Scientist salary scale. The Academy does not recognise science or food science graduates working within the food analytical service, and there are no appropriate professional development opportunities for these staff, limiting their career development. This has a negative affect on the service, and prevents attracting staff with multidisciplinary qualifications.

OFMLs also highlighted that the interpretation of results, the delivery of food safety advice and the development of the service requires a greater input from senior scientists and consultant microbiologists.

5.3.3.4 ADMINISTRATION

The level and grades of administration support nationally is inadequate and quite low throughout the services. While there is on average 1.07 WTE administrative support per laboratory, some laboratories have ≤ 0.5 WTE support. The processing of sample reports for over 24,000 food samples submitted to OFMLs and PALs is resource intensive. Laboratories encounter difficulties in attracting administrative staff, due to the poor promotional opportunities within laboratories.

5.3.3.5 TRAINING AND DEVELOPMENT

Under the terms of the national agreement “Sustaining Progress” employees are entitled to a 4% spend of payroll on training and development.

All laboratories participate in a variety of internal and external training. The requirements of accreditation necessitate considerable in-house staff training on technical procedures, and some laboratory staff members have also availed of other technical, health and safety, IT, management, outbreak skills and financial training.

Each laboratory individually sources appropriate training courses and development opportunities. The extent of the training received by staff varies from laboratory to laboratory. It is not clear what

³¹ There are structural differences between the laboratories.

levels or grades of staff members are encouraged to and actually participate in training events. At present, there are limited opportunities for appropriate professional development on a part-time basis at third level institutions.

The training approval mechanism varies between health boards. In some laboratories, staff members apply to their manager for external training approval. For others, training events require sanction from health board administration. Certain laboratories have limited external training opportunities due to local health board procedures.

A dedicated staff training budget is not provided for all laboratories. Half of the laboratories have a staff training co-ordinator, and seven laboratories have a dedicated staff training plan.

5.4 Accreditation

Accreditation requires the establishment and maintenance of an externally audited quality system in each laboratory. Legislation requires that all official laboratories are accredited (S.I. 85 of 1998), and this will remain so under the new regulation on official feed and food controls. Laboratories must conform to international best practice with respect to their accreditation status and participate in proficiency test schemes and quality of work audits to ensure their results are valid and can withstand challenge. It demonstrates that laboratories produce test reports to the recognised EU 'Official Laboratory' standard that is comparable within all member states. The Irish National Accreditation Board (INAB) oversees the operation of laboratory accreditation in Ireland. All laboratories must comply with the standard ISO/IEC 17025 and all were formally accredited before the deadline of 1 November 1998.

The accreditation process requires significant work on an ongoing basis, reducing the amount of time available for practical work.

The accreditation process requires significant work on an ongoing basis, reducing the amount of time available for practical work. It also represents a change in working practices, including a reduction of the interchange of staff between laboratory sections. Additionally, the role of the quality manager has become increasingly demanding. Accreditation produces a 'value added quality' to laboratory operations and to the services as a whole. Each laboratory has an extensive scope of accreditation which may be viewed on the INAB website at www.inab.ie

Most of the analytical methods employed by OFMLs and the majority of PAL methods are accredited. Accreditation activities account for a significant portion of each laboratory's budget. There is a lot of paperwork, and this has implications on the speed that routine analysis results are reported, and on the speed that new analytical services are brought online. Accreditation also requires extensive method validation and ongoing internal and external quality control work, which has resource implications for each individual laboratory.

An INAB audit surveillance team assesses each laboratory through both annual and random visits. Each laboratory develops its scope of accreditation individually, and interacts with INAB on an individual basis.

5.5 Laboratory functions and analytical activities

5.5.1 RECEIVING SAMPLES FOR ANALYSIS

5.5.1.1 SAMPLING

The service contracts between individual health boards and the FSAI specifies that the laboratories shall analyse samples in accordance with the regional sampling and analysis programme, annual EU Co-ordinated Programmes and national surveys. The regional sampling and analysis programme provides for the laboratory to analyse an agreed number of programmed routine samples annually, based on agreed testing parameters.

Individual laboratories and the EHS devise annual sampling and analysis programmes in conjunction with the FSAI, by necessity on a regional basis, to ensure that they meet the needs of the local area. Typically, the annual programme is a structured surveillance and survey plan, based on criteria such as:

- product type;
- premises category;
- EU and legislative requirements;
- previous experience;
- currently perceived priorities;
- recent problems;
- laboratory capacity.

The majority of food samples taken by the EHS and submitted to laboratories for analysis are taken at retail level.

Samples may be classified by the EHS as either informal or formal. Informal samples are routine programmed samples, while formal samples are usually taken by the EHS in connection with a particular problem or where there is an intention to prosecute a food premises or producer. All laboratories provide a local service to consumers, and some laboratories will accept consumer samples directly. Most samples submitted by consumers are typically complaint samples. The EHS will forward any consumer samples to laboratories for analysis. PALs also accept private food samples from other agencies and private companies for a charge. In addition to routine and survey programmes, the laboratories must also facilitate the urgent analysis of samples related to outbreaks and food-related incidences.

Modern food production and distribution has changed, and so regional stand-alone food monitoring programmes have limited effectiveness. Most samples for chemical analysis are taken at retail level. There are inefficiencies with samples of the same brand, and even the same lot number, being taken at various sampling sites and submitted to different PALs.

5.5.1.2 ACCESSIBILITY

There is some variation between the laboratories in when they will accept routine or survey programmed samples from the EHS. Some laboratories do not accept samples on certain weekdays due to the nature of specific analytical tests. The laboratory's location and restrictions on the time of delivery therefore impacts on the sampling that can be carried out on any particular day. Significant time delays, or problems in transporting samples to laboratories, have the potential to cast doubt on the validity of results from both a legal and quality perspective.

There is no service-wide system for accepting programmed and ad-hoc samples from the EHS outside the core operational times of laboratories. Such a system would allow the EHS to target food sampling programme and control activities during the evening, at night and at the weekend.

There is no formal service-wide 'out of hours' arrangement in place for most laboratories in the event of a food outbreak incident, rapid alert or emergency. The laboratory's response is generally based simply on the goodwill of staff.

5.5.2 FOOD ANALYTICAL ACTIVITIES

Food control is based essentially on a four-fold principle of inspection, audit, sampling and analysis. Samples may be taken to support legal proceedings, taken during enforcement visits to individual food premises or may be related to food-linked emergencies. Samples may also be taken as part of local, regional, national or EU surveillance work to assess wider trends.

Food is sampled mostly at retail level, and microbiologically examined or chemically analysed in the appropriate laboratory to check compliance with specific legal standards and guidelines. Microbiological examination is needed to check hygienic conditions throughout the food chain and to identify food-borne pathogenic and indicator micro-organisms present in food. Chemical analysis is necessary to ensure that foods comply with their label descriptions and claims, comply with statutory compositional standards and limits, and do not contain harmful levels of metals, chemicals, natural toxicants and so on.

5.5.2.1 CORE WORK

Figure 5.7 outlines the workflow of a typical food safety laboratory:

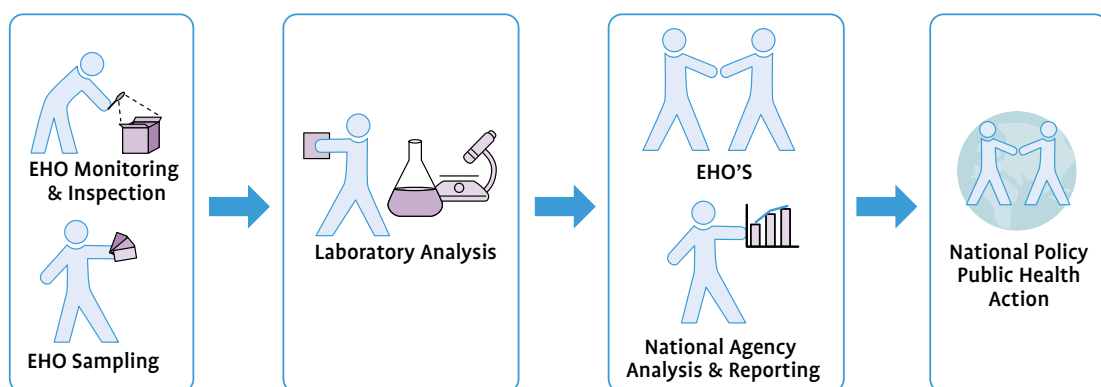


Figure 5.7: Food safety workflow of typical laboratory

All laboratories, in partnership with the EHS, carry out programmed enforcement and monitoring food analysis plans, including local and national FSAI and EU-coordinated programme surveys. They also engage in certain non-programmed work, such as food complaints, outbreak and emergency work. PALs engage in export certification analyses (as arranged with DoHC and FSAI) and private contract work. In general, laboratories conduct multiple-parameter tests on most samples.

5.5.2.1.1 PROGRAMMED WORK

The programmed work of each laboratory is detailed in an annual Sampling and Analysis programme, formulated by each service laboratory individually with the EHS and the FSAI, whose guidance and crucial input provides a national perspective and focus. The tests performed depend on the particular food or parameter, and are determined according to specific legislation, guidelines, or by local agreement. The laboratories meet quarterly with the FSAI and review ongoing activities.

All OFMLs carry out core tests that are all accredited, and include:

- Aerobic colony count;
- Enterobacteriaceae;
- *Escherichia coli*;
- *Staphylococcus aureus*;
- *Bacillus cereus*;
- *Clostridium perfringens*;
- *Salmonella* species;
- *Listeria monocytogenes*;
- *Campylobacter* species;

Laboratories carry out analysis on a wide range of food types and products according to the EU list of food categories.

Previously, each PAL developed its own suite of analytical tests on a regional basis but they have now, in collaboration with the FSAI, moved towards national co-ordination of analytical testing³². PALs carry out a wide-ranging array of programmed multi-parameter tests, which in broad terms may be subdivided into:

- contaminant, residue and toxin analysis;
- food additive analysis;
- compositional analysis;
- labelling and nutritional verification;
- Allergens and authenticity testing.

All laboratories must also comply with Health and Safety legislation in order to handle samples in a safe manner for the protection of laboratory personnel.

For PALs, a substantial portion of programmed work is common to all three laboratories. Therefore, samples of the same product may be sampled by the EHS around the country, resulting in the same parameters being tested at different times of the year by all three laboratories. The three regional chemistry laboratories in Denmark have organised their routine programmed work by designating regulatory analyses to particular laboratories. This has provided an efficient and cost effective service delivery.

³² Please see Appendix 8.7 for details of the core work of the three PALs.

5.5.2.1.2 SURVEYS

Ongoing surveys are critical in informing policy direction, to ascertain the level of compliance and to identify emerging hazards, so that early corrective action can be taken. Focused surveys contribute to the assessment of risk so that proportionate, risk-based responses may be applied to equivalent risks at all points in the food chain. Survey results also help in the refinement of annual sampling and analysis programmes.

With the establishment of the European Food Safety Authority (EFSA), it is anticipated that more proactive food safety analytical measures will be undertaken by Member states. EFSA has indicated that it will seek greater information on all aspects of food-borne illness.

Laboratories participate in a range of national surveys throughout the year, organised by the FSAI and in conjunction with the EHS. Most survey samples are submitted by the EHS, with some taken by the FSAI or other official agencies. These other agencies include the Department of Agriculture and Food and the Department of Communications, Marine and Natural Resources, with samples taken from premises under their supervision.

In the last three years, the OFMLs and the EHS have carried out twelve national surveys, including three EU-coordinated programme surveys. The results of these and other local surveys are forwarded to the FSAI, which collates, analyses and publish all data.

There is no specific funding allocated to the laboratories for survey work. The test methods employed by laboratories are all validated to allow comparable result interpretation.

Table 5.5 outlines details of the four microbiological surveys undertaken in 2002. Topics for the first three surveys were agreed following consultation with the EHS and OFMLs. The fourth survey was undertaken for the EU as required under the EU Coordinated Programme for the Official Control of Foodstuffs.

Dates	Topic	Microbiological parameters tested
Jan-Mar 2002	Ice for cooling drinks	<ul style="list-style-type: none"> • <i>Escherichia coli</i> • Coliforms
Apr-Jun 2002	Pre-prepared and leftover gravy	<ul style="list-style-type: none"> • <i>Clostridium perfringens</i> • Aerobic Colony Count
Jul-Aug 2002	Pre-packaged sandwiches	<ul style="list-style-type: none"> • <i>Listeria monocytogenes</i> • <i>Staphylococcus aureus</i>
Sep-Dec 2002	Microbiological quality of: <ul style="list-style-type: none"> • pre-cut fresh fruits and vegetables • sprouted seeds • fruit and vegetable juices (unpasteurised) 	<ul style="list-style-type: none"> • <i>Salmonella</i> spp. • VTEC • <i>Listeria monocytogenes</i>

Source: Food Safety Authority of Ireland

Table 5.5: Official Food Microbiology Laboratory surveys carried out in 2002

PALs and the EHS also conduct regional and national surveys. For example, in 2002, laboratories carried out two national surveys for the FSAI, testing herbal supplements for irradiation and chicken breast compositional analysis. National survey results are reported in the FSAI newsletter and website, and EU-coordinated programme survey results are returned to the EU by the FSAI.

5.5.2.1.3 NON-PROGRAMMED WORK

At the beginning of the year, each laboratory is committed to its sampling and analysis food programme and the contractual commitments of its service contract. However, this does not account for the complete workload of the laboratories. As well as non-food work (for example, water analysis), each laboratory also tests food complaints and samples from alerts, outbreaks and emergencies as appropriate.

PALs also engage in export certification and private contract work.

5.5.2.1.3.1 EXPORT CERTIFICATION WORK (PALs ONLY)

Export Certificates for foods of non-animal origin may be needed to export foods destined for markets outside the EU. The issuing of these certificates is the legislative responsibility of the FSAI. In 2003, the FSAI issued around six thousand certificates for over fifty different companies on the basis that, amongst other requirements, a satisfactory PAL report had been issued to the producer. The current process involves the PAL testing the product and sending the report to the producer or exporter, who in turn receives the export certificate from the FSAI.

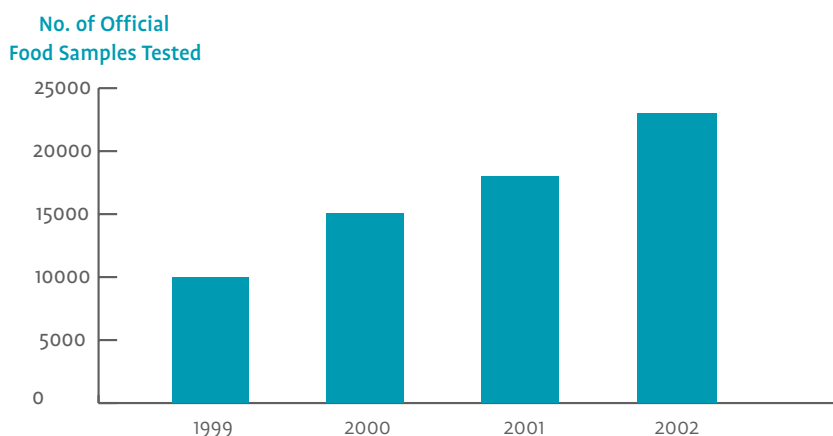
There are variable charges for this work, and in 2002, 2.9 WTE staff members were engaged in and €121,200 was generated from this work.

5.5.2.1.3.2 PRIVATE CONTRACT WORK

PALs test samples submitted by private commercial companies and consumers. There are no national guidelines with regard to analysis charges. Monies collected by some laboratories have to be returned to the health board.

2002 SAMPLE CAPACITIES

There has been a significant increase in throughput, in terms of the number of samples tested, by all laboratories over recent years as shown by graph 5.1.



Source: Food Safety Authority of Ireland

Graph 5.1: Increase in number of Official Food Samples Tested (EHS)

Table 5.6 provides details of the number of programmed and non-programmed food samples tested by OFMLs and PALs in 2002. A number of analyses are performed on each sample, so the number of samples tested is not a true reflection of the work involved. The time required for different tests varies, and many samples require multiple tests, for example, programmed microbiological samples may be tested for up to seven parameters.

Source of sample	PALs	OFMLs
EHS	8,655	14,041
Private/Consumer	1,088	109
Food Safety Agencies	142	377
Miscellaneous/Development Work	315	1,721
Total	10,200	16,248

Source: Laboratory Directors³³

Table 5.6: Number of samples tested by OFMLs & PALs in 2002

5.5.3 APPLIED RESEARCH AND DEVELOPMENT

The nature of food safety makes it essential that a framework is in place to deal with emerging food safety issues. The establishment of an applied research and development (R&D) capability is an essential component of this preventative framework.

R&D, validation and core work all form part of the continuum of scientific work, as opposed to being separate and discrete. The introduction of a new analytical methodology initially requires applied R&D to develop it. Once validated, the test becomes part of a laboratory's core work and may be submitted for accreditation.

While all laboratories are involved in the validation requirements of accreditation, some undertake R&D activity on a planned basis. A number of laboratories are actively engaged in dedicated applied research programmes. Four laboratories are participating in **safe food**-funded inter-laboratory applied research projects on areas such as *Cryptosporidium* and dioxin screening. One OFML is also engaged on an FSAI research project into *E.coli* 026 and 0111 in raw minced meat. OFMLs are engaged in the development of methodologies for the enhanced testing of *Cryptosporidium parvum*, *Salmonella* spp., *Legionella* and *Listeria monocytogenes*, among others. PALs carry out extensive applied research and development into various contaminants, toxins and parameters arising from rapid alerts. After applied research and development, laboratories specialise in these new tests.

In some European countries, dedicated public food safety research facilities deliver this function, staffed by teams of scientists with specific expertise. Examples of this include the Institute for Food Safety and Nutrition in Denmark and the Regional Research and Development Units in The Netherlands. They conduct research into emerging issues and develop new methodologies, with technology transfer to the regional laboratories for routine implementation. In the event of an emerging problem, they carry out targeted surveys to determine the risks, and put policies and procedures in place to deal with it, which may include new legislation.

³³ Approximately 10% of EHS submitted samples are classified as having food legislative infringements

In Ireland there is no wholly government-dedicated or funded central food safety research centre or institute, in contrast with Denmark and The Netherlands. The Irish regional food laboratory system fulfils the dual roles of carrying out routine testing and applied research activity. Teagasc, a semi-state organisation, provides research, advisory and training services for the agriculture and food industry in Ireland and carries out research activities at nine dedicated centres nationally. However, PALs and OFMLs have limited contact with these research centres and funding for applied R&D is not separated from general enforcement funding.

At present, there is no coordinated plan for applied R&D, and each laboratory carries out this development work on an individual basis. These applied research outcomes are incorporated into each laboratory's core work and annual programme.

The continuous introduction of new methodologies and technologies through applied R&D into the services is essential for the expansion of expertise. It will help to ensure we have modern, progressive services that can rapidly respond to a potential public health crisis.

WATERFORD AND CORK OFMLs ENGAGE IN COLLABORATIVE APPLIED METHOD DEVELOPMENT PROJECT

*The Waterford and Cork OFMLs pooled resources and worked together on an ABAX® system project for the rapid detection of food pathogens. Using identical instruments and protocols, extensive validation work was carried out and the new diagnostic method was accepted for accreditation to the ISO/IEC17025 standard by the Irish National Accreditation Board. This **safefood** funded project was the first such funded collaborative food microbiology work to be carried out by two Official Food Microbiology Laboratories in Ireland. Both laboratories now have an accredited rapid test method for the detection of **Salmonella** in **24 hours** and for **Listeria** in **48 hours**.*

5.5.4 SPECIALISATIONS

A specialised test is one that is carried out by one laboratory. After the method has been developed, the specialised test typically becomes part of the core work of the individual designated laboratory that offers this specialised testing to other service laboratories.

Through the concept of a shared or rationalised workload, each laboratory should have increased resources for work into new methodologies, which should help ensure that the purchase of costly equipment and instrumentation and development of staff expertise is not unnecessarily duplicated within the service.

Specialised expertise can be based on a particular sample to be tested, an analytical methodology, or the legislative responsibility for testing. Each specialised test must be performed in sufficient numbers to develop expertise in the test and maintain accreditation. This developmental capacity has enhanced the laboratories' capability to respond to EU food alerts and the analyses required under the annual EU Coordinated Programme.

The EHS takes samples for specialised testing and submits them to the local food safety laboratory, which in turn arranges for the transport of samples to the specialised laboratory.

The present mechanism for deciding and allocating specialisations is based on an ad-hoc, informal arrangement between the laboratories themselves. There is no national strategy or mechanism within the services for the identification of future specialisations or their designation to particular laboratories. In fact, many of the specialisations developed to date have arisen from European food alerts, where a risk to consumers was identified and national action was required.

Each PAL has specialised in various analytical areas according to the availability of equipment, trained staff, analytical techniques and the time staff can dedicate to such tests alongside their routine core activities³⁴. There has been little duplication of specialised chemical analyses amongst the three PALs.

Specialist microbiological testing may involve the testing of isolates from a range of laboratories, which are then sent to a particular laboratory that has specific techniques to enhance the testing of these isolates. Three OFMLs have particular specialisations that are either parameter or equipment-based³⁵. In addition, the Dublin Public Health (SWAHB) OFML is also the designated national laboratory for bacterial bio-terrorism.

There is a need to develop viral food diagnostics nationally and, in particular, to enhance ongoing surveillance and reporting with further work in the area of food-borne viral molecular epidemiology.

5.5.5 OTHER LABORATORY ACTIVITIES

5.5.5.1 WATER TESTING

Water testing is an intrinsic and important part of every laboratory's public health activity and is funded from the overall annual resource allocation. Laboratories have accredited most of their water testing procedures to ISO/IEC 17025. All laboratories routinely test water samples from public and group water schemes, private wells and dialysis waters from hospitals, as well as testing samples for the investigation of outbreaks.

For most OFMLs, testing clinical, food and water samples provides a coordinated service for outbreak investigation. In some cases, samples are linked for this purpose using an outbreak code. OFMLs test water samples for a variety of parameters including general coliform count, *E. coli*, *Pseudomonas*, *Enterococci*, *Clostridium perfringens*, *Salmonella* and *Campylobacter*. PALs test water samples for a variety of physiochemical parameters.

The routine monitoring of public and group water schemes is not included in service contracts between the FSAI and health boards, as the remit of the FSAI does not include this work or legislation. Health boards undertake this work for local authorities, in order to monitor compliance with drinking water legislation.

The microbiological and chemical testing of water has important public health implications in the following areas:

- routine testing to monitor drinking water quality;
- assessment of suitability of water sources;
- assessment of quality of group water schemes;
- part of outbreak investigation;
- food Ingredient and food processing suitability.

³⁴ The range of specialisations currently provided by PALs is shown in Appendix 8.8.

³⁵ The range of specialisations currently provided by OFMLs is shown in Appendix 8.9.

Table 5.7 provides details of the PAL and OFML water analytical activities in 2002:

Water Activities 2002	PALs	OFMLs
Average number of parameters per sample	13	3
Number of staff (WTE, excluding staff from one OFML)	15	13.5
Number of public samples	13,477	18,422
Number of private samples	3,090	2,619
Total number of samples	16,567	21,041

Source: Laboratory Directors

Table 5.7: OFML & PAL water analytical activities in 2002

5.5.5.2 OTHER ACTIVITIES

- The Galway PAL provides a service in the testing of medicines for the Irish Medicines Board (IMB) and air pollution monitoring for Galway City Council.
- The Dublin PAL provides a metal-analysis service for clinical samples submitted by hospitals and physicians nationwide, and an air quality monitoring service.
- Both Cork and Galway PALs conduct Road Traffic Act testing (alcohol in blood and urine) for consumers.
- All PALs carry out some testing of toxicology samples for health board pathologists.

5.6 Reporting and communication

Once the laboratory has completed its analysis, it sends the sample test results to the EHS and the FSAI. Laboratories send the results of food samples submitted by consumers, hospitals or private contractors directly to the client. On occasion, the laboratories may send sample results to the local Department of Public Health in Health Boards to alert the health board of food poisoning isolations both for surveillance purposes and to trigger public health action. Routinely, laboratories conduct multiple tests on a single sample, and consequently a laboratory report will contain several test results. Figure 5.8 provides an overview of the flow of OFML and PAL food control data:

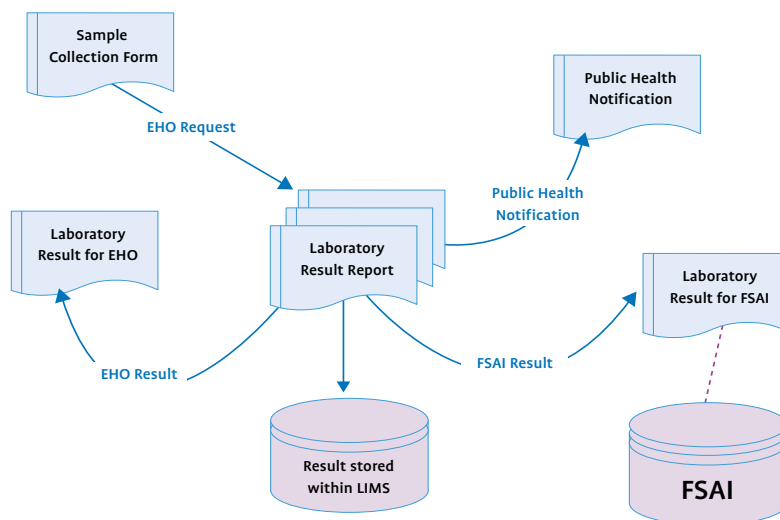


Figure 5.8: Overview of OFML & PAL food control data flow

5.6.1 PRODUCING THE LABORATORY REPORT

To process all sample information efficiently, laboratories need a Laboratory Information Management System (LIMS). This is a database for the acquisition and management of analytical chemical and microbiology laboratory data. As of December 2003, Sligo OFML did not have a LIMS in place. The Dublin Public Health (SWAHB) OFML and the Galway OFML are currently implementing one. The remaining seven laboratories each have a LIMS, which are a mixture of non-standardised systems that include in-house developed units and products from commercial suppliers.

5.6.2 THE FLOW AND EXCHANGE OF INFORMATION

There is no facility for the automatic computerised transfer of laboratory results to the EHS computer systems. However, the EHS have electronic access to finalised laboratory results for one OFML. In addition, there is no facility for the EHS to send sample information to laboratory computer systems electronically, so the EHS manually sends sample forms for submission to laboratories.

All laboratories send paper copies of their sample results to the EHS and FSAI on a completion and monthly basis respectively.

The laboratories send sample result details by telephone or fax to the Health Board public health department as appropriate, which manually enter the details onto another standalone localised public health database. Not all laboratories routinely do this.

The FSAI inputs the laboratory data into its database after appropriate quality assurance and validation. Five laboratories are at various stages of conducting trial electronic data transfers to the FSAI. At present, the FSAI feeds national aggregate data back to the laboratories and the EHS. Laboratories, in collaboration with the FSAI, have worked towards providing a common data set so that the timely and efficient collation, analysis and distribution of data will benefit the planning of national programmes and public health activities.

Discussions are ongoing between the FSAI, **safefood** and the laboratories with a view to exploring information technology options and enhancing the accessibility of data. It is critical to address the information technology deficit for those laboratories without LIMS, or where the LIMS are incompatible with agency databases. Computer links will enhance local and national decision-making by speeding up data access, processing and the reporting of routine and outbreak findings.

5.6.3 SCIENTIFIC COOPERATION AND LABORATORY LINKS

In order to provide a more cohesive national service, we need to enhance the level of interaction between the various laboratories. In addition, over twenty other laboratories nationwide currently are involved in food safety monitoring, analysis and research, directly or indirectly supported by public funding. Insufficient interaction between these laboratories and the OFMLs and PALs can affect the transfer of newly emerging techniques and methodologies.

There are a number of different opportunities and fora for laboratory staff to participate in external activities relating to food safety work. These include:

- EU SCOOP tasks;
- Food Law Enforcement Practitioners (FLEP) meetings;
- EU/FVO Missions;
- FSAI and **safefood** committees and working groups;
- Zoonoses Committees.

In recent years, laboratory staff have had limited participation in these types of fora. Laboratory staff have raised concerns that they tend to reside at the end of the 'information chain', and relevant information is not disseminated adequately. There is insufficient participation of laboratory staff members in EU technical working groups, and the level of interaction between Irish and European laboratories is low.

Representatives from PALs meet on a frequent basis to agree a general approach towards food sampling and analysis programmes. Public Analysts meet with the FSAI frequently to discuss work schedules and other development issues.

In 1996, the OFMLs came together to form the Official Food Microbiology Laboratory Group (OFMLG). Current OFMLG collaboration takes the form of quarterly meetings with the FSAI, contact by telephone and e-mail, joint submissions with regard to food sampling programmes and FSAI contract issues. Collaboration between laboratories has improved in recent years and the establishment of the OFMLG has facilitated this process.

safefood is required by law to promote scientific cooperation and links between accredited laboratories or those working towards accreditation under relevant EU directives. It has put in place various cooperative programmes to promote and facilitate scientific and laboratory collaboration projects and networks. Many laboratories have used these programmes for staff training and applied R&D purposes.

5.7 The capability to respond to emergencies

The ability of the laboratory services to respond both rapidly and effectively to emergencies is of major importance to safeguarding public health. These emergencies involve outbreaks of food-borne disease or chemical emergencies resulting in food contamination.

5.7.1 THE EUROPEAN RAPID ALERT SYSTEM

The EU food alert system, known as the Rapid Alert System for Food and Feeds (RASFF), operates when a member state reports significant contamination in, or hazard associated with a feed or foodstuff. The EU Commission then alerts member states to the problem. The FSAI is the Irish point of contact, and informs all laboratories and the EHS, amongst others. The EHS may send the laboratories samples of food relating to the hazard for testing.

A high proportion of EU food alerts pertain to chemical or physical hazards, 70% of around 700 notifications in 2001. This pattern was similar both in previous years and in 2002.

FSAI and PALs have responded quite rapidly to many EU Alerts including:

- p-TSA (4-Toluenesulphonamide) residues in baby food (1993)
- Aflatoxins in pistachio nuts (1997)
- 3-MCPD (3-monochloropropanediol) in soy sauces (1999 - 2002)
- Benzo-[a]-pyrene in Olive Pomace Oils and Evening Primrose Oils (2001 & 2002)
- Acrylamide in various processed foods (2002)
- MPA (Medroxy Progesterone Acetate) in food and feed (2002)
- Extraneous collagen and DNA (Porcine and Bovine) in chicken fillets (2002)

PALS RAPID RESPONSE TO EU FOOD ALERT - ACRYLAMIDE IN FOODSTUFFS

Following the finding in April 2002 by the Swedish National Food Administration of high levels of acrylamide in certain cooked foods, both Dublin and Galway PALs in collaboration with the FSAI developed analytical methodologies for the testing of acrylamide, a known human genotoxin and a suspected carcinogen.

Its discovery, particularly in potato and wheat based foods, caused considerable concern among consumers and food safety authorities worldwide. Much effort has been expended in determining the cause and extent of the problem and its likely implications. Both PALs validated robust methods for the determination of acrylamide and consequently introduced a new diagnostic service for the testing of acrylamide in Ireland. By the end of 2004, in excess of 300 samples will have been tested by the PALs for acrylamide.

5.7.2 NATIONAL FOOD SAFETY EMERGENCIES

The health boards have responsibility for controlling outbreaks or emergencies. The Director of Public Health (DPH) is the Medical Officer of Health for a health board region. This is a role which is defined in legislation and it confers on the DPH the powers and responsibilities to take all necessary and appropriate action when faced with a public health threat. Each health board has local outbreak management procedures in place for their investigation and control. These include:

- organisational arrangements;
- investigative and epidemiological protocols;
- procedures for collation, analysis and dissemination of information;
- media and legal issues.

The Director of Public Health convenes multidisciplinary outbreak committees. Membership of these committees includes the:

- Specialist in public health medicine (SPHM)
- Senior Area Medical Officer (SAMO)
- Principal Environmental Health Officer
- Consultant Microbiologists
- Public Analysts and other OFML and PAL representatives as required (not all Public Analysts are members of their respective health board committees)
- Others as appropriate

There is a national framework for investigating outbreaks although there is no formally described system for foodborne diseases. At national level, the NDSC links with each health board as necessary and it has a rapid system of communication with regional departments of public health as well as the DoHC. Health Board departments of public health have established outbreak plans which are regularly updated e.g. ERHA Model Plan. Over the past year, considerable effort and new structures have been put in place at national and regional levels to consider the issues around national emergencies and to put systems and processes in place to identify and investigate outbreaks.

OFMLs need immediate access to enteric reference facilities for typing of food isolates and other reference work. Typing is an essential part of microbiology work, and is important in tracing the source of outbreaks or linking food incidents with clinical cases of infection. This work can also support tracing the cause of incidents, that are widespread and diverse.

DUBLIN PUBLIC HEALTH SWAHB OFML INVOLVEMENT IN FOOD BORNE OUTBREAKS & INCIDENTS

The Dublin Public Health OFML was involved in the multidisciplinary investigation and management of 11 major and 58 minor food borne outbreaks or incidents during 2003. These included 2 major VTEC outbreaks, which required national and international investigations. This non-elective work was performed according to robust protocols, which required a surge response from highly skilled public health laboratory staff in refocusing the elective work and optimising the utilisation of the CL3 facility outside core service hours.

The continued development of research activities and molecular diagnostics of public health significance is essential in maintaining the goal of providing a public health diagnostic and advisory service of international standard.

5.7.3 LABORATORY PROVISION FOR EMERGENCIES

All the laboratories reported that they have the capability to adapt their work programmes and provide a 'surge capacity'. They can suspend programmed testing, if necessary, in order to test an increased number of samples in times of crisis, and to transfer their results to the EHS and FSAI, and regional departments of Public Health as appropriate. Many OFMLs merge their clinical microbiology diagnostic scopes with food and water activities in order to enhance the laboratories surge capacity response to outbreaks.

The ability to handle and undertake out of hours testing of a sudden, large surge of samples is vital in order to identify the outbreak source and protect public health. Rapid sample turnaround times are crucial. At present, with the exception of two laboratories, there is no formal service available outside core hours in the event of an emergency. Laboratory staff members participate in these emergencies, but this is on a goodwill basis. There are no national Service-wide formal arrangements in place for continuous emergency cover. In Denmark, there is an overtime procedure in place to cater for emergency situations.

6. Recommendations of the Strategy Review Group

6.1 Introduction

Our findings clearly demonstrate that there have been ongoing developments in food-related public health protection for Ireland. Food Safety Laboratories play a critical role by identifying, preventing and monitoring food safety hazards, and provide operational support in emergency incidents and outbreaks.

However, we have also seen a range of issues that affect their ability to provide a more effective service in the prevention and control of food borne disease. We have prepared this chapter to outline the recommendations of our review. The purpose of these recommendations is to ensure that the issues we have identified are addressed, that future needs are accounted for, and that the service continues to meet both international standards and national requirements.

We categorised our findings into the relevant structures and processes applicable to the laboratory service. However, these structures and processes are interlinked, and so our recommendations must be holistic, and must consider their interaction. We have therefore presented our initial recommendations within the context of the original Terms of Reference, and based on the current structures and processes of the laboratory services.

Although the remit of this review did not include water testing, all laboratories conduct testing on water samples. Following our recommendations linked to the Terms of Reference, we have made a brief comment on water testing.

In section 4.7, we provided an overview of the Health Service Reform and its implications for the management of food safety. In particular, we described how a new national agency, the Health Service Executive (HSE) which will be external to the Department of Health and Children (DoHC), will manage the health service as a single national entity. The HSE will assume responsibility for all of the functions of the existing health boards and the Eastern Regional Health Authority and will provide the service on the basis of three service pillars; the **National Hospitals Office (NHO)**, the **Primary, Community and Continuing Care Directorate (PCCCD)** and the **National Shared Services Centre (NSSC)**. The PCCCD will be made up of four Regional Health Offices (RHOs) who will deliver non-acute regional and local services, including food safety.

The recommendations we provide earlier in this chapter must support the objectives of this reform. In the final section of this chapter, we will develop our existing recommendations and present new recommendations in light of the Health Service Reform.

6.2 Term of Reference 1

“Consider the legislation with regard to the functions and responsibilities of laboratories”

6.2.1 LEGISLATION AND THE NATIONAL AIM

The statutory role of the laboratories is to test food for compliance with the relevant legislation and guidelines, and to assist in the identification, control and monitoring of food-borne disease outbreaks, in order to safeguard the public’s health.

We have seen the importance placed on food safety by the World Health Organisation (WHO), the EU and our own government through the various protective mechanisms they have put in place, the legislative measures they have taken and the new agencies they have created, such as the Food Safety Authority of Ireland, **safefood** and the European Food Safety Authority. With consumers awareness of food safety and their increased interest in how and where their food is produced, this trend looks set to continue.

The national aim should be to have a public food laboratory service that allows Ireland to be self-sufficient in monitoring the safety of the food produced and consumed in the State, and to have the capacity to respond to food-borne hazards, incidences and outbreaks of gastrointestinal disease. In Ireland where food production underpins the economy, a strong responsive nationally focused food safety service is crucial.

It is important for Public Analysts’ Laboratories (PALs) and Official Food Microbiology Laboratories (OFMLs) to have a clearly stated common public health purpose, with the goal of providing a consistent and coherent service. There is a need for central, formal coordination of, and long-term planning for, the development of the overall food chemistry and microbiology services. There is a need to focus and combine the regional activities of all the laboratories towards a cohesive, coordinated structure that encompasses a national perspective and profile.

6.2.2 A SINGLE SERVICE

In order to provide these nationally focused and more effective laboratory services, we recommend that the food safety part of the laboratories be regarded **as one unified Service** that is multi-sited and provides a microbiological and chemical food analytical service. Both elements of the Service should feed directly into Regional Health Offices’ public health mechanisms and processes. We consider that the administrative management of laboratories should continue as before, but initiatives should be put in place to ensure national integration of activities and services. Consequently, all of our subsequent recommendations are for a unified single HSE Food Safety Laboratory Service (FSLs).

This shift would both formalise and integrate the existing services and their management into a network. It would leave day-to-day laboratory management with the heads of the laboratories, and administration with local and regional health offices. However, it would place the service network under the operational control and direction of the HSE or its nominated executive successor. It is crucial that the latter has the authority to ensure that all local and regional health offices exercise appropriate resource management, with accountability for maintaining an adequate laboratory Service, capable of meeting food standard requirements and handling outbreaks and emergencies. The concept of a unified laboratory network would meet most, if not all stakeholder requirements.

Recommendation 1: We recommend that the Public Analyst’s Laboratories and the Official Food Microbiology Laboratories be integrated as a new single official HSE Food Safety Laboratory Service (FSLs).

6.3 Term of Reference 2

“Review the current position with regard to legislative obligations, accreditation, laboratory specialisations, research activities, staff training, survey work, and laboratory capacities.”

6.3.1 LEGISLATIVE OBLIGATIONS AND ACCREDITATION

It is vital that the FSLs should be prepared for the implementation of new food safety legislation in advance of the legislation being finalised. This would allow the FSLs to plan and develop testing facilities as appropriate and to make provisions for purchase of test equipment, train staff and so on.

This would provide us with a more efficient system, with a proactive approach to the requirements of new legislation and a more rapid adoption of the required testing. The Food Safety Authority of Ireland (FSAI) legislation committee, comprising of the DoHC, FSAI and health board representatives (including laboratories and the Environmental Health Service (EHS)) has anticipated such a system.

We recognise the benefits and associated demands of accreditation on the laboratories. We agree that the FSLs should place itself to be the laboratory service for any relevant national and EU legislation on food testing.

However, the maintenance and expansion of this accreditation and quality system over the years has resulted in an increased workload for the laboratories. While we acknowledge that INAB does not have an advisory function, we feel that improved communication and a more structured liaison between INAB and the FSLs would result in a more progressive approach to developments in laboratory accreditation.

Recommendation 2: We recommend that

- ***the HSE Food Safety Laboratory Service (FSLs) and stakeholders continue to be consulted and have an input in the preparation of relevant legislation.***
- ***the Food Safety Laboratory Service be supported to maintain and develop their accreditation to relevant international standards.***

6.3.2 SPECIALISATIONS

We see the development of laboratory specialisations as one of the key areas in which the cost effectiveness of the FSLs could be maximised.

To date, laboratories have undertaken specialisations on an ad-hoc basis, with no clear mechanism for selection and little documented future planning. A more rationalised system where costly equipment, facilities and expertise are allocated effectively would ensure that the FSLs is well equipped, responsive to emerging needs, and that centres of expertise can be established. The laboratories should perform each specialised test in enough numbers to develop expertise in the test and maintain accreditation.

Specialisations should be agreed on an ongoing basis with involvement from all stakeholders. This will be further developed in section 6.10.3.

The analytical services provided by other government laboratories should be taken into account if they are accredited.

We also consider that collaboration between the FSLs and other centres of excellence in the UK & elsewhere within the EU pertaining to emerging pathogens and viruses should be enhanced.

As suitably qualified staff, with relevant experience and expertise in new technologies (such as cell assays, DNA technology and so on) will be required to further develop specialisations, laboratories should ensure that these requirements are reflected in future recruitment policies. At present, there are few dedicated specialist roles within the existing staff structure of the laboratories.

Recommendation 3: We recommend that the Food Safety Laboratory Service continue to develop specialised testing capacities on a nationally co-ordinated basis.

6.3.3 APPLIED RESEARCH AND DEVELOPMENT

An applied R&D capability is essential in ensuring we have a modern, progressive service that can respond rapidly to a potential public health crisis.

An effective way to provide an ongoing, robust and rapid response to food alerts and emergencies is to develop an adequately resourced capability for R&D. Moreover, engaging in an ongoing, sustained programme of applied R&D will ensure that our laboratories become centres of excellence in food testing and control.

We consider that the main research focus of the laboratories should be applied research to address emerging issues using the highest analytical standards. This work should be focused to public health significance and based on risk assessment evaluations. In this regard, closer cooperation with third level institutes would provide scientific support to the FSLs.

Applied research activities should be part of the work of the FSLs. While it would seem sensible that these activities complement the specialised activities of the laboratory, core work should be separate from R&D, where possible, to ensure that it does not affect the R&D activities of the laboratory.

These R&D activities should remain cost effective and be nationally co-ordinated. The scope, role and functions of these applied research activities must be clearly defined and regularly reviewed by all relevant stakeholders. This will be further developed in section 6.10.3

Recommendation 4: We recommend that the Food Safety Laboratory Service develop a capability for developmental applied research on a nationally co-ordinated basis.

6.3.4 TRAINING AND DEVELOPMENT

Staff training is a very important component of the development of a national laboratory service. It improves a laboratory's ability to develop and deliver a quality service. While specific skills will be required to develop the FSL's applied R&D capacity, it is important that staff continue to be motivated and that they are given opportunities to develop and acquire new skills.

We acknowledge that accreditation requires the delivery of one form of training, but feel that additional training in appropriate skills and competencies needs to be provided. This training should include management development, Health and Safety, IT and ongoing technical training with regard to new and emerging technologies.

Laboratory managers need to be able to plan for the training needs of their staff, but relevant supporting structures and mechanisms should be provided, such as staff training budgets that are allocated and monitored at a national level. Laboratory managers should be able to approve training events easily, so that more localised decisions can be made.

While training should not be coordinated centrally, we would suggest that a laboratory forum anticipate and address future training needs, especially with regard to new technologies and legislative commitments. This forum would also identify and provide details of the various types of training and funding opportunities available to laboratories. This will be further developed in section 6.10.3

Recommendation 5: We recommend that the Food Safety Laboratory Service

- establish a robust training framework to develop expertise and address future public health considerations***
- have a dedicated annual training budget that is operational at local level***

6.3.5 SURVEYS AND INFORMATION

The collection, collation and analysis of laboratory data and dissemination of information is necessary in order to ensure that resources are allocated to the most appropriate areas of food-related public health significance and to assure Irish consumers of the safety and hygiene of the food supply. Organised by the FSAI and in conjunction with the EHS, laboratories participate in a range of national and EU annual surveys. The importance and relevance of surveys must be highlighted for all food safety professionals and stakeholders, with increased emphasis placed on survey interpretation when reviewing sampling and testing priorities.

We believe that there is a need to further develop a comprehensive database of the contaminants found in Ireland, and so targeted surveys of chemicals and pathogens in food should continue to be developed.

This may result in increased resource requirements for the FSLs, but improved work coordination will help address this. Where possible, the methodology used for future survey work should be standardised within the service to ensure comparability of data.

We also considered that, in order to provide a fully integrated and comprehensive public health overview, it would benefit public health to have an information network aligning human, food and veterinary data.

Recommendation 6: We recommend that

- ***the systematic planning of national surveys be strengthened amongst stakeholders***
- ***that information from national surveys continue to be aligned with human and animal disease surveillance data***

6.3.6 CORE WORK

Laboratory capacities should be used to their utmost efficiency to address the emergence of pathogens and food contaminants of public health significance.

PALs have been aware of the need to reduce replication within the programmed work of the service and considerable progress has been made in this regard – see appendices 8.7 and 8.8. However, the current regional based system of surveillance whereby laboratories respond to local demand militates against an efficient approach and can result in unnecessary replication of sampling and analysis. A national co-ordinated approach to the programmed work of the FSLs will maximise laboratory capacity. The proportion, variability and viability of non-programmed work need to be reviewed. These measures, coupled with a coordinated approach within the FSLs, will release resources that could be made available for other technical areas, including applied R&D, specialisations and rapid response measures to food alerts.

For the purposes of this review, each PAL submitted a list of their current programmed routine food activities. This should be reviewed in consultation with stakeholders, and take into account changing requirements and circumstances. To improve national sampling and analysis programmes, many regulatory analyses could be designated to particular laboratories, although agreement amongst the PALs and the EHS would be necessary with regard to subsequent allocation of these analyses to designated laboratories.

OFMLs must be able to test for all significant micro-organisms, due to the nature of microbiological analysis. As a minimum, each OFML has the capability to test for:

- ACC;
- *Enterobacteriaceae*;
- *Escherichia coli*;

- *Staphylococcus aureus*;
- *Bacillus cereus*;
- *Clostridium perfringens*;
- *Salmonella species*;
- *Listeria monocytogenes*;
- *Campylobacter species*.

The findings from the existing control programmes over recent years need to be further examined and analysed by the FSAI on a national basis, and their implications considered. The infringement rate for some of the analytical parameters, included in routine programmes, is low. While reassuring, this raises questions as to whether the focus of the sampling programme is still optimal. The low infringement levels of some current chemical analyses, such as food additive analysis or the monitoring of certain chemical contaminants, suggests that these could be reduced without reducing consumer protection.

In addition, many routine microbiology samples have low infringement rates, and the use of rapid automated techniques and screening procedures should be considered where appropriate. This will allow for increased sample throughput and a rapid turnaround time for results. All OFMLs offer an analytical food testing service that is multi-parameter. In other words, laboratories may test routine samples for five to seven parameters according to FSAI guidelines, and the rapid screening of samples for particular indicator organisms may be a more efficient alternative than testing the sample for all parameters.

It is desirable that, for both microbiological and chemical analysis, there should be a standardised national FSLS list of parameters that should be tested for in each food type, with accompanying agreement on whether single- or multi-parameter testing is appropriate.

Each laboratory must have the capability to cater for complaint, outbreak or emergency food samples and other analyses, which are critical to providing an effective regional service. However, the range, appropriateness and amount of this work needs to be examined. For example, all PALS engage in private export certification work. Frequently, food export samples impinge on routine laboratory work, as they are non-programmed, often submitted with very little notice, and can involve lengthy method set-up. In some cases, insufficient information is supplied with samples, such as product ingredients, and laboratories are unsure of the appropriate test for the product. Due to their nature, export samples often have to be prioritised resulting in the suspension of routine programmed work. During the Strategy Review Groups visit to the Danish food control laboratories, it was noted that the regional public chemistry laboratories in Denmark do not carry out any export certification work.

Recommendation 7: We recommend that

- ***the analytical activities of the Food Safety Laboratory Service be continually reviewed to ensure that the Service addresses emerging pathogens and contaminants of public health significance***

- *rapid screening technologies be introduced for core work where appropriate*
- *standard national protocols, specifying the parameters to be tested, be developed for the Food Safety Laboratory Service*
- *the export certification process be reviewed*

6.4 Term of Reference 3

“Review the facilities and resources of the laboratories.”

6.4.1 FACILITIES AND EQUIPMENT

The DoHC has made significant investment in the staffing and equipping of laboratories in recent years, resulting in the implementation of quality assured systems to an international standard and an ability to accommodate increased sampling. However, meeting new legislative requirements, health and safety standards, targeting emerging hazards and providing food safety data requires an enhancement of the FSLs.

Many laboratories cannot expand due to space limitations and the physical capacity of the laboratories. In many laboratories, there has not been a proportionate increase in laboratory accommodation relative to the increased numbers of staff and samples.

We recognise that microbiological practices and facilities for the isolation of hazard group 3 pathogens, especially *E. coli* O157:H7, are of concern especially in relation to Health and Safety.

Laboratories will need to replace technical equipment over time, and while financial provisions could be made for its eventual replacement at the time of purchase, this is difficult to achieve without a multi-annual budget system.

As part of a ‘national procurement policy’, a system of centralised tendering for the purchase of some laboratory consumables, would be cost effective. However, any such system needs to be flexible to allow laboratories the facility to purchase materials if required.

Recommendation 8: We recommend that

- *laboratory accommodation be reviewed to meet the current and future service requirements including the requirement for containment level 3 facilities*
- *the Food Safety Laboratory Service consider the common procurement of consumables*

6.4.2 HUMAN RESOURCES

In section 5.3.3, we identified a variety of issues relating to staff in both PALs and OFMLs, and across a variety of roles from technical to administrative.

The resolution of these issues requires an equitable and appropriate staffing structure. It is important to ensure that there is an attractive career structure in place for laboratory staff. We feel that these issues should be considered quickly, to minimise any effect on the motivation and morale of laboratory staff and, consequently, the FSLs.

The different staffing structures and associated qualifications of the OFMLs have given rise to certain inequities and limitations in the development of the service. In particular, senior laboratory technicians with food science qualifications who work outside the clinical environment, and who are not members of the Academy of Medical Laboratory Science, cannot progress beyond the fifth point of the Senior Medical Scientist salary scale. This anomaly needs to be addressed.

The role of EACs has developed to include their legislative appointment as Food Examiners, increased management functions, participation in regional/national committees as well as directing developmental research and validation work. Unlike most civil or public service laboratory services, there is a limited promotional structure for EACs within the PALs. This results in EACs supervising others of the same grade. To reflect these changes and their enhanced supervisory roles, a claim for a new promotional grade of Senior Executive Analytical Chemist has been lodged with the Health Service Employers Agency.

The importance of skilled administrative support in helping to manage the FSLs, especially financial management, has been highlighted. Having regard to the increasing complexity and volume of the work involved, consideration should be given to increasing the number and grading structure of administrative staff in order to support the managers of laboratories. Such staff should have acquired skills relevant to the new requirements of this rapidly developing area.

Recommendation 9: We recommend that

- ***the filling of all approved vacancies should be prioritised and expedited appropriately***
- ***a new promotional grade of ‘Senior Executive Analytical Chemist’ should be introduced into the Service’s PALs***
- ***the staffing anomalies of the Food Safety Laboratory Service as a whole be reviewed as a priority***

6.4.3 FUNDING FOR FOOD CONTROL

The laboratories must provide a service that is effective while delivering value for money. There has been in recent years a considerable investment in the laboratories. In section 5.2.5., we identified a number of issues relating to how the laboratories are funded, such as the inconsistencies between

health board funding management, ineffective budgetary mechanisms and the insufficient dissemination of budgetary information. In particular, due to the latter, it has not been possible to evaluate the cost-effectiveness of the laboratories. Under these constraints, the laboratory manager's ability to financially manage the laboratory may be adversely affected. The Brennan Report also pointed out that health board budgetary deficiencies were indicative of an absence of clear accountability for relating budgets to outputs³⁶.

We considered it necessary that appropriate financial systems, including coding systems for all laboratory analytical activities, are put in place or enhanced, in order to obtain an accurate breakdown of the budget for the FLS and to allow for adequate financial control.

All PALs carry out private contract or fee-paying food work to varying degrees. The revenue earned from this work generally goes to the Health Boards. The overriding purpose of the FLS is to provide a service to protect public health, and it should ensure that any commercial confidentiality associated with such private work does not adversely affect the overriding public health responsibilities of laboratories. We considered that private work should be self-financing, and that each laboratory should retain the revenue accrued from this work for development of the laboratory.

Some health boards do not include any operational details or other details of their laboratories in their annual service plans that they submit to the DoHC. Accordingly, it is difficult to obtain a national overview of food analytical activities and proposed developments. The Brennan Report has stressed that improved information flows on health service activities and their associated costs will be necessary to underpin the proposed changes in the business focus of the DoHC and the HSE. Fundamental to this will be the further development of the service planning process.

Recommendation 10: We recommend that

- ***the Food Safety Laboratory Service have a ring-fenced budget with transparent accountability to ensure a value for money service***
- ***the laboratory managers be informed of their annual allocations at year begin***
- ***financial management systems be implemented to provide detailed information with regard to the analytical activities of the Food Safety Laboratory Service***
- ***national guidelines be developed governing involvement of the HSE Food Safety Laboratory Service in 'private work'***

³⁶ Brennan Commission on Financial Management and Control Systems in the Health Service, January 2003

- *local and regional health offices include in their annual service plans to the HSE details of operational plans and financial provisions for their food safety laboratory service*

6.5 Term of Reference 4

“Identify the needs of Food Safety Agencies in terms of their laboratory requirements.”

All laboratories work in collaboration with the EHS, public health departments, FSAI and **safefood**, who rely on the laboratories for up to date, robust food safety data to protect consumers. A strong laboratory service, as part of a multi-disciplinary, multi-agency team, is needed to deliver on national statutory obligations. This broad public health remit of the FSLs differentiates them from private laboratories.

We have presented and discussed many of the requirements of the food safety agencies in other sections of this report. It is our intention here to summarise the overriding principle concepts and specifications that are required by the food safety agencies of the FSLs.

Protection of food-related public health may best be achieved through a coordinated, national sampling framework that avoids gaps in food microbiology and chemical surveillance, yet has the flexibility to cope with changing requirements. It is imperative that the FSLs possess a public health emergency response capability, coupled with rapid sample turnaround times.

Laboratories must continue to support the enforcement of food law through working effectively with the EHS and FSAI, meeting requirements of new food law, and by proactively introducing appropriate monitoring in advance of new legislation.

The FSAI, **safefood** and public health agencies need to be able to analyse the validated analytical data from the FSLs. It is crucial that laboratories are able to deliver information electronically, in a consistent form, and coupled with faster reporting that will provide an early warning of food problems or hazards. Flexibility in dealing with changing requirements for the provision of information is critical to satisfy the requests of the European Commission, parliamentary questions, media enquiries, and so on. Both FSAI and **safefood** will continue to work with laboratories to develop effective data transfer systems, so that they can continue to provide a flexible and enhanced service with regard to ad-hoc data and information requests from relevant agencies.

We recognise that the laboratories have responded most positively to the requests and additional demands from agencies over recent years. We also acknowledge that there is a need for a documented strategic approach to assist the FSLs in planning future operational food analytical activities, which will indicate the optimum level of service that the laboratories will be expected to provide.

Recommendation 11: We recommend that the Food Safety Laboratory Service and stakeholders develop a structured strategic approach to operational planning which would encompass annual business plan cycles

6.6 Term of Reference 5

“Examine the factors which influence the effectiveness of the present arrangements and to recommend measures to improve them.”

Laboratories do not operate in a vacuum, but as part of a wider framework within the health board’s programme to prevent and control food borne disease. To ensure that the FSLs is as effective as possible, it is crucial that there is a close collaboration between the laboratories and the EHS. Our examination of the laboratories has highlighted certain cross-functional issues, and recommendations 12 and 13 have implications with regard to sampling, with the aim of enhancing the FSLs.

It is important to improve the quality and relevance of the samples submitted to the laboratories in order to improve the significance and validity of the test result. Individual laboratories and the EHS devise annual sampling programmes in conjunction with the FSAI. This is done on a regional basis to ensure that they meet the needs of the local area.

6.6.1 SAMPLING CRITERIA AND POINT OF SAMPLING

The planning of monitoring programmes and the criteria used is not standardised throughout the country. Testing should be risk-based, planned and organised, so as to produce the most valuable and cost effective information. A standardised national framework for sample selection criteria, based on risk priorities, should be adopted. This will generate information that will inform future sampling and testing priorities. The stakeholders should review these selection criteria on a regular basis, and take into account new product distributions and the changing work of the laboratories. While allowing for these planned activities, the laboratories should also maintain the flexibility to deal with any emergencies and to analyse unplanned samples.

Improving both regional and national sampling and analysis programmes would be a cost effective method to minimise any replication of work, and would broaden the scope and value of the work of the FSLs. As samples of the same brand and lot number are being taken at various sampling sites and submitted to different PALs, there should be high-degree of coordination between the FSAI, the EHS and the FSLs nationally to minimise this replication and improve the breadth and scope of the service.

Retail sampling is a necessary component for microbiological examination, due to the limited lifespan of some products, and for some chemical testing as part of ongoing surveillance. However, consideration should also be given to the importance of industry-specific in-process sampling (at the manufacturing level), or at early food distribution points (at the import level). It is essential that we identify, isolate and resolve or control any potential food-borne hazards at the earliest possible stage in the food chain.

6.6.2 SAMPLE DELIVERY SYSTEM

The designation of some regulatory analyses to particular PALs and the development of laboratory specialisations for both OFMLs and PALs requires an improved sample delivery system. Currently, the system involves local laboratories forwarding samples they received from the EHS on to the designated laboratory. Sampling for routine and specialised testing should be coordinated on a national basis, to ensure the cost effective distribution of samples to the appropriate laboratories. There should be an assessment of the cost effectiveness of the current system, and other options, such as the use of an enhanced national courier service, should be explored.

Recommendation 12: We recommend

- *that sampling criteria be based on risk priorities*
- *that the sampling selection point mechanism should be optimised to ensure cost effectiveness*

6.6.3 CLIENT FOCUS AND EMERGENCY PLANNING

The laboratories' core working hours should be reviewed, to enhance their ability to accept delivery of programmed and non-programmed samples, taken both during and outside these hours. The latter would allow the EHS to target food sampling programme and control activities during the evening, at night and at the weekend.

Both the EHS and the FSLs should also give consideration to simplifying the sample forms that accompany food samples, and the labelling of samples. Enhanced IT links between the laboratories and the EHS could support this.

The ability of the FSLs to effectively and rapidly respond to food alerts and emergencies is of paramount importance. There is currently no service-wide arrangement for a 24-hour, 7-day service to ensure cover for emergencies. Instead, we rely on the goodwill of laboratory staff to attend to these emergencies.

Appropriate mechanisms should be put in place to handle and undertake the out of hours testing of a large surge of samples.

Furthermore, establishing links between laboratories of the FSLs and reference laboratories to share expertise and advice when needed would also be desirable.

Recommendation 13: We recommend that

- *laboratory operational times be expanded to provide a more client focused and risk-based service delivery*
- *a Food Safety Laboratory Service wide agreement for an out of hours service be put in place*
- *appropriate access to reference facilities for organism and toxin detection be provided*

6.7 Term of Reference 6

“Assess current arrangements for rapid access to laboratory test data.”

Various agencies and groups have need of food safety laboratory data and information. We considered that laboratories, in accordance with good practice, should provide appropriate data to stakeholders. As already outlined in section 5.6, the current arrangements for food safety agency access to test data are not ideal. Real-time reporting would provide both an early warning and a timely response to food hazards.

At present, some Laboratory Information Management Systems (LIMS) are limited in scope, and one OFML does not have one. It is not possible to provide a modern, cohesive and effective service without an integrated computerised data management system.

Computer links would dramatically enhance both local and national decision-making, and consequently an investment must be made to the LIMS infrastructure of some laboratories. Ideally the system must be able to accommodate routine programmes, surveys, and special requests including analytical quality control data on recovery and uncertainty of measurement. The system should also allow analysed national data to be fed back to the laboratories and the EHS, as this would give a national picture that would inform the design of future programmes. At the moment, there are discussions taking place between the FSAI, **safefood** and the laboratories, exploring information technology options and the accessibility of data.

It is also necessary to enhance the standardisation of food sample information between the EHS and the FSLs on a national basis. Consideration should be given to developing electronic links between the EHS and their local laboratories, to facilitate bi-directional transfer of sample information.

Recommendation 14: We recommend that appropriate electronic data management systems be established for the Food Safety Laboratory Service to ensure management and timely transfer of surveillance data for public health and food control purposes

6.8 Term of Reference 7

“Report on collaboration between laboratories and the need for enhanced scientific cooperation and laboratory linkages.”

In section 5.6.3, we identified that collaboration is a crucial mechanism in ensuring the cost effective development of the FSLs. Partnerships and collaborations between the service laboratories and other agencies are critical to a coordinated and cohesive network to enhance food safety, and to create a more effective and responsive service.

There is a clear need to develop further cooperative links with other publicly-funded food analytical laboratories, academia and public institutions, both nationally and across the EU. This is essential to the concept of ‘best practice’. There is a wealth of scientific expertise and practical experience in these other agencies and institutions, and a forum where this information can be shared is needed.

There is also a need to introduce an international dimension to our scientific endeavours. There is insufficient participation of laboratory staff members in EU technical working groups, and the level of interaction between Irish and European laboratories is low.

Besides developing these laboratory links through the enhancement of human networks, we should also nurture scientific cooperation through the formation of electronic frameworks to support the transfer of knowledge. For example, computerised food safety information networks would enable new approaches to information retrieval, education and training, communication and collaboration for laboratory personnel.

Recommendation 15: We recommend that the Food Safety Laboratory Service develop close cooperation and interaction with official laboratory agencies and research institutions across the EU

6.9 Water Testing

All laboratories test water samples supplied by the EHS, consumers and private companies. Laboratories fulfill an essential role in the microbiological and chemical analysis of water, which can pose a hazard to public health by its direct consumption or by its use in food preparation. The OFMLs will be required to test bottled water under their service contract with the FSAI³⁷.

Many laboratories felt that the remit of the Review should have included water testing activities, as this is an essential public health protective measure. As water analytical services have implications on space and resources for all laboratories, they need to be coordinated nationally, and identified for funding in their own right.

6.10 The Health Service Reform

So far in this chapter, we have proposed recommendations to enhance the effectiveness of the FSLs. Our major recommendation, outlined in section 6.2.2, was that PALs and OFMLs should be regarded as a single National HSE Food Safety Laboratory Service.

In section 4.7, we provided an overview of the Health Service Reform and its implications on the management of food safety. Our recommendations must be in line with the objectives of this reform programme, so in this section we will develop our existing recommendations and provide new recommendations in light of the Health Service Reform.

6.10.1 THE NEW HSE FOOD SAFETY LABORATORY SERVICE

Earlier in this chapter, we outlined our recommendations to improve and strengthen the laboratory service. At the forefront of our considerations was the need to provide consistency and coherence within a regional service that plays an important role in the protection of public health, while also ensuring that the Service can operate effectively and efficiently.

The Health Service Reform aims to 'preserve and build on the strengths of the existing system'. The current food safety laboratory arrangements are a solid base on which to build for the future and make best use of its resources. A single, unified network of existing laboratories is essential in moving forward.

³⁷ S.I. No.6 of 2004 European Communities (Natural Mineral Waters, Spring Waters and Other Water in Bottles or Containers) Regulations 2004

This solution addresses the major administrative weaknesses of the existing arrangements while maintaining the integrity of the component parts of the system as coordinated and coherent. The group considered that the HSE should place a clear duty on local and regional health offices to ensure that a comprehensive service is provided and delivered, and to complement the clear direction of travel of Health Service resources. This would be within an operational framework set centrally, covering all components, including transparent financial provisions and the testing levels to be undertaken by laboratories, as specified in the service contract with the FSAI.

The group considered that the HSE and its component parts would continue to operate the service contract model with the FSAI for the enforcement of food legislation and the undertaking of food surveillance. Existing activities with all stakeholders should continue, to ensure that successful initiatives such as the development of national surveillance programmes can be further developed.

6.10.2 HEALTH SERVICE REFORM AND THE LABORATORY SERVICE

The implementation of all of the components of the Health Service Reform programme is estimated to take eighteen to twenty four months. In this section, we will outline the potential implications of the reform programme on the future operations of the recommended new FSLs, and suggest further recommendations to streamline and enhance its functions.

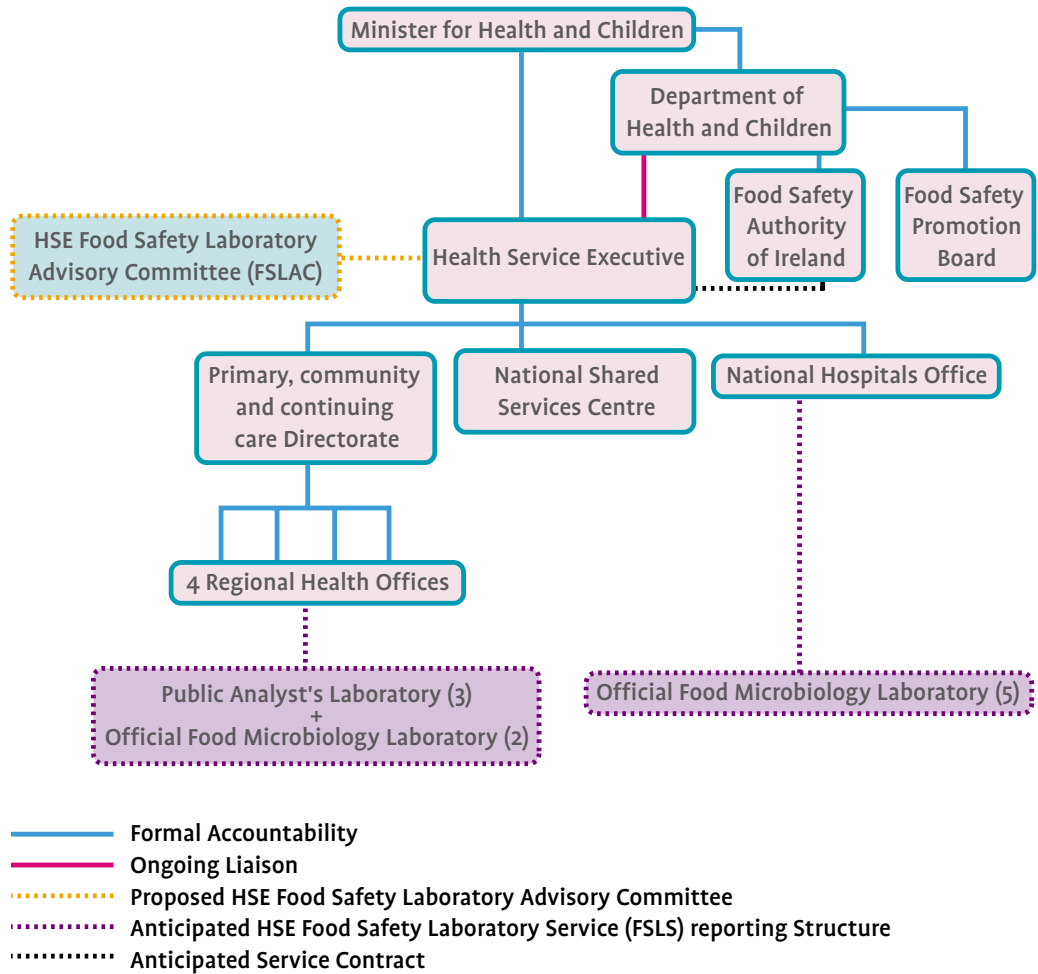
The new unified service will have to operate within this new environment, and so our recommendations will have to be accomplished within this new environment. We will therefore recommend a model of how the existing functions can be built upon to create a service where the management, coordination and reporting mechanisms are transparent, with clear accountability.

6.10.2.1 THE MANAGEMENT OF THE LABORATORY SERVICE

As outlined in section 4.7.2, the HSE through one of its pillars, the PCCCD, will manage and assume responsibility for food safety and the FSLs. However, food laboratories are in different settings, so it is likely that under the future management structure, different HSE pillars will administer different laboratories.

We expect that three RHOs will separately administer the three PALs, as well as two of the non-hospital based OFMLs. The NHO will administer those OFMLs situated in a hospital environment. Figure 6.1 shows the anticipated reporting relationships in the reformed health service:

Figure 6.1: Anticipated Reporting Relationship in the Reformed Health Service



The successful implementation of many of the recommendations in this report might be hindered by the fact that there are likely to be a number of different executive management structures within the reformed Health Service dealing with the food safety laboratories. Therefore, to overcome this, the individual directors of laboratories **should report to a single scientific laboratory coordinator within the HSE**, which would have the responsibility for overall coordination of the FSLs.

6.10.2.2 STANDARDS, SPECIFICATIONS AND PROTOCOLS

A robust mechanism is needed to integrate and standardise the requirements of the FSLs within the reformed health service, and to ensure that all laboratories benefit from decisions made by the HSE. Accordingly, we recommend that national laboratory standards, specifications and outputs should be formulated for the FSLs, and that appropriate internal Health Service protocols should be put in place between the HSE and the PCCCD and NHO.

6.10.2.2.1 SUGGESTED STANDARDS AND SPECIFICATIONS

Our suggested key elements for laboratory standards and specifications are as follows:

- Set specifications for a sufficient number of accredited, accessible laboratories with facilities appropriate to their function, in order to meet food-testing requirements. This should cover standards, protocols and outputs along with agreed general turnaround times, appropriately qualified staff and agreed quality controls within the FSLs;
- Set minimum requirements to be met by laboratories to cover emergency outbreak situations, such as out of hours cover, surge planning and access to staff resources, appropriate turnaround times and reporting of results;
- Outline arrangements to ensure a systematic approach to customer input and adequate liaison mechanism with medical microbiologists, the EHS and departments of public health as appropriate;
- Prepare an annual report and business plan outlining the contribution of the FSLs to public health;
- Ensure all physical laboratory facilities are appropriate to their function and comply with Health and Safety legislation and EU specifications.

6.10.2.2.2 INTERNAL HEALTH SERVICE PROTOCOLS

Some OFMLs operating within the hospital system (NHO) may encounter difficulties in accessing HSE-allocated funding for food testing. The needs and priorities of these laboratories may not be satisfactorily met within the highly pressurised hospital environment. This may be addressed by the provision of an appropriate internal Health Service protocol between the HSE and the PCCCD and NHO, with provision for continual reassessment and evaluation.

These protocols should ensure that laboratories under PCCCD and NHO administration have agreed budgetary allocations and support, in order to deliver the required level of service and comply with health and safety legislative standards. Such protocols should take into account and complement the FSAI service contract.

It is necessary to resolve the present financial difficulties with regard to budgetary mechanisms, and in particular to ensure that:

- financial management systems developed by the RHOs and NHO are capable of comprehensively costing all activities;
- transparent budgetary information and control are provided by the RHOs and NHO to laboratory directors at the start of every financial year;
- food safety laboratory surveillance, enforcement and outbreak testing levels on behalf of individual local and regional health offices, such as RHOs and NHO are set down;
- transparent and accountable financial provisions are provided.

It is crucial that each laboratory has a clear local reporting structure and budgetary mechanism that is feeding into an overall national HSE framework.

6.10.3 COORDINATION OF THE FOOD SAFETY LABORATORY SERVICE

We have just described the proposed day-to-day management of individual laboratories within the new health service. However, the laboratories need to be collectively and formally linked within a coordinated framework to truly represent a laboratory service network that provides a national cohesive and consolidated service. This network needs to have sufficient capacity and be capable of adapting to meet future demands.

However, for this model to be successful, network laboratories must be coordinated so that the present regional structure is strategically consolidated and nationally focused. We consider this particularly crucial in order to advance the “cost effective development of the service”. In the new health service management structure, individual laboratories will still operate as at present. However, a number of recommendations in this report indicate the need for permanent coordination to both formalise links between laboratories, and to implement various measures contained in the recommendations. Additionally, there is a real need for closer interaction between the FSLs as a whole and the new Health Service Executive and regional public health departments.

In view of the recommendations and our subsequent discussion of laboratory coordination under the HSE, we recommend that a HSE Food Safety Laboratory Advisory Committee (FSLAC) be established as a non-executive body, with the remit of working with and providing strategic planning advice on the development of the FSLs to the HSE.

The FSLAC’s other responsibilities should include the promotion of national coordination and service development, and it should facilitate in the implementation of some measures contained within the recommendations of this report.

The role of the FSLAC is about the shaping the future of the Food Safety Laboratory Service as a whole in order to address the health and welfare of all. The FSLAC should have strong representation from laboratories and also include other key stakeholders, the HSE, the DoHC, the EHS, regional departments of public health, NDSC, FSAI and **safefood**. The FSLAC should be supported by a permanent secretariat.

As there are two different scientific disciplines within the FSLs with different activities and requirements, the FSLAC should have two formal expert subgroups; an Official Food Microbiology Laboratory Group (OFMLG) for microbiology, and Public Analyst’s Laboratory Group (PALG) for chemistry (these are already in place but need to be recognised officially). The FSLAC will be a national source of expertise for advice and will provide representation to national and international committees. It will provide guidance on future specialisations and the R&D required within the FSLs, and should be supported centrally through development funding placed under the control of the HSE.

Existing liaison meetings between the laboratories and FSAI would need to continue, to ensure that progressive initiatives such as the development of national surveillance programmes can be further developed. This would encompass FSAI-PAL & FSAI-OFML meetings, representation of the laboratories at FSAI-HSE service contract liaison meetings and PAL/OFML participation in FSAI meetings with other official agency laboratories. The role of the FSLAC will not supplant meetings and contractual obligations of FSAI service contracts.

The Review Group has identified the need for enhanced coordination within the FSLs by the FSLAC for the following activities, among others:

- public health programme contribution including surveillance;
- development of specialist centres within the service;
- promotion of applied R&D capabilities;
- establish staff training framework to identify needs and specialist requirements;
- expanding and maintaining accreditation systems;
- same-discipline science and activity meetings – formal OFML and PAL subgroups;

- joint collaborative OFML and PAL fora;
- evaluation of facilities and resources;
- ongoing evaluation and optimisation of the work of the FSLs.

Recommendation 16: We recommend

- *the establishment of a HSE Food Safety Laboratory Advisory Committee (FSLAC) to provide national strategic planning advice to the HSE with regard to the Service.*
- *the appointment of a senior scientific coordinator within the HSE with overall responsibility for ensuring the co ordination of the Food Safety Laboratory Service taking account of national strategy planning advice*
- *that the Food Safety Laboratory Service develop nationally agreed laboratory standards and specifications*
- *an internal HSE protocol between the three pillars of the Health Service Executive be established*

6.10.4 INTERNAL AND EXTERNAL SERVICE COMMUNICATIONS

It is important to ensure that there are clear and effective communication pathways, both internally and externally, to the new unified multi-sited network of laboratories. Information sharing and exchange is critical to the development of a well co-ordinated service.

Our recommendations in sections 6.7 and 6.8 were focused on improving access to laboratory data and enhancing laboratory links. These links would be further enhanced through the formation of electronic frameworks to support knowledge transfer. To facilitate this, we propose that a website be developed for the new FSLs, to be underpinned by the work of the FSLAC and its expert subgroups. Such a website should allow access to information pertinent to the laboratories, and help ensure that the laboratories are not at the end of the information chain. The website would also allow information to be shared, including applied research and development output, would enable access to European networks and would act as a focal point for the unified Food Safety Laboratory Service.

A combined, biennial report, published for the FSLs and providing regional food safety data, statistics and information, would be a further positive step. It could be used as a tool to publicise the Service, and to reassure the consumer of the safety of Irish food.

As each of the laboratories also provide a local service, regional and national requirements must also be met and continue to focus on public health. Within each new RHO area, a forum to facilitate those who fund, provide and use the laboratories is needed. At present, in some health boards this interaction happens to a greater or lesser extent through the existing regional food sampling and zoonoses committees.

In the new system, these should be formalised and conducted on a regional (RHO) basis. These would involve laboratory managers, local consultant medical microbiologists, EHS, food safety agency representatives, public health personnel and other appropriate disciplines as required. We envisage that their main task would be to strategically plan for regional needs and to ensure that all the regional requirements for outbreak emergencies were effective within the overall emergency-planning regime. Also, as there may be two OFMLs within one RHO, such regional planning will be necessary.

The Review Group consider it vital that the prime focus of the FSLs should be focused towards the protection of public health at all times, and so should demonstrate the maximum degree of public openness consistent with responsible assessment of risk to public health. The new Food Safety Laboratory Service should and needs to be a system that engenders public confidence.

7. Glossary of Acronyms

ACC	Aerobic Colony Count
BSE	Bovine Spongiform Encephalopathy
CL3	Containment Level 3
DAF	Department of Agriculture and Food
DCMNR	Department of Communications, Marine and Natural Resources
DoHC	Department of Health and Children
DPA	Deputy Public Analyst
DPH	Director of Public Health
EAC	Executive Analytical Chemist
EFSA	European Food Safety Authority
EHS	Environmental Health Service
ELISA	Enzyme Linked Immuno Sorbent Assay
ERHA	Eastern Regional Health Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FSAI	Food Safety Authority of Ireland
FSL	Food Safety Laboratory Service
FLEP	Food Law Enforcement Practitioners
FSLAC	Food Safety Laboratory Advisory Committee
FVO	Food and Veterinary Office
GMO	Genetically Modified Organism
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
IMB	Irish Medicines Board
IMS	Immunomagnetic separation
IT	Information Technology
LIMS	Laboratory Information Management System
INAB	Irish National Accreditation Board
MOH	Medical Officer of Health
NCEA	National Council for Education Awards
NDSC	National Disease Surveillance Centre
NHO	National Hospitals Office
NSSC	National Shared Services Centre
OFML	Official Food Microbiology Laboratory
OFMLG	Official Food Microbiology Laboratory Group
PA	Public Analyst
PAL	Public Analyst's Laboratory
PALG	Public Analyst's Laboratory Group
PCCCD	Primary, Community and Continuing Care Directorate
PCR	Polymerase Chain Reaction
R&D	Research and Development
RASFF	Rapid Alert System for Food and Feeds
RHO	Regional Health Office
SAMO	Senior Area Medical Officer
SCOOP	Scientific Cooperation (EU Programme)
SI	Statutory Instrument (as in S.I. 95 of 1998)
SPHM	Specialist in Public Health Medicine
SWAHB	South Western Area Health Board

vCJD	variant Creutzfeldt-Jacob disease
VTEC	Verocytotoxigenic <i>E.coli</i>
WHO	World Health Organisation
WTE	Whole Time Equivalent
WTO	World Trade Organisation

8. Appendices

8.1 PAL and OFML addresses

PUBLIC ANALYST'S LABORATORIES (PALS)

Public Analyst's Laboratory

Sir Patrick Dun's Hospital
 Lower Grand Canal Street
 Dublin 2
 Tel: 01 6612022
 Fax: 01 6628532

Public Analyst's Laboratory

Seamus Quirke Road
 Galway
 Tel: 091 581122
 Fax: 091 581212

Public Analyst's Laboratory

St. Finbarr's Hospital
 Douglas Road
 Cork
 Tel: 021 4923358
 Fax: 021 4923367

OFFICIAL FOOD MICROBIOLOGY LABORATORIES (OFMLs)

Food Microbiology Laboratory

St. Finbarr's Hospital
 Douglas Road
 Cork
 Tel: 021-4923308
 Fax: 021-4923372

Dublin Public Health Laboratory, South Western Area Health Board

Cherry Orchard Hospital
 Dublin 10
 Tel: 01-6206175/76
 Fax: 01-6231908

Food Microbiology Laboratory

Department of Microbiology
University College Hospital
Galway
Tel: 091 544410
Fax: 091 524216

Microbiology Laboratory

Food Microbiology Department
Mid Western Regional Health Board
Dooradoyle
Limerick
Tel: 061 482840
Fax: 061 482631

Public Health Laboratory

Microbiology Department
Sligo General Hospital
Sligo
Tel: 071 74558
Fax: 071 74658

Public Health Laboratory

Microbiology Department
Waterford Regional Hospital
Dunmore Road
Waterford City
Tel: 051 842606
Fax: 051 848566

Public Analyst's Laboratory – Food Microbiology

Sir Patrick Duns Hospital
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Dublin 2
Tel: 01 6612022
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8.2 The Strategy Review Group Members

STRATEGY REVIEW GROUP MEMBERS

Dr. Mary O'Mahony	Director, Local and Regional Services, Health Protection Agency, London, UK
Dr. Eleanor Mc Namara	Consultant Microbiologist, Dublin Public Health Laboratory, South Western Area Health Board, Dublin
Ms. Helen Cowman	Technologist, Food Microbiology Laboratory, Cork
Dr. Des Feeley	Public Analyst (Galway), Retired
Dr. Margaret Fitzgerald	Specialist, Public Health Medicine, Eastern Regional Health Authority, Dublin
Dr. Bernard Hegarty	Contracts Manager, Food Safety Authority of Ireland, Dublin
Ms. Siobhan Mc Evoy	Chief Environmental Health Officer, Dept. Health and Children, Dublin
Mr. Kevin Moyles	Public Analyst, Dublin.
Ms. Lil Manley	Administrator, Community Services Department, Southern Health Board, Cork.
Secretariat	Ms. Sinead Guckian Dr. Gary A. Kearney Dr. Thomas Quigley safefood , the Food Safety Promotion Board

8.3 List of Laboratory Staff who participated in visits

CHEMISTRY VISIT TO THE DANISH VETERINARY AND FOOD ADMINISTRATION (DVFA)

Sites visited: DVFA Headquarters Copenhagen - Mørkhøj
Regional Laboratory Copenhagen - Fläsketorvet

Date: Wednesday 11th June – Thursday 12th June, 2003

Chemistry Participants

Dr. Michael O'Sullivan, Deputy Public Analyst, Dublin
Dr. Fred Davidson, Deputy Public Analyst, Cork
Dr. Pdraig Burke, Executive Analytical Chemist, Galway
Dr. Bernard Hegarty, FSAI

FOOD MICROBIOLOGY VISIT TO KVV, THE NETHERLANDS

Site visited: The Inspectorate for Health Protection & Veterinary Public Health, Southern Region in Eindhoven.

Date: Friday July 4th, 2003

Microbiology Participants

Dr. Anne Moloney, Consultant Microbiologist, Waterford Public Health Laboratory
Ms. Helen Cowman, Technologist, Cork Food Microbiology Laboratory
Ms. Elizabeth Murphy, Senior Medical Scientist, Limerick Public Health Laboratory
Dr. Bernard Hegarty, FSAI

8.4 List of subgroup members

CHEMISTRY SUBGROUP	ORGANISATIONAL SUBGROUP	MICROBIOLOGY SUBGROUP
Mr. Kevin Moyles (Chair)	Dr. Des Feeley (Chair)	Dr. Geraldine Corbett-Feeney (Chair)
Dr. Des Feeley	Ms. Helen Cowman	Dr. Eleanor Mc Namara
Dr. Bernard Hegarty	Dr. Bernard Hegarty	Ms. Helen Cowman
Dr. Fred Davidson	Ms. Siobhan Mc Evoy	Dr. Margaret Fitzgerald
Dr. Pdraig Burke	Mr. Kevin Moyles	Dr. Bernard Hegarty
Prof. Jeremy Glennon	Ms. Lil Manley	Dr. John Moore
		Mr. Vincent Young

8.5 Invited Stakeholders Consultation List

PUBLIC ANALYST'S LABORATORIES

Public Analyst's Laboratory, Cork
Public Analyst's Laboratory, Dublin
Public Analyst's Laboratory, Galway

OFFICIAL FOOD MICROBIOLOGY LABORATORIES

Microbiology Laboratory, Limerick
Food Microbiology Laboratory, Cork
Public Health Laboratory, Waterford
Dublin Public Health Laboratory, SWAHB
Public Health Laboratory, Sligo
Food Microbiology Laboratory, Galway

ENVIRONMENTAL HEALTH SERVICE

Environmental Health Service, Northern Area Health Board (ERHA)
Environmental Health Service, East Coast Area Health Board (ERHA)
Environmental Health Service, South Western Area Health Board (ERHA)
Environmental Health Service, Midland Health Board
Environmental Health Service, Mid-Western Health Board
Environmental Health Service, North-Eastern Health Board
Environmental Health Service, North-Western Health Board
Environmental Health Service, South-Eastern Health Board
Environmental Health Service, Southern Health Board
Environmental Health Service, Western Health Board

HEALTH BOARD MANAGEMENT

Northern Area Health Board (ERHA)
East Coast Area Health Board (ERHA)
South Western Area Health Board (ERHA)
Midland Health Board
Mid-Western Health Board
North-Eastern Health Board
North-Western Health Board
South-Eastern Health Board
Southern Health Board
Western Health Board

FOOD SAFETY AUTHORITY OF IRELAND

THE NATIONAL GROUP OF HEALTH BOARD DIRECTOR'S OF PUBLIC HEALTH

8.6 Legislation in Health Board Service Contracts

SCHEDULE 1 OF TYPICAL FSAI - HEALTH BOARD SERVICE CONTRACT – AS PER REVISION 4, 15/01/04
List of the Food Legislation contained in the First Schedule to the Act for which the Official Agency has responsibility.

Duties and responsibilities for food safety activities for the Official Agency will derive from the following list of legislation.

- When
- a) the Minister for Health and Children makes an order amending the First Schedule of the Act, or
 - b) any Act passed by the Oireachtas or any statutory instrument made thereunder or regulation made under the European Communities Act, 1972, is deemed to be food legislation for the purposes of the Food Safety Authority of Ireland Act, 1998,

the new legislation may be inserted by the Authority into this Schedule and the Authority will agree the enforcement priorities as per Schedule 6 with the official Agency.

In this context, both parties to the contract accept that any increase in workload for the Official Agency will require the provision of additional resources.

Membership of the Authority's Legislation Committee will include representatives of the Health Boards' Chief Executives.

A reference to an enactment, (including any instruments made thereunder) shall be construed as a reference to that enactment as amended, adapted, extended or replaced by or under any subsequent enactment, including the Food Safety Authority of Ireland, Act 1998.

A reference to a Statutory Instrument shall be construed as a reference to that instrument as amended, adapted or extended by any subsequent Statutory Instrument

- Food Safety Authority of Ireland Act, 1998 (No.29 of 1998)
- Health Act, 1947
- EC (Official Control of Foodstuffs) Regulations, 1998 (SI No. 85 of 1998)
- EC (Hygiene of Foodstuffs) Regulations, 2000 (SI No. 165 of 2000)
- EC (Official Control of Foodstuffs) (Approved Laboratories) Order, 1998 (SI No. 95 of 1998)
- Butter and Margarine Act, 1907
- Food Standards Act, 1974
- Margarine Act, 1887
- Poisons Act, 1961
- Sale of Food & Drugs Acts, 1875 to 1936
- European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002 (SI No. 483 of 2002)
- European Communities (Erucic Acid in Food) (Method of Analysis) Regulations, 1982 (SI No. 271 of 1982)
- European Communities (Food Additives) (Purity Criteria Verification) Regulations, 1983 (SI No. 60 of 1983)
- European Communities (Vinyl Chloride in Food) (Method of Analysis) Regulations, 1984 (SI No. 92 of 1984)
- European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations, 1998 (SI No. 541 of 1998)
- European Communities (Materials and Articles Intended to Come Into Contact With Food stuffs) Regulations, 1991 (SI No. 307 of 1991)
- European Communities (Flavourings for use in Foodstuffs for Human Consumption) Regulations, 1992 (SI No. 22 of 1992)
- European Communities (Quick Frozen Foodstuffs) Regulations, 1992 (SI No. 290 of 1992) and 1995 (SI No. 370 of 1995)
- European Communities (Infant Formulae and Follow-on Formulae) Regulations, 1998 (SI No. 243 of 1998)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000 (SI No. 437 of 2000)
- European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996 (SI No. 147 of 1996)
- European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 1996 (SI No. 170 of 1996)
- European Communities (Food additives, other than Colours and Sweeteners) Regulations, 1999 (SI No. 288 of 1999)
- European Communities (Meat Products and Other Products of Animal Origin) Regulations, 1995 and 1997
- European Communities (Minced Meat) Regulations, 1994 (S.I. No.215 of 1994)
- European Communities (Egg Products) Regulations 1991 (SI No.293 of 1991)
- European Communities (Extraction Solvents in Foodstuffs and Food Ingredients) Regulations, 2000 (SI No. 141 of 2000)

- European Communities (Processed Cereal-based Foods and Baby Foods for Infants and Young Children) Regulations, 2000 (SI No.142 of 2000)
- European Communities (Foods intended for use in energy-restricted diets for weight reduction) Regulations, 1998 (SI No. 242 of 1998)
- European Communities (Labelling of Beef and Beef Products) Regulations, 2000 (SI No. 435 of 2000)
- European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001 (SI No. 400 of 2001)
- European Communities (Sampling Methods and the Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations, 2003 (SI No. 267 of 2003)
- European Communities (Imposing Special Conditions on the Import of Figs, Hazelnuts and Pistachios and Certain Products derived thereof originating in or consigned from Turkey) Regulations, 2002 (SI No. 79 of 2002)
- European Communities (Import from Third Countries of Star Anise) regulations, 2002 (SI No. 80 of 2002)
- European Communities (Import of Peanuts and Certain Products derived from Peanuts originating in or consigned from China) Regulations, 2002 (SI No. 81 of 2002)
- European Communities (Foodstuffs Treated with Ionising Radiation) Regulations, 2000 (SI. No. 297 of 2000)
- European Communities (Foodstuffs intended for Particular Nutritional Uses) Regulations, 2002 (SI No. 379 of 2002)
- European Communities (Dietary Foods for Special Medical Purposes) Regulations 2001 (S.I. No.64 of 2001)
- European Communities (Suspending the Placing on the Market, the Importation and the Use in Manufacture of Jelly Confectionary Containing the Food Additive E425 Konjac) Regulations, S.I. No. 442 of 2002
- European Communities (Labeling of Fishery and Aquaculture Products) Regulations 2003 (S.I. No.320 of 2003)
- European Communities (Special Conditions on the import of Brazil Nuts in shell originating in or consigned from Brazil) Regulations 2003 (S.I. No. 327 of 2003)
- European Communities (Marketing of Fruit Jams, Jellies, Marmalades and Sweetened Chestnut Purée) Regulations 2003 (S.I. No. 294 of 2003)
- European Communities (Marketing of Fruit Juices and Certain Similar Products) Regulations 2003 (S.I. No. 240 of 2003)
- European Communities (Marketing of Cocoa and Chocolate Products) Regulations 2003 (S.I. No.236 of 2003)
- European Communities (Marketing of Honey) Regulations 2003 (S.I. No. 367 of 2003)
- European Communities (Marketing of Sugar Products) Regulations 2003 (S.I. No. 289 of 2003)
- European Communities (Dehydrated Preserved Milk) Regulations 2003 (S.I. No.298 of 2003)
- European Communities (Food Supplements) Regulations 2003 (S.I. No. 539 of 2003)
- European Communities (Emergency Measures regarding Hot Chilli and Hot Chilli Products) Regulations 2003 (S.I. No. 471 of 2003)
- European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2004 (S.I. No. 6 of 2004)

- Council Regulation 1139/98/EC (OJ L159, p4 3/6/98) of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC as amended by:
- Commission Regulation 49/2000/EC (OJ L6, p. 13, 11/1/2000) of 10 January 2000 concerning the compulsory indication on the labelling of certain foodstuffs produced from the genetically modified organisms of particulars other than those provided for in Directive 79/112.
- Commission Regulation 50/2000 (OJ L6, p.15, 11/1/2000) of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms.
- Commission Regulation 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Regulation 258/97/EC (OJ L43, p.1, 14/2/97) of 27 January 1997 concerning novel foods and novel food ingredients.

8.7 PAL – Core Chemical Food Testing

Parameter	Food Type
FOOD ADDITIVES	
PRESERVATIVES	
Benzoic Acid	Soft drinks
Sorbic Acid	Confectionary, sauces, dairy products
Sulphur Dioxide	Sausages, minced meat, meat products, wine
Sodium Nitrate & Sodium Nitrite	Meat products
Propionic Acid	Bread
ARTIFICIAL COLOURS	
E100 series	Confectionary, soft drinks, jams, jellies, wines
SWEETENERS	
Acesulfame K, Aspartame, Saccharin	Soft drinks
ANTIOXIDANTS	
BHA, BHT, GALLATES	Fats, oils, sauces
CONTAMINANTS	
Aflatoxins (B1, B2, G1, G2)	Nuts, nut products, vine fruits, spices, coffees, beers.
Ochratoxin A	Cereals, baby foods
Patulin	Apple juices
Metals – As, Cd, Pb, Cu, Zn, Fe, Mn, Hg, Sn.	All varieties of food and drink
Biogenic Amines (Cadaverine, Histamine, Putrascine, Tyramine, Spermidine)	Fresh, frozen & canned fish
Nitrate	Vegetables, baby foods
Gluten	“Gluten Free Foods”
Congeners (Acetal, Methanol, Ethyl Acetate, Propanol, Isopropanol, Butanol Isomers, Pentanol Isomers)	Spirits, wines, beers, liqueurs
Post Harvest Fungicides (Biphenyl, o-phenylphenol, Thiabendazole)	Citrus fruits and juices, bananas
Polymerised Triglycerides	Used cooking oils
Total Volatile Nitrogen	Fish spoilage test
P-Toluene Sulphonamide	Prepared baby formulae, baby foods (Cork & Galway)
Acid Value / Peroxide Value	Rancidity test in oils, fats, meat products
Fumonisin A	Cereals (Dublin & Galway)
Irradiation Testing	Herbs, spices, dietary supplements (Cork & Galway)
Alpha- Amylase	Pasteurisation test in liquid eggs

COMPOSITIONAL ANALYSES

Alcohol Content	Alcoholic beverages
Ash Content	Meat & fish products
Moisture	Meat products
Total Fat Content	Meat products
Fat & Total Solids	Milk, cream, cheese, ice cream, yoghurt.
Salt	All foods
Total Sugar Content	Confectionary, soft drinks, honey, jam.
Protein	Meat products
Vitamin C	Fruit juices, fruit drinks.
Caffeine	Soft drinks, tea, coffee (Cork & Dublin)
Hydroxyproline / Collagen	Meat products (Cork & Dublin)
Iodine Value	Fats & oils.

OTHER ACTIVITIES

Food Complaints	All Foods
Labelling Regulations	All Foods
Food Export Certification	All Foods
Tap Water & Bottled Water - C3 analyses & metals	

8.8 Specialised Chemical Analyses Carried out by PALs

CORK		GALWAY		DUBLIN	
PARAMETER	DETAILS	PARAMETER	DETAILS	PARAMETER	DETAILS
VITAMINS	Vitamins A, B1 & B2 in milk, milk powders, and infant formulae.	MARINE BIOTOXINS	Analysis of DSPs, ASP & AZA in shellfish by LC – MS.	ACRYLAMIDE (Low LOQ)	Analysis of acrylamide in asparagine rich foods such as crisps, chips, rye bread, biscuits, breakfast cereals, baby foods and onion rings.
GENETICALLY MODIFIED ORGANISMS	Qualitative analysis of GMO's in cereals and snack foods by PCR techniques.	DIOXIN SCREENING	Screening of cooking oils (e.g. pomace olive oil) by cell assay method.	BIOGENIC AMINES	Detailed analysis of fish products for agmatine, phenylthylamine, serotonin and tryptamine.
FOOD AUTHENTICATION	Meat Authentication by PCR techniques. This area of specialisation is being developed in 2003.	PHYTOESTROGENS	Analysis of phytoestrogens in soya based infant foods by HPLC.	SWEETENERS	Analysis of cyclamates and sweeteners in drinks.
OLIVE OIL AUTHENTICATION	Analysis of Sigmastadiene in olive oils and Virgin olive oils by solvent extraction and Gas liquid Chromatography.	INDUSTRIAL CONTAMINANTS	Analysis of Benzene, Toluene and Xylene in carbonated bottled waters and soft drinks by GC-MS.	FOOD CONTACT MATERIAL	Analysis of BADGE in cans.
METALS AT PPB LEVEL IN FOOD & WATERS BY ICP- MS.	Analysis of the following metals : Pb, Cd, Cu, Zn, Al, Fe, Hg, Cr, Ni, Zn, K in foods and waters. Also Uranium in drinking waters by Inductively Coupled Plasma – Mass Spectrometry. This area of specialisation is being developed in 2003.	FOOD PROCESSING CONTAMINANTS	Analysis of chloropropanols (e.g. 3-MCPD) in soy sauces.	NATURALLY OCCURRING FOOD TOXINS	Analysis of Fumonisin B2, Zearalenone, Serigmatocystin, and Cyclopiazonic Acid in cereals.
FAT PROFILES OF FOODS	Determination of Saturated, Monounsaturated and Polyunsaturated fats in oils, margarines, butter spreads using a dedicated Buchi Gas Chromatograph.	GOATS CHEESE ADULTERATION	Detection of cow's milk in goat's cheese.	FRUIT JUICE AUTHENTICATION	Authentication of fruit juices by quantification of Hesperidin, iso-Citric Acid, Malic Acid, Naringin, Narirutin and Neohesperidin

CORK		GALWAY		DUBLIN	
PARAMETER	DETAILS	PARAMETER	DETAILS	PARAMETER	DETAILS
IODINE IN FOOD BY HPLC – ECD METHOD	Analysis of Iodide in milk, baby formulae by HPLC – Electrochemical Detector method.	ANTI-BACTERIAL COMPOUNDS	Analysis of antibiotic residues in raw meat and poultry.	COFFEE AUTHENTICATION	Quantification of low levels of carbohydrates by electro chemical detection.
AFLATOXIN M1 IN MILK	Determination of Aflatoxin M1 in liquid milk samples by a CHARM method.	IVERMECTIN	Analysis of Ivermectin in farmed fish.	POLYAROMATIC HYDROCARBONS	Analysis of PAHs in oils and smoked foods.
GLUTAMIC ACID (MSG)	Analysis of glutamic acid (flavour enhancer) in snack foods, soups, sauces & meat dishes.	GENERIC LC/MS	Fumonisin B1 and other contaminants in foods	OTHER FOOD CONTAMINANTS	Detection of propylene glycol (in wine), safrole (in spices) and methyl tert-butyl ether (in various foods).
LACTOSE	Lactose in lactose free baby foods and baby formulae.	GLUTEN	Gluten in gluten-free foods, Method development and optimisation, linkage with FSAI on gluten control issues	ALLERGENS	Detection of peanut traces in food by an ELISA method.
CALORIFIC VALUE	Determination of calorific value of foods by bomb calorimetry.	ADULTERATION OF CHICKEN FILLETS	Compositional studies on chicken fillets	METALS AND OTHER ELEMENTS	Analysis of antimony, chromium, nickel, silver and selenium by AAS in various foods.
POLYAROMATIC HYDROCARBONS	Analysis of benzo-(a)-pyrene in fish and oils by HPLC.	FOOD IRRADIATION	PSL screening test for food irradiation (Herbs, Spices, etc.)	DIETARY FIBRE	Quantification of dietary fibre in bread and breakfast cereals.
CHLORINATED PESTICIDES	Analysis of chlorinated pesticides (e.g. DDT, DDE, Aldrin, indane, BHC etc.) in water supplies.			FOOD COMPLAINTS / INVESTIGATIONS.	Use of specialised microscopy in examination of foreign matter, analysis of maltose and lactose in foods.
NATURALLY OCCURRING FOOD TOXINS	Detection and quantification of Fusarium Toxins (Trichothecenes) by solvent extraction and GLC/ ECD & GCMS analysis. Analysis of the following toxins in Cereals :DON, 3-AcDON, FusX, 15-AcDon, Nivalenol, DAS & T2-Toxin.				

8.9 Specialised Microbiological Analyses carried out by OFMLs

Current Specialised
OFML Microbiological
Analyses

Identification and molecular typing of *Salmonella*

Identification and molecular typing of *Listeria Monocytogenes*

Detailed VTEC studies including IMS and PCR

Ribotyping of isolates

Testing for *Cryptosporidium* and *Legionella*

Rapid pathogen detection using ABAX and other PCR assays

safefood –
the Food Safety
Promotion Board
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Eastgate, Little Island
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