

Periodic Critical Review of the Food Safety Authority of Ireland

Report

Submitted to

Department of Health

Prepared by

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February 2025

Contents

Page

Glossary of Terms and Abbreviations	i
Executive Summary	ii
1 Introduction and Background to Review	1
1.1 Introduction	1
1.2 Background and Context	1
1.3 Rationale and Objectives of PCR	4
1.4 Methodological Approach	4
1.5 Structure of this Report	5
2 Rationale, Statutory Mandate, and Legislation	6
2.1 Rationale and Business Case for Establishment of FSAI	6
2.2 Role and Functions of FSAI	6
2.3 Legislative Basis	7
2.4 Statutory Mandate	9
2.5 Oversight Relationships	12
2.6 Food Safety Policy Function of Department of Health	15
2.7 Summary of Main Findings	18
3 Review of Performance and Ongoing Business Case for Agency	20
3.1 Introduction	20
3.2 Assessment of FSAI's Performance	20
3.3 Staff Views on FSAI Functional Effectiveness	31
3.4 Stakeholder Views on FSAI's Performance	33
3.5 Summary of Main Findings	34
4 Assessment of Organisational Capacity and Performance	35
4.1 Introduction	35
4.2 Organisational Structure of FSAI	35
4.3 FSAI's Capacity	35
4.4 Annual Expenditures, Income and Financial Viability	39
4.5 Business Planning and Reporting	40
4.6 Documented Procedures	42
4.7 Oversight Relationships	43
4.8 Performance Metrics	44
4.9 Summary of Main Findings	45
5 Governance and Oversight	46
5.1 Introduction	46
5.2 Corporate Governance Framework	47
5.3 Role, Functioning and Effectiveness of FSAI Board	47
5.4 Risk Management Policy	51
5.5 Financial Oversight	57
5.6 Governance Framework of FSAI Consultative Council	58
5.7 Scientific Committee – Code of Conduct	58
5.8 Department of Health Oversight	59
5.9 Summary of Main Findings	59

Contents

Page

6	Conclusions and Recommendations	61
6.1	Summary of Key Conclusions	61
6.2	Recommendations	62
6.3	Implementation of Recommendations	65
Annex 1	Evolution of FSAI Organisational Structure	66
Annex 2	FSAI Employment by Functional Area and financials	70
Annex 3	PESTLE analysis	73
	Introduction and Summary of 'PESTLE' Analysis	73
	Political Developments	73
	Economic Developments	75
	Social Developments	76
	Technological Developments	77
	Legal Developments	78
	Environmental Developments	79
	Future Considerations	80
	Summary	84
Annex 4	Operational Detail	Error! Bookmark not defined.
Annex 5	Additional Details from Stakeholder Consultation	85
Annex 6	Overview of Levels of Activity by Official Agencies	90

Tables, figures and boxes

Page

Table 2.1: Overview of Role of Each Official Agency	12
Table 2.2: Overview of Audits Undertaken on Official Agencies 2017-2024	15
Table 3.1: Assessment of Current Status of FSAI's Functions under FSAI Act	21
Table 3.2: FSAI Progress Report – % of Deliverables Reached by Goal (2023)	23
Table 3.3: FSAI Enforcement Actions by Type (2018-2023)	30
Table 3.4: Selected Examples of Stakeholder Views on FSAI's Performance	33
Table 4.1: Breakdown of FSAI Employment Contracts by Type (as of July 2024)	36
Table 4.2: Breakdown of FSAI Staff by Functional Area (Headcount as of July 2024)	37
Table 4.3: Number of Years Working with the FSAI	37
Table 4.4: How Effective Do You Believe the FSAI Has Been in Achieving its Strategic Goals (as identified in the Statement of Strategy)?	38
Table 4.5: FSAI Breakdown of Annual Expenditures and Income 2019-2023 (€ 000s)	40
Table 4.6: Priorities and Goals of the FSAI Business Plan 2024	42
Table 5.1: Improvement Opportunities Identified (2023)	49
Table 5.2: Risk Management Responsibilities by Organisational Structure	55
Table 6.1: Summary Conclusions	61
Table 6.2: Recommendations	62
Figure 1.1: Percentage Reporting 'Trust' in their National Authority as a Source of Information on Food Risks	2
Figure 1.2: EU - Extent of Agreement on Presence of Regulations to Ensure Safety of Food	3
Figure 2.1: Organisational relationships between FSAI, Government Departments, Official Agencies, and public sector bodies	11
Figure 2.2: Food Safety Quality & Control Activities by Agency (2022)	14
Figure 2.3: Government Ministries Responsible for Food Safety in EU Member State as of September 2024	18
Figure 3.1: FSAI Advice Line Customer Complaints Received by Type (2019-2023)	24
Figure 3.2: FSAI Advice Line Queries* from Food Sector Workers (2019-2023)	25
Figure 3.3: FSAI Reported Food Incidents and Alerts 2018-2023	27
Figure 3.4: Food Safety Quality & Control Activities by Agency (2023)	29
Figure 3.5: FSAI Enforcement Actions by Type (2018-2023)	30
Figure 3.6: Overall, to What Extent do You Believe the FSAI is Delivering Effectively on its Statutory Remit/Obligations in Respect of Each of the Following Areas?	32
Figure 4.1: Current Organisational structure of FSAI	35
Figure 4.2: FSAI Employment 2015-June 2024* (WTEs)	36
Figure 4.3: Food Safety Quality & Control Activities by Agency (2022)	43
Figure 5.1: FSAI Organisational Chart 2023	46
Figure 5.2: FSAI Risk Appetite Statement Framework	52
Figure 5.3: FSAI Risk Management System	53
Figure 5.4: FSAI Risk Management Governance Framework	54

Glossary of Terms and Abbreviations

BSI	British Standards Institution
BTORs	Back to Office Reports
BTSF	Better Training for Safer Food
CGF	Corporate Governance Framework
DAFM	Department of Agriculture, Food and the Marine
DPENDR	Department of Public Expenditure, NDP Delivery and Reform
DoH	Department of Health
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EU PAFF	(EU Standing Committee on) Plants, Animals, Food, and Feed
FAO	Food and Agriculture Organization
FBO	Food Business Operator
FEHU	Food and Environmental Health Unit
FSAI	Food Safety Authority of Ireland
FSCC	Food Safety Consultative Council
FTE	Full-Time Equivalent (person employed)
GDPR	General Data Protection Regulation
GMO	Genetically Modified Organism
HACCP	Hazard Analysis Critical Control Point
HSE	Health Service Executive
HPSC	Health Protection Surveillance Centre
KPI	Key Performance Indicator
LAVS	Local Authority Veterinary Service
MANCP	Multiannual National Control Plan
NSAI	National Standards Authority of Ireland
NEHS	National Environmental Health Service
PAS	Publicly Available Specifications
PCR	Periodic Critical Review
PDA	Performance Delivery Agreement
RASFF	Rapid Alert System for Food and Feed
SFPA	Sea Fisheries Protection Authority
SI	Statutory Instrument
WHO	World Health Organisation
WTE	Whole Time Equivalent

Executive Summary

Introduction

This report is submitted to the Department of Health by Indecon International Economic and Strategic Consultants (Indecon) in support of a Periodic Critical Review (PCR) of the Food Safety Authority of Ireland (FSAI), which is being undertaken by the Department. The report considers the ongoing business case for the FSAI, as well as key developments in its external environment. Indecon also assessed the FSAI's organisational capacity and its governance, financial and risk management, and decision-making processes.

Ongoing Business Case

The FSAI is an independent agency whose function is to ensure that food produced in Ireland (whether or not distributed or marketed in the State), and the food marketed, or distributed within Ireland meets the highest standards of food safety and hygiene. In July 1999, the FSAI took over responsibility for the enforcement of all food safety legislation, which had previously been the responsibility of seven¹ different State agencies. The establishment of the FSAI has aligned all these separate bodies under a single, unified structure, dedicated to ensuring the highest possible standards of food safety and food hygiene in partnership with all those involved in the food chain.

There are currently some 1,656 Whole Time Equivalent (WTE) staff engaged across the public service in food control services, working to protect consumer health. A major function of the Authority is to co-ordinate the efforts of these professionals across all the relevant State agencies to maintain the highest standards of safety and hygiene in food businesses. The rationale for the FSAI to operate under the aegis of the Department of Health reflects FSAI's public health responsibility, policy, and regulatory independence; its expertise and resources; the requirement for coordination between food safety policies and the healthcare system, of which the FSAI is an integral part; and its role in respect to consumer protection and in meeting international standards and obligations.

Assessment of Organisational Capacity

This review assessed the FSAI's organisational capacity by reference to the structure of the agency, the budget and number of staff allocated, the documented procedures undertaken, and the Agency's business planning process. The main findings were as follows:

- The broad organisational structure for FSAI remained broadly stable between 2011 and 2022. However, changes took place in 2012 with the addition of a Consumer Protection Division and in 2018 with the removal of the Consumer Protection Division and addition of Public Health and Nutrition Policy to report directly under the CEO, and addition of a new Risk Management and Regulatory Affairs Division. Changes were also implemented in 2021 with the formation of a new functional area, Regulatory Affairs and Compliance Building (RACB), and the move internally of Risk Management to Audit, Incidents and Investigations (AI&I).
- There is some reliance within FSAI on contracted staff to fulfil day-to-day business requirements.
- The review noted the broadly positive view of stakeholders with regard to the FSAI's capacity to deliver. Representatives of external organisations who are members of the Food Safety Consultative Council reported generally positive feedback overall, with some comments noting the recent external challenges faced by the Authority. References were made to FSAI's service delivery, responsiveness, engagement, and focus on international best practice. In terms of organisational capacity, Indecon's survey of FSAI staff found that:
 - A majority of respondents (63%) felt that the work across their area is evenly and fairly distributed;

¹ Local Authorities are treated as one Agency, in alignment with the FSAI Annual report.

- 67% of respondents agreed or strongly agreed that they have the resources needed to perform their job effectively; and
 - 91% of respondents indicated that they believe they had the necessary skills to perform well in their FSAI role.
- The quality of scientific expertise of FSAI (in relation to food science) was noted by many stakeholders.
- The present FSAI organisational structure appears appropriate but may be subject to change when a new CEO is appointed and/or in the context of the newly published strategy.
- The importance of effective communications is recognised within the current organisation structure (reporting to CEO).
- The positioning of the Public Health Nutrition policy unit (reporting to CEO) may need future consideration.
- The current Functional Area structure clearly aligns with the core functions of the FSAI.
- A significant element of the FSAI activity is the management of service contracts with seven Official Agencies (six from 1st January 2025).
- The transfer of the LAVS to DAFM is a positive move that will give the FSAI as the competent authority greater focus and emphasis on its overarching legal, regulatory and enforcement mandate.
- FSAI has recently undertaken some food-related activities outside its core functions. Where requested to do so, these project-based activities should be clearly defined and resourced appropriately.

Evaluation of Governance Arrangements, Financial, Risk and Decision-Making

Based on our desk-based assessment of relevant documentation and our discussions with Board members, the FSAI Senior Leadership Team (SLT), and DoH officials with policy and other responsibilities vis-à-vis the FSAI, Indecon is of the view that the governance arrangements for the FSAI are clearly articulated and well understood by all parties. We are also of the view that the governance relationship between the FSAI and the Department is sufficiently strong and robust, and benefits from the clear understanding on both sides of the respective roles of each party. It also appears that there is a good and constructive dialogue between the Department and the FSAI at the regular oversight meetings.

Overall Conclusions

The table overleaf indicates the overall conclusions reached on the bases of the consultations and detailed assessments undertaken as part of this Periodic Critical Review. Overall, the FSAI is an appropriately situated, well-established authority with a consistent track record of effective performance of its core statutory functions. Service contracts with seven Official Agencies form the bases upon which specific controls and enforcement activities are carried out in the food sector. These activities have been successful over the years in identifying food safety risks and incidents, as well as issuing enforcement orders and public notices. There is also some room for improvement of process whereby data sharing between agencies and the FSAI lacks efficiency. The FSAI currently co-ordinates these reports but the collection of the required data is done by the Official Agencies. This is currently quite a time-consuming process for both the FSAI and the Official Agencies. Improvements in terms of harmonisation and standardisation of data gathering and reporting between the FSAI and Official Agencies would improve efficiency of the overall food safety system. The FSAI has recently undertaken some projects outside the scope of its core statutory duties, and emerging issues in the sector would suggest that future review and consideration of statutory clarity and a whole-of-Government (i.e., cross-departmental) approach is warranted.

Summary Conclusions	
1	FSAI is a well-established statutory, independent, and science-based regulatory enforcement body dedicated to protecting public health and consumer interests in areas of food safety, hygiene, integrity, and authenticity. It was the first such authority established in the EU. Its functions under the DoH are generally in line with Irish and EU requirements.
2	The operating environment of the FSAI is influenced by a range of factors as considered in the 'PESTLE' analysis. FSAI has responded well to recent challenges (Brexit, COVID-19) and performed effectively on delivery its functions.
3	FSAI generally discharges its official control responsibilities by means of service contracts with seven Official Agencies (six from 1 st January 2025), which were previously responsible for food control.
4	Emerging issues in food safety are likely to include EU-level developments, e-commerce, increased complexity of the food chain, and technological developments in the food industry. This could increase complexity of workload; FSAI will need to adapt to remain responsive.
5	The present FSAI organisational structure is broadly appropriate, but may be subject to change with appointment of a new CEO and/or in the context of the newly published strategy.
6	The current functional area structure aligns with the core functions of FSAI, including management of service contracts with the Official Agencies. Positioning of Public Health Nutrition policy unit may need future consideration.
7	FSAI has recently undertaken some food safety-related activities outside the scope of its core statutory duties, and emerging issues in the sector would suggest that future review and consideration of statutory clarity and a whole-of-Government approach is warranted.
<i>Source: Indecon Assessment</i>	

Recommendations

Based on our assessment and evaluation of the FSAI's organisational capacity and its governance arrangements, Indecon has drafted a set of potential recommendations for consideration by the Department. These recommendations are set out in the table overleaf and focus on possible measures to enhance the functioning of the FSAI and the wider food safety system of which FSAI has a central role.

Recommendations	
1	FSAI should place continued focus in the implementation of its recently launched strategy on the Agency becoming a data-centric organisation. ² This will require FSAI to show leadership and disseminate information to the various Official Agencies. This data-centric approach will also assist in enhancing efficiency and effectiveness. This will also require Agencies to cooperate with FSAI in providing requested data.
2	A detailed review of Food Safety Legislation should be considered to ensure clarity of roles and responsibilities and enhance accountability, particularly on emerging issues. The enforcement powers of the FSAI (including the Official Agencies) in relation to the harmonisation of official controls may also be considered as part of this review.
3	FSAI to continue to work with the Official Agencies to improve the consistency/harmonisation of application of the official controls across the food safety system. Consideration should be given to enhanced oversight of governance and performance of Official Agencies.
4	Clarity should be provided by DoH regarding the role of FSAI in relation to wider food safety issues. Issues that are of relevance across multiple Government Departments and Agencies may require a whole-of-Government approach and food safety is just one aspect of this. How FSAI contributes in this context should be considered.
5	Business Planning appears to be of a high standard in the FSAI and Annual Business Plans are agreed with DoH. However, there may be scope for FSAI to have similar Business Planning processes in place as part of the SLAs with the Official Agencies, where FSAI communicates a small number of priority actions to these agencies to be focussed on and delivered in the course of the year.
6	Consideration should be given to the merits of enhancing the tracking of expenditures across different functions and units within FSAI. This would allow the identification of opportunities for productivity gains and increased efficiencies, especially in the context where savings are made against the budget profile, to ensure that best value for money is achieved from the annual allocation to the Agency.
7	It is important that any significant new activities assigned to FSAI by DoH should be designated under an agreed process in accordance with legislation, ensuring that new activities are resourced adequately following the standard estimates process, and do not impact on delivery of the FSAI's core remit.
Source: Indecon Assessment	

² "Data-centric" refers to the core, shared asset of data used for purposes of gathering information and insight as well as disseminating information in an efficient and timely manner.

1 Introduction and Background to Review

1.1 Introduction

This report is submitted to the Department of Health by Indecon International Economic and Strategic Consultants (Indecon) in support of a Periodic Critical Review (PCR) of the Food Safety Authority of Ireland (FSAI), which is being undertaken by the Department.

1.2 Background and Context

Background to FSAI

The Food Safety Authority of Ireland (FSAI) was established in 1998 under the Food Safety Authority of Ireland Act, 1998. This Act came into effect on 1 January 1999. The Authority is a statutory, independent, and science-based regulatory enforcement body dedicated to protecting public health and consumer interests in the areas of food safety, hygiene, integrity, and authenticity. It reports to the Minister for Health and has a 10-member Board. It also has a 15-member Scientific Committee which assists and advises the Board on scientific matters. In order to consult relating to functions undertaken by the Authority, a Food Safety Consultative Council was also established.

Food and Environmental Health Unit (FEHU) within the Department of Health (DoH) has governance responsibility for the FSAI. FEHU, in carrying out this governance responsibility, ensures that FSAI complies with the Code of Practice for the Governance of State Bodies 2016, as amended.

The Authority's key remit is the enforcement of food legislation, which is coordinated through working in partnership with other food regulatory authorities ("Official Agencies"). The FSAI has service contracts with the following Official Agencies:

- Local Authorities;³
- The Health Service Executive (HSE);
- The Department of Agriculture, Food and the Marine (DAFM);
- The State Laboratory;
- The Marine Institute (MI);
- The National Standards Authority of Ireland (NSAI); and
- The Sea-Fisheries Protection Authority (SFPA).

In general, food legislation is enforced on behalf of the Authority by a network of Official Agencies through a service contracts programme, which the Authority monitors. The Authority also reports on the agencies' activities and seeks continuous improvement and accountability through a programme of regular audits. The FSAI also carries out certain complex direct official controls in house, e.g., checks on composition of foods for specific groups, and novel food applications.

One of the delivery mechanisms FSAI employs to ensure that its legal remit is delivered is its multi-annual corporate strategy. FSAI's multi-annual strategy sets out its scope of functions, considering the changes in external and internal environment in which it operates. This is to ensure that it is well structured to meet any future and impending challenges and better value for money for its stakeholders. FSAI's 2019–2023 Strategy was extended until end-2024 in agreement with the

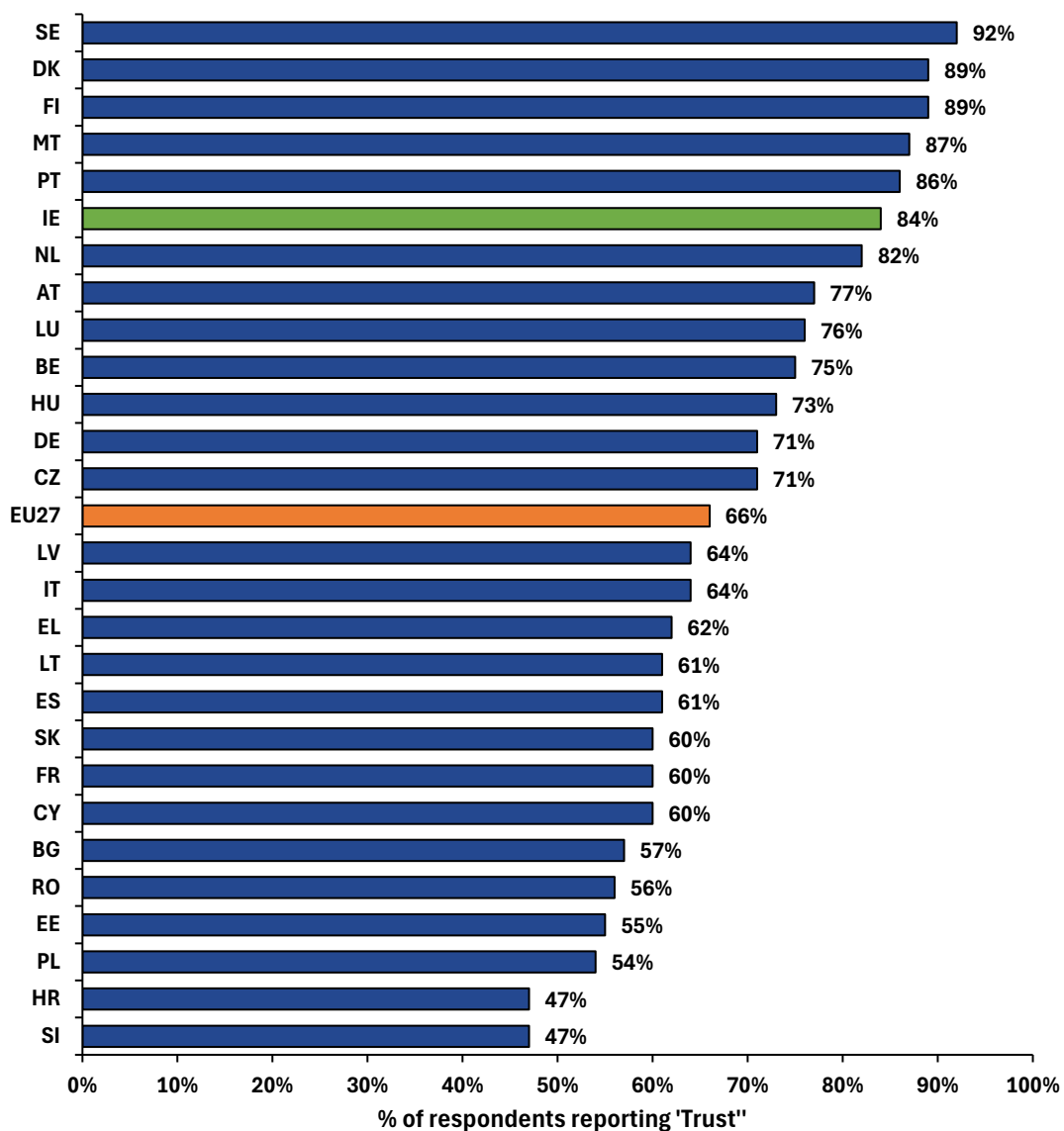
³ Note: The role of Local Authorities is being transferred to the Department of Agriculture, Food and the Marine.

Department of Health for a number of reasons, including to align with the appointment of the new Board Chairperson.

Perceptions of food safety in Ireland

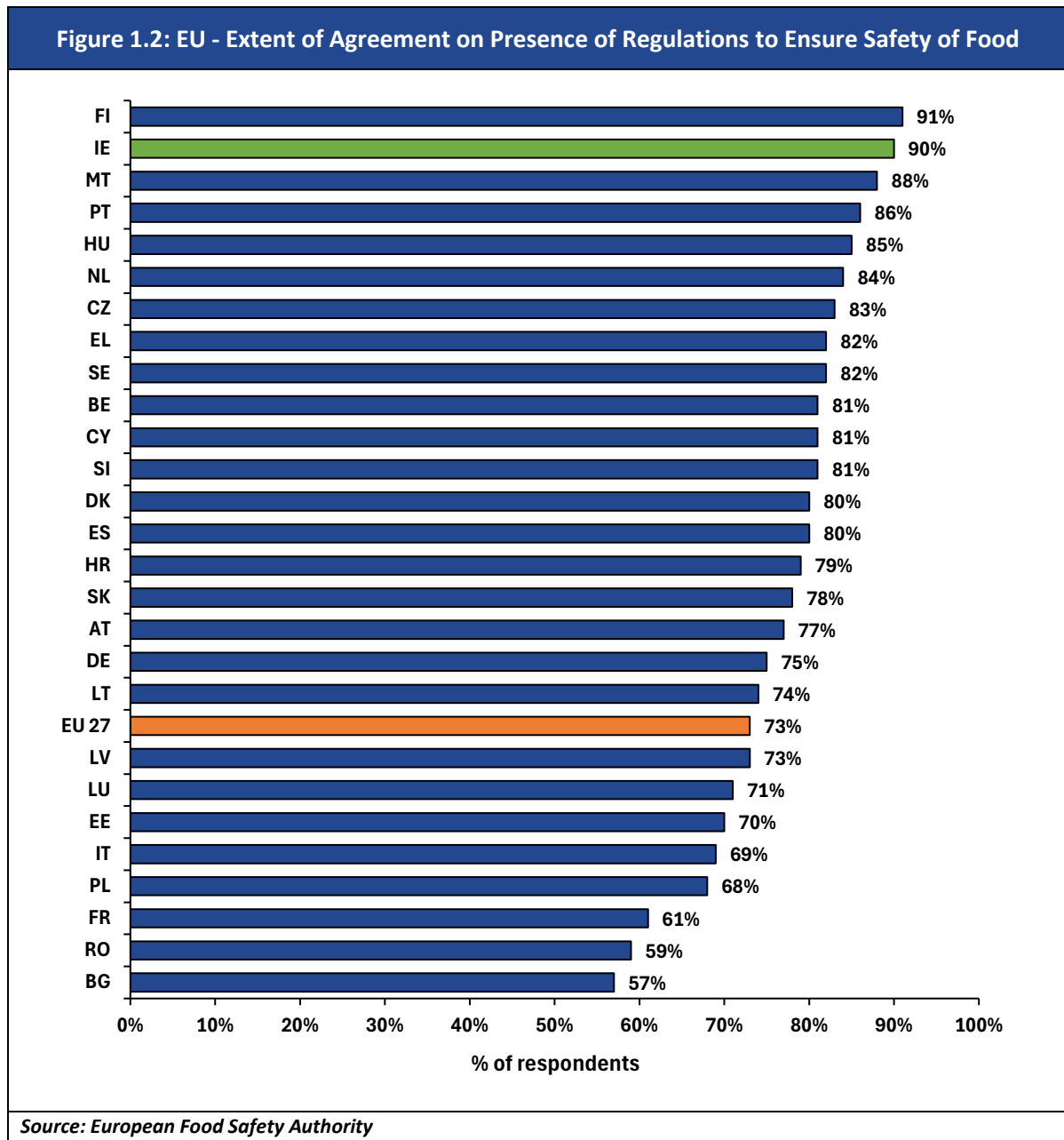
Each year the European Food Safety Authority (EFSA) undertakes a Eurobarometer survey which aims to gauge Europeans' perceptions of and attitudes towards food safety. The proportion of respondents who trust national authorities as a source of information about food risks in each EU Member State is shown in Figure 1.1. Trust was highest in Sweden (92%), followed by Denmark and Finland (both 89%). Ireland ranked 6th among EU Member States, with 84% of respondents expressing trust in their national authorities, significantly surpassing the EU average of 66%.

Figure 1.1: Percentage Reporting 'Trust' in their National Authority as a Source of Information on Food Risks



Source: European Food Safety Authority

Additionally, as shown in Figure 1.2 below, 90% of respondents in Ireland agreed that there are effective regulations in place to ensure the safety of the food they consume, the second-highest proportion in the EU, just behind Finland (91%). This figure far surpasses the EU average of 73%. This high level of public confidence in food safety regulations and trust in national authorities in Ireland relative to other EU countries reflects positively on the FSAI. It highlights the FSAI's effectiveness in implementing and enforcing stringent food safety standards and reinforces its reputation as a transparent and reliable source of information on food-related risks.



1.3 Rationale and Objectives of PCR

A Periodic Critical Review is intended to assess the effectiveness of the organisation in delivering its legal mandate, to evaluate the effectiveness and the ability of the organisation to meet the challenges posed by the environment where it operates. The Department of Public Expenditure, NDP Delivery and Reform (DPENDR) *Guide to Periodic Critical Review of Non-Commercial Bodies*⁴ was published in September 2020 and lists all the requirements for a PCR. The focus of a PCR is to “assess how well the non-commercial State body in question is delivering against the mandate originally set out by Government.” The Code of Practice for the Governance of State Bodies (2016) (The Code) requires that Government Departments review each State body under their aegis, at least once in every five-year period. As required by the Code, this Periodic Critical Review focuses on the ongoing business case for the entity, its performance and efficiency and effectiveness, and its governance arrangements.

The Department has selected for review the Food Safety Authority of Ireland (FSAI), as a body under its aegis. Discussions have taken place with the FSAI Board and Executive, both of which are supportive of the PCR process and welcome the nomination to be selected as the first Agency under the Department’s remit for assessment under this process. The aim is that the completion of the PCR will provide recommendations that can be implemented in the coming years in accordance with the commencement of the new FSAI Strategy at the beginning of 2025.

The overall objective of the PCR of the FSAI is to assess the effectiveness of the agency in delivering on its legal mandate and to evaluate the effectiveness and the ability of the organisation to meet the challenges posed by the environment in which it operates. The PCR focuses on several themes, including:

- External Context
- Organisational Capacity
- Organisational Performance

Recommendations arising from the PCR process will inform actions to be implemented in the coming years in accordance with the commencement of the new FSAI Strategy, beginning in 2025.

1.4 Methodological Approach

The completion of the PCR involved a combination of desk-based research and stakeholder consultations. A large number of documents (provided by FSAI/DoH) were reviewed as part of the review process. These documents were requested based on the requirements set out in the DPENDR guidelines on undertaking a PCR. The documents included:

- The Department’s own Statement of Strategy and Business Plan;
- The original business case and rationale for establishment of the non-commercial State body;
- Recent Statements of Strategy prepared by the non-commercial State body;
- Annual Performance Delivery Agreement (PDA);
- Results of the annual review of the PDA;

⁴ [Guide to PCR of non-Commercial State Bodies.](#)

- Recent Annual Reports and Chairperson’s report submitted by the non- commercial State body;
- Recent reviews or evaluations of the non-commercial State body or aspects of its performance, including surveys of customers or stakeholders undertaken;
- Risk Management Strategy, i.e., the Risk Register and Audit and Risk Committee Minutes for the non-commercial State body; and
- Internal and External Audit Reports.

As noted in the DPENDR guidance, these documents should provide an important basis for the PCR. The absence of certain documents may be indicative of issues of relevance to the PCR. It will be important to note that the purpose of the PCR is not to act to create a case for improved funding for the Agency under review. Decisions about resources are a matter for the relevant Department, in line with the estimates process and the normal process of prioritisation within the Department.

The document review was supplemented with a detailed stakeholder consultation which included:

- Interviews with Key Stakeholders: Chair, CEO and Chair of the Scientific Committee;
- Written consultation with Board Members;
- Focus Group with Members of the Senior Leadership Team;
- Staff Survey;
- Meetings with Department of Health officials;
- Written submissions received from the three main stakeholders:
 - The Department of Agriculture, Food and the Marine
 - The Health Service Executive (National Environmental Health Service)
 - The Sea Fisheries Protection Agency; and
- Submissions received from a range of stakeholder members of the FSAI Food Safety Consultative Council (including industry representatives).

1.5 Structure of this Report

The remainder of this report is structured as follows:

- Section 2 describes the rationale for, and statutory mandate and legislation governing the FSAI;
- Section 3 assesses the performance and ongoing business case for the Agency;
- Section 4 examines the organisational capacity and performance of the Agency;
- Section 5 assesses the governance and oversight of the Agency; and
- Section 6 integrates the findings from the detailed assessments carried out in the preceding sections to develop overall conclusions and recommendations.

There are a number of relevant annexes at the end of the report including a review of the developments in the strategic and external context impinging on the FSAI’s work.

2 Rationale, Statutory Mandate, and Legislation

2.1 Rationale and Business Case for Establishment of FSAI

In March 1996, the Government initiated a comprehensive review of Ireland's food safety system and an Interdepartmental Group was established by the Government. It submitted a report to Government in September 1996 recommending, among other things, the establishment of an independent food safety organisation.

The Government's Action Programme for the Millennium recognised that customer confidence, both at home and abroad, in Irish food products needed to be paramount. It maintained that Ireland must be in a position to give independent and verifiable assurances as to the quality and purity of its food products. It proposed the Food Safety Authority as a statutory, independent, and science-based body, overseeing all functions relating to the food safety regulation of the food industry.

The Food Safety Authority of Ireland is an independent agency whose function is to ensure that food produced in Ireland (whether or not distributed or marketed in the State), and the food marketed, or distributed within the State meets the highest standards of food safety and hygiene. There are currently some 1,656 WTEs engaged across the public service, either full-time or part-time, in the food control services, working to protect consumer health. A major function of the Authority is to co-ordinate the efforts of these professionals across all the relevant State agencies to maintain the highest standards of safety and hygiene.

The FSAI has aligned all the separate agencies and organisations under one unified, focused structure dedicated to ensuring the highest possible standards of food safety and food hygiene in partnership with all those involved in the food chain. Of course, the responsibility for, and ownership of excellence and standards primarily and ultimately lies with all of those involved in the food chain from farm to fork. This involves farmers, processors, retailers, caterers, and consumers. The FSAI engages with every sector along the food chain from the farm gate onwards to develop awareness of the importance of good practice, the controls to be applied and the risks to be managed.

2.2 Role and Functions of FSAI

The Food Safety Authority of Ireland was formally established by the Government on 1st January 1999. The FSAI has national responsibility for co-ordinating the enforcement of food safety legislation in Ireland. In July 1999, the FSAI took over responsibility for the enforcement of all food safety legislation which had prior to that date been the responsibility of a range of other State agencies. This responsibility is discharged by means of service contracts with the agencies, which prior to the establishment of the FSAI were responsible for food control. These were (at the time) the Department of Agriculture, Food and Rural Development, the Department of the Marine and Natural Resources, the Department of Enterprise, Trade and Employment, 39 local authorities and 8 health boards and organisations such as the Radiological Protection Institute of Ireland and the Office of the Director of Consumer Affairs.

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 attainable and to ensure that food complies with legal requirements, or where appropriate with recognised codes of good practice.

2.3 Legislative Basis

Establishment and purpose of the FSAI

As referenced above, the Food Safety Authority of Ireland was formally established in January 1999 on the statutory basis of the Food Safety Authority of Ireland Act, 1998 (the Act). Its statutory mandate has evolved through the years with legislative amendments to the Act⁵ as well as regulations made under the Health Act 1947 as amended by section 25 of the Irish Medicines Board Act 2006, and regulations made under the European Communities Act 1972 and deemed to be food legislation for purposes of the Act. The FSAI's statutory purpose and functions are set out in Part II of the Act and are summarised as follows:

- Take all reasonable steps to ensure food produced in Ireland (whether or not distributed or marketed in the State), and the food distributed, and/or marketed in the State meets highest standards of food hygiene and safety;
- Promote establishment and maintenance of high standards of food hygiene and safety at all stages of food production (including activities and inspections directed towards bringing about general acceptance of responsibility for food safety amongst producers and sellers of food);
- May itself establish food safety assurance schemes for the protection of consumer interests and shall promote, encourage and facilitate establishment of such schemes based on best available practice and standards and evidence relating to raw materials, processing, preparation, packaging, storage, and labelling of foodstuffs; Shall prepare guidelines to be observed by the Authority in relation to establishing food safety assurance schemes and report to the Board on any guidelines, scheme performance and implementation;
- Provide advice to the Minister for Health or another Minister on issues relating to statutory developments relating to food safety and hygiene; technology and industrial practices; the organisation and administration of systems for the approval, licensing and registration and inspection of premises; food production and the cultivation and production of shellfish and breeding or rearing of animals for slaughter and for food production; labelling and packaging of food (including materials used in packaging); and any other matter relevant to food safety and hygiene;
- Collect and assess data on official control of food and food-borne diseases;
- Review and report to Minister on the efficacy of food inspection services;
- Participate in research projects relating to food involving parties out of State; and
- May provide a system of certification of food for sale.

Enforcement powers granted to the FSAI are set out in Part IV of the Act and are summarised as follows:

- Enforcement of the food safety standards legislation shall be deemed to be a function of the Authority;
- FSAI shall carry out or arrange on its behalf to determine compliance with food legislation:

⁵ One of the biggest changes was enacted by the British Irish Agreement and respective legislation that established Safefood.

- Inspection, approval, licensing, or registration of premises and equipment used in manufacture, processing, disposal, transport, and storage of food;
- Inspection, sampling, and analysis of food (including ingredients); and
- Inspection and analysis of food labelling;
- Provision of food safety & hygiene education to the food industry; and
- Issue improvement notices and orders; closure orders, prohibition orders for withdrawal of food products, and prosecution of summary offences under food legislation.

In addition to the functions summarised above, the Act provides for the establishment of a 24-member Food Safety Consultative Council to advise and consult on safety and hygiene standards, as well as a 15-member Scientific Committee to advise on matters of a scientific nature relating to its functions, e.g., scientific questions relating to food safety/hygiene; implementation of food inspection services; and nutritional content of food.

The First Schedule to the Act lists the food legislation under the FSAI remit.⁶ This includes the Acts (including any instruments made thereunder) specified in Part I, the statutory instruments specified in Part II and the Regulations of an institution of the European Communities specified in Part III, in so far as they relate to food safety and hygiene. These include numerous regulations relating to standards targeted to specific food products, supplements and additives, substances and contaminants, marketing and conditions of preparation/service. Schedule 2 of the Act lists the Official Agencies for the purposes of the Food Safety Authority of Ireland Act 1998⁷ as follows:

- Environmental Protection Agency
- Health Service Executive
- Local Authorities
- Marine Institute
- Minister for Agriculture, Food, and the Marine
- Minister for Health
- National Standards Authority of Ireland
- Sea Fisheries Protection Authority
- State Laboratory

Compliance with EU law

Currently, Regulation (EU) 2017/625 governs Member States on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, and plant protection products. Section 26 of the regulation requires:

“Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify and decide which are the competent authority or authorities to designate for each area or part thereof, they should also be required to designate a single authority that for each area or part of area ensures appropriately

⁶ Schedule 1 is updated regularly and the current list can be found at [food-legislation-and-official-agencies-under-fsai-act-1998-june-2024.pdf](#).

⁷ FSAI Act and Related Legislation | Food Safety Authority of Ireland.

coordinated communication with other Member States' competent authorities and with the Commission."

There are many specific European food regulations applicable to the Irish market, but it is worth noting that Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 established the European Food Safety Authority; and sets out general principles and requirements of food law as well as procedures in matters of food safety.⁸ The regulation defines food as any substance or product "intended to be, or reasonably expected to be ingested by humans." It includes any substance intentionally incorporated into food during its manufacture, preparation, or treatment.⁹ Food businesses and food business operators are defined for purposes of the regulations, and the placing of unsafe food on the market is deemed "illegal".¹⁰ Food traceability (full traceability at every stage of production and distribution process) is required under this regulation, with recall and withdrawal from the market as remedies. Emergency measures and crisis management are detailed, and EU guidance notes are provided for FBOs in terms of meeting their compliance requirements.

Additionally, EC 852/2004 sets out general rules for food business operators (FBOs) relating to safety and hygiene at all stages of production, processing, and distribution of food and exports, as well as specific rules for food hygiene. These rules form a common basis for the hygienic production of all food, including "new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety." This regulatory development at the EU level has resulted in greater consistency of food safety and hygiene across Europe and internationally, benefitting consumers and FBOs alike.

While the FSAI is the competent authority for the enforcement of food legislation in Ireland, it must be noted that the responsibility for compliance rests primarily with the Food Business Operators.

2.4 Statutory Mandate

This section considers the extent to which the FSAI is fulfilling its statutory mandate and whether it is positioned to continue to do so in the context of modern developments in food safety issues. Overall, the rationale for and objectives of the FSAI are fully justified for the continued allocation of public money.

The FSAI is the central competent authority for food legislation with significant independence and expertise. According to key stakeholders consulted as part of this review, the FSAI's greatest achievements include high levels of trust and food safety awareness by both the public and industry. Food crises have been avoided and/or successfully managed, and the Authority has risen to the challenges presented by Brexit and the COVID-19 pandemic. Earlier examples of crisis management success include incidents relating to pork dioxins (2008) and horse meat (2013).

The FSAI has grown over time and has filled gaps through temporary staffing. It is considered a small and agile organisation which can accomplish its functions quickly and easily, e.g., its online portal (Advice Line) for complaints from the public about food safety and hygiene in food businesses, and for food industry members to make enquiries relating to food safety training, labelling requirements, or any other compliance issue.

The FSAI is an independent statutory organisation under the remit of the Department of Health. It protects consumers by ensuring that food safety and hygiene standards are met in food businesses,

⁸ [Regulation - 178/2002 - EN - EUR-Lex](#)

⁹ [General Principles of Food Law | Food Safety Authority of Ireland](#)

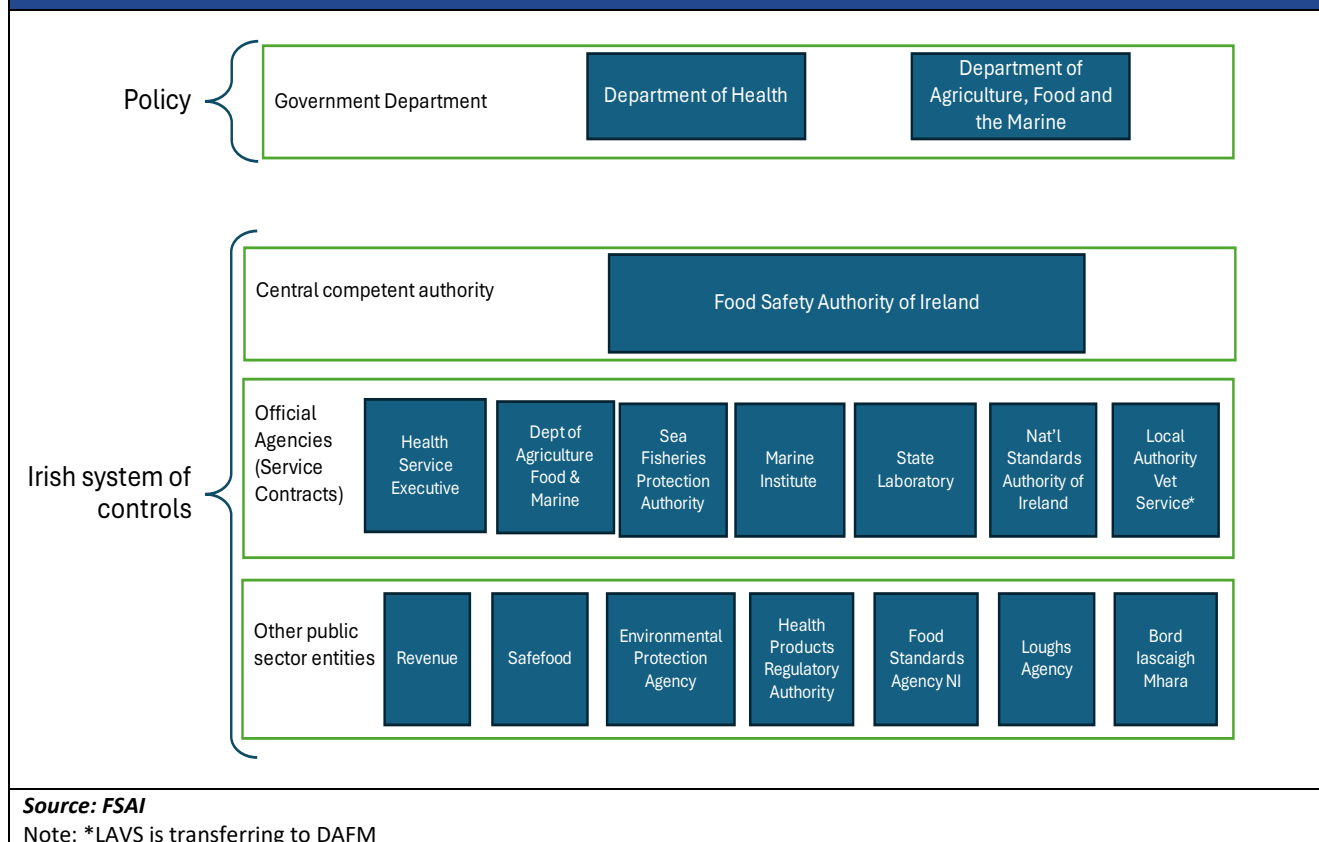
¹⁰ Ibid.

including production, processing and distribution of food, retail premises/shops, and catering establishments such as restaurants, hotels, and market stalls.

It does this by completing various activities such as:

- Arranging for food sampling and testing programmes to be carried out by Official Agencies;
- Training food safety inspectors and other food industry workers on food law;
- Developing food safety guidelines;
- Advising on national nutrition policy;
- Providing FBOs advice on food safety training and compliance requirements;
- Investigating food labels and fraudulent food;
- Conducting audits, investigations, and managing food safety incidents;
- Conducting risk assessments in accordance with food safety science;
- Managing food composition risks, compliance, and labelling requirements;
- Communicating to the public when there is a food safety issue, such as a product recall or restaurant closure; and
- Managing corporate governance and functions relating to inter-agency data sharing, communications, and scientific research.

Figure 2.1 illustrates the organisational relationships between the Department of Health, the Department of Agriculture, Food and the Marine, and FSAI, as well as the Official Agencies under service contract agreements with FSAI, and other public sector bodies which carry out functions relating to food safety in Ireland.

Figure 2.1: Organisational relationships between FSAI, Government Departments, Official Agencies, and public sector bodies

In discussing the FSAI statutory mandate in Ireland, it is important to consider the broader European context, as EU developments can have an impact on the FSAI role.

The European Food Safety Authority (EFSA) is an independent EU agency whose main role is to provide independent scientific advice. It also assesses risks relating to the food chain and informs the public accordingly.¹¹

While the European Food Safety Authority advises on possible food safety risks, other EU institutions (including the European Commission, Parliament, and Council) are responsible for risk management. These EU institutions take advice from the European Food Safety Authority, and then propose and adopt legislation. They also audit the regulatory and control measures enacted by Member States as required.

The European Commission includes a Directorate-General for Health and Food Safety, which is responsible for EU policy on food safety and health. It also monitors the implementation of related laws. DG SANTÉ develops and carries out the Commission policies on both Food Safety and Public Health.

¹¹ FSAI's legislation predates EFSA's formation and the FSAI has had to adapt to its existence.

2.5 Oversight Relationships

Service Contracts

As outlined in Section 1.2 of this PCR, the Food Safety Authority of Ireland is the competent authority with overall responsibility for the enforcement of food legislation in Ireland and generally manages this remit through service contracts with a network of Official Agencies, including the Health Service Executive (HSE), Department of Agriculture, Food and the Marine (DAFM), Local Authorities (LAs), and the Sea-Fisheries Protection Authority (SFPA). The Authority also reports on the agencies' activities and seeks continuous improvement and accountability through a programme of regular audits.

Table 2.1: Overview of Role of Each Official Agency

Official Agency	Overview of Role
Local Authorities	- Responsible for an extensive range of services, including veterinary services.¹² - Official controls in slaughterhouses, meat processing, wholesale, and distribution establishments. - In general, the Department of Agriculture, Food and the Marine is responsible for controls in establishments with a high throughput and the local authorities are, until end 2024, responsible for controls in establishments with a low throughput. - Cork County Council currently operates a Veterinary Food Safety Laboratory (VFSL) for the provision of services to support the Local Authorities Food Safety function being carried out under contract to the FSAI.
HSE	- Responsible for official controls in certain manufacturing/processing establishments, certain wholesale/distribution operations, imports of foods of non-animal origin, and all retail sector (retail and catering) establishments. - The HSE food control services include environmental health services, food safety laboratory services, and public health medical services. - HSE administers a Food Safety Laboratory Service (FSLs) which comprises three Public Analyst Laboratories (PALs) and seven Official Food Microbiology Laboratories.
DAFM	- Responsible for official controls in slaughterhouses, meat and milk processing, wholesale, and distribution establishments. - Responsible for official controls on imports from third countries of products of animal origin at border control posts (BCPs¹³).¹⁴ - Implements the residues monitoring programme to monitor primary animal products to detect residues of unauthorised or banned substances. - Implements the pesticide residues control plan for the monitoring of food of animal origin and food of plant origin for pesticide residues. - Approval and supervision of organic certification bodies. - The Department's Laboratories provide accredited biological and veterinary testing and chemical testing.
State Laboratory	- The State Laboratory carries out analysis in relation to chemicals in food and feed, including the national residues control plan.

¹² We note that the Local Authority Veterinary Services are in the process of transferring to DAFM.

¹³ These were previously known as Border Inspection Posts (BIPs).

¹⁴ The impact of Brexit should be noted in this context.

Table 2.1: Overview of Role of Each Official Agency

Official Agency	Overview of Role
The Marine Institute	- Carries out analyses to ensure compliance with legislative requirements with respect to general food law, official controls, food hygiene, contaminants, residues of veterinary medicines, microbiological criteria and marine biotoxins. - Acts as a National Reference Laboratory for certain parameters (i.e., marine biotoxins in bivalve molluscs, bacteriological and viral contamination of bivalve molluscs, monitoring of certain substances and residues thereof as far as they apply to finfish aquaculture).
The National Standards Authority of Ireland (NSAI)	- The recognition of natural mineral waters bottled in Ireland. - Official controls on the production and distribution of food contact materials.
Sea Fisheries Protection Authority (SFPA)	- Responsible for enforcement of national and EU regulations on food safety, sea-fisheries conservation and health conditions for the production and placing on the market of fish, shellfish, and fisheries products. - Carries out official controls of seafood at all stages of production, processing, and distribution with the exclusion of retail establishments. - Provides assistance to the DAFM for official controls on imports from third countries of fish and shellfish.
<i>Source: FSAI</i>	

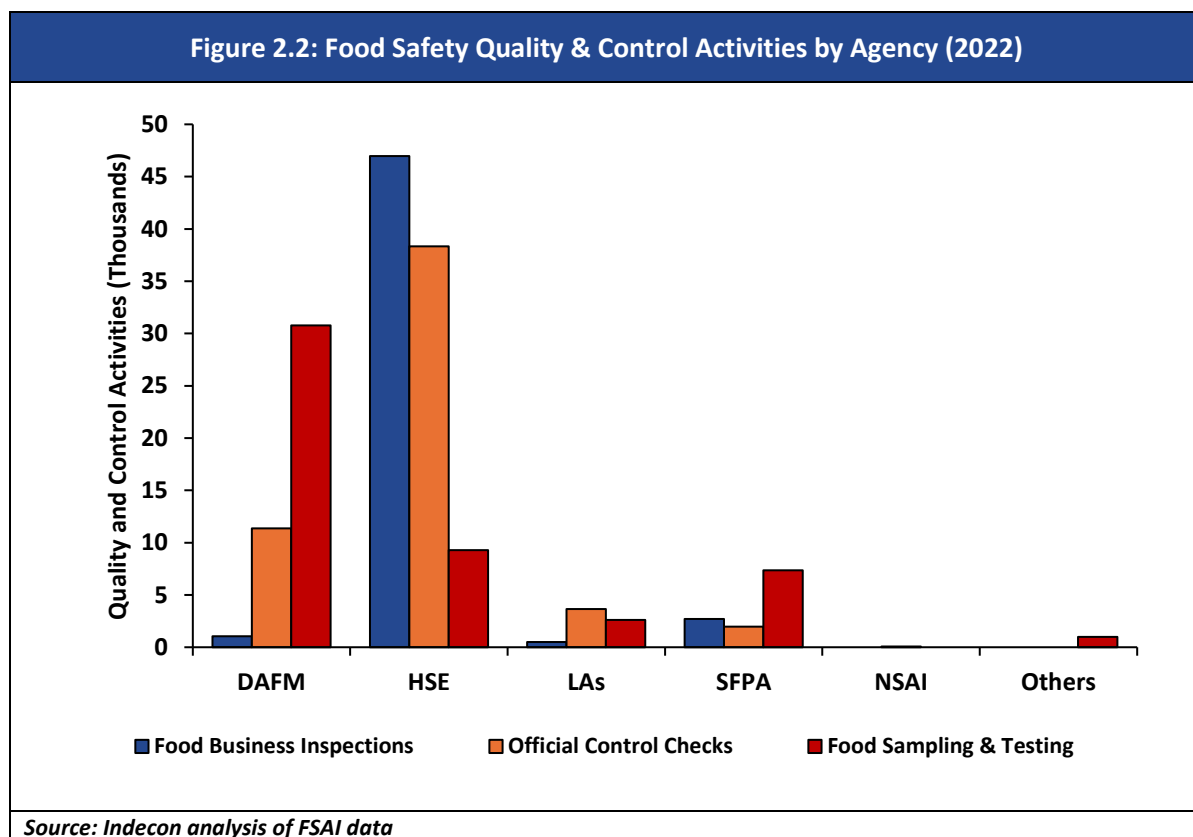
Local Authorities under service contract with the FSAI, are responsible for food law enforcement at certain food businesses, including small meat manufacturing plants and slaughterhouses, and to a lesser degree cold stores, poultry plants, and butchers with wholesale activities. Historically, funding for the Local Authority Veterinary Services (LAVS) service contract has been channelled through the FSAI's allocation from the Department of Health. Financial audits commissioned by the FSAI and carried out by KOSI Corporation identified the need to maximise value for money, efficiency, consistency of this service and FSAI and DG-SANTE audits found inconsistency between the LAVS and DAFM in conduct of official controls. The FSAI has supported the establishment of a single State veterinary service to address these issues.

It is planned that the LAVS will transition to the Department of Agriculture, Food and the Marine and will integrate into DAFM's "One Health, One Welfare" function, which includes inspection services through on-site presence in larger food production establishments and regular inspections in others.

It is envisaged that this transition will allow for greater focus and emphasis on the overarching legal, regulatory, and enforcement mandate of the FSAI in its role as competent authority.

Figure 2.2 illustrates the numbers of food safety quality and control activities performed in 2022 by the agencies responsible for reporting to the FSAI. The HSE was the most active agency, reflecting the large number of businesses under its supervision (46,971 in 2022). The HSE undertook over 45,000 inspections of FBOs; nearly 40,000 official control checks; and almost 10,000 food sampling and testing services. DAFM was the second most active agency (1,037 businesses under its supervision in 2022), with the majority of its food safety activities in the food sampling and testing category (approx.

30,000); and over 10,000 official control checks. Food sampling has increased by 5% between 2019 and 2023.¹⁵



One feature of the oversight arrangements by FSAI is the undertaking of audits on specific aspects of the official controls undertaken by each Official Agency. A summary of the recent audits that have been undertaken by FSAI are shown in Table 2.2. It must be noted that it is the role of the Official Agency to review and respond to the findings of these audits and make any remedial actions necessary if required.

¹⁵ FSAI Annual report 2023.

Table 2.2: Overview of Audits Undertaken on Official Agencies 2017-2024

Official Agency	Description of Audit
Local Authorities (Veterinary Service)	- Audit of official controls carried out by the Local Authority Veterinary Service (Commission Regulation (EC) No 2073/2005), April 2019 (5 Counties)
HSE	- Audit of Compliance of Public Analyst's Laboratories (PAL) with Regulation (EC) No. 882/2004 and Service Contract Obligations - January 2024 - Audit of Official Controls in Bottled Water Establishments - Environmental Health Service of the Health Service Executive - September 2023 - Audit of Compliance of Official Food Microbiology Laboratories with Regulation (EC) No 882/2004 and Service Contract Obligations - published November 2015 (Updated March 2020) - Official Controls carried out by the HSE (Regulation (EC) No 853/2004) - May 2018
DAFM	- Audit of Official Controls carried out on the Dairy Production Chain - December 2023 - Audit of Official Controls carried out on the Table Egg Production Chain - June 2022 - Official controls of sheep identification, acceptance, and traceability within slaughter plants - June 2018 - Official controls in DAFM supervised infant formulae and follow-on formulae establishments - June 2018
National Standards Authority of Ireland	- Audit of Official Controls carried out by the National Standards Authority of Ireland, 2017
Sea Fisheries Protection Authority (SFPA)	- Audit of the Official Controls Undertaken by the Sea Fisheries Protection Authority (SFPA) regarding the Microbiological Classification of Shellfish Waters - November 2019
<i>Source: FSAI - https://www.fsai.ie/enforcement-and-legislation/official-controls/audit/audit-reports</i>	

2.6 Food Safety Policy Function of Department of Health

Across the European Union, different agencies are responsible for food safety and environmental health services. In Ireland the Government Departments with policy responsibility relating to food safety are:

- The Department of Health (DoH) which is responsible for the overall policy on food hygiene and safety in Ireland and
- The Department of Agriculture, Food and the Marine (DAFM) which is responsible for animal health and welfare, animal feed, as well as some areas of plant health.

There are several reasons why food safety policy falls under the remit of the Department of Health rather than any other Department:

1. **Public health responsibility:** The primary focus of the Department of Health is to protect and promote public health. Food safety is directly linked to public health, as contaminated or unsafe food can lead to foodborne illnesses, outbreaks, and even deaths. Food safety policy under the Department of Health ensures that the focus remains on protecting the health and well-being of the wider population.
2. **Policy and Regulatory Independence:** It is important to keep food safety policy separate from trade influence for several reasons:
 - **Public Health Protection:** The primary focus of food safety policy is to protect public health by ensuring that food is safe for consumption. Trade considerations, such as promoting exports or facilitating imports, should not compromise the public health objective. Should food safety policy be placed within the remit of a trade-focussed lead Department, there may be a risk of relaxed standards or inadequate enforcement, putting public health at risk.
 - **Conflict of Interest:** There is potential for trade interests to conflict with public health interests when it comes to food safety. Trade negotiations often involve compromises and concessions, which could undermine the integrity of food safety regulations. Placing food safety policy under a separate authority ensures that decisions are made solely based on scientific evidence and public health considerations, without the influence of trade interests.
 - **Avoidance of Regulatory Capture:** When food safety policy is influenced by trade, there is a risk of regulatory capture. Regulatory capture occurs when the industry being regulated gains undue influence over the policy and regulatory process, potentially undermining regulations and enforcement. This can compromise the effectiveness of food safety measures and undermine public trust in the regulatory system.
 - **Transparency and Accountability:** When food safety is under the remit of a dedicated authority, there is greater transparency in decision-making processes, public consultations, and in the setting and enforcement of standards. This allows for public scrutiny and input, ensuring that decisions are made in the best interest of public health.
 - **International Reputation:** Maintaining a strong and independent food safety policy enhances a country's international reputation. Countries with robust food safety systems are seen as reliable trading partners and can gain a competitive advantage in the global market. Placing food safety in a trade-focused lead Department has the potential to erode this reputation and lead to concerns about the safety of exported food products.
3. **Expertise and resources:** The FSAI, under the remit of the Department of Health, has the necessary expertise and resources to effectively regulate and enforce food safety standards. The FSAI has trained professionals, such as food scientists, who can assess risks, conduct inspections, and provide guidance on food safety practices. Having expertise within the FSAI ensures that food safety policies are evidence-based and grounded in scientific knowledge.
4. **Coordination with healthcare systems:** Foodborne illnesses can have a significant impact on healthcare systems, leading to increased hospitalisations, medical costs, and strain on healthcare resources. Placing food safety under the Department of Health allows for better coordination between food safety policies and healthcare systems.

5. **Consumer protection:** Food safety is a critical aspect of consumer protection. Consumers have the right to expect that the food they purchase and consume is safe and free from contaminants. Placing food safety under the Department of Health ensures that there are robust regulations in place to protect consumers from potential hazards, such as foodborne pathogens, chemical contaminants, or allergens. The Department drafts and transposes food safety legislation which sets standards, including for food hygiene, and labelling to protect public health and consumer interests.
6. **International standards and obligations:** Many countries have international obligations and commitments to ensure food safety. Placing food safety under the Department of Health allows for better alignment with international standards and regulations and ensuring the safety of imported food products. The Department works closely with the Commission, and takes account of international developments from bodies, such as the World Health Organization (WHO) and the Food and Agriculture Organisation (FAO), to stay updated on global food safety issues and best practices.

The rationale to position the FSAI as an agency reporting to the Department of Health is in accordance with WHO advice that “Governments should make food safety a public health priority” in the context of the disease burden caused by 31 foodborne agents (bacteria, viruses, parasites, toxins, and chemicals) at global and sub-regional levels, highlighting that more than 600 million cases of foodborne illnesses and 420 000 deaths could occur in a year. It emphasises that “Food safety is a shared responsibility among different national authorities and requires a multisectoral, one health approach, to be addressed in all the steps of the food chain.”¹⁶

Figure 2.3 overleaf provides a list of EU countries and their Government Departments or ministries responsible for food safety. The table reflects the fact that most Member States approach food safety via their Department of Agriculture/Food, or Department of Health. However, it must be noted that the exact functions of a food safety organisation may vary by Member State and this makes exact comparisons difficult. The exact functions of the FSAI may not directly align with other competent authorities across the EU which may impact the choice of oversight Department/Ministry in other EU jurisdictions.

In summary, keeping food safety policy separate from trade policy is viewed as crucial to protect public health, avoid conflicts of interest, prevent regulatory capture, promote transparency and accountability, and maintain a strong international reputation. Ensuring that food safety decisions are based on scientific evidence and public health considerations can better protect consumers and maintain the integrity of the food supply chain.

As part of this review, Indecon examined the DoH *Statement of Strategy 2023-2025* and notes that the document does not mention food safety or FSAI specifically. However, its strategic priorities in relation to promotion of public health (including disease prevention) and improvement of oversight and partnership with its agencies relate to the purpose and functions of the FSAI.

¹⁶ WHO [Food Safety](#), 4 October 2024.

Figure 2.3: Government Ministries Responsible for Food Safety in EU Member State as of September 2024

Member State	Department/ Ministry
Austria	Federal Ministry of Social Affairs, Health, Long-Term Care, and Consumer Protection
Belgium	The Federal Public Service (FPS) Health, Food Chain Safety, and Environment
Bulgaria	Ministry of Agriculture, Food, and Forestry
Croatia	Ministry of Agriculture
Cyprus	Ministry of Health
Czech Republic	Ministry of Agriculture
Denmark	Ministry of Food, Agriculture, and Fisheries
Estonia	Ministry of Regional Affairs and Agriculture
Finland	Ministry of Agriculture and Forestry
France	Ministry of Agriculture and Food
Germany	Federal Ministry of Food and Agriculture
Greece	Ministry of Rural Development and Food
Hungary	Ministry of Agriculture
Ireland	Department of Health
Italy	Ministry of Health
Lativa	Ministry of Agriculture
Lithuania	Ministry of Agriculture
Luxemburg	Minister of Health and Social Security
Malta	Ministry of Agriculture
Netherlands	Ministry of Agriculture, Fisheries, Food Security, and Nature
Poland	Ministry of Agriculture and Rural Development
Portugal	Ministry of Agriculture and Food
Romania	Ministry of Agriculture and Rural Development
Slovakia	Ministry of Agriculture and Rural Development
Slovenia	Ministry of Agriculture, Forestry, and Food
Spain	Ministry of Health and Consumer Affairs
Sweden	Ministry of Agriculture, Food, and Consumer Affairs

Source: DoH

Key: Agriculture Ministries; Health Ministries; other

2.7 Summary of Main Findings

A significant portion of the FSAI's statutory mandate involves provision of advice to the Minister on various food safety issues. This includes advice in relation to industrial practices relating to food preparation, food production, labelling and packaging of food, and communication of information to the public. The key findings of the review in this section include:

- Statutory Basis:

- The Food Safety Authority of Ireland (FSAI) was established under the Food Safety Authority of Ireland Act, 1998. This Act came into effect on 1 January 1999. Significant amendments to FSAI functions followed the British-Irish Agreement Act.
 - The Authority is a statutory, independent, and science-based regulatory enforcement body dedicated to protecting public health and consumer interests in the areas of food safety, hygiene, integrity, and authenticity.
 - The Food Safety Authority of Ireland was the first in Europe to be set up with this independent status - independent of industry and sectoral interests, an independence which is very important to consumers.
- Rationale for the Establishment of the FSAI:
- The FSAI is an independent agency whose function is to ensure that food produced in Ireland (whether or not distributed or marketed in the State), and the food marketed, or distributed within the State meets the highest standards of food safety and hygiene.
 - In July 1999, the FSAI took over responsibility for the enforcement of all food safety legislation which had prior to that date been the responsibility of a range of State agencies.
 - This responsibility is discharged by means of service contracts with the agencies, which prior to the establishment of the FSAI were responsible for food control.
 - The FSAI has "service contracts" with Official Agencies.
- Rationale for FSAI under Dept. of Health:
- Public health responsibility;
 - Policy and regulatory independence;
 - Expertise and resources;
 - Coordination with healthcare systems;
 - Consumer protection; and
 - International standards and obligations.
- While it must be noted that there is no explicit mention of food safety in the Department of Health *Statement of Strategy 2023-2025*, the promotion of public health (and prevention of disease) is included in its strategic priorities.

3 Review of Performance and Ongoing Business Case for Agency

3.1 Introduction

This section examines the functions of the FSAI as per the original legislation and assesses whether these are still being undertaken by FSAI and whether they remain relevant in the context of ensuring safe food and sufficient regulatory oversight to ensure this. The purpose and responsibilities of the FSAI are enumerated in the Oversight Agreement (OA) and Performance Delivery Agreement (PDA) executed annually between the DoH and FSAI. The 2024 PDA sets out the purpose of the Authority; the legal framework and environment in which it operates; its responsibilities in line with statutory requirements; compliance and Code of Governance requirements; reference to the 2024 Business Plan (objectives and performance targets) and FSAI Strategy (2019-2023);¹⁷ and arrangements for oversight, monitoring, and reporting on conformity with the OA. This is in accordance with the relevant section of the *Code of Practice for the Governance of State Bodies*.

3.2 Assessment of FSAI's Performance

The following table lists the intended functions of the FSAI as enumerated in the Food Safety Authority of Ireland Act, 1998. Each required function is then discussed in subsequent paragraphs, with examples of the actions taken by FSAI in fulfilment of these functional requirements.

¹⁷ A new FSAI Strategy 2025-2029 has recently been published.

Table 3.1: Assessment of Current Status of FSAI's Functions under FSAI Act

Statutory Functions	Still undertaken by FSAI	Still Relevant
Take all reasonable steps to ensure food produced, distributed, and/or marketed in the State meets highest standards of food hygiene and safety	✓	✓
Foster establishment and maintenance of high standards of food hygiene and safety at all stages of food production (including activities and inspections directed towards bringing about general acceptance of responsibility for food safety amongst producers and sellers of food)	✓	✓
Promote, encourage, and facilitate food safety assurance schemes, including guidelines, relating to raw materials, processing, preparation, packaging, storage, and labelling of foodstuffs, and report to the Board on performance and implementation	✓	✓
Collect and assess data on official control of food	✓	✓
Review and report to Minister on the efficacy of food inspection services	✓	✓
Participate in, commission, and undertake research projects relating to food involving parties out of State	✓	✓
Provide a system of certification of food for sale	✓	✓
FSAI shall carry out or arrange on its behalf to determine compliance with food legislation, including food equipment and premises inspection; sampling and analysis of food; and inspection/analysis of food labelling	✓	✓
Certify results of any test or analysis carried out in accordance with regulations	✓	✓
Issue improvement notices and orders; closure orders, withdrawal of food products, and prosecution of summary offences under food legislation	✓	✓
Provide advice to Government Minister, on its own initiative, on issues relating to all or any matters relevant to food safety & hygiene	✓	✓
Source: Indecon Assessment		

Take all reasonable steps to ensure food produced, distributed, and/or marketed in the State meets highest standards of food hygiene and safety

In its 2023 Business Plan Year End Delivery Report, FSAI notes that it:

“...achieves this mandate through the co-ordination of the enforcement of all food law. The FSAI holds this principle of protection at the forefront of all activity and resourcing when planning its annual activities and annual business plan. Resources are optimised to deliver the greatest impact to public health and consumers’ interest while ensuring they are utilised to provide maximum value to the Exchequer and consumers in Ireland and consumers of Irish food abroad...This end of year report is based on a detailed Business Plan that outlined key agreed deliverables and performance measures for 2023 which were aligned to the four strategic goals of the FSAI Strategy 2019 -2023. The Business Plan, prepared in line with the Code of Practice of Governance in State Bodies [sic], was based on a budget allocation of €21.2 million as confirmed in the FSAI’s letter of allocation 2023 received from the Department of Health. Throughout 2023, quarterly management reports and detailed operational reports were provided to the Board and to the

Department of Health in advance of quarterly Governance Meetings to assess delivery against the plan.”

This report sets out how the FSAI uses the resources assigned to it and reports on its activities to the Department of Health. In turn, as part of the FSAI’s oversight of Official Agencies and to accomplish its goals, FSAI has delivered (annually) a Service Level Agreement with the four main Official Agencies (HSE, DAFM, SFPA, and LAs). The FSAI provides Governance Reports to the Department that include references to the operation of service contracts. Furthermore, the 2023 Year End Delivery Report states that:

“FSAI’s legal mandate requires a responsive and agile approach to dealing with risks as they arise within the food system, and this brings with it significant reactive work. The FSAI has systems in place to manage this, based on prioritisation of the protection of public health. The volume and complexity of the reactive work varies year on year and may require us to prioritise our response over and above other planned work, as was done for example in 2023 to manage the [retail chain] food incident.¹⁸ The FSAI delivered the operations within the context of these challenges; focussing our activities on our legal commitments to enforce food law; and in doing so, fully achieved 75% of our business plan deliverables and substantially achieved 85% of the remaining deliverables.”

The documents examined as part of this Periodic Critical Review indicate that the Authority’s performance is reviewed as part of the annual governance reporting arrangements and shows the delivery progress for each of the four strategic goals for the year as shown in Table 3.2.

¹⁸ Recall of imported frozen food of animal origin sold in [retail chain] | Food Safety Authority of Ireland.

Table 3.2: FSAI Progress Report – % of Deliverables Reached by Goal (2023)

Strategic Goal	Status		
	Green	Amber	Red
Goal 1: To enforce food law & increase compliance, in collaboration w/regulatory partners through a world-class food control system	73%	27%	
Goal 2: To advance food safety & integrity through independent science, expertise & a strong evidence base	91%	9%	
Goal 3: To be a leader in safety & integrity of food through communication, partnership, collaboration & advocacy	60%	30%	10%
Goal 4: To empower our people, strengthen our system, & develop our culture to achieve organisational excellence & maximise our impact	69%	31%	
<i>Source: FSAI Business Plan 2023: Year End Delivery Report, pp. 2-3</i>			

Our review of FSAI documentation suggests that despite challenges such as Brexit-related uncertainties, staff turnover, geopolitical factors, and a protracted food incident involving [a retail chain], the FSAI successfully delivered 75% of its deliverables and substantially completed 85% of the remaining deliverables. Throughout 2023, quarterly management and operational reports were submitted to the Board and the Department of Health ahead of quarterly Governance Meetings to evaluate progress against the plan. Achievements included enhanced stakeholder engagement and processes, staff training in collaboration with the European Commission, and other achievements as detailed in **Error! Reference source not found.** The Authority prioritised innovation, improved business processes, and strengthened compliance with public sector guidelines.

While some deliverables faced delays due to external supplier issues and staffing challenges, these were carried forward without immediate public health impacts and were discussed and accepted by the Department. Specifically, of the 12 deliverables not fully achieved in 2023, 11 (amber) were substantially achieved and completion brought forward to 2024. Reasons were noted for the delays, and this is elaborated upon in **Error! Reference source not found.** Additionally, the FSAI responded to additional demands from key stakeholders that were critical to support the wider food safety system and Government priorities.

Promote establishment and maintenance of high standards of food hygiene and safety at all stages of food production (including activities and inspections directed towards bringing about general acceptance of responsibility for food safety amongst producers and sellers of food)

The FSAI represents Ireland at EU expert and legislation meetings and Codex Alimentarius Commission meetings, and provides technical advice for policy, legislation, and food standards development. Specifically, Commission/Council meetings and working groups are attended by FSAI, who then reports on expert inputs to the DoH Food Unit and other relevant stakeholders. The FSAI provides data and information requested by the Commission for the further development of food legislation, and coordinates briefings for the DoH Food Unit on relevant EU legislation, including those from the Standing Committee on Plants, Animals, Food, and Feed (EU PAFF) as well as Back to Office

Reports (BTORs). Through the FSAI, Ireland has contributed to the development of international standards through the Codex Alimentarius Commission, its committees, and their working groups.

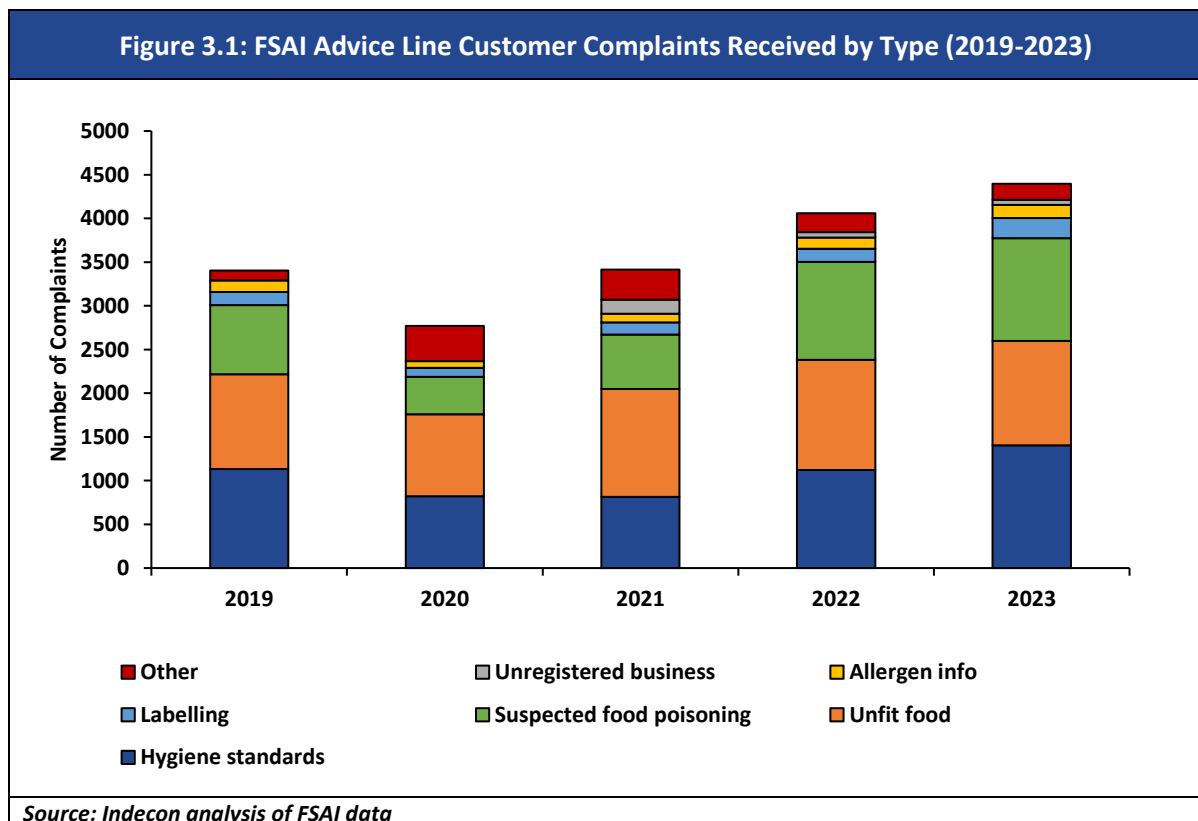
FSAI also develops and shares best practice in enforcement approaches with EU and other countries. For example, it participates in annual meetings of the International Heads of Food Agencies Forum and contributes to the relevant heads of food agencies' working groups, including supplements, e-commerce, food safety culture, and import controls, amongst other things.

According to its 2023 Business Plan Year End Delivery Report, the FSAI fulfilled the "Development and delivery, in conjunction with the European Commission, of two sustained training missions for 120 Irish inspectors in priority areas for official controls in Ireland. The training was tailored to Ireland using Irish scientific expertise, from within FSAI and past FSAI staff."

Additionally, the FSAI handles customer complaints as well as queries from FBOs and workers in the sector who seek advice on a variety of start-up and compliance issues. These are discussed in detail below.

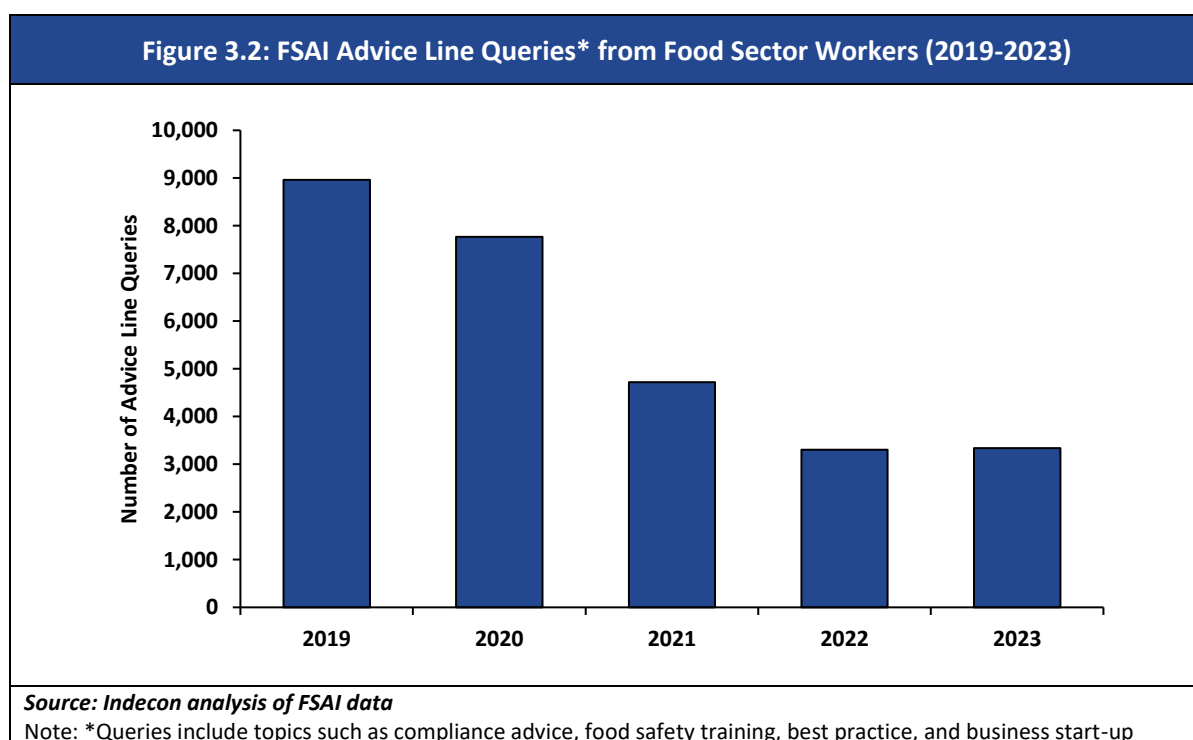
Customer complaints

The FSAI is responsible for maintaining a dedicated line of communication for customers and sector workers to lodge complaints or submit queries. This can be done by telephone or by submitting an online form through the FSAI website, known as Advice Line. Figure 3.1 shows the levels and trends in types of complaints received by FSAI through Advice Line channels from 2019-2023. The two largest areas of complaint are for hygiene standards and unfit food, with suspected food poisoning following closely. Total numbers of complaints have risen steadily throughout the period, except for a slight decrease during the COVID-19 pandemic.



Queries by food sector workers

The FSAI Advice Line is not only a resource for customers with complaints, but also for food workers with questions and requests for clarification on matters of food safety compliance and related matters. Queries by food sector workers included topics such as label requirements, food safety training, best practice, business start-up compliance, import/export compliance, etc. Numbers of such queries are illustrated in Figure 3.2, showing a downward trend generally from 2019 to 2023; however, this period includes the COVID-19 pandemic which impacted activity levels in the food sector due to many businesses being closed during that period.



Promote, encourage, and facilitate food safety assurance schemes, including guidelines, relating to raw materials, processing, preparation, packaging, storage, and labelling of foodstuffs, and report to the Board on performance and implementation

Publications by the FSAI include guidance notes for FBOs on topics such as food-specific guidance, food safety training, food supplements, labelling, scientific reports, and starting/running a food business. These publications are readily available on the FSAI website and are designed to help FBOs understand their food safety obligations in a clear and practical way. Updates on current food safety issues are also published, e.g., food labelling challenges in the context of regional conflicts, and taskforce notes on food reformulation targets.

In July 2024, the FSAI published its Resources Booklet for Small Food Businesses, which contains a comprehensive list of links to relevant information relating to all aspects of food safety, including allergens, hygiene, chemical contaminants, food safety staff training, labelling, and more.

Additional guidance notes published by the FSAI relate to a range of compliance issues such as approval and operation of meat production/preparation, infant formula regulations, food flavourings, cook – chill systems, determination of shelf life, and updated hygiene regulations.

Since 2000, FSAI has participated in the technical advisory groups for the production of standards on Food Safety by the National Standards Authority of Ireland which are certified and accredited, and on food safety requirements for Bord Bia Quality Assurance Schemes.

Feedback from FSAI indicates that these resources are widely used by other authorities outside of Ireland and the level of interest internationally in the FSAI as an exemplar of good practice in this area is also a positive indicator of the FSAI's reputation in this area.

Food incidents and alerts

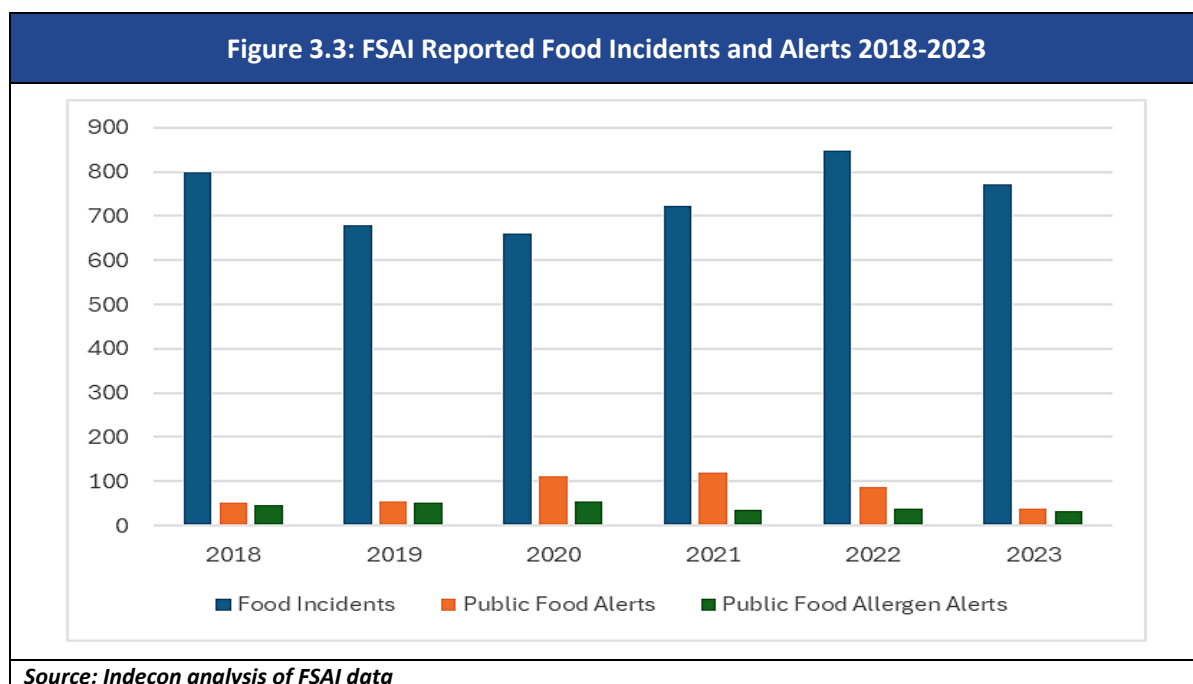
The FSAI collects significant amounts of data from the agencies under the 48/8 returns from agencies is analysed and published in the annual report and used in service contract management.

The FSAI published its Management of Outbreaks Protocol in 2016 and contains a detailed description of the methodology and data used when an event may be related to a food borne illness outbreak. A summary of steps to be taken by the Outbreak Control Team is as follows:

- Preliminary investigation (includes initial case interviews, questionnaires, and systematic case interviews, specimen collection, food premises inspection, preliminary hypothesis, and early control measures);
- Descriptive epidemiology (involves examination of routine surveillance data, descriptive data collection, descriptive data analysis, and description of outbreak);
- Food business investigation (includes examination of Hazard Analysis Critical Control Point (HACCP) system of food safety management system as well as data relating to all food handlers, food and water sampling and testing, and traceback through the supply chain);
- Microbiological investigation (includes clinical samples, food, water, and environmental samples, identification and typing of isolates);
- Hypothesis generation (includes analytical epidemiology, case control studies, and interpretation of results);
- Implementation of control measures (includes control of source, control of secondary transmission, and infection control precautions);
- Communication (public dissemination of information relating to outbreak, control measures, and precautions advised); and
- End of outbreak and outbreak report (includes assessment of effectiveness of outbreak control measures and implementation issues, identification of prevention measures, and final outbreak report drafted by outbreak control team).

The FSAI is responsible for investigating food incidents and for issuing alerts to the public where required, relating to food safety and allergen notices. In its 2023 Business Plan Year End Delivery Report, FSAI notes its “successful management of the [retail chain] food incident, which was protracted, complex and cross-agency.” The recall of imported frozen food of animal origin from a retail chain was an example of the FSAI using its powers to serve notice on a commercial entity for the immediate withdrawal and recall of food due to concerns around the necessary food safety controls. This demonstrates the responsiveness of the organisation and its ability to respond to risk without fear or favour. Figure 3.3 shows the numbers and breakdown by types of food incidents and

alerts for 2018-2023. Levels declined from 2022-2023, after a downturn and subsequent rise during the COVID-19 pandemic but we note that this is not a significant reduction.



Review and report to Minister on the efficacy of food inspection services

The FSAI regularly conducts targeted audits and official control audits, which examine the effectiveness and appropriateness of official controls as implemented by Official Agencies in relation to food law, service contracts, and Multi-Annual National Control Plan (MANCP) requirements (see below for additional detail on MANCP compliance). Where necessary, corrective action plans are developed and implemented by the Official Agencies to address any issues arising from the audits. FSAI monitors the implementation of the plans, which are updated periodically on their website.

In addition, the FSAI issues quarterly progress reports on its annual business plans to the DoH Food Unit, with a comprehensive annual delivery report at the end of each year. This includes deliverables, performance indicators, and actions taken.

Participate in, commission, and undertake research projects relating to food involving parties out of State

The FSAI participates in research with other EU countries and beyond. During 2022, the FSAI's participation in the EU Food Safety Project continued. This involved participation on the implementation of activities in Albania to strengthen food safety, veterinary and plant health standards.

The 2023 year-end report to the DoH indicates delivery of the 2023 requirements of EU research project FoodSafer, and data collation with the EU and EFSA on zoonosis, with the report published on the FSAI website. A consortium of Irish government agencies and their international partners successfully tendered for a €5 million EU grant to support Albania as a candidate for accession to the

European Union, by strengthening its food safety, veterinary and plant health standards. The consortium was led by FSAI and included the Department of Agriculture, Food and the Marine, Sustainable Food Systems Ireland, the Finnish Food Authority, and an Albanian partner, Creative Business Solutions.

According to the FSAI's 2023 annual report, "FSS scientists maintained FSAI influence on the direction of important food safety research by serving on the steering boards of 11 major national research programmes funded by the DAFM and the Environmental Protection Agency (EPA), covering topics such as the safety of horticulture foods, the control of mycotoxins, and waterborne infection with Shiga toxin producing *Escherichia coli* (STEC). The FSS team also delivered a successful and innovative 'Living Lab' for 50 European regulators as part of its contribution to an EU-funded research project, FoodSafeR, which is aimed at developing tools for emerging risk identification and evaluation. Food surveys were also completed in order to establish consumers' exposure to sulphites and to establish the microbiological safety and quality of ice. Data on zoonoses in Ireland for 2021 and 2022 were published on the FSAI website, and 2023 zoonoses data were submitted to EFSA."¹⁹

Prepare a Multi-Annual National Control Plan

The FSAI prepares a Multi-Annual National Control Plan or MANCP, which is a requirement of the European Union's agri-food chain legislation. Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products sets out the requirements for MANCPs. The European Commission has also published guidance to help Member States. All EU countries must prepare and publish a MANCP. Responsibility for Ireland's National Control Plan is shared between the Food Safety Authority of Ireland (and its "Official Agencies") and the Department of Agriculture, Food and the Marine.

The DAFM and SFPA are responsible for export certification for animal and seafood products. The HSE is responsible for export certification for foods of non-animal origin. Noted in its 2023 Business Plan Year End Delivery report, the FSAI delivered response "to regulatory and political developments associated with Brexit, including the introduction of the Windsor Framework Protocol, new incidents associated with food imports through NI and uncertainty and changes associated with preparation for export certification to Great Britain."

The MANCP process also involves significant data collection and collations from the agencies. Official control data is provided to the FSAI under section 48 (8) of the FSAI Act. This data is analysed and published in the annual report and used in service contract management.

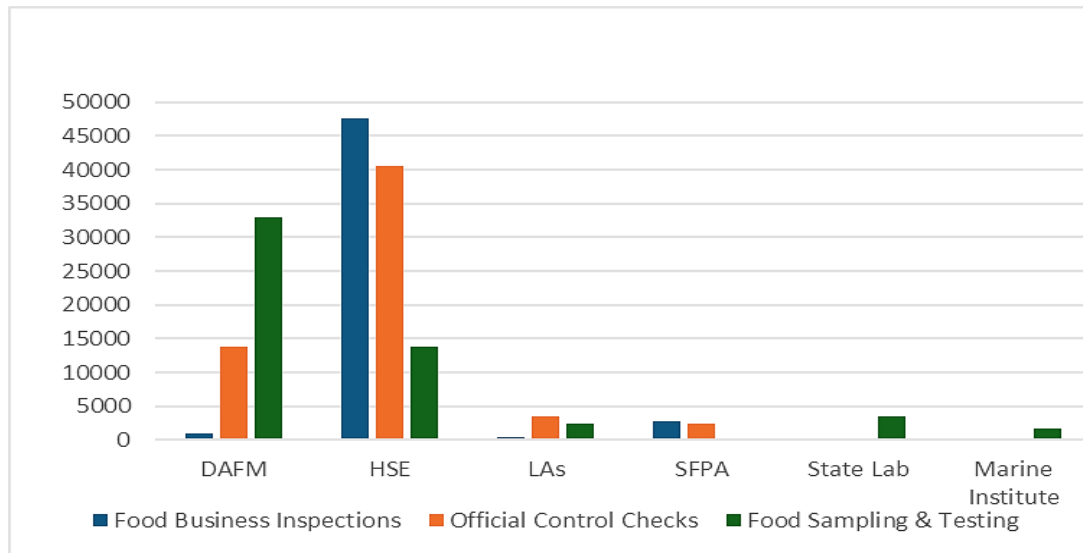
FSAI shall carry out or arrange on its behalf to determine compliance with food legislation, including food equipment and premises inspection; sampling and analysis of food; and inspection/analysis of food labelling

FSAI arranges for inspections and other compliance functions through agencies including DAFM, HSE, local authorities, Sea Fisheries Protection Agency (SFPA), and the State Laboratory. Figure 3.4 illustrates the numbers of food safety quality and control activities performed in 2023 by these agencies responsible for reporting to the FSAI. The HSE conducted over 45,000 inspections of FBOs;

¹⁹ FSAI Annual Report, 2023, p. 67

nearly 40,000 official control checks; and almost 10,000 food sampling and testing services. The DAFM conducted the majority of its food safety activities in the food sampling and testing category (approx. 30,000), and over 10,000 official control checks.

Figure 3.4: Food Safety Quality & Control Activities by Agency (2023)



Source: Indecon analysis of FSAI data

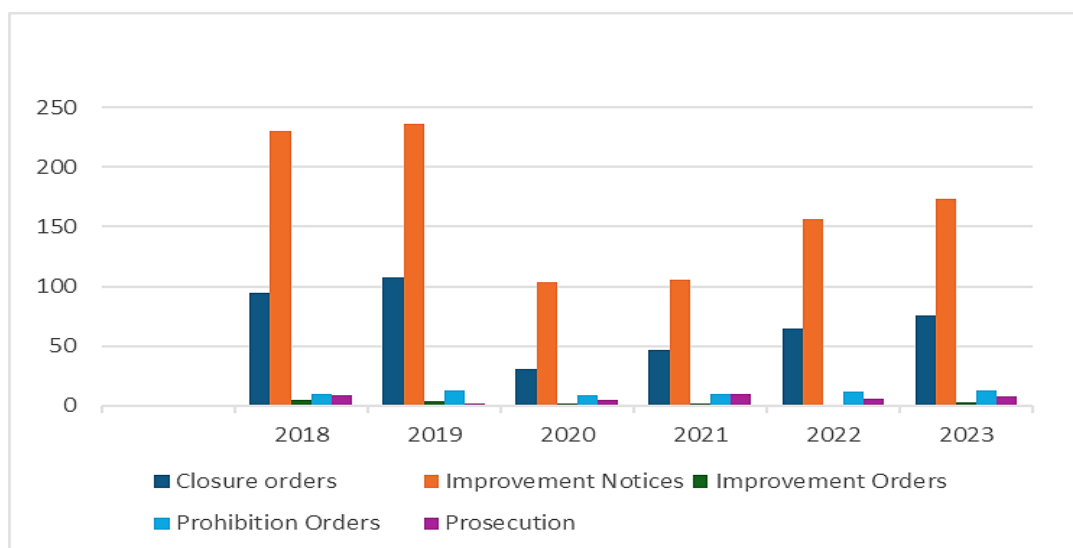
Certify results of any test or analysis carried out in accordance with regulations

The DAFM agri-labs, the HSE official laboratories and the State Laboratory conduct and certify analysis/test results conducted in accordance with the MANCP. Service Contracts agreed between the FSAI and the Official Agencies lay out the scope, methodologies, and turnaround times for laboratory testing, as well as any subcontracted testing. This includes the development and validation of analytical methods.

Issue improvement notices and orders; closure orders, withdrawal of food products, and prosecution of summary offences under food legislation

The FSAI is responsible for enforcing food safety standards and regulations. The FSAI and its Official Agencies' various enforcement activities are shown for the period 2018-2023 by type in Figure 3.5. The data suggest an overall downward trend of enforcement actions have been implemented; however, this period includes the COVID-19 pandemic when food business activities were curtailed. Actions have increased from 2021-2023. According to FSAI reports, the types of recurring food safety issues which lead to Enforcement Orders and Improvement Notices are poor cleaning and sanitation of premises; poor personal hygiene; lack of running water; inadequate hand-washing facilities; incorrect food storage; lack of or an ineffective pest control programme; structural problems arising from lack of ongoing maintenance; and lack of or an inadequate food safety management system.

Figure 3.5: FSAI Enforcement Actions by Type (2018-2023)



Source: Indecon analysis of FSAI Annual Report data

Data showing enforcement actions by type is presented in tabular format in Table 3.3. Overall, after the sharp drop in FSAI enforcement actions during 2020 and 2021, caused by the closure of businesses during the COVID-19 crisis, the reopening of the economy saw a return towards previous numbers of actions, with a total of 273 actions issued in 2023. The largest component of action remains the issuing of improvement notices, of which a total of 173 were issued in 2023.

Table 3.3: FSAI Enforcement Actions by Type (2018-2023)

Enforcement Actions	2018	2019	2020	2021	2022	2023
Closure orders	95	108	31	47	65	76
Improvement Notices	230	236	104	106	156	173
Improvement Orders	5	4	2	2	0	3
Prohibition Orders	10	13	9	10	12	13
Prosecution	9	2	5	10	6	8
Total	349	363	151	175	239	273

Source: Indecon analysis of FSAI data

Provide advice to Government Minister, on its own initiative, on issues relating to all or any matters relevant to food safety and hygiene

An Oversight Agreement and Performance Delivery Agreement are executed annually by the DoH and the FSAI.²⁰ The contents of these embed the FSAI's obligations under the Food Safety Authority of Ireland Act, 1998, including to:

“...provide advice on its own initiative or at the request of the Minister for Health or of another Minister of the Government on:

- statutory developments relating to food safety and hygiene
- technology and industrial practices relating to food and food preparation
- the organisation and administration of systems for the approval, licensing and registration and inspection of premises carrying on a food business
- food production, including cultivation of crops, fruit and vegetables, the harvest of uncultivated foods, the cultivation and production of shellfish and breeding or rearing of animals for slaughter and for food production
- labelling and packaging of food (including materials used in packaging)
- any other matter relevant to food safety and hygiene.”

The Scientific Committee assists and advises the Board on decisions relating to food safety and hygiene according to the latest and best scientific information available. Meeting minutes from the committee indicate that in 2024, the Biological Safety Subcommittee drafted a risk ranking of microbiological hazards, and the Hepatitis E in Pigs and Pigmeat Working Group drafted a report on this issue.²¹ The Chemical Safety Subcommittee drafted reports on dioxins and PCBs, as well as biomarkers relating to food/beverages exposures in humans.²² The Food Hygiene Rating Systems Subcommittee was initiated in September 2024, and began work with a literature review on rating schemes used in other countries.²³ Efficacy of these systems and implementation issues will be examined by the subcommittee going forward.²⁴

The DoH/FSAI Governance Framework Report (February 2023) issued by FSAI to DoH supports our findings that the FSAI provides advice to the Minister as required under this subsection of the Act (1998).²⁵ The report contains details relating to food incidents, food science and standards (including sections on findings from the Scientific Committee, the Food Reformulation Taskforce, recent scientific issues relevant to future food safety policy/legislation, public health nutrition policy, food supplements, and others.²⁶

3.3 Staff Views on FSAI Functional Effectiveness

Indecon conducted a survey of FSAI staff in September 2024. As depicted in the table below, most staff respondents (>80%) believe that the FSAI is delivering effectively or very effectively on its statutory remit, specifically in respect to food law enforcement, audits, food incident management, training, fostering compliance, providing advice to Government, risk assessment and science, public health nutrition, food reformulation, and corporate functions such as governance, legal, and customer communications. These figures point to the success of the FSAI in carrying out a wide variety

²⁰ See FSAI, Oversight Agreement between The Department of Health and the Food Safety Authority of Ireland for 2024, p.4. Earlier annual OAs contain the same language.

²¹ <https://www.fsai.ie/about/what-we-do/science-evidence/sc-meetings/scientific-committee-meeting-14-october-2024>

²² Ibid.

²³ Ibid.

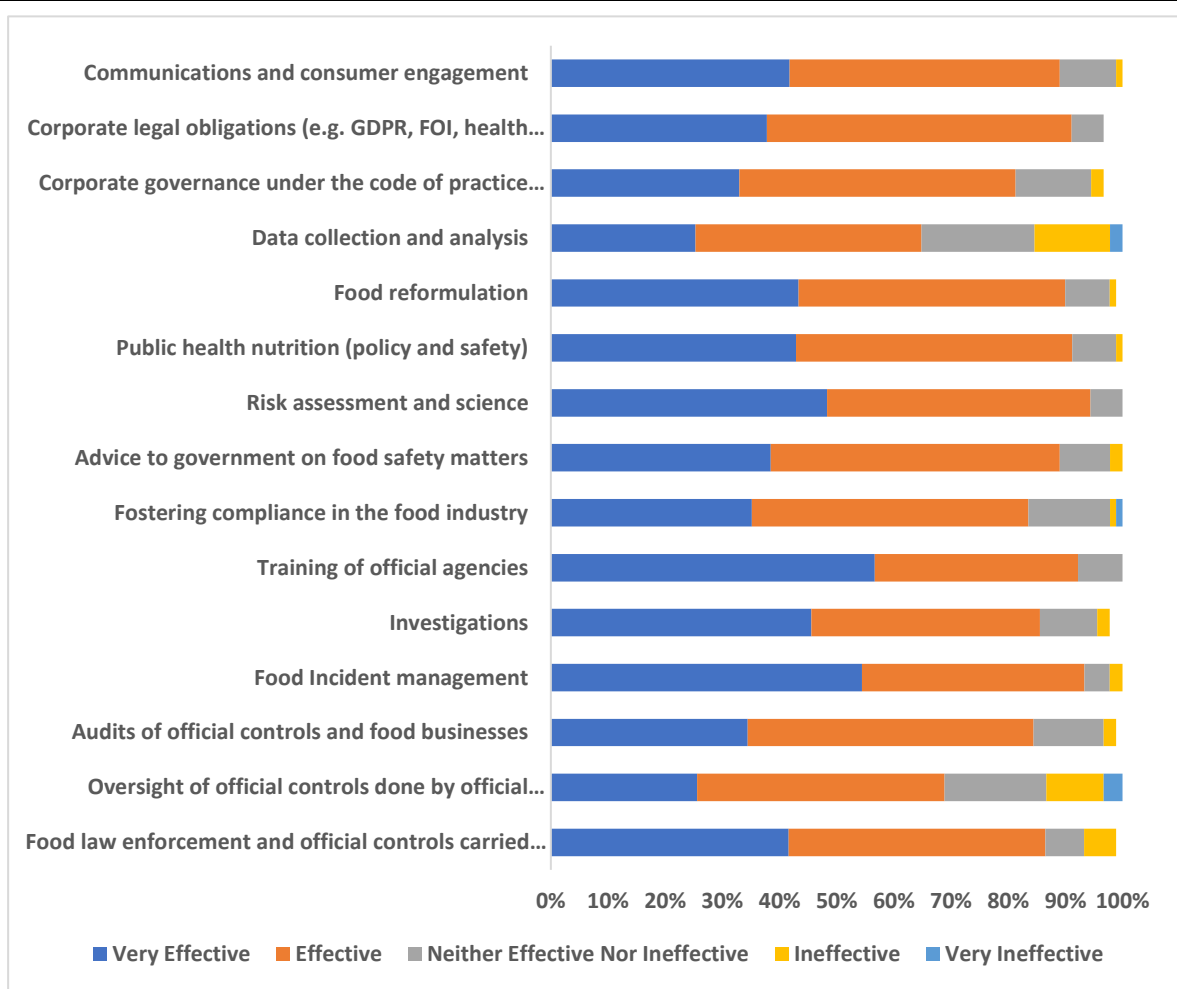
²⁴ Ibid.

²⁵ FSAI, DoH/FSAI Governance Report, February 2023.

²⁶ Ibid.

of activities under its statutory remit. Slightly lower proportions of respondents also believe the FSAI is effectively or very effectively delivering on its oversight of Official Agencies (68.9%) and data collection and analysis functions (64.9%). In addition, respondents were provided with an opportunity to leave relevant comments during the survey, which gave important insights into their views on FSAI. These were generally positive but there were a couple of suggestions for improvement within the Authority, specifically re the service contract model and data collection/sharing.

Figure 3.6: Overall, to What Extent do You Believe the FSAI is Delivering Effectively on its Statutory Remit/Obligations in Respect of Each of the Following Areas?



Source: Survey of FSAI Staff

3.4 Stakeholder Views on FSAI's Performance

As part of this review, Indecon sought the views of stakeholders on FSAI's performance. These stakeholders are representatives of external organisations, some of whom are members of the Food Safety Consultative Council. Statements were generally positive overall, with some comments noting the recent external challenges faced by the Authority. References were made to FSAI's service delivery, responsiveness, engagement, and focus on international best practice. A sample of stakeholder remarks is shown in the following table.

Table 3.4: Selected Examples of Stakeholder Views on FSAI's Performance

*"External environment has changed drastically during the last 5 years – Brexit, Covid, war in Ukraine, etc. Hence, big changes in the risk profile of supply chains and FBO activity...developments in sustainability regulations, where there are food safety considerations, necessitates the involvement of the FSAI in such legislative developments...Overall, the **FSAI has responded thoroughly though sometimes conservatively** to these challenges."*

*"The transition of the UK to a Third Country has posed challenges for the FSAI and the SFPA's interaction with the FSAI particularly in relation to Border Control breaches. The imperative to digitalise processes and ensure that shared systems remain fit for purpose poses challenges. **Engagement [by FSAI] has been positive and collegiate.**"*

*"FSAI has **demonstrated leadership** in terms of investing in improved training infrastructure (online learning)...and been genuinely open to input from the Food Safety Consultative Council...Need clarity in terms of roles and responsibilities of FSAI v SafeFood* in terms of food safety training – there appears to be duplication. I have found the **FSAI to be highly professional and overall, scientifically rigorous.**"*

*"I have had an excellent experience at the meetings that I have attended. The **FSAI have a wide skill set and experience.**"*

*"FSAI are very aware and focused on the changing environment for food production and manufacturing. **The agency is part of a strong international network** of organisations which means that the organisation is exposed to best practice international thinking – which is essential given the pace and extent of change in the sector."*

*"In general, I consider their **delivery of service to be satisfactory**, they are a young and enthusiastic organisation, forward looking and ambitious. One of the topics of discussion between FSAI with its Official Agencies that arise on an occasional basis over the years is a level of disagreement on the delineation of remit, e.g., with respect to notification of unannounced audits to Official Agencies, service of enforcement and determination of what actions may be considered adequate to lift enforcement notices."*

Source: Confidential Survey of Stakeholders

Note: SafeFood is an all-Ireland body, set up under the British-Irish Agreement Act 1999, whose role is to promote awareness and knowledge of food safety and nutrition on the island of Ireland by providing healthy eating and food safety advice to the public; carrying out research into food safety; promoting scientific co-operation between labs; providing independent assessment of the food supply; and carrying out surveillance of diet-related disease.

3.5 Summary of Main Findings

The detailed analysis in this section highlights the significant work undertaken by FSAI (and the Official Agencies) to ensure a safe and trusted food system. A review of the key activities undertaken by or on behalf of FSAI were assessed against the original functions set out in the FSAI Act. The assessment indicates that FSAI still undertakes or is responsible for the completion of these activities to meet functional requirements. As noted in the PCR guidelines, the purpose of the PCR is not to question Government policy and thus, the continued relevance of these functions is not under review. However, these functions do support the fundamental principles of protecting public health by ensuring that Ireland has a safe and trusted food system. The next section will consider emerging external challenges that the FSAI (and the wider food system) may face in the coming years.

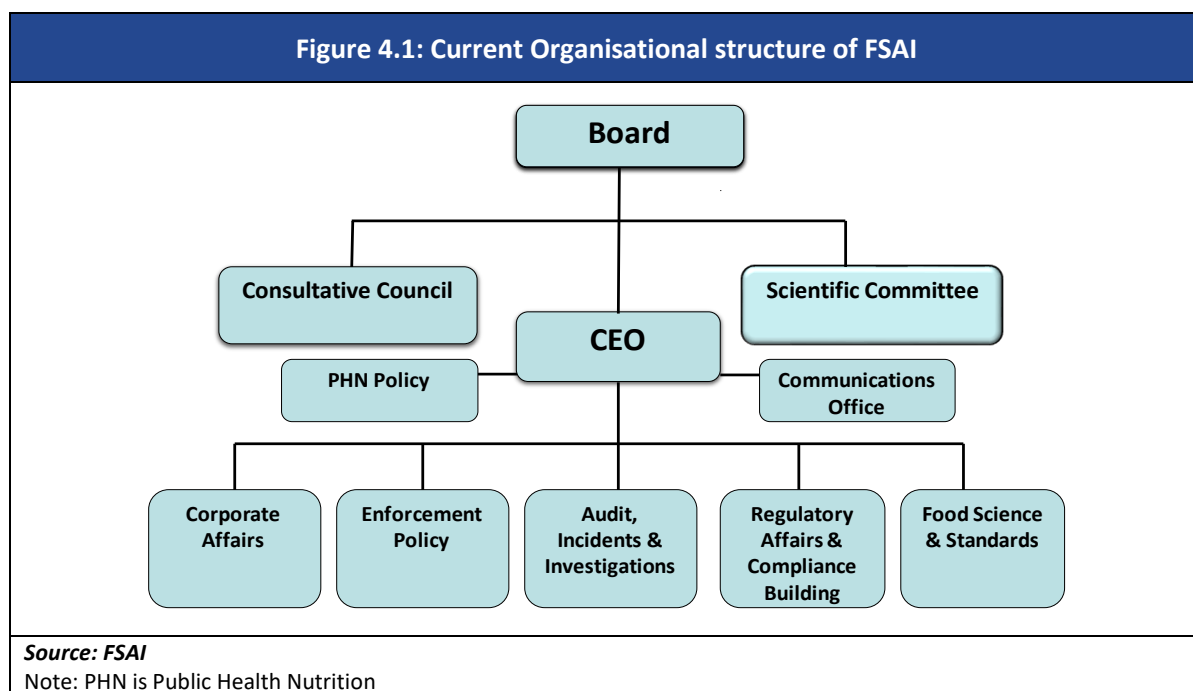
4 Assessment of Organisational Capacity and Performance

4.1 Introduction

In this section, we consider the organisational capacity of the FSAI in terms of its structure, staffing, budget, and documented procedures. These factors are important to consider when examining the organisational capacity of the organisation. This section also briefly considers the performance of the organisation which was also examined in Section 1.

4.2 Organisational Structure of FSAI

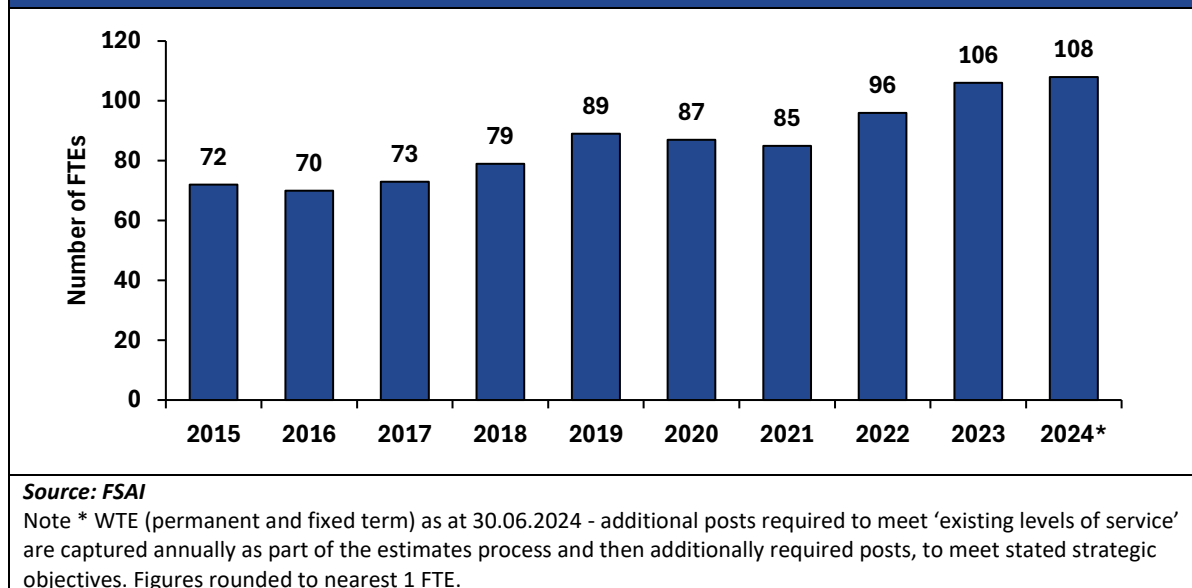
In addition to a Board, the FSAI is advised by a Consultative Council and a Scientific Committee, both of which are provided for under the legislation. The figures in Annex 1 illustrate the organisational structure for FSAI from 2011-2022. The broad structure of the authority has remained similar throughout the period. However, changes can be seen in 2012 with the addition of a Consumer Protection Division and in 2018 with the removal of the Consumer Protection Division and addition of Public Health and Nutrition Policy to report directly under the CEO, and the addition of a new Risk Management and Regulatory Affairs Division. The current organisational structure of the organisation is shown in Figure 4.1.



4.3 FSAI's Capacity

Figure 4.2 shows the number of WTEs employed by the FSAI annually, from 72 in 2015, to 108 as of June 2024, with an overall steady increase throughout the period, except for a slight decrease during the COVID-19 pandemic.

Figure 4.2: FSAI Employment 2015-June 2024* (WTEs)



As of July 2024, the FSAI employs 140 employees on various employment contracts. A breakdown of contracts by employment type is shown in Table 4.1. The majority (127) are employed on a full-time basis: 84 of which are employed on a permanent basis; 20 are on fixed-term contracts; and the remainder are students, consultants, and agency employees. Eleven are employed on a part-time basis, of which six are permanent positions. FSAI currently has an approved WTE staff complement of 112.5 WTEs plus six fixed-term contract food reformulation staff. There are also some additional student/research interns and part-time staff that make up the above approved figure.

Table 4.1: Breakdown of FSAI Employment Contracts by Type (as of July 2024)

Breakdown of contract	Agency	Career Break	Consultant	Fixed Term Contract	Permanent	SFI Fellow	Paid Student	Totals
Career break		2						2
Full-time	7		7	20	84	1	8	127
Part-time	1		1	2	6	1		11
Totals	8	2	8	22	90	2	8	140

Source: FSAI
 Note: The 108 WTE figure is based on fixed contract and permanent staff (104 full-time and 8 part-time staff)

FSAI is organised into five functional areas as well as the CEO's Office as listed in Table 4.2, where the number of current employees is shown as of July 2024. Food Science and Standards is the largest functional area with 34 employees, followed by Corporate Affairs with 31. Audit, Incidents, and Investigations employs 17 employees, Enforcement Policy has 13, Office of the CEO has 17 and Regulatory Affairs and Compliance Building employs 28. Within these six functional areas, there are 34 teams. A detailed divisional breakdown of employees at FSAI is shown in the annexes to this report. No team is assigned more than nine staff.

Table 4.2: Breakdown of FSAI Staff by Functional Area (Headcount as of July 2024)	
Functional Area	Totals
Audit, Incidents, & Investigations	17
Corporate Affairs	31
Enforcement Policy	13
Food Science & Standards	34
Office of the CEO	17
Regulatory Affairs & Compliance Building	28
Total	140
<i>Source: FSAI</i>	

Table 4.3 shows length of service with FSAI for staff survey respondents. This staff survey had a response rate of around 80%. Just over half (51.1%) have less than five years working in the Authority. About 25% of respondents have been with FSAI between 5 and 15 years; and just under 25% have been with the FSAI for 15+ years. Over half of respondents were either Technical Executives or Senior Technical Executives, highlighting the nature of the work undertaken by the organisation and the specific scientific expertise required.

Table 4.3: Number of Years Working with the FSAI	
	Proportion of Respondents
0-5 Years	51.1%
5-10 Years	22.2%
10-15 Years	2.2%
15-20 Years	5.6%
20+ Years	18.9%
Total	100%
<i>Source: Survey of FSAI Staff</i>	

This influx of new staff is largely reflective of an increase in recent retirements. As a result, new staff were hired as replacements for outgoing staff. The Annual Business Plan 2021 indicates:

“...a number of vacancies in the Authority and further vacancies will arise over the course of the year due to known retirements from the team...the Authority will prioritise vacancies in line with urgent business needs, and subsequently seek sanction to fill these posts from the DoH, whilst at the same time ensuring any new resources are cognisant of the future skills needs of the Authority.”

These staff changes are further reflected in the financial analysis which shows expenditures on pension costs for 2022 and 2023 as €396,853 and €453,000, respectively.

In the survey of staff, FSAI staff were asked for their views on how effective the Authority has been in achieving its strategic goals. Results are presented in Table 4.4. The majority of respondents (>80%) indicated the belief that the FSAI has been very effective or effective in meeting all four of its strategic goals in the areas of compliance and enforcement; science, expertise, and evidence; engagement and communications; and organisational excellence.

Table 4.4: How Effective Do You Believe the FSAI Has Been in Achieving its Strategic Goals (as identified in the Statement of Strategy)?

	Very Effective	Effective	Neither Effective nor Ineffective	Ineffective	Very Ineffective	Total
Enforcement & Compliance	37%	45.7%	12%	3.3%	2.2%	100%
Science, Expertise & Evidence	46.7%	44.6%	6.5%	1.1%	1.1%	100%
Engagement & Communications	45.7%	40.2%	8.7%	3.3%	2.2%	100%
Organisational Excellence	33.7%	46.7%	12%	4.3%	3.3%	100%

Source: Survey of FSAI Staff

However, staff assessment of the effectiveness of the FSAI in delivering on organisational excellence was slightly less positive than on the other goals, with 7.6% of respondents indicating that they believe FSAI is ineffective or very ineffective in this area.

More generally, most respondents (>90%) indicated agreement or strong agreement with the overarching purpose of the FSAI and that their role is meaningful and valuable. They have a clear sense of who benefits from their work and the work of the FSAI overall. A majority (70.7%) does not agree that the FSAI could do more with its current level of resources. Over 90% of respondents agreed or strongly agreed that they have the necessary skills to perform their job, but only 67% agreed or strongly agreed that they have the necessary resources to perform their job effectively. Most respondents (c. 80%) agreed or strongly agreed that goals, performance measures, and feedback are appropriate, measurable, and motivating factors for them.

4.4 Annual Expenditures, Income and Financial Viability

Table 4.5 shows the breakdown of FSAI annual expenditures for 2019-2023. The table shows that gross expenditure has increased by 30% over the period, with total pay and pensions growth of 41% and total non-pay expenditure growth of 24%. In the context of efficiency and appropriate use of public funds, it is important to understand the reasons for this increase and put the figures in perspective, also considering wider developments in wages and prices over the period. Table 4.5 shows that the increase in FSAI pay costs by 46% between 2019 and 2023 is driven by increases in gross basic pay, pensions and PRSI costs. This is partly driven by increased staffing, with FTE growing by 19%, as discussed in a later section (Figure 4.2). During the same period, average hourly total labour costs increased by 19%, reflecting increases in wages (for instance, minimum wage increased by 15.3%), PRSI and pension costs. This suggests that a large portion of the increase in pay costs can be attributed to increased unit labour costs, with the remainder being due to increases in staffing.

As regards the increase in non-expenditure growth by 24%, it should be noted that the period between 2019 and 2023 has been characterised by unusually high inflation, with a cumulative inflation rate of 18% over the period. This indicates that non-pay expenditure has grown only slightly above the general increase in prices over the period.

Overall, inflation and wage growth are the main drivers of increased FSAI costs over the period, with a smaller role played by increased resources. This moderate increase in resources seems to be appropriate, given that the regulatory environment in which the FSAI operates has become more demanding. While not formally altering the FSAI's core responsibilities, developments such as the Official Controls Regulation (EU) 2017/625, post-Brexit regulatory changes, the General Food Law Regulation (EU) 2019/1381, and the European Green Deal (including the Farm to Fork Strategy) all have contributed to increasing the workload and complexity of the FSAI regulatory oversight.

These developments have led to a natural progression in the FSAI's functions, aligning with its mandate to protect public health and consumer interests in Ireland. This progression is a necessary response to the dynamic nature of food safety and public health requirements, rather than an uncontrolled expansion of scope.

It must be noted that the expenditure on the Local Authority Veterinary Service (LAVS) has been transferred to the Department of Agriculture, Food and the Marine (as of 1st January 2025). This would have reduced the expenditure in 2023 to under €15 million. Of this, 57% of expenditure relates to existing staff costs. The other main expenditure categories include recruitment, IT and Rent. The recruitment category includes expenditure on employing agency staff.

The vast majority of FSAI's income comes directly from the Exchequer (via the standard budgetary process). In addition to this, the FSAI has a small number of other income sources such as sale of publications and training. It also gets additional funding from the Department of Health to support capital projects. Currently, it also receives distinct funding from the DoH in relation to reformulation. This funding is provided to complete specific tasks for the DoH which is governed by a separate Service Level Agreement. FSAI also received funding from delivery of EU research projects and EFSA and can generate small income sources through providing expertise to other countries in relation to various aspects of food safety. The work that the FSAI has done in conjunction with DAFM in Albania would come under this category.

It must be noted that the FSAI does not charge Food Business Operators (FBOs) to complete any part of the food safety compliance process such as registration, inspection, compliance, or certification. Some other competent authorities charge the FBOs to complete some of these tasks. Similarly, the Health Products Regulatory Authority (HPRA) charge fees to cover the cost of some of the services it provides. It must be noted that there is a strong rationale for the current funding model. Charging for

these services could lead to unintended consequences of small business not registering with FSAI and potentially putting unsafe food on the domestic market.

Table 4.5: FSAI Breakdown of Annual Expenditures and Income 2019-2023 (€ 000s)					
	2019	2020	2021	2022	2023
Income					
Oireachtas Grant	16,357	17,536	19,959	19,091	21,077
Other Income Operating Income	1,051	981	1,532	2,162	1,848
Operating Income	17,408	18,517	21,491	21,253	22,925
Total Income	17,408	18,517	21,491	21,253	22,925
Expenditure					
Administration, Operations & Promotion	9,723	9,697	10,655	11,326	13,366
<i>Of which: Remuneration and other Pay Costs</i>	<i>6,307</i>	<i>6,327</i>	<i>6,832</i>	<i>7,377</i>	<i>8,900</i>
Communications activities	449	369	384	372	373
Depreciation of Fixed Assets	642	619	613	719	590
Albanian Project	565	499	769	1,267	867
Reformulation Taskforce	-	-	148	272	383
Local Authority Veterinary Service	6,205	6,923	8,090	6,962	7,275
Total Expenditure	17,584	18,107	20,659	20,918	22,854
Surplus/(Deficit) for Year before appropriations	(176)	410	832	335	71
<i>Source: FSAI Annual Reports</i>					

The DoH operational grant (€21.8 million in 2024) comprised about 95% of gross income (€23.1 million) for FSAI. Operating expenditures comprised 65% of gross expenditures, with a significant portion (33%) going to LAVS.²⁷ Expenditures on corporate affairs was just over €7 million, with the Food Science and Standards, and Regulatory Affairs and Compliance building areas ranking next in line at just over €2 million each. Enforcement Policy and Audits, Incidents and Investigations functional areas spent €1.3 million and €1.2 million, respectively.

4.5 Business Planning and Reporting

The FSAI Business Plan for 2024 was approved by the Board in December 2023 and was then forwarded to the DOH. Upon approval, a letter of allocation was received by the FSAI, confirming resourcing assumptions underpinning the plan. Quarterly reporting mechanisms are in place to monitor progress.

The 2024 FSAI Business Plan details the key goals, objectives, deliverables, and key performance indicators to be achieved over the year. The plan was developed in line with the FSAI Business Planning and Reporting Lifecycle and is based on the FSAI Strategy 2019-2023 (extended to 2024) which is organised around four overarching goals, including 4-5 objectives associated with each goal and 1-9 deliverable actions under each objective. Specific core activities and development projects

²⁷ Funding for LAVS has moved (as of 1st January 2025) to the Department of Agriculture, Food and the Marine when that function formally transitions to the Department.

are noted as performance indicators associated with each deliverable action. Goals and objectives are shown in Table 4.6.

As the parent department, the DoH oversees the FSAI's strategic direction as well as delivery. In addition to the approval of the FSAI's Board members, the DoH approves the FSAI strategic plans and monitors implementation on a regular basis. A performance delivery assessment process is in place in the form of regular reporting of clear and specific KPIs.

The FSAI's 2024 Corporate Governance Framework explains:

"The annual business plan is developed by the Chief Executive, in conjunction with Senior Management and staff and contains a summary of the deliverables, activities and outputs for the year ahead. Each corporate goal is also allocated performance indicators and measurable outputs are defined in order to assess performance. The functional area work plans are developed within each functional area of the FSAI in consultation with the Chief Executive. The functional areas are responsible for the operational activities in the areas of service contracts, food science and standards, audit and compliance, consumer protection and corporate services. This planning focuses on defining the work activities, processes and procedures needed to carry out the FSAI's overall principal functions and achieve key objectives."

The business planning and performance delivery assessment process in the FSAI is an example of good practice, as performance indicators are listed clearly and distinguished in terms of core activities (i.e., of a regular, ongoing nature) or development projects (e.g., research, publication, planning, IT improvements, etc.). Details of performance indicators are clear and concise.

The Business Planning and Reporting Lifecycle requires regular management reporting to the Board. FSAI issues quarterly reports to the DoH, indicating whether progress is in line with the business plan. Each quarterly report is presented by FSAI management to the Board, and then issued to the DoH for discussion as part of the DoH Governance meetings. The RAG (red, amber, green) status method is used as part of the quarterly reporting, with exception reporting for any items that are not green in terms of progress. This is an effective method of highlighting areas of slippage for immediate focus, oversight, and attention. The Risk and Opportunities Register is updated regularly throughout the year as part of this process and included in the quarterly reports to the DoH.

The Indecon assessment is that the current specification of goals, objectives, deliverables, and key performance indicators are in line with the current FSAI Strategy and are supported by robust oversight processes including quarterly reviews and quantifiable KPIs for outcome measurement.

Table 4.6: Priorities and Goals of the FSAI Business Plan 2024

Goals	Objectives
1. Enforcement & Compliance: to enforce food law and increase compliance, in collaboration with our regulatory partners, through a world-class food control system	1.1 Lead and support Ireland's food safety regulators to implement a fair, consistent, and effective system of enforcement
	1.2 Manage risks in the food chain and respond effectively to any national or international food incident or crisis
	1.3 Ensure the safety, integrity, and authenticity of the food chain by detecting, deterring, and preventing breaches of food law, and taking action to protect consumers
	1.4 Strive for a world-class official food control system for Ireland which delivers the best outcomes for consumers
2. Science, Expertise, & Evidence: to advance food safety and integrity through independent science, expertise, and a strong evidence base	2.1 Support risk-based decision-making and policy with high-quality, independent expertise
	2.2 Expand the evidence base through research, coordinated studies and scientific collaboration
	2.3 Advance risk assessment practice to promote trust and engagement
	2.4 Grow our ability to identify emerging risks and threats to the food chain
	2.5 Influence the development of food standards and enforcement approaches at European and international level
3. Engagement & Communication: to be a leader in the safety and integrity of food through communication, partnership, collaboration, and advocacy	3.1 Provide clear and evidence-based advice and information to promote food safety and build compliance with food law
	3.2 Work in partnership with Government, other State agencies, academia, and civil society organisations to champion food safety within Ireland
	3.3 Collaborate with key stakeholders to foster and promote a culture of food safety and compliance within Ireland's food industry
	3.4 Improve our capacity and capability by working with others to advocate for safe and trustworthy food for everyone
4. Organisational Excellence: to empower our people, strengthen our systems, and develop our culture to achieve organisational excellence and maximise our impact	4.1 Ensure a high-performing and empowering culture for our people, built on innovation, shared values, and teamwork
	4.2 Provide a robust and targeted information framework to deliver internal efficiencies and meet stakeholder and customer needs
	4.3 Ensure that our governance structures support informed and accountable decision-making underpinned by responsive leadership, risk management processes and compliance
	4.4 Embed a culture of quality through ensuring that systems, processes, and procedures meet the highest standards
	4.5 Enhance recognition of the FSAI's identity, influence and reputation among staff, stakeholders, and customers

Source: FSAI Business Plan 2024

4.6 Documented Procedures

The FSAI is accredited to ISO 9001:2015 Business Management Standard, and currently relies on a set of 180 documents laying out formal procedures for employees to follow when performing duties. These cover a range of investigation and enforcement activities, including the audit and investigations processes, as well as biological and chemical safety risk assessments. Notification processes relating to food and allergen alerts, infant and follow-on formulae, total diet replacements, supplements, and foods for special medical purposes are individually documented.

Technical/scientific advice on food sampling and laboratory services are documented as well as training and development procedures. This includes external laboratory consultants when required. Templates for each of the enforcement actions are provided to ensure accuracy and consistency of records. Compliance points with international standards and EU requirements are also documented.

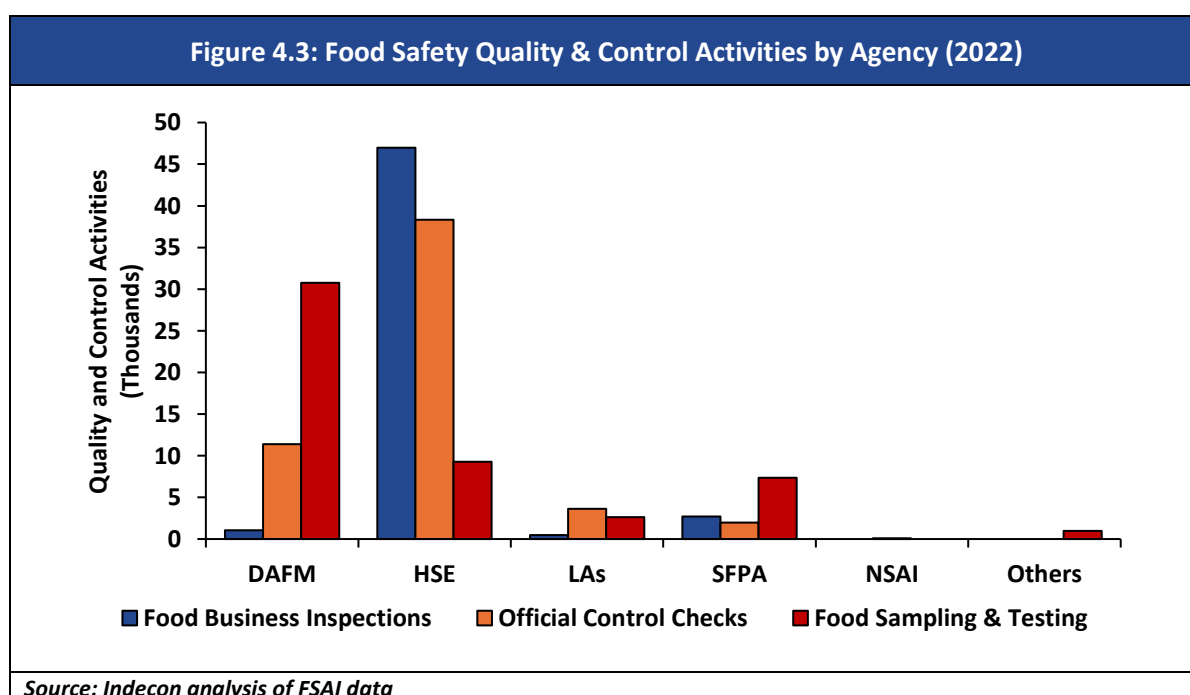
Internal administrative processes such as quality assurance, audit, recruitment, budgets, payroll, and travel/mileage reimbursements are also clearly documented. Additionally, communications procedures are set forth in documents relating to press releases/queries, website content, Advice Line handling of queries and complaints, and responses to parliamentary questions. Legal procedures are fully documented regarding prosecutions as well as legal opinions. Finally, documents relating to training and management procedures, document control, and management review ensure a complete and consistent application of overall project management and ensure quality of FSAI outputs.

4.7 Oversight Relationships

Service Contracts

As outlined in Section 1.2 of this report, the Food Safety Authority of Ireland is the competent authority with overall responsibility for the enforcement of food legislation in Ireland and manages this remit through service contracts with a network of Official Agencies, including the Health Service Executive (HSE), Department of Agriculture, Food and the Marine (DAFM), Local Authorities (LAs), and the Sea-Fisheries Protection Authority (SFPA). The Authority also reports on the agencies' activities and seeks continuous improvement and accountability through a programme of regular audits.

Figure 4.3 illustrates the numbers of food safety quality and control activities performed in 2022 by the agencies responsible for reporting to the FSAI. The HSE was the most active agency, with over 45,000 inspections of FBOs; nearly 40,000 official control checks; and almost 10,000 food sampling and testing services. The DAFM was the second most active agency, with the majority of its food safety activities in the food sampling and testing category (approx. 30,000); and over 10,000 official control checks.



It must be noted that there is no funding provided by the FSAI to these Official Agencies²⁸ and each official agency completes their food safety activities within their own Departmental/Agency budget. Thus, FSAI has no budgetary levers to enforce if an official agency completes fewer inspections than agreed in the oversight agreement. There is a continued need to ensure that there is harmonisation in the application of food law across each of the Official Agencies. The FSAI uses the service level agreements/service contracts to support this objective.

Each Official Agency (OA) has an SLA with the FSAI, which must also develop an Annual Control Plan on how they will implement the official controls. These plans are prepared and reported upon in line with the Code of Practice for the Governance of State Bodies. These OAs then provide data on how they have implemented the official controls (such as number of inspections) and these reports are sent to FSAI who then co-ordinate the production of the annual Multiannual National Control Plan (MANCP) report which is sent to the European Commission.

Indecon notes that there are some differences in the Service Level Agreements between the FSAI and the various Official Agencies. There are also some differences in when these SLAs were originally developed. Many of these SLAs were originally developed a number of years ago, but have since been updated. The FSAI can choose such an approach but there may be merit in reviewing these SLAs and consider if they are still suitable and consistent with the latest EU and national policies. There may also be scope for some of these SLAs to have specific KPIs. We note, for example, that the SPFA SLA has two very specific KPIs around the time taken for samples to arrive at laboratories and the number of samples taken each year. Similarly, some SLAs explicitly outline the number and type of meetings that will be held between the OA and the FSAI.

4.8 Performance Metrics

Key Performance Indicators for 2024 are as set out in the 2024 Business Plan, are reported on quarterly and at year end.

As set out in Section 4.5 above, the business planning process in the FSAI is an example of good practice, as performance indicators are listed clearly and distinguished in terms of core activities (i.e., of a regular, ongoing nature) or development projects (e.g., research, publication, planning, IT improvements, etc.). Details of performance indicators are clear and concise.

The Business Planning and Reporting Lifecycle requires regular management reporting to the Board. Quarterly reports indicate progress is in line with the business plan. The RAG (red, amber, green) status method is used as part of the quarterly reporting, with exception reporting for any items that are not green in terms of progress. This is an effective method of highlighting areas of slippage for immediate focus, oversight, and attention. The Risk and Opportunities Register is updated regularly throughout the year as part of this process.

As noted previously, performance metrics are also an important part of the annual MANCP reporting process. Metrics also outlined in each of the Annual Control Plans developed by each of the Official Agencies.

Indecon's assessment is that this reporting model is effective and provides clear and relevant performance metrics to both the Board and the Department.

²⁸ Except for the funding provided historically for the LAVS and currently to the NSAI in respect of Food Contact Materials.

4.9 Summary of Main Findings

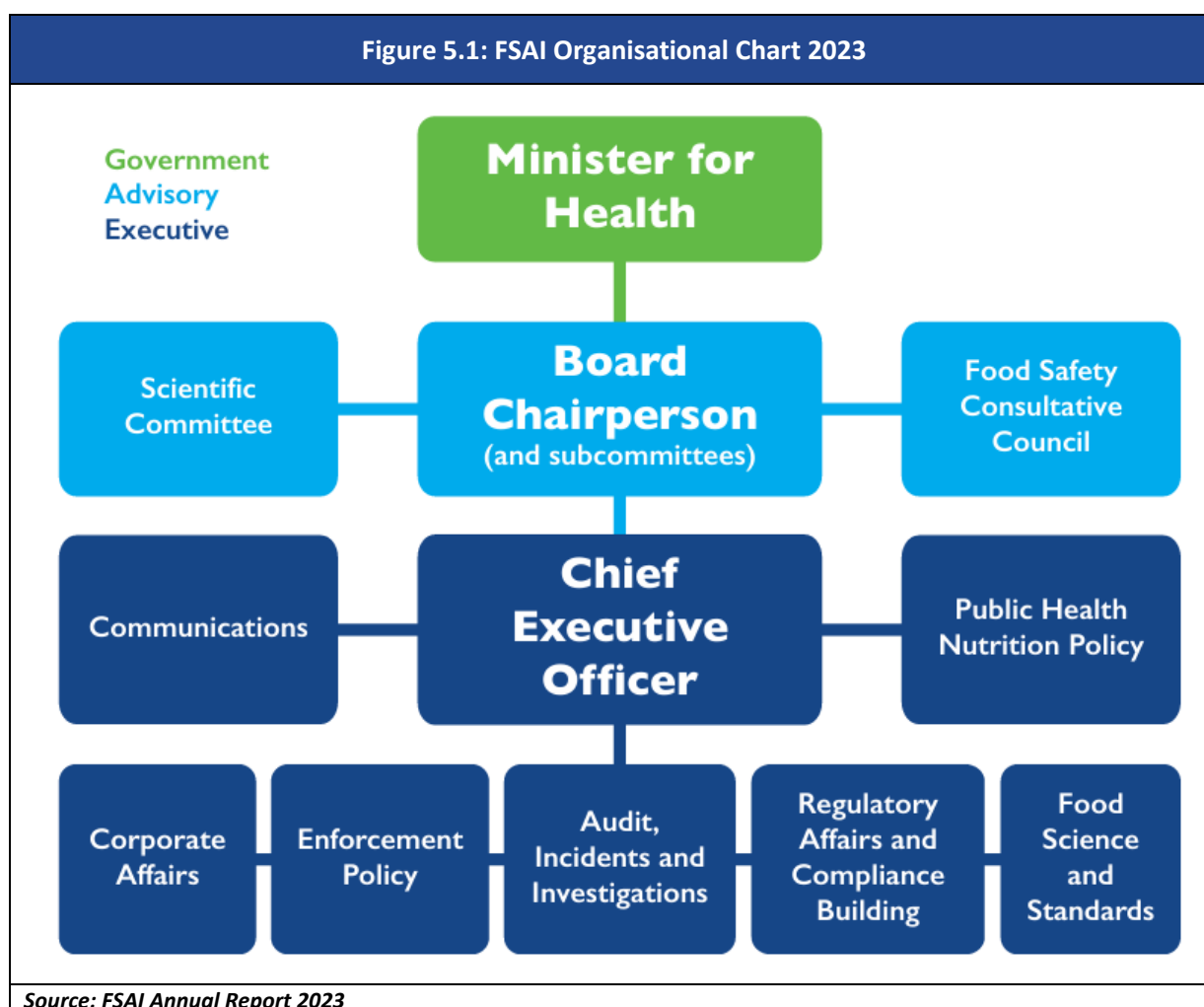
FSAI's organisational capacity was assessed by reference to the structure of the agency, the budget and number of staff allocated, the documented procedures undertaken, and the Agency's business planning process. The main findings were as follows:

- The capacity of the FSAI as an organisation has been strengthened in recent years.
- There is some reliance within FSAI on contracted staff to fulfil day-to-day business requirements.
- The review noted the broadly positive view of stakeholders with regard to the FSAI's capacity to deliver. Indecon's survey of FSAI staff found that:
 - A majority of respondents (63%) felt that the work across their area is evenly and fairly distributed;
 - 67% of respondents agreed or strongly agreed that they have the resources needed to perform their job effectively; and
 - 91% of respondents indicated that they believed they had the necessary skills to perform well in their FSAI role.
- The quality of scientific expertise of FSAI (in relation to food science) was noted by many stakeholders.
- The present FSAI organisational structure appears appropriate but may be subject to change when a new CEO is appointed and/or strategy is updated.
- The importance of effective communications and stakeholder engagement is recognised within the current organisation structure (reporting to CEO).
- The positioning of the Public Health Nutrition policy unit (reporting to CEO) may need future consideration.
- The current Functional Area structure clearly aligns with the core functions of the FSAI.
- One core role of the FSAI is the management of service contracts with seven Official Agencies.
- The transfer of the LAVS to DAFM is a positive move that will give the FSAI as the competent authority greater focus and emphasis on its overarching legal, regulatory and enforcement mandate as well as creating a single veterinary service for the State leading to greater efficiency and effectiveness of controls.
- FSAI has recently undertaken some food safety-related activities outside its core functions. Where requested to do so, these project-based activities should be clearly defined and resourced appropriately.

5 Governance and Oversight

5.1 Introduction

In this section of the report, we consider governance arrangements at the FSAI including the governance relationship with the DoH as well as the internal operation of FSAI and its executive functions. Core responsibilities of the Board include financial and risk oversight which we also review. The Authority comes under the aegis of the Minister for Health, and has a Board which is advised by the Scientific Committee and Food Safety Consultative Council, with the CEO as a direct link to the FSAI Board.²⁹ See Figure 5.1. A set of historical organisational charts for the FSAI can be found in Annex 1 of this report.



²⁹ FSAI Annual Report 2023

5.2 Corporate Governance Framework

The most recent Corporate Governance Framework (CGF) for the FSAI was published in June 2024 and so has been recently reviewed. The Framework provides details of the governance of the Authority as follows:

- Overview of the Authority’s mission, values, and functions;
- Governance structure of the Authority and its responsibilities;
- Business planning, management and financial control processes present within the Authority;
- Risk management framework in place within the Authority;
- Standards of behaviour expected by the Authority;
- Relationship in place between the Authority, the Minister for Health, and the Oireachtas; and
- Supporting documentation.

The document provides a useful reference for all matters relating to the governance of the FSAI. The CGF includes a commitment to effective Information Governance, in line with the relevant legislation governing freedom of information, data protection, and access to information on the environment.

It also sets out the reserved functions of the Board, emphasises the importance of collective responsibility and the roles of the committees under the auspices of the Board.

The Corporate Governance Framework sets out the human resources management structures in place within the Authority; the financial management and control measures in place to support the achievement of value for money; the system of internal controls; remuneration; procurement; asset management; and tax compliance. The CGF also sets out the Code of Conduct for the Board and staff of the FSAI. The CGF references the External Committees of the FSAI – the Scientific Committee and the Food Safety Consultative Committee - and includes details of how the members of these committees are appointed in accordance with the relevant legislation. The Chair of the Scientific Committee is a member of the Board and so the Code of Conduct applies to them. Indecon believes that the CGF is a comprehensive governance document which clearly sets out the internal oversight structures in the organisation.

5.3 Role, Functioning and Effectiveness of FSAI Board

Under S31(1) of the FSAI Act 1998, the Board of the FSAI is required to direct and carry out the functions of the Authority, satisfy itself as to the adequacy of the systems in place for that purpose, and otherwise manage and review the workings of the Authority. The FSAI Scientific Committee provides scientific advice to the Board, including on the nutritional value or content of food, and collaborates in evidence-based research.

The FSAI complies with the *Code of Practice for the Governance of State Bodies* (2016) and continues to focus upon improving its governance structures and Board effectiveness, and ensuring on-going compliance with the Code of Practice 2016. The FSAI Board conducts an annual review of its effectiveness and a separate review of the effectiveness of the Audit and Risk Committee, which includes any matters arising from a review of internal audits conducted during the year. Where enhancements to governance arrangements are identified through this process, these will be presented to the FSAI Board and the DoH where appropriate.

The Board ensures that there is efficient and effective use of the financial and staff resources assigned to it in order to meet the FSAI's stated objectives. Senior officials of the DoH meet with the CEO and Chairman of the FSAI Board to discuss issues, including progress towards achieving strategic goals and objectives, policy developments review of the OA/PDA, and to strengthen the relationship between the two organisations. Officials from DoH meet with the FSAI on a quarterly basis to review progress towards completing the objectives outlined in the Annual Business Plan. Useful governance reports are prepared by the FSAI to support these engagements.

Achievement of business plan objectives and key performance measures are monitored by the Board and its committees and documented in quarterly progress meeting reports.

The FSAI Board operates its effectiveness reviews on a 3 year cycle - in years one and two, it undertakes a self-assessment survey. In the third year of the cycle it engages the services of an external independent consultant to undertake the review. Each year, when the results of the review are received, they are shared with the Board and an action plan is agreed and implemented in full. It is worth noting that the 2023 and recent 2024 survey results showed a marked improvement across all areas.

Navigo Consulting was appointed by the Board of the Food Safety Authority of Ireland (FSAI) to perform an independent and externally facilitated Board effectiveness review. The review was completed in May 2023.

The work was based on surveying and interviewing Board members across the themes of:

- Leadership
- Ethical standards
- Compliance
- Oversight role
- Collective responsibility
- Board behaviours
- Overall assessment of Board and committees

The process was based on the questionnaire in the *Code of Practice for the Governance of State Bodies* (2016) and included some additional questions on emerging governance areas. Overall, the review found that the Board is generally effective and highlighted the following positive findings:

- Committed and engaged Board that contributes its expertise to good effect;
- Good capability in management group (recently added);
- Strength in many of the fundamental structures, processes, and behaviours; and
- A respected and skilled Chair.

The report also identified a number of dimensions on which it could improve in terms of effectiveness and efficiency. These are set out in Table 5.1.

Table 5.1: Improvement Opportunities Identified (2023)	
Areas in which average score <3.7 identified as improvement opportunities	Ave. score*
1. Sufficient flow of information from management to allow Board to assess achievement of objectives & plan to get back on course to achieve objectives	3.5
2. Strong accountability framework & culture within executive management (reliability of duty fulfilment to provide information to Board, explain decisions & “own” outcomes)	3.5
3. Satisfaction with quality of Board papers/minutes (clear & concise re key issues, setting out decisions/actions required)	3.5
4. Satisfaction with written oversight agreement w/the Department which defines FSAI’s relationship w/DoH & Minister	3.38
5. Sufficiency of Board agenda & work to focus on climate & sustainability matters	3.25
6. Satisfaction w/overall effectiveness & efficiency of Board meetings held remotely	2.63
Source: Navigo Consulting for FSAI, May 2023	
Note: *Average score out of possible maximum of 5.0	

As part of this review, Indecon examined minutes from FSAI Board meetings to assess the follow-up response to the identification of improvement opportunities listed above. We note the following:

1. Sufficient flow of information from management to allow Board to assess achievement of objectives and plan to get back on course to achieve objectives:
 - Minutes from the June 2023 Board meeting indicate that the Board agreed that the FSAI Board and SLT should have an ‘away day’ to focus on the respective roles of the Board and SLT; clarify reporting and accountability expectations; and discuss the concept of a high performing organisation by a facilitated session. This was scheduled as workshops to be incorporated with the Board’s scheduled meeting in October.
 - Minutes from the October 2023 Board meeting indicate the Board/SLT workshops took place 23-24 October 2023. This resulted in the scheduling of four workshops to be held by management during the development of the strategy. Board members were invited to attend one or more of the workshops according to their areas of expertise/interest. Workshops were scheduled for November 2023, February 2024, March 2024, and April 2024 and included topics were: identifying challenges; strategic direction and guiding policy; testing, resourcing, and implications; and review of advanced strategy draft. A poll was circulated to Board members to facilitate their participation across the workshops.
2. Strong accountability framework and culture within executive management (reliability of duty fulfilment to provide information to Board, explain decisions and “own” outcomes):

- Minutes from the May 2023 Board meeting indicate that a values framework was in the process of being updated. This item remained on the action list at subsequent Board meetings until March 2024, when, due to time constraints, the values framework document was circulated by email link and Board members were invited to track any changes or comments.
- 3. Satisfaction with quality of Board papers/minutes (clear and concise regarding key issues, setting out decisions/actions required):
 - Minutes from Board meetings in May and June 2023 indicated draft of minutes will be shared for comment prior to issuance to ensure accuracy and clarity, and that, “any draft minutes amended by the Board would be forwarded to the Chair for final approval prior to posting.” October 2023 minutes indicate all items on action list are to be timebound going forward. December 2023 minutes reflect that minutes from the prior meeting were emailed in advance and confirmed/approved in advance of the meeting.
- 4. Satisfaction with written oversight agreement w/the Department which defines FSAI’s relationship w/DoH and Minister:
 - Minutes from the June 2023 Board meeting indicated that a draft of the Oversight Agreement was shared and circulated for comment. There were no additional references to OA/PDA on Board meeting action lists until May 2024, when minutes indicate, “The Chair and CEO will request a meeting with DoH to discuss the OA/PDA the new strategy and holding regular such meetings with the DoH will assist with strengthening the working relationship.”
- 5. Sufficiency of Board agenda and work to focus on climate and sustainability matters:
 - Board meeting minutes from June 2023 indicate a presentation would be made to the Board by year end relating to environmental, climate, and sustainability issues identified in the Board Effectiveness Review. Minutes from the Board meeting in December 2023 indicate this was deferred to May 2024, when this presentation was held. Minutes indicate that the “Board expressed their support for the proposed plan” and indicated that a progress report should be made at a future Board meeting. Additionally, the Board requested that the planned actions contain timelines for implementation.
- 6. Satisfaction w/overall effectiveness and efficiency of Board meetings held remotely:
 - January 2024 Board meeting minutes reflect apologies for moving meeting from in-person to online as this was due to illness. Attendees were notified in advance to give time for them to adjust plans. Other meeting minutes from 2024 did not indicate attendees participating via videoconference.

The views of stakeholders were positive towards the FSAI Board and the proactive role of the Board in the current strategy development process was noted. Sometimes, the DoH will deal directly with the Executive and issues are resolved before the following Board meeting. This is an effective approach given the types of dynamic issues that may arise and need to be dealt with promptly.

The 2024 results of the Board Self-Assessment Evaluation Questionnaire indicate that progress was made in several areas noted as needing improvement in the 2023 report, namely:

- Board indicated slight improvement in satisfaction with strategic aims and optimal use of resources to meet its objectives (score: 3.7);
- The Board indicated slight improvement that the State body’s mission and vision have been defined and communicated to all levels of the organisation (score: 3.8);
- Board indicated satisfaction with its key role in setting ethical tone (score: 4.3);
- Board indicated improved satisfaction with written oversight agreement and its clearly defined terms (score: 4.1);
- Board indicated improved satisfaction with sufficiency and effectiveness of board meetings (score: 4.7); and
- Board indicated improved satisfaction with meeting agendas and related material (score: 4.4).

This improvement in the scores indicates that there has been an increase in the satisfaction of the Board in relation to these issues.

5.4 Risk Management Policy

A Risk Management Policy Document was provided to the PCR Team which includes details of the risk management framework in place in FSAI and the roles and responsibilities of the Board, the Audit and Risk Committee, the Chief Risk Officer, Internal Audit, members of the Senior Leadership Team, as well as the responsibility of all staff to identify and report risks to their line manager. The Chief Risk Officer is appointed and reports directly to the Board and its Audit and Risk Committee (ARC) on all risk management issues, and an external review of the effectiveness of the risk management system is completed on a regular basis (at least every three years).

The FSAI Risk Management Policy (June 2024), defines risk in a governance context according to the ISO Standard (IS) 31000: 2009 Risk Management – Principles and Guidelines), as “the effect of uncertainty on objectives.” Effects can be positive or negatives, and objectives can relate to various levels and aspects of the organisation, such as financial, health and safety, or strategy.

A Risk Appetite Statement has been approved by the Board, setting out the risk appetite across all strategic goals and objectives of the FSAI, in addition to a Risk and Opportunities Register. The framework for the Risk Appetite Statement is shown in Figure 5.2. This is in accordance with the key elements of the Board’s oversight of risk management as set out in the *Code of Practice for the Governance of State Bodies*.

Figure 5.2: FSAI Risk Appetite Statement Framework

Assessment	Description
High Risk Appetite	The FSAI accepts opportunities that have an inherent high risk that may result in reputational damage, financial loss or exposure, major breakdown in information system or information integrity.
Medium Risk Appetite	The FSAI is willing to accept some risks in certain circumstances that may result in reputational damage, financial loss or exposure, major breakdown in information system or information integrity.
Low Risk Appetite	The FSAI is not willing to accept risks in most circumstances that may result in reputational damage, financial loss or exposure, major breakdown in information system or information integrity.
Zero Risk Appetite	The FSAI is not willing to accept risks under any circumstances that may result in reputational damage, financial loss or exposure, major breakdown in information system or information integrity.

Source: FSAI Risk

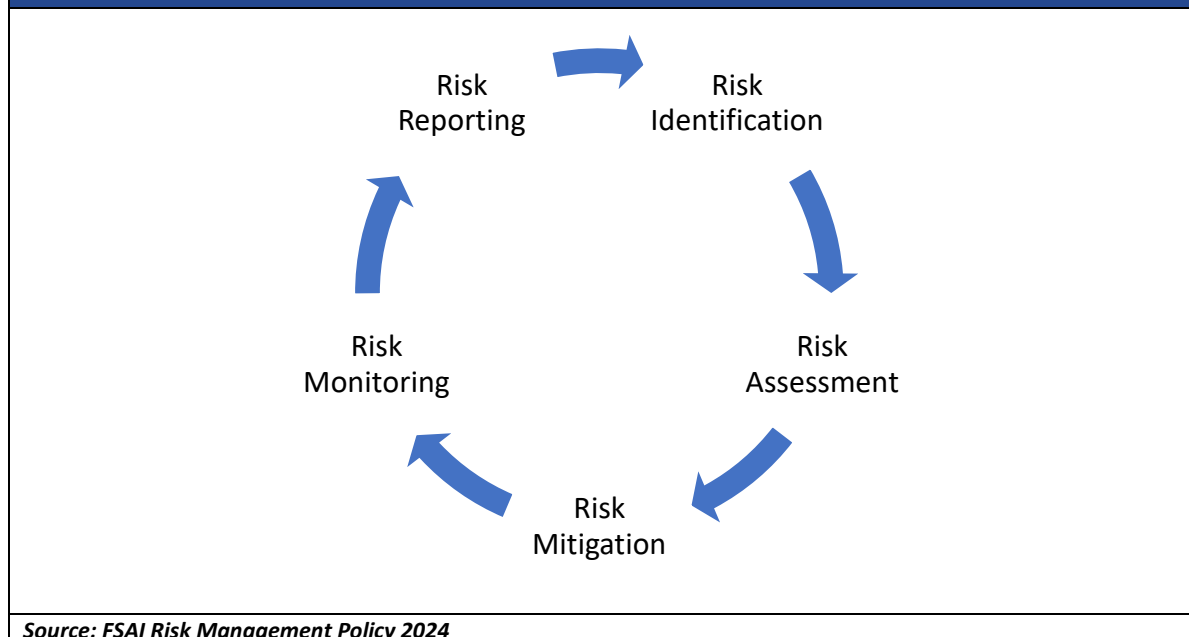
The Board is required to establish the FSAI's risk tolerance and issue a Risk Appetite Statement which outlines the tolerance for risk across its four strategic goals. The risk management system involves the identification, classification, and control of events and activities to which the Authority is exposed. Figure 5.3 illustrates the FSAI risk management system.

The FSAI maintains a Risks Register which is updated regularly and submitted to the DoH as part of the quarterly governance update.

Risks are identified through regular monitoring throughout all units. They are assessed and evaluated as to their potential impact by those involved in managing identified risk areas. Once risks have been identified, analysed, and reported, they are ranked in order of likelihood and potential impact, with an outline of key mitigating measures. Risk mitigation may involve "the four T's": treat, tolerate, transfer, or terminate. FSAI policy requires risks to be categorised as follows:

- Strategic: Risks arising from external factors, such as economic climate, key stakeholder relationships;
- Operational: Significant risks which relate to, or derive from, the FSAI's operational activities including critical procedures or technologies;
- Financial: Risks which could give rise to a financial loss including reduction in DoH allocation or other external funding;
- Reputational: Risks to the reputation of the Authority; and
- Legal and Regulatory: Failure to comply with laws, legislation or regulation as well as damages or compensation claims.

Figure 5.3: FSAI Risk Management System



The Chief Risk Officer and rest of the Senior Leadership Team ensure that all staff and stakeholders are aware of risk issues and develop a risk register to document risk mitigation strategies used in response. The risk register is regularly reviewed by the Senior Leadership Team and the Audit and Risk Committee, which reports regularly to the Board.

Section 2.3 of the FSAI Business Planning and Reporting Lifecycle (2024) states:

“Aligned to Risk Management Framework, the FSAI Board approved the Risk Appetite Statement (RAS) in 2023 and, in addition, the FSAI maintains a Risk and Opportunities Register (ROR). The objective is to ensure that the FSAI has an effective risk management system which involves a cycle of identifying risks, evaluating their potential consequences and determining the most effective methods of responding to them (i.e. of reducing the chances of them occurring and reducing the impact if they do occur). The cycle is completed by a system of regular monitoring and reporting. The identification, management and monitoring of risks is aligned to the development of the organisations business plans, should be considered as part of reviewing progress, identifying priorities and to the assignment of the FSAI’s resources. To this end, the ROR is updated by the SLT throughout the year and it is a standing item for consideration at each Board, ARC and DoH Governance meeting.”

The corporate Risk Register is regularly reviewed by the SLT and the Audit and Risk Committee, as part of their governance and management obligations. It shows each identified risk, along with an assessment of its likelihood and potential impacts being faced. Risks are ordered and ranked from highest risk/impact to lowest. Risk mitigation measures are listed and put into place where possible, although some risks may be outside the control of the FSAI. Risk mitigation measures are classified as the “Four T’s”: Treat, Tolerate, Transfer, or Terminate, according to appropriateness and likelihood of successful mitigation.

Figure 5.4 shows the structural organisation of the Authority as it relates to risk management. The Risk Management Policy contains detailed instructions and templates for recording, monitoring, and

mitigation of risks under the terms of the policy, providing a clear and straightforward process for implementation.

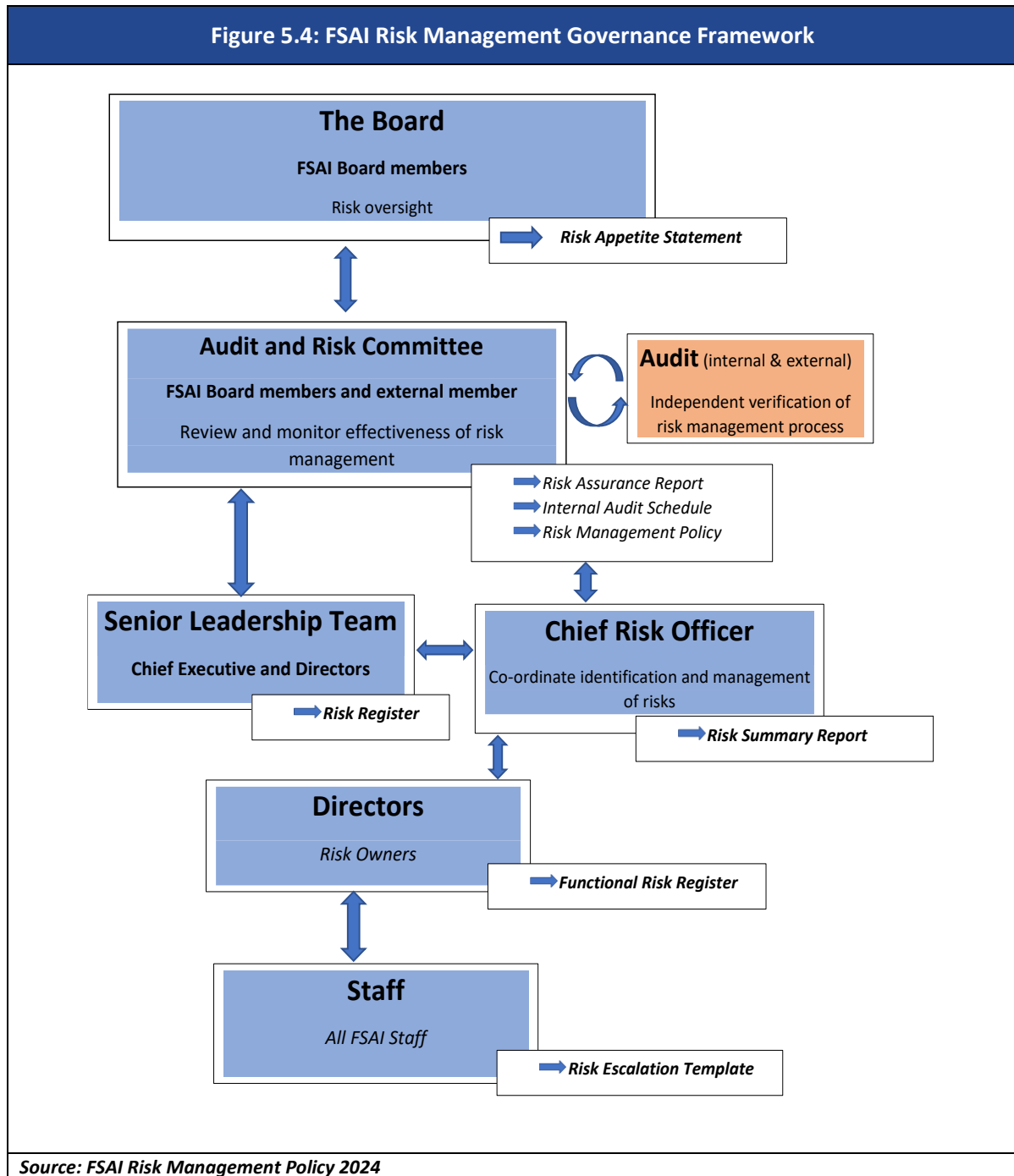


Table 5.2: Risk Management Responsibilities by Organisational Structure

Organisational structure	Responsibilities
The Board	The Board shall approve the risk management framework, policy and systems, and is responsible for providing oversight to the risk management process within the FSAI. Key elements of the Board's oversight of risk management includes: • Assume ownership of Board level risks. • Make risk management a standing meeting agenda item. • Establish and oversee the Audit and Risk Committee. • Ensure that there is risk management experience/expertise in the competencies of at least one board member. Where composition of the Board does not provide for this, expert advice should be sought externally. • Approve the Risk Management Policy, set FSAI's risk appetite, and approve the Risk Management Business Plan and Risk Register at least annually. • Review the Audit and Risk Committee's reporting on risk management and note/approve actions as appropriate. • Ensure that external review of the effectiveness of the risk management framework is undertaken on a periodic basis. • Ensure that risk management is implemented at all levels within the FSAI. • Provide confirmation in the Annual Report that the Board has carried out an assessment of the FSAI's principal risks.
FSAI ARC	The Audit and Risk Committee is responsible for reviewing and agreeing the processes for managing risk. The Committee has risk management as a standing agenda item at its meetings and exchanges information with the Board, Internal Audit and the Chief Risk Officer regarding the effectiveness of the risk management framework. This role includes: • Review material risk incidents via the Risk Registers and address management's actions, as appropriate. • Review Risk Summary Reports and monitor the effectiveness of risk management. • Develop and approve the Internal Audit Plan and all amendments/revisions to same. • Review the Risk Management Policy (and supporting templates) and all amendments/revisions to same. • Provide guidance to the Internal Audit Function focusing on key areas for review.
Chief Risk Officer	The Chief Risk Officer, who reports to the Board in this role, co-ordinates the identification and management of risks. This role includes: • Provide a summary report to the Audit and Risk Committee on strategic risks facing the FSAI and issues impacting the FSAI's risk environment. • Oversee compliance with this policy within the FSAI.

	• Attend meetings of the Audit and Risk Committee. • Report directly to the Board, as necessary • Coordinate the identification and management of risks. • Provide guidance to risk owners regarding the identification and management of risks. • Escalate risks to the Senior Leadership Team, Finance, Audit and Risk Committee and Board, as appropriate.
Internal Audit	Internal Audit, who report to the Chair of the Audit and Risk Committee, will provide a quarterly (or as required) report to the Audit and Risk Committee on the effectiveness of organisation risk management generally, or specific aspects of same. This role helps to ensure key business risks are being managed appropriately and that the system of internal control is operating effectively.
SLT	The Senior Leadership Team assumes primary responsibility for the identification of organisation risks and the implementation of actions in the Functional Risk Registers and Strategic Risk and Opportunity Register (SROR). This role includes: • Meet quarterly to identify, assess, prioritise and address risks. • Meet monthly to identify and summarise the key risks to be reported to the Board. • Being a risk management champion and mentor managers and staff in the management of risks. • Integrate risk management into business processes, including the annual business plan. • Develop plans for the management of risks and controls. • Contribute to the development of the Risk Management Policy. • Provide risk management training to staff. • Monitor effectiveness of risk management. • Promote ongoing enhancement of risk management processes. • Comply with controls stated in Risk Register and report any control gaps/weaknesses. • Report systematically and promptly to the Chief Risk Officer any perceived new risks or failures of existing control measures.
All Staff	All staff in the FSAI are responsible for identifying and reporting risks to their line Manager.
Source: FSAI Risk Management Policy	

In Indecon's view, the processes in place and described above for risk identification, mitigation, management, and monitoring are detailed and robust, with clear paths for ownership of responsibility and reporting. Evidence of risk management actions is clearly documented in FSAI's Annual Business Plan Quarterly Progress Reports.

5.5 Financial Oversight

The Department issues a Letter of Allocation each year, which outlines the funding available to the FSAI along with any specific requirements. The Senior Leadership Team in the FSAI is engaged in the establishment of the budget as well as monthly meetings to monitor expenditures and any variances. The team identifies areas of variance and is responsible for reallocations where appropriate to maintain overall alignment with the business plan.

The DoH monitors expenditures against budget and FSAI's cashflow throughout the year at the end of each month. Additionally, FSAI must submit monthly expenditure reports showing actual expenditures to date and projected expenditures for the rest of the year. A brief explanation is required where there is a discrepancy between projected and actual expenditures. These monthly reports are managed under the direction of the Principal Officer, Head of Food Unit, at the Department of Health.

The FSAI is also subject to annual audit by the Office of the Comptroller and Auditor General (C&AG) who present their report before the Houses of the Oireachtas. The statement on internal control disclosed that in 2023 the FSAI incurred significant expenditure where the procedures followed did not comply with public procurement guidelines.

In 2022, the FSAI Statement on Internal Control highlighted seven expired contracts that were not compliant with procurement requirements, although they had previously been procured appropriately. The FSAI reported to the Public Accounts Committee that:

“Certain contracts, 7 in total, had to be extended beyond their original timeline to provide continuity of operational support to the FSAI. In respect of some instances, the tendering process did not produce an acceptable outcome.”

The Statement of Internal Control for the year ended 31 December 2023 provides details as follows:

“In the 2022 statement on internal control the FSAI highlighted seven expired contracts that were not compliant with procurement requirements. The FSAI is committed to procurement compliance and during 2023 put in place actions to resolve the expired contracts, which had previously been procured appropriately. The scheduled procurement will ensure these contracts will be resolved by the end of June 2024. Six of the seven contracts have been appropriately procured, as of the end of May 2024, with a public tender process underway in relation to the remaining contract.”

During 2023 expenditure of €872,000 including VAT (2022: €694,750) was incurred in relation to these seven contracts. The Authority concluded procurement procedures, including the use of OGP frameworks, to resolve the remaining contracts.

The actions taken by the FSAI during 2023 and 2024 to resolve the expired contracts, included:

- Contract Procurement Plan for 2023 - 2024 to address the seven contracts;
- Regular reporting to the FSAI Board, the Board Audit & Risk Committee (ARC) and Department of Health on progress against the plan; and
- A programme of internal audits, undertaken by FSAI's external auditors, including an annual review of and statement, by the Board on Internal (Financial) Controls.

The Chairperson's letter to the Minister dated June 2024 states that: "With the exception of procurement, no internal control weaknesses were identified in 2023. Steps have been taken to rectify the procurement breaches. Details are set out in the Statement of Internal Control."

The FSAI confirmed that new contracts are in place for 2024. The FSAI has a documented Procurement process included in its standard operating procedures.

5.6 Governance Framework of FSAI Consultative Council

The FSAI Food Safety Consultative Council (FSCC) is a statutory Council established under Section 14 of the FSAI Act, 1998. Its purposes are: to facilitate consultations and discussions; promoting higher standards; or for any other matters relating to the functions of the FSAI, with representatives of consumers, producers, retailers, distributors, caterers, manufacturers, the food inspectorate, and academia. The Consultative Council was first formed in April 2001 with the following objectives:

- Advise the FSAI on specific issues;
- Enable the FSAI to discharge its function to consult widely for the purposes of promoting higher food safety and hygiene standards; and
- Progress the food safety agenda.

The FSCC consists of 24 members, 12 of which may be appointed by the Minister for Health in accordance with Section 14 of the FSAI Act³⁰ and the remaining 12 appointed by the FSAI Board. It must have an appropriate mix of diversity, skills, and gender balance. The Council develops an annual work programme and may establish sub-groups to support its delivery. The Council Chair attends FSAI Board meetings at least once annually, and a member of the FSAI senior leadership sits on the Council and assists in formulating discussion topics.

5.7 Scientific Committee – Code of Conduct

The Code of Conduct for Members of the Scientific Committee of the FSAI and its Subcommittees and Working Groups provides requirements of members under the FSAI Act, as follows:

- Members are appointed in their individual capacity, independent of their employers;
- Members must acknowledge duty to conform to highest standards of business ethics;
- Members not allowed to participate if declaration of interest forms are not signed and returned;
- Members must read and comply with Rules of Procedure;
- Members must strive to attend all meetings when possible;
- Members must refrain from expressing views in public or representing views of the Committee without prior consent of the Chair;
- Members speaking generally on matters within the terms of reference of the Committee must clarify they are not doing so in their official capacity as Committee Member;
- Members must comply with applicable statutory provisions (e.g., data protection); and

³⁰ Food Safety Authority of Ireland Act, 1998, Section 14

- Members must strive to reflect FSAI values of teamwork, collaboration, integrity, respect, transparency, and passion during their work with FSAI.

Additionally, members of the Scientific Committee must:

- Disclose in advance any pecuniary or beneficial interest in any matter which is to be considered by the Scientific Committee;
- Neither influence/seek to influence a decision related to the matter;
- Take no part in any consideration of the matter; and
- Withdraw from the meeting so long as the matter is being discussed or considered, and shall not vote or act as a member in relation to the matter.

The Chair of the Scientific Committee is also a member of the Board of the FSAI and this means that this is a significant role in terms of the time commitment required to undertake both governance functions, particularly in instances where the Chair is a non-remunerated role under the “one person-one salary” principle.

5.8 Department of Health Oversight

In compliance with the Code of Practice for the Governance of State Bodies (the Code) there is an Oversight Agreement (OA) in place between the Department of Health (DoH) and FSAI. The OA outlines the existing legal framework; the operating environment; purpose and responsibilities of FSAI; expected level of compliance with the Code; details of the Performance Delivery Agreement; and governance arrangements including sanction for areas of expenditure. As part of the OA, a Performance Delivery Agreement (PDA) is agreed with DoH.

The PDA contains annual and multi-annual targets and outlines an agreed level of service, with an aim to improve the efficiency and effectiveness in the delivery of FSAI’s services. The PDA aligns the statutory framework of FSAI with the DoH’s Statement of Strategy and Government policies for the reform and modernisation of the Public Service.

As has already been outlined previously, Governance Meetings take place between the Department of Health and the FSAI on a quarterly basis. Material provided by the FSAI in preparation for these meetings includes evidence of comprehensive governance update documents, with questions from the Department being followed up by the FSAI. These quarterly reports provide updates on progress towards achievement of key performance indicators and updates to the risk register.

5.9 Summary of Main Findings

The main findings from the review of governance and oversight arrangements for FSAI were as follows:

- FSAI governance arrangements and procedures are well articulated and understood.
- There is good dialogue between Department of Health and FSAI through regular oversight meetings.
- This is based on positive working relationships and needs to be reinforced to ensure that this is maintained when personnel change.
- Significant sharing of relevant documentation underpins these meetings.

- There may be some merit in having clear communication of a small number of priorities for the year with the Official Agencies.
- Board is active and well-informed on the organisation.
- Significant Board involvement in the recent Strategy development process.
- Strong evidence of regular engagement between the Executive and Board.
- Risk and financial management functions are well managed.
- Some Procurement challenges with one large contract ended.
- The FSCC positively supports the overall consultative requirement of the organisation.
- The Scientific Committee is an independent committee providing critical information to the FSAI.

6 Conclusions and Recommendations

6.1 Summary of Key Conclusions

The table below indicates the overall conclusions reached on the bases of the consultations and detailed assessments undertaken as part of this Periodic Critical Review. Overall, the FSAI is an appropriately situated, well-established authority with a consistent track record of effective performance of its core statutory functions. Service contracts with seven Official Agencies form the bases upon which specific controls and enforcement activities are carried out in the food sector. These activities have been successful over the years in identifying food safety risks and incidents, as well as issuing enforcement orders and public notices.

There is some room for improvement of process whereby data sharing between agencies and the FSAI lacks efficiency. The FSAI has recently undertaken some projects outside the scope of its core statutory duties, and emerging issues in the sector would suggest that future review and consideration of statutory clarity and a whole-of-Government (i.e., cross-Departmental) approach is warranted. This PCR has undertaken detailed engagement and consultation with the FSAI Board, the Senior Leadership Team and FSAI staff which has assisted in developing an evidence-base to assess the Agency. Wider industry stakeholders as well as the key Official Agencies were invited to provide detailed inputs to the review process and a number of written submissions were received. The Indecon team also undertook a detailed document review which considered various aspects of the FSAI and its operations. These research tasks assisted in developing an evidence base to make conclusions and support the development of recommendations that could improve the efficiency, effectiveness and accountability of the organisation.

Table 6.1: Summary Conclusions

Table 6.1: Summary Conclusions	
1	FSAI is a well-established statutory, independent, and science-based regulatory enforcement body dedicated to protecting public health and consumer interests in areas of food safety, hygiene, integrity, and authenticity. It was the first such authority established in the EU. Its functions under the DoH are generally in line with Irish and EU requirements.
2	The operating environment of the FSAI is influenced by a range of factors as considered in the 'PESTLE' analysis. FSAI has responded well to recent challenges (Brexit, COVID-19) and performed effectively on delivery of its functions.
3	FSAI generally discharges its official control responsibilities by means of service contracts with seven Official Agencies (six from 1 January 2025), which were previously responsible for food control.
4	Emerging issues in food safety are likely to include EU-level developments, e-commerce, increased complexity of the food chain, and technological developments in the food industry. This could increase complexity of workload; FSAI will need to adapt to remain responsive.
5	The present FSAI organisational structure is broadly appropriate, but may be subject to change with appointment of a new CEO.

6	The current functional area structure aligns with the core functions of FSAI, including management of service contracts with 7 Official Agencies. Positioning of Public Health Nutrition policy unit may need future consideration.
7	FSAI has recently undertaken some food -related activities outside the scope of its core statutory duties, and emerging issues in the sector would suggest that future review and consideration of statutory clarity and a whole-of-Government approach is warranted.
<i>Source: Indecon Assessment</i>	

6.2 Recommendations

Based on the detailed assessment and conclusions, this report developed a set of recommendations. These are designed to address the challenges and inefficiencies arising from this review. As evidenced throughout this report and summarised in Section 6.1, the role of the FSAI is still relevant, the authority is fit for purpose and has a proven history of effectively fulfilling its core statutory responsibilities. However, there is potential to enhance the data-sharing processes between the FSAI and other agencies. In addition, emerging sectoral challenges suggest that future reviews may be required to ensure continuous statutory clarity and explore a whole-of-government, cross-departmental approach.

The recommendations are summarised in Table 6.2 and elaborated upon in the subsequent text.

Table 6.2: Recommendations	
1	FSAI should place continued focus in the implementation of its recently launched strategy on the Agency becoming a data-centric organisation. ³¹ This will require FSAI to show leadership and disseminate information to the various Official Agencies. This data-centric approach will also assist in enhancing efficiency and effectiveness. This will also require Agencies to cooperate with FSAI in providing requested data.
2	A detailed review of Food Safety Legislation should be considered to ensure clarity of roles and responsibilities and enhance accountability, particularly on emerging issues. The enforcement powers of the FSAI (including the Official Agencies) in relation to the harmonisation of official controls may also be considered as part of this review.
3	FSAI to continue to work with the Official Agencies to improve the consistency/harmonisation of application of the official controls across the food safety system. Consideration should be given to enhanced oversight of governance and performance of Official Agencies.
4	Clarity should be provided by DoH regarding the role of FSAI in relation to wider food safety issues. Issues that are of relevance across multiple Government Departments and Agencies may require a whole-of-Government approach and food safety is just one aspect of this. How FSAI contributes in this context should be considered.
5	Business planning appears to be of a high standard in the FSAI and annual business plans are agreed with DoH. However, there may be scope for FSAI to have similar business planning processes in

³¹ "Data-centric" refers to the core, shared asset of data used for purposes of gathering information and insight as well as disseminating information in an efficient and timely manner.

	place as part of the SLAs with the Official Agencies, where FSAI communicates a small number of priority actions to these agencies to be focussed on and delivered in the course of the year.
6	Consideration should be given to the merits of enhancing the tracking of expenditures across different functions and units within FSAI. This would allow the identification of opportunities for productivity gains and increased efficiencies, especially in the context where savings are made against the budget profile, to ensure that best value for money is achieved from the annual allocation to the Agency.
7	It is important that any significant new activities assigned to FSAI by DoH should be designated under an agreed process in accordance with legislation, ensuring that new activities are resourced adequately following the standard estimates process, and do not impact on delivery of the FSAI's core remit.
<i>Source: Indecon Assessment</i>	

Continued focus on use and collection of data

It is important that there is a continued focus in the next Statement of Strategy on the FSAI becoming a more data-driven and data-centric organisation. This will require FSAI to act as an exemplar and disseminate information more effectively to and from the various Official Agencies. Such an approach will enhance efficiency and effectiveness. There are currently significant reporting requirements set out by the EU in relation to the application of the official controls. Consultation with FSAI staff highlights the significant time spent on data collection and collation. The FSAI currently co-ordinates these reports but the collection of the required data is done by the Official Agencies. This is currently quite a time-consuming process for both the FSAI and the Official Agencies. Improvements in terms of harmonisation and standardisation of data gathering and reporting would improve efficiency of the overall food safety system. Aside from reporting requirements, the availability of accurate and timely data in relation to food safety is very important. Timely access to such information will enable detailed analysis and appropriate risk management strategies which will improve effectiveness and efficiency.

Undertake a review the Food Safety Legislation

The primary legislation that underpins the FSAI (the FSAI Act) was introduced in 1998. This review has identified a number of issues faced by FSAI that may require amendments to this legislation. It is recommended that no changes should be made without a detailed review of the legislation. Ideally, this would involve consultation with key stakeholders (including industry, where appropriate). Such a review would help to ensure clarity of roles and responsibilities and enhance accountability, particularly on emerging issues. The enforcement powers of the FSAI in relation to the harmonisation of official controls may also be considered as part of this review. The review may also consider whether additional Statutory Instruments (SIs) are sufficient to address any current issues that may arise, or whether amendment to the primary legislation is required.

Continue to work to improve the harmonisation of application of the official controls across the food safety system, and consideration should be given to enhanced oversight of governance and performance of Official Agencies

There are currently six Official Agencies (previously seven) implementing the official controls as part of the food safety system. These organisations vary considerably in size and scope of their official controls and the number of activities they undertake. It is important that the FSAI continues to work with the Official Agencies to improve the consistency/harmonisation of application of the official

controls across the food safety system. Activities that the FSAI can undertake to support this include dissemination of information to the OAs, provision of training materials, research, and access to data repositories. There may also be scope to enhance oversight of governance and performance of OAs by reviewing the SLAs and the Annual Control Plans for each Official Agency. In some cases, there may be scope for strengthening the SLA agreements by introducing specific KPIs where these are not sufficiently detailed.

Clarity on the role of FSAI in relation to wider food safety issues

As outlined in the review of the external environment (see Annex 3) facing FSAI, there is increasing complexity in the food chain. There is also a significant demand in the sector to move towards greater sustainability. This will have significant implications on the overall food system and in turn food safety. There is a need for clarity on the role of FSAI in relation to wider food safety issues. There are likely to be issues that are of relevance across multiple Departments and Agencies that may require a whole-of-Government approach. Food safety may only be one aspect. The role of the FSAI in this context should be considered and clarified. Without such clarification, there is a risk that FSAI (as the competent authority for food safety) may not have an opportunity to input into wider policy areas where food safety may be only one component. Conversely, there is also a risk that the FSAI may be asked to input and participate in wider issues (with some food safety elements) that are beyond its remit.

Review annual business planning processes in place as part of the SLAs with the Official Agencies

The documentation in relation to business planning appears to be of a high standard in the FSAI. Annual Business Plans are agreed with DoH and are reviewed quarterly. This is a standard oversight arrangement between an agency and parent Department. Indecon believes that this process is mature and well-defined and importantly consistent with the Code of Practice for the Governance of State Bodies. However, there may be scope for FSAI to have similar business planning processes in place as part of the SLAs with the Official Agencies. One aspect that could be considered is that the FSAI would communicate a small number of priority target actions to the Official Agencies to be undertaken each year. Indecon's review of the SLAs also noted some differences in terms of reporting and performance across the various OAs.

Review the process for the tracking of expenditure across different functions and units

The FSAI is a relatively small organisation with an annual budget of circa €15 million. The majority of its costs are fixed and relate to staff and facilities. However, there are some expenditures on specific projects which may vary year-on-year. There may be merit in reviewing the tracking of expenditure across different functions and units, especially in the context where savings are made against the budget profile, to ensure that best value for money is achieved from the annual allocation from the Department. This would allow for the identification of opportunities for productivity gains and increased efficiencies across the organisation.

Review and outline agreed process in relation to how FSAI undertakes new activities

It is important that any significant new activities assigned to FSAI should be designated under an agreed process in accordance with legislation. This process should ensure that these new activities are resourced adequately in accordance with the standard annual budgetary process. The process should also consider whether any new activities impact on delivery of the FSAI's existing core remit. Having an agreed process in place will ensure that the FSAI is able to deliver its core remit in an efficient and effective manner.

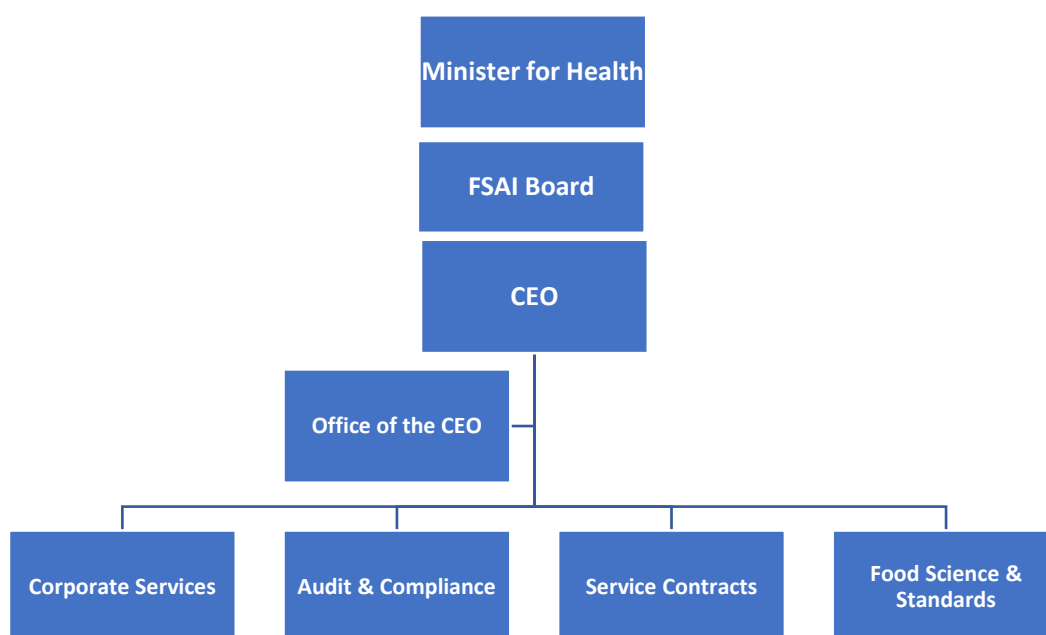
6.3 Implementation of Recommendations

An Action Plan for the implementation of the recommendations arising from this Periodic Critical Review should be developed in collaboration between the Department of Health and the FSAI and reported on as part of the existing Governance and Oversight arrangements. The implementation of these recommendations should secure improvements in the accountability, efficiency and effectiveness of the FSAI in how it delivers its functions. However, it must be noted that the overall conclusions of this PCR have found that FSAI is a well-established authority with a consistent track record of effective performance of its core statutory functions.

Annex 1 Evolution of FSAI Organisational Structure

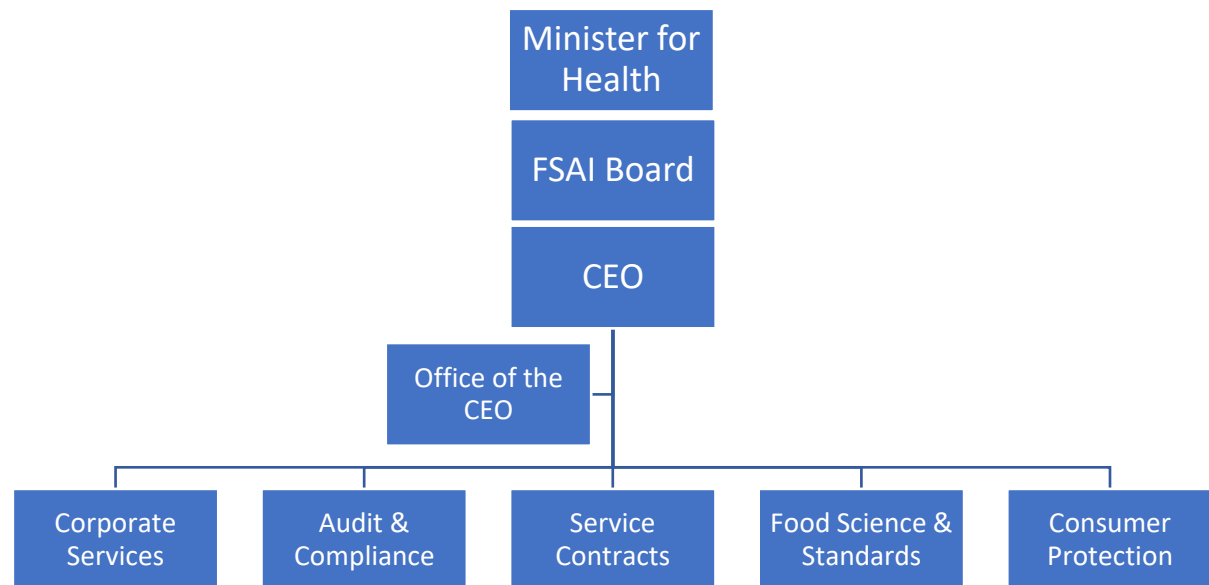
The following figures illustrate the organisational structure for FSAI from 2011-2022. The broad structure of the authority has remained similar throughout the period; however, changes can be seen in 2012 with the addition of a Consumer Protection Division and in 2018 with the removal of the Consumer Protection Division and addition of Public Health and Nutrition Policy to report directly under the CEO, and addition of a new Risk Management and Regulatory Affairs Division.

Figure A1.1: FSAI Organisational Chart 2011



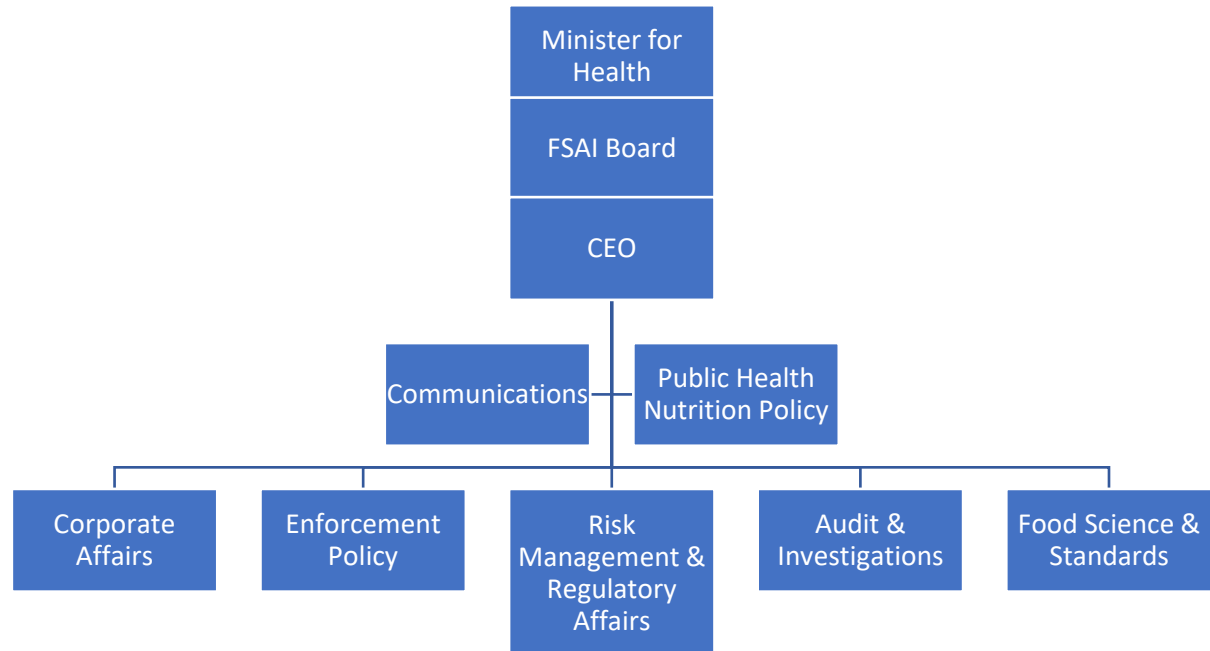
Source: FSAI Annual Report 2011

Figure A1.2: FSAI Organisational Chart 2012



Source: FSAI Annual Report 2012

Figure A1.3: FSAI Organisational Chart 2018



Source: FSAI Annual Report 2018

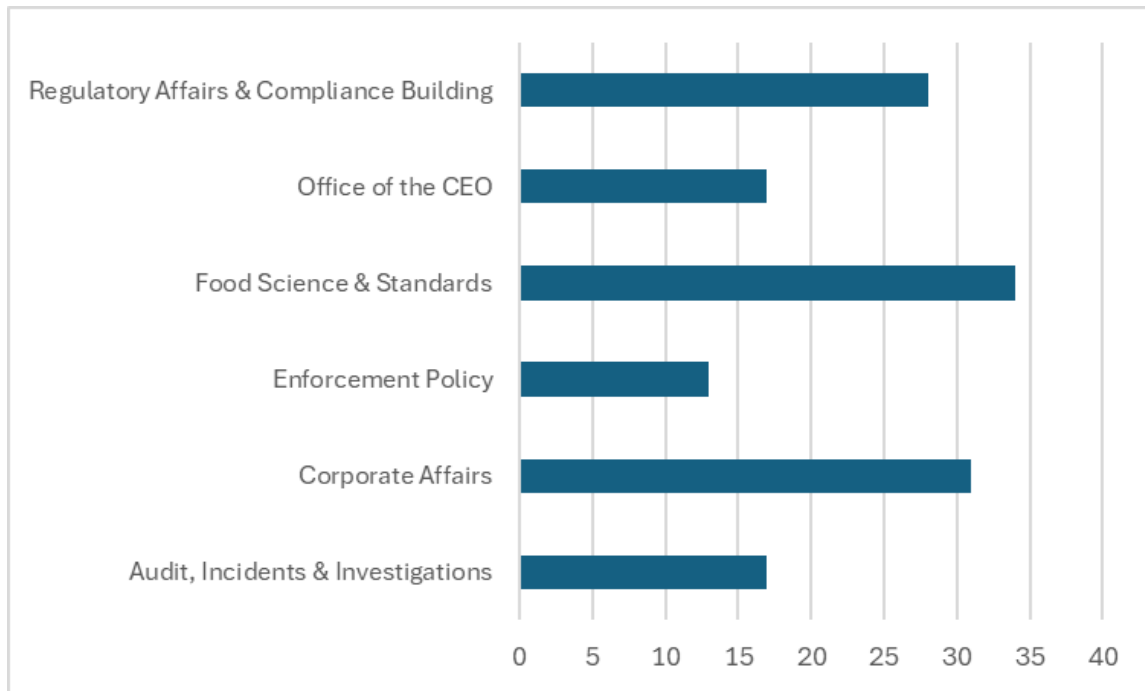
Figure A1.4: FSAI Organisational Chart 2022



Source: FSAI Annual Report 2022

Annex 2 FSAI Employment by Functional Area and financials

Breakdown of Employment by Functional Area in FSAI (Headcount as of July 2024)



Source: Indecon analysis of FSAI data

Oireachtas Grants (€'000)					
	2019	2020	2021	2022	2023
Grants for current expenditure	15,972	17,172	19,713	18,583	20,922
Grant for capital expenditure	385	364	246	508	155
Total	16,357	17,536	19,959	19,091	21,077

Source: FSAI Annual Reports

Other Income (€'000)					
	2019	2020	2021	2022	2023
Superannuation Deductions	232	237	234	235	256
Sale of Publications	82	156	184	209	192
Sundry Income	172	88	198	166	94
Reformulation taskforce	-	0	147	285	439
Albania CE Fund	565	499	769	1,267	867
Total	1,051	981	1,532	2,162	1,848
<i>Source: FSAI Annual Reports</i>					

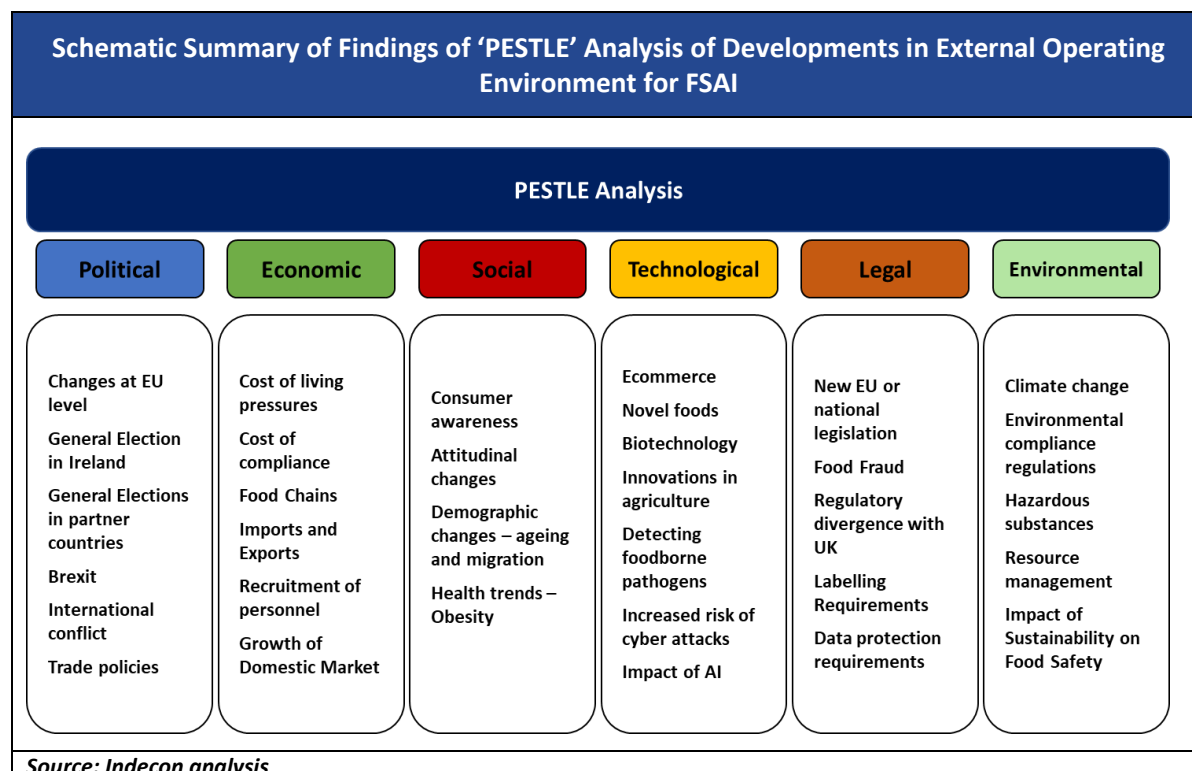
Administration, Operations & Promotion (€'000)					
	2019	2020	2021	2022	2023
Remuneration and Other Pay Costs	6,307	6,327	6,832	7,377	8,900
Rent, rates, service charges and insurance	1,483	1,491	1,470	1,544	1,663
Research costs	40	87	54	93	59
Legal and consulting fees	103	44	212	272	371
IT, telephone and Internet	985	1,220	1,064	1,349	1,450
Operating expenditure	805	526	1,023	691	923
Total	9,723	9,697	10,655	11,326	13,366
<i>Source: FSAI Annual Reports</i>					

Operating expenditure (€'000)					
	2019	2020	2021	2022	2023
Recruitment Expenditure	28	14	45	76	31
Stationery and Postage	27	15	42	24	27
Cleaning and Catering	50	2	0	13	26
Repairs and Maintenance	196	190	210	234	223
Audit Fee	15	15	15	15	15
Food Legislation Compliance	114	57	115	149	106
Training - Official Agency Staff	16	41	23	134	149
Food supplement database	24	67	14	14	138
Committee Expenses	5	11	0	7	8
Library Supplies	76	53	60	73	68
Dilapidations	-	0	208	-	-
General Expenditure (including hospitality)	254	61	291	48	132
Total	805	526	1,023	691	923
<i>Source: FSAI Annual Reports</i>					

Annex 3 PESTLE analysis

Introduction and Summary of 'PESTLE' Analysis

Indecon conducted a 'PESTLE' analysis of developments in the external operating environment for the FSAI, which was informed by stakeholder engagements and desk research. The 'PESTLE' analysis considers impacts on the FSAI strategic context in terms of Political, Economic, Social, Technological, Legal, and Environmental factors. A summary of findings is reflected in the graphic below, and factors listed under each heading are discussed in subsequent paragraphs.



Political Developments

Changes at EU Level

New European Commission and New EU Parliament and Council may introduce new direction in terms of policies and legislation. Ireland will hold the Presidency of the Council of the European Union from July to December 2026, creating opportunities to shape policy, and thus an additional role for FSAI to support the achievement of national objectives under the Presidency.³²

General election in Ireland

As food safety laws and regulations are set out by Government, the new Programme for Government has affected the configuration of Government Departments, and may result in a change of emphasis in the Government's priorities. Government initiatives such as the provision of hot school meals can

³² <https://www.consilium.europa.eu/media/56627/presidencies-until-2030.pdf>

affect food safety oversight. Other potential impacts of an election are changes to trade policies, Government initiatives such as public health campaigns and Government-funded research concerning food practices and technologies. These may be enhanced or diminished, according to government priorities and budgeting.

General election in partner countries

National elections in France, the UK, and the US could lead to policy shifts in these countries and alter the food safety relationship between Ireland and partner countries. Changes to trade policy, research, and public health initiatives in countries where Ireland is a food importer or exporter will affect the environment in which the FSAI operates. For example, Brexit has impacted food trade between Ireland and the UK, as well as that between Ireland and the rest of the EU.³³

Brexit

Brexit has led to increased complexities in monitoring the movement of food products, from Great Britain and Northern Ireland under the Windsor Framework. There is potential for regulatory divergence and increased risk of food fraud. The need for additional official controls and certification requirements on imports and exports has had (and will continue to have) a significant impact on the FSAI's operating environment. Additionally, Brexit has affected third-country status, impacting information sharing and access to scientific resources, which were previously more fluid within the EU.

International conflict

Conflicts and/or wars may inhibit cooperation between countries and may disrupt traditional logistics routes. (For example, the war in Ukraine has disrupted exports to European countries of wheat, corn, and sunflower oil.³⁴) Such disruptions could result in supply chain risks, such as transportation delays and food contamination. Extended transport times may impact the quality and safety of perishable goods. Food safety oversight may be disrupted as regulators may face challenges in maintaining inspection and monitoring processes. International cooperation on food safety can be inhibited during conflict, reducing the ability to implement unified standards and responses to food safety incidents across the globe.³⁵ Import/export restrictions during conflicts can severely disrupt the flow of key agricultural exports, and force reliance on alternative sources that may not meet the same food safety standards. Rapid responses to food shortages, including those caused by international conflict, can lead to relaxation of regulatory compliance and potentially compromise food safety standards.³⁶

Trade policies

Changes in trade policies in Ireland and internationally could alter the landscape of imported and exported food products. In addition to food safety regulations, these policies could impact the costs of doing business and affect international market prices. For example, as Ireland navigates post-Brexit trade agreements and potential new partnerships, changes in import regulations and standards could introduce risks associated with varying food safety practices of trading partners. Stricter trade policies might enhance food safety by ensuring that only products meeting high standards are allowed into the market, while more lenient policies could increase the risk of contamination and lower quality. Additionally, policies promoting local production over imports could improve traceability and control

³³ https://ireland.representation.ec.europa.eu/strategy-and-priorities/key-eu-policies-ireland/impact-brexit-ireland_en

³⁴ <https://www.consilium.europa.eu/en/infographics/ukrainian-grain-exports-explained/>

³⁵ https://knowledge4policy.ec.europa.eu/publication/addressing-another-threat-food-safety-conflict_en

³⁶ https://www.oecd.org/content/dam/oecd/en/publications/reports/2021/07/covid-19-and-food-systems_393169b7/69ed37bd-en.pdf

over food safety. However, any significant policy shifts must balance trade facilitation with rigorous enforcement of food safety standards to protect public health.

Economic Developments

Cost of living pressures

The effects of inflation and higher food prices are still leading to cost-of-living pressures on people in Ireland.³⁷ These cost-of-living pressures might affect consumer choices, resulting in a shift towards cheaper food options which may be reflective of lower nutritional quality and risk-taking behaviours by consumers on the safety of food products consumed. However, cheaper food products must still be safe and are subject to the same safety standards as all other food products.

Cost of doing business, including compliance

Increasing costs of doing business, including those associated with compliance, can increase risks associated with non-compliance for businesses and consumers. Investments in processes, training, and technology can impact the financial standing of food producers; lack of such investments can result in non-compliance and violations whereby unsafe food products reach consumers and cause harm.

Food chains

Global food supply chains present risks associated with varying food safety standards and practices in different countries. Achieving consistency in food safety across all products in all markets is challenging.

Imports & exports

Shifts in import and export partners may complicate compliance by changing the international frameworks within which Irish importers and exporters operate. Food producers must adhere to labelling requirements; therefore, any substitutions or supply alternatives would require updates in labelling to accurately reflect new ingredients. This includes the need for country-of-origin and allergen information, as well as language requirements to also be updated as supply sources shift.

Recruitment of personnel

The current prevailing labour market conditions point to full employment.³⁸ This means that there is a shortage of labour supply which could adversely affect staff recruitment and replacement. This presents an operational risk to the FSAI if they experience staff turnover while these labour market conditions prevail.

Growth of the Domestic Market

The growth of the domestic food market,³⁹ driven by an increasing population and rising consumer demand, places additional pressure on the food supply chain. As the market expands, food producers must scale their operations to meet this demand while ensuring compliance with food safety regulations. This growth can lead to challenges in maintaining food quality and safety.

³⁷ <https://tradingeconomics.com/ireland/food-inflation>. Food inflation in Ireland in November 2024 increased by 1.9% over November 2023.

³⁸ <https://www.cso.ie/en/releasesandpublications/ep/p-lfs/labourforcesurveyquarter12024/unemployment/>

³⁹ <https://www.statista.com/outlook/cmo/food/ireland#:~:text=Revenue%20in%20the%20Food%20market,US%242.61bn%20in%202025.>

Social Developments

Consumer awareness

Increasing awareness among consumers about food safety can drive demand for higher standards and more transparent information about food sourcing and production practices. However, with the rise of social media and the ease with which information spreads, including misinformation, consumers are increasingly influenced by social media influencers, many of whom lack formal qualifications. This can lead to confusion regarding food safety and nutrition, presenting a new challenge for authorities like the FSAI to combat misinformation and maintain consumer trust.

Attitudinal and Food Consumption changes

Changes in consumer attitudes and consumption such as the growing popularity of plant-based diets, organic food, and eating-out habits can increase the need for food safety policies. Also, the rise in ready-prepared and takeaway foods sold through online platforms and social media may call into question whether current inspection protocols are adequately assessing these new types of food businesses. Inspectors may need additional expertise to assess the safety and compliance of new types of food businesses.

Consumers are increasingly influenced by health trends and "diets" promoted online, many of which are not within the FSAI's remit. However, it remains vital for the FSAI to address food safety concerns related to popular diet trends, including accurate labelling of claims such as organic, vegan, vegetarian, free-from, and other food marketing terms that could mislead consumers.

The increasing public knowledge regarding data collection, analysis, and risk management means that consumers are less forgiving of lapses in food safety, both in Ireland and abroad. Maintaining the trust that Ireland is a producer of safe food for the global consumer is critical for the FSAI's reputation and the broader economic landscape.

Demographic changes

Demographic changes such as the aging population and net migration can affect the operating environment. For example, older adults living in Ireland are more affected by overweight and obesity than other age groups.⁴⁰ An aging population increases the need for research into the incidence and effects of nutrition deficiencies in older adults, as dietary needs differ from those of younger populations and sometimes require specialised food products.⁴¹ Ensuring safety of fortified or low-sodium food products involves regulation and monitoring to ensure nutritional adequacy and safety. Residential settings such as nursing homes require rigorous standards and frequent inspections to ensure that food provided in these settings is safe and uncontaminated. Additionally, different cultural practices and dietary habits can impact food safety. For example, certain traditional food preparation methods may pose unique risks that need to be managed.

Health trends

Trends in health of the Irish population are affected by food choices as well as activity levels and other lifestyle components. It is well established that cardiovascular disease, diabetes, osteoporosis, cancer, and other conditions are linked, at least in part, to dietary intake. The Government can

⁴⁰ <https://www.statista.com/statistics/825763/age-distribution-ireland-bmi/>

⁴¹ Baugreet, S., Hamill, R., Kerry, J., and McCarthy, S., "Mitigating Nutrition and Health Deficiencies in Older Adults: A Role for Food Innovation?" *Journal of Food Science* Vol.82, No. 4, 2017.

provide dietary public health advice in the form of guidelines and the food pyramid.⁴² For example, the rise in obesity in all age groups requires work to implement Healthy Eating Guidelines and continuous development of practical advice based on scientific research. Healthy Ireland,⁴³ The Obesity Policy and Action Plan,⁴⁴ as well as more recent Food Based Dietary Guidelines⁴⁵ and the work of Obesity Policy and Implementation Group all contribute to recent developments in this area. The FSAI Scientific Committee will finalise the scientific recommendations for all population groups in 2025, taking into account sustainability.

Technological Developments

Ecommerce

An increase in food sales via online aggregator sales and social media platforms may require new approaches to inspection and enforcement actions.

Novel foods

An increase in novel foods, which must be in accordance with Regulation (EU) No. 2015/2283, may require additional food safety research and policy development.

Biotechnology

Innovations in biotechnology, such as gene editing techniques of genetically modified organisms (GMOs) and advanced preservation techniques present opportunities and challenges which may require extensive food safety research and policy.

Innovations in agriculture

Innovations such as urban/vertical farming and alternatives to pesticides may require additional food safety research and policy.

The general shift to more technology in food production introduces new complexities in ensuring food safety. While engineers are designing and implementing advanced systems for food manufacturing, logistics, and processing, they may lack food safety expertise.

Detecting foodborne pathogens

Advancements in foodborne pathogen detection techniques, such as on-site food safety detecting approaches, rapid testing kits, and blockchain for traceability, offer potential advantages such as portable devices, user-friendly operations, cost reductions and rapid on-site detection.⁴⁶

⁴² https://www.fsai.ie/getmedia/be0e5ec0-c1ce-40b9-8f66-51bb834bac44/10507_fsai_healthy-eating-guidelines-accessible-fa1.pdf

⁴³ <https://www.hse.ie/eng/about/who/healthwellbeing/healthy-ireland/>

⁴⁴ <https://www.hse.ie/eng/about/who/healthwellbeing/our-priority-programmes/heal/heal-docs/-a-healthy-weight-for-ireland-obesity-policy-and-action-plan-2016-%E2%80%932025.pdf>

⁴⁵ <https://www.fsai.ie/getmedia/c0610e7f-9bfa-457a-9dca-3f97149e43a1/scientific-recommendations-for-food-based-dietary-guidelines-for-older-adults-in-ireland.pdf?ext=.pdf>

⁴⁶ Yanke Shan, Yu-Nan Lu, Weijie Yi, Bin Wang, Jiahao Li, Jiajing Guo, Wenzhi Li, Yulong Yin, Shouyu Wang, Fei Liu, (2023), "On-site food safety detection: Opportunities, advancements, and prospects" Biosensors and Bioelectronics: X, Volume 14, 2023, 100350, ISSN 2590-1370, <https://doi.org/10.1016/j.biosx.2023.100350>.

Increased risk of cyber-attacks

Increased risks and complexity of cyber-attacks place FSAI (as all organisations) in a vulnerable position on storing and archiving sensitive and commercial data.

Artificial Intelligence (AI) and Innovation

There are both risks and opportunities associated with AI. For example, the increasing use of AI offers opportunities for the FSAI to improve operational efficiency, data collection and enhance the accuracy of food safety assessments.⁴⁷ Conversely, the use of AI in targeting misinformation to susceptible audience poses a potential risk. There may also be opportunities to adapt to modern inspection techniques, including the potential for remote monitoring.

The rapid pace of technological change presents a unique challenge to regulatory bodies like the FSAI (and all competent food safety authorities across the EU). Innovations in food production, data analytics, and automation are evolving faster than the current regulatory frameworks can adapt.

The growth of e-commerce has transformed food retail, allowing consumers to purchase food online. However, this expansion presents regulatory challenges in ensuring the safety and authenticity of products sold remotely. This poses challenges in ensuring compliance and monitoring potential food fraud in these contexts will require technological innovation.

Internet of Things (IoT) devices can provide real-time data on temperature, humidity, and other critical conditions, ensuring compliance with food safety standards.⁴⁸ These systems reduce human error and remove the need for paper, creating a more transparent, traceable supply chain. Such advances could benefit the oversight available to the FSAI and its Official Agencies.

Legal Developments**New EU or national legislation**

Changes in food safety laws and regulations can place an additional burden on the FSAI and its Official Agencies in the context of resources and timelines. Adhering to rules among multiple legal frameworks can be increasingly complicated for food companies operating globally; this increases complexity of the operating environment for the FSAI.

For example, recent significant legislative measures proposed through the Farm to Fork work programme, sustainability regulations, Regulation 2017/625, SI 79 of 2020, and SI 22 of 2020, are likely to impact the FSAI's operations and regulatory frameworks. The FSAI must continually assess how to address these and other legislative changes.

Food fraud

Illegal activity such as food fraud and adulteration of food products can increase the need for compliance checks and enforcement actions, as risks are increased where food supply chains are disrupted (e.g., conflicts, shortages, etc.)⁴⁹ Increased risks of food fraud due to supply chain disruptions have led to stricter labelling regulations, requiring authorities to conduct more rigorous

⁴⁷ Abass, T., Eruaga, M., Itua, E., and Bature, J., "Advancing Food Safety Through IOT: Real-Time Monitoring and Control Systems," International Medical Science Research Journal, Volume 4, Issue 3, pp. 276-283, March 2024

⁴⁸ Ibid.

⁴⁹ See, e.g., [https://www.fsai.ie/enforcement-and-legislation/official-controls/investigations-\(fraud\)](https://www.fsai.ie/enforcement-and-legislation/official-controls/investigations-(fraud))

checks to ensure that labels accurately represent the product contents, origin, and safety certifications.

Regulatory divergence with UK

Divergence between regulation in Ireland and the UK will require the FSAI to adapt its operations to manage increased complexity, maintain food safety standards, and protect consumer health. This requires the FSAI to develop and enforce different compliance and monitoring processes for products coming from/going to the UK, increasing complexity and workload of the FSAI. Divergent standards and regulations could complicate inspection and enforcement measures. Furthermore, the FSAI would need to closely monitor supply chains particularly for products produced or processed in both Ireland and the UK, ensuring that all stages of production and processing comply with EU and national standards. The FSAI would need to establish new protocols and agreements to ensure effective communication and cooperation in managing cross-border food safety issues and responses to foodborne illness outbreaks. Regulatory updates and training are required for FSAI staff to keep up with changing standards in both jurisdictions.

Labelling requirements

Flexibility in the implementation of certain labelling requirements was a necessary response to the disruptions caused by the crisis in Ukraine and the sanctions on Russia and Belarus. The FSAI continues to consider and review, as necessary, such geopolitical situations.

Moves towards more sustainable food systems have also led to an increase in initiatives to reduce food waste through food labelling initiatives, for example, date marking. The FSAI has a role in reviewing such initiatives to ensure compliance with food labelling rules and that consumers are not misled.

Data protection requirements

Increased complexity of data processing, storage, and protection is a result of maintaining compliance with the EU General Data Protection Regulation (GDPR).

Environmental Developments

Climate change

Changes in climate can affect food safety by altering the prevalence of pests and diseases, impacting crop yields, and challenging current food production practices.⁵⁰ The impact of climate change identified by stakeholders include:

- Sustainability in terms of the re-use of materials;
- Reductions in food waste and the transportation of food;
- Security of supply;
- Substitute foods; and
- Degradation of water and water scarcity.

⁵⁰ Singh, B.K., Delgado-Baquerizo, M., Egidi, E. et al. Climate change impacts on plant pathogens, food security and paths forward. *Nat Rev Microbiol* 21, 640–656 (2023).

Any changes to food production practices may require updates to food safety regulations and FSAI operational practices, and may require new risk assessments and management of new risks. Additionally, regulations promoting sustainable agricultural practices can impact food safety by reducing the use of harmful pesticides and chemicals.

Environmental regulations compliance

Climate action commitments could have cost and/or reporting implications for the FSAI. There is increasing focus on organisations, particularly public sector, and governmental organisations, adopting climate action commitments such as reduced electricity/gas use, retrofitting, or insulating offices.⁵¹ These commitments could affect the operations and governance of the FSAI in terms of its office space, how it uses electricity, international travel, and increasing reporting requirements.

Hazardous substances

Increased presence of hazardous substances in the environment can increase risks of entry to the food system. This may impact FSAI in terms of increased needs for inspection and enforcement measures, as well as additional research into new hazardous substances and detection methods.

Resource management

Efficient management of natural resources, such as water and soil, is crucial for maintaining food safety. Contaminated water sources or depleted soils can lead to unsafe food products. FSAI inspection and testing processes may be impacted by changes to resource management methods.

Impact of Sustainability on Food Safety

The impact of sustainability in food production may have unintended consequences for food safety.

Future Considerations

The preceding 'PESTLE' analysis highlights a range of areas where the role of the FSAI is evolving and may change in the future. In addition, there are a number of specific areas where the FSAI has been assigned to specific roles. These are outlined below.

Food Contact Materials

It should be noted that a wide number of Government Departments and agencies are involved with legislation and controls relating to Food Contact Materials (FCMs). National legislation governing FCMs is the European Union (Plastics and other materials) (Contact with food) Regulations 2017 (S.I. No. 49 of 2017), and amendments in S.I. No. 257 of 2018, S.I. No. 278 of 2019. Changes in FCM products may require further updates to legislation in order to be effective.

The Food Safety Authority of Ireland participates in EU Working Groups in this area and undertakes stakeholder engagement. The safety of FCMs is evaluated by the European Food Safety Authority (EFSA). Industry in Ireland submit applications for evaluation of new FCM substances and processes to the FSAI which is the national contact point.

In terms of the monitoring of FCM, agencies involved in this sphere include the FSAI, the National Standards Authority of Ireland (NSAI) the Health Service Executive, the Department of Agriculture, Food and the Marine, the Sea-Fisheries Protection Authority, and/or Local Authorities. These

⁵¹ <https://www.seai.ie/plan-your-energy-journey/public-sector/obligations-and-targets>

agencies undertake official controls in establishments that use FCM in the manufacture, storage, distribution, and supply of food.

The FSAI has a service contract with the NSAI to undertake official controls and other official activities in establishments (other than food establishments) that import, manufacture, convert, distribute or supply (other than by retail) FCMs. In addition, the NSAI undertakes official controls in establishments that manufacture FCMs and recycle plastic for use in FCMs. The HSE's National Environmental Health Service also carries out official activities on FCMs at the point of entry/import into the State. The official controls can include sampling of FCMs, and the Dublin Public Analyst Laboratory analyse these products to determine compliance with legislation.

In view of the complexities and range of Food Contact Materials and legislation, the Department of Health has set up an Inter-Departmental Steering Group which will coordinate across Government Departments/Agencies. The FSAI will continue to represent Ireland at EU Working Group level meetings and will provide technical support and advice to relevant Departments/Agencies as required. NSAI is also funded by FSAI, for official controls on FCMs.

Drinking Water Directive

Under the European Union (Drinking Water) Regulations 2023 (S.I. No. 99 of 2023), Regulation 3(3) and Regulation 3(4), the FSAI has a role in exemptions for specific food businesses with their own water supply in relation to the water used for the specific purposes of the food business.

As part of this role, the FSAI attends meetings of the Expert Group for the Implementation of the Recast Drinking Water Directive, which are chaired by the Department of Housing, Local Government and Heritage (DHLGH). The FSAI also establishes the exemption criteria for FBOs and the system of controls related to this.

FSAI chairs the FSAI Food Business Operators Exemption Subgroup of the DHLGH Expert Group for the Implementation of the Recast Drinking Water Directive.

Emerging Issues

Key stakeholders consulted as part of this review were asked whether the original objectives of the FSAI are still relevant, considering the evolving policy priorities and EU legislative changes. The overall response indicates that current legislation is still relevant, but due to shifts away from a linear food supply chain toward a more complex one, food safety laws should be strengthened in the areas of data usage, sustainability, and nutrition. These are summarised below and discussed subsequently.

Outline Summary of FSAI Emerging Issues and New Areas of Activity	
Emerging Issues	New Areas of Activity
Data usage	FSAI has had to create data "workarounds" to remedy inter-agency data transfer problems and timeliness issues
Transition to sustainable food systems	FSAI has to promote food safety as we progress toward healthy and sustainable food systems.

Nutrition	Interrelation between food safety and nutrition has resulted in FSAI oversight of voluntary food reformulation as relating to public health
Food innovation	FSAI has to address the challenges and opportunities brought by innovation in the food industry.
<i>Source: Indecon Analysis of FSAI data</i>	

Data usage

Data usage by the FSAI is an integral part of its core functions and is key to meeting and reporting on its strategic goals and objectives. As part of this review, the FSAI Senior Leadership Team indicated that it relies on the Official Agencies for collecting data in accordance with their service agreements (i.e., negotiated contracts).

The team noted that as a data-driven organisation, the FSAI needs data inputs from other agencies. The FSAI has a statutory role under Section 16(2) of the FSAI Act to collect and assess data on official controls; the Official Agencies are required to cooperate with the FSAI to meet this requirement. This has implications for the other agencies and others in terms of demands on their own resources, and in terms of any requirements that may impact priorities. In some instances, delays or failure to provide data to FSAI creates a need for “workarounds” to progress its functions. Strengthening alignment between FSAI and other official agency strategies could improve data flow between Official Agencies and FSAI.

In terms of its own data systems evolution, the FSAI 2022 Annual Report indicates, “As one of the world’s pioneering food safety agencies, it is imperative that the FSAI continues to evolve by utilising data and cutting-edge science, keeping food safety and authenticity at the forefront of the public health agenda.” The report notes continued progress on upgrading system work and planning review processes to “build and improve on existing data collection processes and frameworks.” Key databases in corporate functions were updated, e.g., internal audit, Advice Line, and Rapid Alert System for Food and Feed (RASFF) database, which is an EU-wide network facilitating the exchange of information regarding food safety risks among member states and is used to manage food alerts and notifications. The FSAI has redeveloped its food notification system to improve functionality for end-users.

The Food Science and Standards (FSS) functional area focuses on evaluating scientific evidence and generating data to support risk assessment, development of compliance tools, and issuing technical advice. It engages with the international scientific community to remain on the cutting edge of food safety research and developments. The management of data is integral to its core functions.

The FSAI Annual Report 2022 shows that various actions were taken by FSAI for meeting its data related objectives, for example:

- Objective 4.2 Provide a robust and targeted information framework to deliver internal efficiencies and meet stakeholder and customer needs; and
- Objective 4.4 Embed a culture of quality through ensuring that systems, processes, and procedures meet the highest standards.

The 2023 Annual Report indicates the following additional steps completed under Objective 4.4:

- Retention of ISO 9001 certification;

- Business Management System project plan delivered;
- Open audit findings and improvement opportunities closed as agreed;
- Secure resources for and implement a project management framework for the FSAI;
- Identify, agree, and implement a Project Management Office to assure successful delivery of key projects;
- Provide support to project managers to enable efficient use of resources, mitigate project and organisational risks and to maximise lessons learned to further improve business operations.

Transition to sustainable food systems Stakeholders indicated that a gap exists between FSAI legislation and that of other related areas, e.g., in matters of sustainability. Food production methods have evolved since the inception of the Act, which interact with policy changes in areas of energy and waste, as well as use of chemicals on crops and as food additives. FSAI is alert to issues and unintended consequences on issues such as the use of biosolids on land, biomethane, impacts on water, etc. Amendments to sustainability legislation could reflect these changes in the supply chain and increase food safety compliance. The Navigo review (2023) indicated that the FSAI Board should examine the use of (for example) the UN Sustainable Development Goals as a framework with which to evaluate this area.

Nutrition

Stakeholders reported a lack of legislative clarity in relation to the role of FSAI in nutrition policy, e.g., as the establishment of SafeFood (1999) under the British Irish Agreement Act, 1999, and of Healthy Ireland under the Department of Health are two bodies operating in the food/health/nutrition/safety areas of public service. Food safety and nutrition are both implicated in the emerging area of food reformulation. However, food safety falls under the remit of Food Unit within DoH and not Healthy Ireland, and nutritional advice falls under the remit of FSAI only with regards to food legislation and public health. FSAI's 2024 Business Plan indicates that it is working on a compliance building tool for businesses and inspectors on nutrition and health claims, which is to be reviewed and, if agreed, developed over 2024-25.

Food innovation

The FSAI has to ensure that advancements in the food sector do not compromise consumer health and interests, continuing to maintain high standards amid industry innovations.

Summary

The main findings of the assessment undertaken in this Annex were as follows:

- The operating environment of FSAI is influenced by a range of factors, as considered in the 'PESTLE' analysis.
- FSAI has responded well to recent challenges (COVID-19/Brexit) and performed effectively on delivering its functions in this context.
- Key factors going forward likely to include EU Commission developments, e-commerce, increased complexity of the food chain attitudinal trends, technological developments, and possible (EU) legislative changes.
- These could increase the complexity of the workload for the FSAI and its Official Agencies.
- FSAI will need to continue to adapt and remain responsive, and its future strategic plans should articulate objectives and deliverables that take this uncertainty into account.

Annex 4 Additional Details from Stakeholder Consultation

This annex presents a summary of findings and views ascertained during the stakeholder consultation process undertaken as part of this report. Indecon found generally positive views of FSAI, highlighting the importance of ongoing oversight of food safety.

The FSAI's responsiveness to various challenges, according to stakeholders, can be summarised as follows:

- Positive Reputation:
 - Professional, expert organisation
 - Provides leadership in food safety
 - Keeps pace with food production/manufacturing changes
 - Part of a strong international network
- Strong real-time awareness of the impact of Geo-political situations
 - Communicates risks with authorities, agencies, businesses, and consumers
- Challenges were noted:
 - Communication gaps – passing of information obtained at a European or cross-governmental national level
 - Lack of expertise can lead to delays in certain circumstances

Examples of stakeholder views on FSAI's organisational capacity are presented below.

Box A5.1: Examples of Stakeholder Views on Organisational Capacity

"Adequately resourced, however, the profile of expertise within the FSAI has changed significantly in recent years with fewer staff holding qualifications and experience as food safety inspectors and regulators which does impact the FSAI's capacity to deliver in certain circumstances."

"Growing demands on the FSAI in the future due to regulatory divergence with the UK, comprehensive engagement with Codex, and the growing EU regulatory agenda in sustainability and other areas such as labelling (with strong interface to food safety)."

"Resource constraints have been articulated in relation to the maintenance and development of shared IT systems."

Source: Confidential Indecon Stakeholder Consultation

Examples of stakeholder views on the future of the FSAI are noted below.

Box A2.2: Examples of Stakeholder Views on the Future of the FSAI
<i>"Mandate and structure of the FSAI seems appropriate. The FSAI is a very visible and active part of the Food sector connecting with private and public sector partners across a range of diverse areas."</i> <i>"Better coordination and agreed decision making processes between FSAI, DAFM and NEHS that some cross agency food functions may work better."</i> <i>"The current system has developed over a number of decades and could be described as mature."</i>
Source: Confidential Indecon Stakeholder Consultation

Examples of stakeholder views on service delivery are presented in the following box.

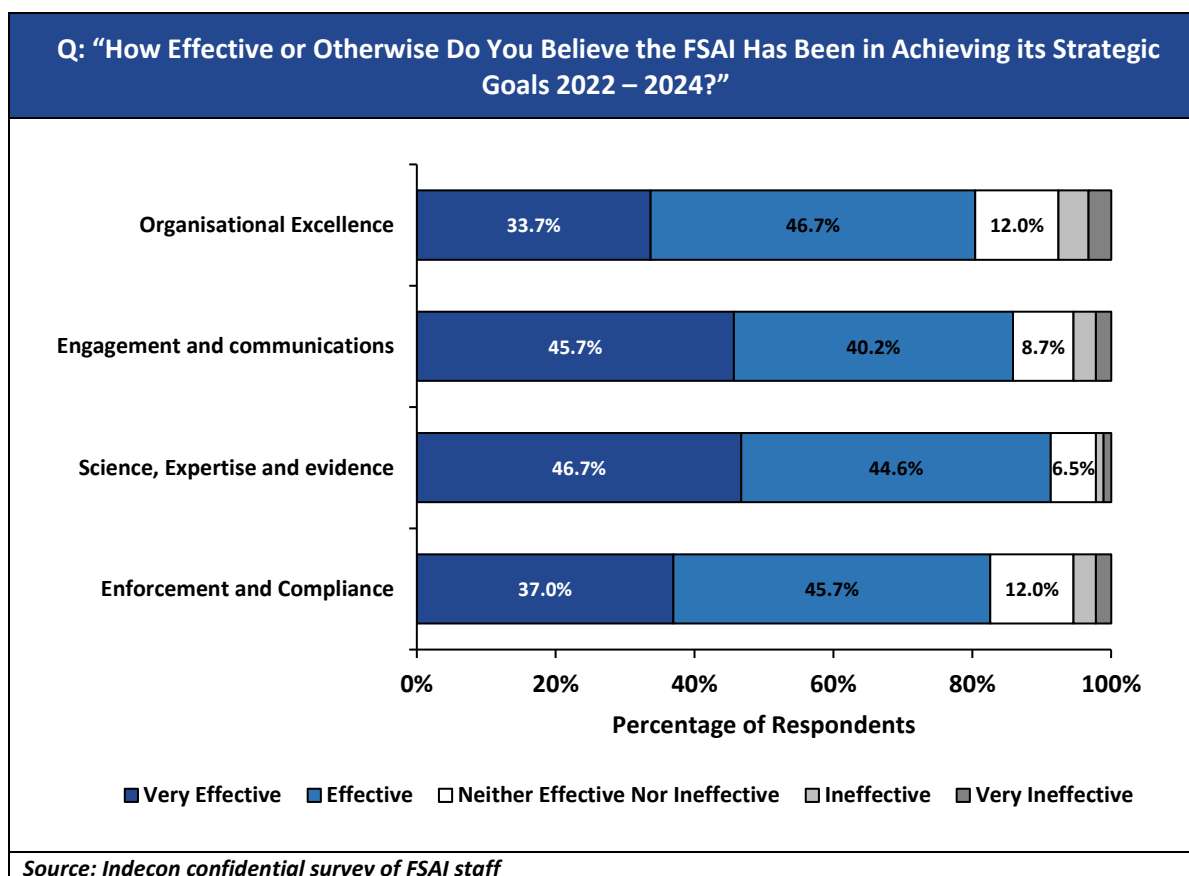
Box A2.3: Examples of Stakeholder Views on Service Delivery
<i>"Proactive and impactful body where there is transparency and insightful debate, with active follow up on the key areas that aim to assist the FSAI to discharge their mandate."</i> <i>"Improved communication between the FSAI and competent authorities in the UK with a view to reducing and resolving issues arising from regulatory divergence."</i> <i>"It is important that there is a clear understanding of the roles and responsibilities under the service contract and within the broader EU and National legislative process."</i>
Source: Confidential Indecon Stakeholder Consultation

Summary of Stakeholder Consultation: Staff Survey

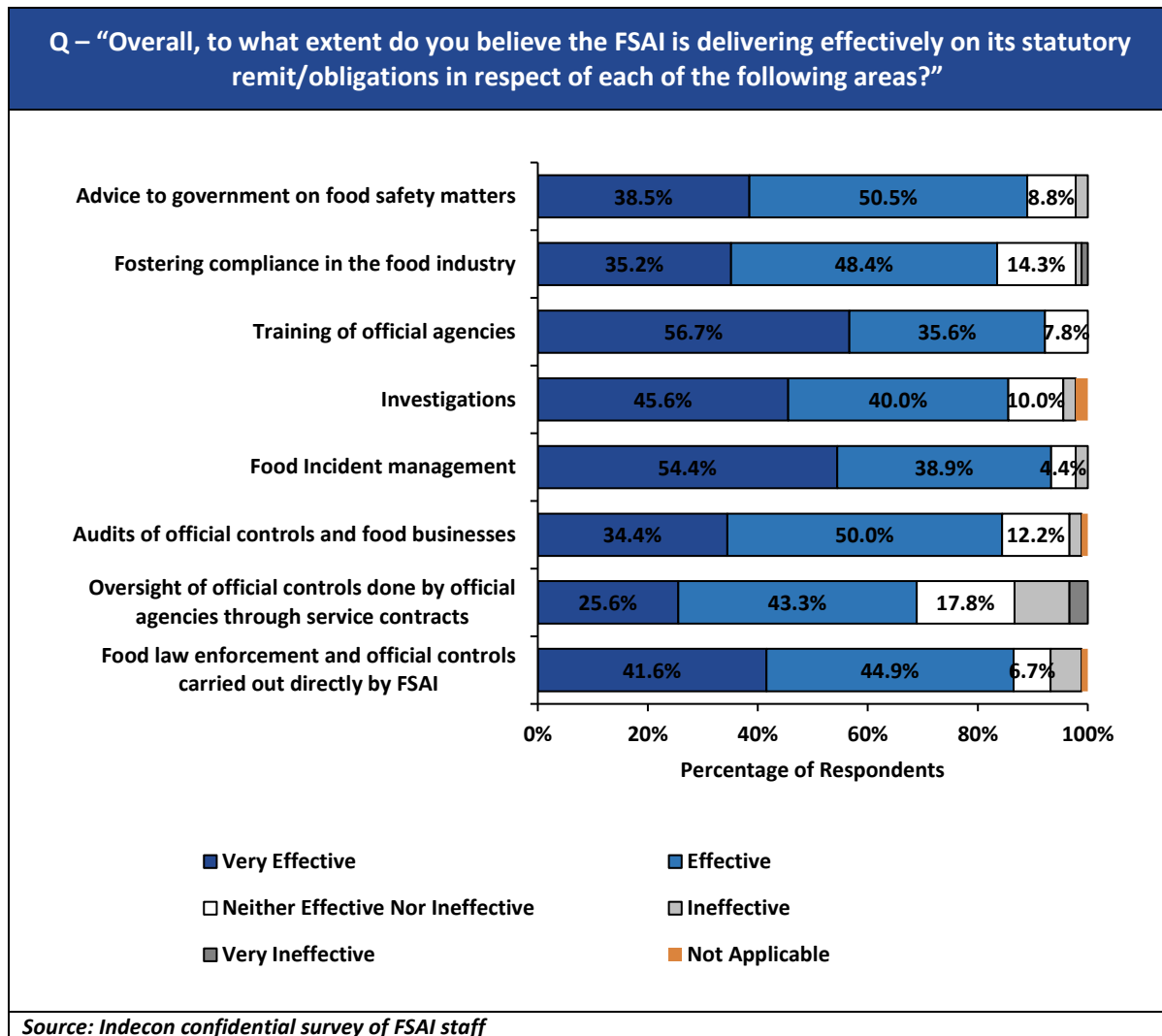
As part of the confidential stakeholder consultation process, Indecon asked for views of FSAI staff. Respondents comprised a significant proportion (51%) of the staff within the organisation and have worked with FSAI for less than 5 years; and there was a high proportion of technical grades, as expected in an organisation with requirements for specialist expertise. The table below indicates the proportion of respondents to the consultation survey by job grade.

Respondents' Grades within FSAI	
Job Grade	Proportion of Respondents
Director	3.4%
Chief Specialist	7.9%
Veterinary/Agricultural Office	1.1%
Manager	16.9%
Technical Executive	43.8%
Sr Technical Executive	9.0%
Enforcements Executive	4.5%
Administrative Assistant	4.5%
Sr Administrative Assistant	9.0%
Total	100%
Source: Confidential Indecon Survey of FSAI Staff 2024	

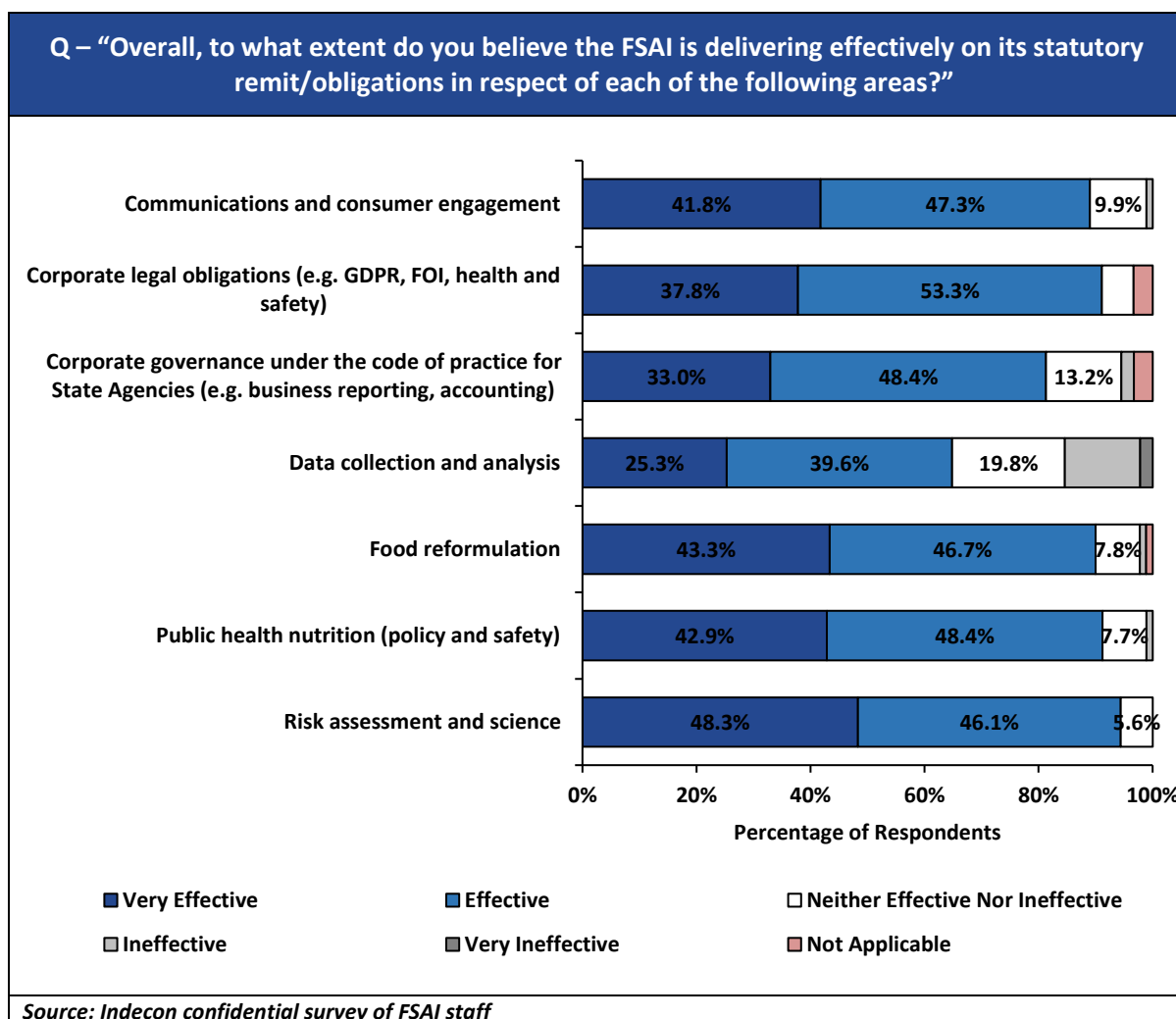
The following figure presents staff survey results relating to the effectiveness of FSAI in achieving its strategic goals from 2022-2024.



The following figure shows the distribution of answers given by FSAI staff in relation to their beliefs about FSAI’s delivery effectiveness in accordance with its statutory obligations.



The following figure is a continuation, and shows the distribution of answers given by FSAI staff in relation to their beliefs about FSAI's delivery effectiveness in accordance with its statutory obligations.



Annex 5 Overview of Levels of Activity by Official Agencies

