

Report of the Scientific Committee  
of the Food Safety Authority of Ireland

2015

# A Review of the Official Control System in Ireland and Opportunities for Improvement



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## **GLOSSARY**

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**DAFM**

Department of Agriculture, Food and the Marine

**FSAI**

Food Safety Authority of Ireland

**HACCP**

Hazard Analysis Critical Control Point

**HSE**

Health Service Executive

**OAPI**

Official Agency Premises Inspection database

**SFPA**

Sea-Fisheries Protection Authority

## EXECUTIVE SUMMARY

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The Food Safety Authority of Ireland (FSAI) was established by statute in 1999 as an independent, science-based organisation with statutory responsibility for the enforcement of food safety legislation. The Food Safety Authority of Ireland Act, 1998 created a set of institutional arrangements for the administration of official food control inspections that are particular to Ireland. The law prescribed the responsibility for the enforcement of food legislation to the FSAI and to enforce the laws, the FSAI was required to enter into service contract agreements with those agencies previously involved in official food controls. The four main agencies contracted included: the Department of Agriculture, Food and the Marine (DAFM) veterinary inspectors and agriculture inspectors, the Health Service Executive (HSE) environmental health service, local authorities and the Sea-fisheries Protection Authority (SFPA). Much has been achieved over the last 16 years to make the State's system of food inspections fair, consistent and effective. The current system has much to commend it. However, this needs to be monitored and reviewed to ensure consumers of Irish food, both domestically and internationally, continue to be protected and that the system of official controls is monitoring and auditing food businesses effectively.

In December 2012, in response to a request by the FSAI, the Scientific Committee established an *ad-hoc* Subcommittee designated the Official Food Control Review Steering Group (Steering Group). The Steering Group was tasked with reviewing the effectiveness of the official food control inspection system in Ireland and to report on its findings to the Scientific Committee. The Scientific Committee has further developed and amended the Steering Group's report and its recommendations, resulting in this document. The scope of the review is limited to food business inspections and does not cover official control sampling and surveillance.

The Steering Group commissioned independent consultants to support their work and the commissioned study had two phases. Phase I included an evidence review, consultations with stakeholders and the identification and selection of performance measures. Phase II involved an assessment of the current official control inspection system in Ireland and selected other countries, and included a survey of inspection staff. The independent consultant's report identified operational, structural and strategic issues that need to be addressed to strengthen the effectiveness of the official control inspection system. Operational issues can to a large extent, be addressed through improvements to the information infrastructure, staff skills and working procedures. Adequate financial resources should be made available to provide the necessary staff and other resources for official controls.

Some issues would benefit from a collaborative effort on a cross-agency basis, while others can be tackled by individual agencies alone. A system-improvement plan setting out the priorities and each agency's role in delivering the change needed would help to provide a structure for this transformation. The current set of organisational arrangements presents the FSAI with many strategic challenges in fully implementing its legislative mandate.

Thirteen recommendations are proposed which, if implemented across the FSAI and its official agencies, would facilitate improvements in the current system and make the official control inspections more effective. In particular, a new performance management system in which a set of key indicators are monitored at an agency level, will increase the transparency of how the system is performing and enhance accountability. This will result in an improved official control system for the continued protection of public health and public interest.

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## **Recommendations:**

1. A cross-agency performance management system to measure the effectiveness of the official control system should be established
2. A suite of performance measures should be put in place across all official agencies to ensure the effectiveness of the system by allowing it to be properly monitored and reported
3. Realistic targets should be established for each of the key performance measures
4. Data and information at a sufficiently detailed level should be collected by official agencies and provided to the FSAI. This will allow the official agencies to manage and report on official controls and the FSAI to carry out and report on its oversight function
5. The current funding arrangements for food safety controls should be reviewed along with the measures available to the FSAI in the case of non-performance of the official agencies, with a view to strengthening the current organisation model for official controls and maintaining the independence of the FSAI
6. Measures to further improve the consistency of official controls need to be strengthened to ensure all businesses are inspected fairly
7. All official agencies need to develop and implement effective internal audit systems and ensure timely close-out of findings in line with legislative requirements
8. The FSAI, in collaboration with the agencies, should establish a procedure to estimate and monitor the stock of risk in the system
9. A consistent and transparent approach to use of the enforcement powers available needs to be established across all official agencies
10. The FSAI should coordinate a review of the flexibility arrangements provided in the EU Hygiene Package whilst ensuring the continued protection of public health
11. The system of oversight and control for potential institutional conflicts of interest needs to be strengthened
12. The FSAI should monitor how resources are aligned to risk across the food chain with a view to strengthening the effectiveness of official controls
13. Expertise in specialist food safety control areas needs to be enhanced and maintained commensurate with the requirements of effective official controls

## CHAPTER 1. INTRODUCTION

The FSAI was established by statute in 1999 as an independent, science-based organisation with statutory responsibility for the enforcement of food safety legislation. The FSAI engages with the food sector to promote a culture of compliance based on a commitment and acceptance of their legal responsibility to produce safe food. The FSAI's mission is:

***'To protect consumers' health and consumers' interests by ensuring that food consumed, produced, distributed or marketed in the State meets the highest standards of food safety reasonably attainable and that people have accurate and worthwhile information about the nature of the food they eat.'***

The establishment of a single national agency was a major departure from the previous arrangements under which enforcement duties were carried out by over 46 agencies, each acting to a significant extent, independently of one another.

The FSAI oversees the food safety work of a Government department and several State agencies that historically comprised the nation's food control and enforcement system. Since July 1999, these agencies have operated under service contract to the FSAI. They are accountable for their food safety programmes and standards of work, their actions and their information systems, in so far as these fall within the terms of service contracts and food legislation. It is the role of the FSAI as an independent agency to coordinate the activities of these agencies in order to achieve the most effective use of State resources in protecting consumer health and continually improving standards, both in terms of official controls implemented by the agencies and within the food industry.

It is important to note that no matter how elaborate the official control system, the primary responsibility in law for placing safe food on the market rests with the food business operator. The State has invested considerable resources in developing an effective official control system. A robust control system protects consumers, supports the food industry and facilitates exporters of Irish food. It is the responsibility of the FSAI to oversee and coordinate this multi-agency system, but also to:

- Keep under constant review, the effectiveness of the food inspection system in place
- Ensure it can rapidly react to an ever-changing environment
- Assess how well it is designed
- Determine whether it is achieving the intended effects and where the scope for improvement lies

The food safety legislation for which the FSAI has responsibility is clearly defined and set down in the First Schedule of the Food Safety Authority of Ireland Act, 1998, as amended. European Regulation 882 of 2004 sets down how Member States should carry out official controls (inspections) and the aim of those controls;

*'(a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and*

*(b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information'*



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Official controls are the inspections, sampling and other control activities prescribed under EU and national law, on the food chain. The scope of this report considers the implementation and management of the inspections services under the terms of reference provided to the Scientific Committee<sup>1</sup>. Administration, management and implementation of official controls are shared among the FSAI and four main agencies: DAFM, the HSE, local authorities and the SFPA. Food legislation is enforced on behalf of the FSAI by these four agencies through service contract arrangements. Since its establishment in 1998, the FSAI has aimed to build a more integrated food safety control system. Lyons, 2006 stated that *'In keeping with the 'Paradigm of New Public Management' the FSAI does not operate in a command-and-control fashion through a traditional bureaucratic hierarchy. Rather, it is a key actor in what can be described as the food safety policy network and seeks to generate collaborative advantage from these arrangements.'*

There is much in Ireland's official food control inspection system that is working well. Dedicated staff are applying coherent procedures to inspect food business operators. The available evidence suggests there is effective enforcement and oversight. Inspections are particularly effective in core food safety areas such as hygiene, traceability, HACCP procedures, microbiological contamination and labelling. At the same time it is clear that, as with any such system, there is scope for improvement. This report focuses on improvements and changes that should be implemented to make the system more effective.

<sup>1</sup> See Appendix I, Terms of Reference

## CHAPTER 2. METHODOLOGY

In December 2012, in response to a request by the FSAI, the Scientific Committee established an *ad-hoc* Sub-committee designated the Official Food Control Review Steering Group (the Steering Group). The Steering Group was tasked with reviewing the effectiveness of the official food control inspection system in Ireland and to report on its findings to the Scientific Committee. The terms of reference are included in Appendix I of this report. The Steering Group was requested by the Scientific Committee to consider how resources are aligned to risks in the food chain and to include, in their report, the following:

1. Review the organisation, quality and operation of the official control system in Ireland, advise the FSAI on the strengths and weaknesses of the current inspection system and identify any potential changes to improve its control of risks
2. In the context of the official controls as detailed in the scope, examine the oversight and accountability arrangements within and between the FSAI and the official agencies and identify opportunities for improvement where necessary
3. Review how best regulatory practice and regulatory assessment might be applied in the FSAI and the official agencies
4. Consider the data on official controls activities collected by the FSAI, advise on whether they are suitable for monitoring the efficacy of the official control system and make recommendations for improvements where necessary

To facilitate this work, the Steering Group commissioned an independent study undertaken by private consultants which incorporated two phases (see [www.fsai.ie](http://www.fsai.ie) *Evaluation of the Official Control Inspection System in Ireland*).

Phase I included an evidence review, consultation with industry and official agencies and the identification and selection of performance measures. Phase II involved an assessment of the current system in Ireland and other countries, including a survey of official agency inspection staff.

For the evidence review, EU and Irish legislation and service contracts were compared and existing information on the effectiveness of the Irish system was reviewed. The evidence review output was a map of the official controls system that indicated the main strengths and weaknesses in the system and identified priority issues to address in subsequent tasks. Engagement with the agencies and industry included face-to-face interviews and telephone interviews with representatives from each of the agencies within the study scope and with industry representatives. The interviews covered the strengths and weaknesses of the current official controls system, how the performance of official food controls could be better monitored and evaluated, and how official controls could be improved in the future.

A framework was developed for selecting performance measures and this was used to identify an initial set of measures to evaluate the effectiveness of the official controls system for further exploration in the later phases of the work.

Finally, an evaluation of the official controls system in Ireland was undertaken, drawing on the information obtained through the first part of the study including the consultation (interviews and survey) with the official agencies, and information on other official control systems. The independent consultants produced an assessment of the current official controls system, recommendations on potential options to improve the system where weaknesses were found and refinements to the set of performance indicators that could be used in the future<sup>2</sup>.

This information was assessed by the steering group which also drew on the experience of its members in drafting a report for consideration by the FSAI Scientific Committee. The Scientific Committee has further developed and amended the Steering Group report and its recommendations, resulting in this document.

<sup>2</sup> See [www.fsai.ie](http://www.fsai.ie) for *Evaluation of the Official Control Inspection System in Ireland*

## CHAPTER 3. SUMMARY OF THE REVIEW OF THE OFFICIAL CONTROL SYSTEM

The focus of this report is to propose ways by which the official controls system in Ireland can be improved and identify the changes necessary to achieve those improvements. This section of the report provides a summary of the main issues facing the current system based on the findings of the independent consultants, the report prepared by the Steering Group and the views of the Scientific Committee itself. It is acknowledged there are many positive characteristics in the inspection system and although these are not highlighted here in any detail they are recognised and reflected in the independent consultant's report *Evaluation of the Official Control Inspection System in Ireland* ([www.fsai.ie](http://www.fsai.ie)).

The main issues facing the current system fall under the following headings:

- **Roles and Responsibilities:** The effectiveness of intra- and inter-agency cooperation, collaboration and coordination and the extent to which agency representatives are free from conflicts of interest in undertaking control activities
- **Control Activities Implementation:** How effectively the agencies prioritise and verify control implementation
- **Enforcement:** The extent to which sufficient powers are available to the FSAI and the official agencies and the use of effective, proportionate and dissuasive enforcement measures
- **Reporting and Transparency:** The effectiveness of data collection and reporting systems to demonstrate control implementation and the extent to which there is effective information sharing
- **Staff Resources and Expertise:** The extent to which there is effective resource distribution across control activities and that staff have sufficient expertise and experience to effectively carry out their control activities.

The recommendations made in Section 5 of this report are based around these issues.

### 3.1 Roles and Responsibilities

#### 3.1.1 Governance arrangements

The FSAI is an independent food regulatory authority and the central competent authority with overall responsibility for official controls dealing with food safety and food legislation. Implementation of official controls is shared among FSAI and its agencies. The main agencies are DAFM, the HSE, local authorities and the SFPA although other smaller agencies also participate, e.g. the National Standards Authority of Ireland (NSAI) and the Marine Institute. Food legislation is enforced on behalf of the FSAI by these agencies through service contract arrangements. Each agency is responsible for the enforcement of the legislation listed in its service contract and its activity is often limited to specific types of businesses (such as small or large companies) and/or specific stages of the food chain. The FSAI is required to specify in the service contracts, the objectives and targets for food inspections it wishes the official agency to meet with regard to the resources available to the official agency. This arrangement creates a set of institutional dynamics that are particular to Ireland.

Much has been achieved since the creation of the FSAI and the official control system has much to commend it. There is generally good cooperation amongst the agencies and the FSAI has been effective in building a more integrated food safety control system. But the existing arrangements create challenges for effective governance of the system. For example, the FSAI has responsibility for enforcement of food law and oversight responsibilities for the related activities of its agencies but does not control funds (with the exception of the local authorities). It relies on the agencies to provide full information on the system, does not have management control or the power to prescribe the terms of service, nor does it have access to proportionate sanctions in the event of non-performance by the agencies. Hence, it is not in a strong position to exercise in full, the functions required of it in law.

There are alternative governance arrangements for the official control system in which the FSAI would have different roles. These can be summarised into three models as follows:

- 'Auditor': The FSAI works at arm's length from other agencies, audits them and packages information supplied from the constituent parts of the system for use by national stakeholders and the European Commission
- 'Information integrator': The FSAI is the hub of a fully integrated information system across all agencies and a centre of risk intelligence. It has the capacity to interrogate available data to identify specific and systemic risks and flag issues for investigation by inspectors in other agencies. Agencies retain their existing inspection functions but there is better ring-fencing of food control staffing and a much more robust performance management system
- 'Primary agency': Inspection duties are transferred to the FSAI from one or more official agencies. The FSAI becomes an inspection delivery agency rather than an auditor, analytical and advisory body

In relation to potential change to the current governance arrangements, the consultant's report stated "*A more detailed analysis of the benefits, costs and wider implications of the primary agency model would be needed, together with a mapping of potential transition pathways, before a decision on such change could be made with confidence*". While governance issues are acknowledged, it is considered that direct management control would threaten the independent role of the FSAI and its unique contribution to the oversight of official controls. Progressing the 'information integrator' model, enhanced by actions on financial flows and sanctions, could deliver some of the functional benefits of a primary agency model without the organisational disruption that institutional changes would entail. The latter approach is favoured as a means of affirming the independence of the FSAI. In drawing this conclusion, it was also noted that, while the FSAI's administration of the funding stream for the local authority veterinary service had resulted in a degree of influence on the activities of this service, it has also placed an additional administrative burden on the FSAI.

Paragraphs 48(12) and (13) of the FSAI Act specify the mechanism by which the FSAI can turn to sanctions under the service contract system. This statutory mechanism requires that the FSAI, having identified a significant breach of a service contract, consults with the relevant Minister/department and then puts an alternative arrangement in place for official controls. The FSAI may also report breaches to the Minister for Health who must inform the Oireachtas. However, these sanctions are regarded as impractical because the FSAI does not have sufficient resources or structures to replace the existing activities of the official agencies and the activities requiring replacement are specialist and complex and not easily replicated by another agency. The alternative sanction allowed in the FSAI Act of reporting unsatisfactory performance by an agency of its service contract, to the Minister for Health and to the Oireachtas would be a major escalation of a dispute between the FSAI and the agency which would elevate the profile of the issue without certainty that the matter would be addressed. For example, there are additional complications arising from the limitations to budgets and staffing in the agencies so that if the FSAI required additional control activities, the agencies would not be able to increase the workload without additional resources. Alternatively, more practical sanctions could be an obligation on agencies to report breaches of service contract and to implement a corrective action plan, allow the FSAI to issue binding directions to an agency to correct a breach of service contract and/or create proportionate sanctions such as fines for failure to comply with one or more terms of a service contract.

### 3.1.2 Potential conflicts of interest

A further issue regarding roles and responsibilities in the current official control system relates to management of potential conflicts of interest. As outlined earlier, the official controls system in Ireland is implemented through a number of autonomous agencies under oversight of the FSAI. However, none of these agencies is exclusively responsible for food controls which may lead to potential conflicts of interest at an institutional level. For example, amongst its many responsibilities, DAFM is responsible for supporting the agri-food sector in accessing export markets as well as carrying out official controls on food businesses in the same sector. On a smaller scale, the HSE is responsible for running food business operations in its care institutes as well as carrying out official controls on those same food businesses via the work of its environmental health officers. The SFPA is tasked with supporting a sustainable and profitable commercial fishing sector at the same time as carrying out official controls on the food businesses in that sector. Local authorities are engaged with the support and promotion of local businesses whilst their veterinary inspection services carry out official controls on local food businesses handling foods of animal origin.

Similarly, potential conflicts of interest can exist at an individual level. For example, officers carrying out official control inspections in the same facility for a long period of time and those located within the community of food businesses with which they work could be subject to regulatory capture<sup>3</sup>. Additionally, the inspectors working in the agencies may find themselves carrying out industry support work from time-to-time as well as their food inspection work. Therefore, there is a need to be aware of and manage potential conflicts of interest at an institutional level and a personal level. The aim is to conduct official controls in a fair, transparent and consistent manner in order to protect public health. Recognition of the need to manage potential institutional conflicts of interest was one of the drivers that created the FSAI in 1998 as an independent, non-conflicted organisation with oversight of the conduct of agencies in matters concerning official controls. The FSAI has an interest in ensuring that potential conflicts of interest are managed in the agencies under service contract and the matter is addressed through the service contract management process and verified by the independent audits of the agencies conducted by the FSAI.

It is reassuring that the study carried out by the independent consultants found that overall, potential conflicts of interest for individual inspectors are well managed and the agencies have mechanisms in place to manage the potential personal conflict of interests of their staff. For example, agencies design their inspection rosters and procedures so as to reduce the risk of the kind of informal regulatory capture that can happen when inspectors develop a close working relationship with the businesses they are inspecting. Additionally, agency representatives from the HSE, DAFM and the SFPA indicated that in some cases, two inspectors visit a premises together. Local authorities ensure that any enforcement action taken also involves both the inspector and their line manager/the FSAI. Another approach is to change inspectors for a premises from time-to-time to provide a 'fresh pair of eyes' on an establishment's activities.

However, the independent consultant's report also highlighted the challenges faced in managing potential institutional conflicts of interest and noted the systemic risk which needs to be managed. Robust systems are needed to ensure that the wider public interest is safeguarded. Ongoing vigilance of this matter is necessary since evidence from the survey of inspectors suggested that potential institutional conflicts of interest may not always be well managed in agencies with an industry promotional role. For example, 21% of agency respondents identified this potential conflict of interest and considered that it was not well managed. Whilst recognising that this evidence is opinion-based, it highlights the need to actively address potential institutional conflicts of interest in the official control system. The FSAI's oversight and audit helps to identify and address potential institutional conflict of interests and the study noted that there was no evidence that public health had been compromised by the current governance arrangements. Separating sponsorship and inspection functions within agencies would entail reallocation of responsibilities and a reconfiguration of existing institutional arrangements. Such change could have benefits for managing potential institutional conflicts of interest but would entail additional staff costs and ancillary resources.

<sup>3</sup> Regulatory capture is the process whereby regulated industries are able to gain influence over their regulator, so that the regulator established to serve the public interest actually supports the interest of the industry concerned.

## 3.2 Control Activity Implementation

### 3.2.1 Risk-based official controls

Official controls are carried out on food and food businesses in Ireland to verify compliance with food law and to protect the health of consumers. Controls can range from audits of hygiene and other general food safety areas applicable to all food businesses, to specialist controls applicable to specific food businesses, e.g. food supplement controls. The official controls regulations require official controls to be carried out regularly, on a risk basis and with appropriate frequency. It also requires that the official agencies should carry out internal audits or may have external audits carried out, and should take appropriate measures in light of their results to ensure that they are achieving their objectives. Audits should be subject to independent scrutiny and carried out in a transparent manner. It is also important that the agencies have the legal powers to carry out official controls. The agencies should have procedures in place to ensure that corrective action is taken when needed and that documentation on the procedures adopted is updated. Sanctions provided in food law must be effective, proportionate and dissuasive.

Risk-based approaches have been adopted by all official agencies as a means of prioritising their work. A risk-based approach should ensure that the burden of official controls is lower for food business operators that pose less risk to food safety, and that more activity is undertaken to monitor and enforce food safety risks for those food business operators that pose a greater risk to food safety. The HSE environmental health service and the FSAI agreed a risk profiling system for food establishments (FSAI Guidance Note No.1, Rev 2). The risk profile for each establishment is used to determine the inspection frequency. The risk profile takes into account the type of food produced, the processing or handling of food, the scale of the operation and the type of consumers. It does not take into account the risk management practices of the business or the inspector's confidence in food safety management systems. The risk category only changes if there is a significant change to an establishment's products and/or processes. Following an inspection, if a public health issue arises or there is poor compliance, the inspection frequency can be changed but not the risk category. This type of risk categorisation makes it more difficult to verify that inspection activity is meeting requirements and to determine the aggregate 'stock of risk' in the system.

On the other hand, DAFM and the SFPA include a review of a food business operator's history and risk management tools. The differences in approaches to risk ranking of food businesses by agencies makes it difficult to track changes in the stock of risk in the system and to assess the overall effectiveness of control activities. A consistent approach would benefit the system as a whole and there are international models, e.g. Denmark and the Netherlands that may serve as a template.

### 3.2.2 Documented procedures and flexibility

Each agency follows documented procedures to determine control frequency and standards for inspection that have been developed within their agency. This is a regulatory requirement as documented procedures assist in consistency of inspection and training of staff. However, evidence from the survey of staff conducted by the independent consultants suggests that there are varying views between agency staff of whether procedures in their agency are fit-for-purpose. Additionally, some audits of these procedures have demonstrated that they are not always consistently adhered to. There are concerns by staff in some agencies that procedures may be too complex (DAFM, local authorities, the SFPA) or too rigid to facilitate the flexible approach to official controls that is envisaged in European regulations (HSE, local authorities). This latter issue is mirrored by representatives from the retail, food manufacturing and processing, restaurant and catering, and artisan industry who were also concerned about the consistency of inspections and use of flexibility options.

A process to review Ireland's use of the 'flexibility' clause in the EU Hygiene Package (2004) and EU derogations on traditional food production may assist in assessing these concerns whilst ensuring the continued protection of public health. These provisions are specifically designed to assist small businesses and those working in traditional food production areas to meet their food safety obligations and facilitate the focusing of food control inspections on those areas of greatest risk.

### 3.2.3 Audits

The official control system is verified by audits which are used to evaluate the efficient functioning of the official control system. Agencies have a legal obligation to audit their own activities. In addition, the FSAI provides an independent audit of the work of the agencies under service contract and the European Commission's Food and Veterinary Office audits the FSAI and its agencies as a collective when evaluating the official control system in Ireland as a whole. However, whilst some agencies like DAFM have a well-developed and well-functioning internal audit system, other agencies like the HSE and the SFPA have yet to establish internal audit systems although work is well underway towards this goal. The FSAI's audit system was considered to be functioning well in terms of scrutiny and transparency. Nevertheless, some agency staff highlighted the danger of 'audit fatigue' leading to resource problems due to the number of audits conducted by/on them.

## 3.3 Enforcement

Enforcement of food law is conducted by the FSAI and its agencies based on powers provided in the legislation that make up food law, including the FSAI Act. Powers for authorised officers are provided in the relevant legislation along with the sanctions that can be brought to bear on food businesses failing to comply with the legislation. Formal enforcement activities range in severity from notices to ensure remedial action is taken to the closure of food businesses in the case of a grave and immediate danger to public health.

FSAI audits of the official agencies have not reported any issues with the available enforcement mechanisms and the audit reports show that in general, enforcement measures are implemented effectively and appropriate actions taken. The independent consultant's report raises two instances in which enforcement measures have been compromised by lack of timely follow-up and close-out but these are not reflective of normal practice. The evidence is that generally, agencies have sufficient powers to take enforcement actions in cases of food business operator non-compliance, and sanctions are available in law which are effective, proportionate and dissuasive. However, powers available to inspectors in the area of food fraud need to be addressed.

### 3.3.1 Consistency of enforcement

Standard operating procedures (SOPs) adopted by the agencies specify how non-compliances should be addressed and inspectors often have considerable freedom to decide how to respond to non-compliances. Providing scope for use of such discretion is helpful but it does mean that agencies need to have procedures in place to ensure consistency, especially for higher level corrective actions. Agencies have different approaches to ensure consistency between inspectors, e.g. annual training of supervisory officers, escalation of significant decisions to line management, shadow inspections of junior staff by senior staff, the HSE/FSAI Consistency of Enforcement Group, systematic file review. Nevertheless, the consistency of use of enforcement powers could be improved in some areas. For example, local authorities face particular difficulties in maintaining continuity and consistency of service given the small size of their veterinary teams and the fragmented nature of the service. That said, amongst respondents to the staff survey by agency, HSE and local authority staff members believed that the powers available to them for enforcement in the event of food business operator non-compliance were sufficiently used, whereas DAFM and SFPA staff member views were mixed on this issue. About a half said they were sufficiently used, while about a third said that they weren't sufficiently used. In relation to the agencies and the effectiveness of the official controls, the Food and Veterinary Office did an audit of the official controls system in 2013 (reference DG (SANCO) 2013-6859) and it concluded that all competent authorities met could demonstrate that they were capable of identifying issues undermining the effectiveness of official controls and of taking actions to address these issues.

### 3.3.2 Transparency of enforcement

Transparency of enforcement action is also an issue raised in the independent consultants report. The FSAI Act is available to all agencies to address issues of non-compliance and orders made under the FSAI Act are published on the FSAI website. The HSE, the SFPA and local authorities regularly use these powers, however DAFM uses other enforcement powers which are not publicly disclosed unless in the case of a prosecution.

The effect of current practice is that enforcement actions taken against food business operators regulated by DAFM under S.I. No. 432/2009, which tend to serve export markets, are escalated to a higher level before they are placed in the public domain, i.e. where the food business operators are taken to court. Actions taken under the FSAI Act appear in the public domain at an earlier stage of the enforcement process. This is because of the FSAI policy to publicise enforcement orders taken under the FSAI Act and the legal requirement of the District Court to issue Improvement Orders.

In such cases, where the official agencies rely on legislation for enforcement actions that are not publicly reported, there is a need to consider how to align this use with the objectives of the Irish food inspection system. The FSAI does not have sufficient powers to require a more standardised approach to enforcement across agencies

Data on actions taken from more serious non-compliances are available, but information about provision of verbal advice and letters that are not formal notices is not available. In general, the legislation is not prescriptive but instead sets out broad parameters for enforcement. Further guidance is needed if enforcement procedures are to be standardised and consistent data generated on which to base an indicator that measures the numbers of actions.

### 3.4 Reporting and Transparency

The FSAI is responsible for ensuring that official controls are implemented effectively. Official agencies are responsible for the implementation of controls, and provide information to the FSAI to enable it to monitor the implementation and outcome of official controls. In order to exercise its oversight function with respect to food safety controls in Ireland, the FSAI must have timely access to the right data from the agencies. Some parts of the official control system offer the potential to create a single cross-agency 'information environment' in which data move freely. Other parts are working to a model of periodic submission of reports of pre-agreed content, isolated information systems and restrictions on FSAI access to detailed data.

Systematic data collection and reporting issues make it difficult to assess whether compliance is being effectively demonstrated. The official agencies provide summarised annual reports to the FSAI on the control activities undertaken but these reports are not sufficient for the overall effectiveness of the official controls system to be fully established. Aggregated or summarised data are insufficient to allow the FSAI to monitor the effectiveness of official controls because it often masks variations that occur at local or regional levels. For example, the achievement of a national inspection target by an official agency could disguise that some regions are not achieving targets. The need to analyse detailed data is also important to identify anomalies or trends in official controls in order to determine the most appropriate actions.

Official controls data are part of EU reporting obligations. For example, the EU return under the multi-annual national control plan is built using information provided to the FSAI by the agencies that implement the controls. As such, the content of the report is determined by the sophistication of the agencies' data capture and reporting systems and the sub-set of data from those systems that is provided to the FSAI. Therefore, whilst in general, Ireland meets its EU reporting obligations, the compilation of comprehensive and consistent reports on official control activity is a major challenge at present. The FSAI has the mandate to obtain such information but does not have the power to effectively enforce that mandate when this information is not provided. Modes of data collection, e.g. paper vs. electronic, differ within and across agencies. The SFPA and local authorities use two different, and incompatible, Official Agency Premises Inspection databases (OAPI) for the sharing of data with the FSAI. DAFM and the HSE use entirely different systems. The FSAI, along with the agencies, face IT system management issues and resource constraints.



The allocation of controls across agencies and across several information systems does not facilitate integrated, system-wide analysis of risk or effective controls. It is not possible to provide integrated risk assessment and risk management in a context where information is partitioned and data are collected using summarised reports. The FSAI's strategy of pooling data on shared information platforms while retaining individual institution's roles, accountabilities and lines of management control could help create a more intelligent and effective system. With better access to information held within the system, use of data from beyond the controls system, appropriate technologies and analytical capacity, the FSAI would be well placed to be an 'intelligence hub' for the system as a whole.

### **3.5 Staff Resources and Expertise**

Competent authorities must have a sufficient number of suitably qualified and experienced staff. Staff performing official controls should receive, for their area of competence, appropriate training covering the areas listed in Annex II of Regulation (EC) No 882/2004, such as control techniques and procedures and food law. Staff performing official controls should be up-to-date in their area of competence and receive regular additional training as necessary. Adequate financial resources should be made available to provide the necessary staff and other resources for official controls.

The independent consultant's report notes that the official control system benefits from having many dedicated staff who take pride in their work and wish to see the system perform and improve.

#### **3.5.1 Staff numbers**

Staff resources are a major influence on the effectiveness of official controls and the ability of the FSAI and agencies to implement the full breadth of food law currently required. During the recession, staff numbers decreased significantly in all agencies due to the public service recruitment embargo coupled with inducements for early retirement and natural reduction in numbers as staff move into other jobs. Staffing data for the FSAI and official agencies show that the overall full-time equivalent staff complement for official food controls declined by 15% over the 2009-2013 period.

The independent consultants found that the available evidence suggested that inspections are effective overall. They also found that there was much in Ireland's official food control inspection system that is working well with dedicated staff members applying coherent procedures to inspect food business operators. This finding is a testament to the hard work and dedication of the staff responsible for official controls. Increases in productivity through changes to practices and ways of working have achieved significant gains in the efficiency of official controls. An example of improvements in practice is the way in which agencies have worked together to remove inspection duplication in the system and their joint efforts to manage food crises. But this can only go so far in addressing resource constraints without affecting the effectiveness of official controls. For example, the independent consultant's report has highlighted areas of difficulty within DAFM in maintaining the legal requirement to supervise every slaughter plant and understaffing in the horticulture and dairy inspectorate. The HSE representatives noted in the consultation that the gender balance and age structure of its staff meant that its operational planning had to accommodate comparatively high levels of maternity leave. There are also concerns amongst HSE staff members that those on maternity leave are not being replaced and hence, some inspectors are bearing a disproportionate burden of inspection activities.

A well-resourced, well-staffed official control system in Ireland is essential for protecting consumer's health and interests in a climate where there is significant expansion and economic development plans for the agri-food sector.

### 3.5.2 Training

Staff self-evaluation of the quality of their control activity was very positive with 84% of agency staff rating their official control activities as excellent or good. However, staff were more confident in their general control activities like the evaluation of food hygiene, HACCP systems and labelling but less confident about their control activities in more specialist areas like food contact materials, contaminants and food fraud. There was a view that training needs in these specialised areas coupled with specialisation for some inspectors as practiced in the HSE, are required to achieve more effective official controls. Industry would also welcome training of inspectors in specialised production methods and traditional production methods.

### 3.5.3 Staff deployment

Staffing assumptions are incorporated into service contracts but the resources actually deployed may vary from those figures. Agencies have functions beyond the application of food controls, so events in other parts of their business can result in staff being reallocated at short notice to other duties. Agencies are also constrained in their ability to adjust allocation of staff across regions. For example, due to recruitment embargoes and human resource constraints within the HSE, the environmental health service cannot transfer staff across local areas. The result is staffing resources are not always appropriately aligned to the area of greatest need across the environmental health service. The HSE has conducted a detailed study of relative staffing levels across the organisation taking into account hygiene/non-hygiene controls and non-food safety controls, and the population in each region. The HSE is now negotiating with the unions and others to redistribute resources across the regions.

As demonstrated in the example above, under current arrangements for official controls in Ireland, workforce planning and HR issues are a matter for individual agencies. Data on capacity actually deployed each year on controls should be tracked and reported by each agency (ideally on the basis of full-time equivalent roles engaged in control activity). Variations from the commitments made in the service contract should be explained and actions should be agreed and taken to address these issues.

### 3.5.4 Future challenges for official control system resources

It should be recognised that Food Harvest 2020 and Food Wise 2025 have targeted a significant increase in production from Ireland's agri-food industry over the coming years. This increase will bring additional food safety and consumer interest/food fraud challenges. This leads to the need for additional resources and expertise to deal effectively with the risks that may emerge. For example, the HSE environmental health service devotes a significant amount of time to responding to queries from people setting up or considering setting up new food businesses and this is a valuable exercise in building compliance and developing a good working relationship between inspector and food business. The correct number of staff with the correct training, deployed effectively will be an important factor in meeting Ireland's agri-food expansion plans.

It is clear that there is a need to address the staffing deficit brought about by the economic downturn in Ireland. It is important that adequate financial resources are made available by the official agencies to provide staff and other resources to deliver on the terms of the service contracts and that resources allocated to official controls are not diverted to work on other non-food safety duties.

## CHAPTER 4. PERFORMANCE MANAGEMENT SYSTEM TO MEASURE THE EFFECTIVENESS OF THE OFFICIAL CONTROL INSPECTION SYSTEM

The independent consultant's report proposed the introduction of performance measures into the service contracts with the official agencies and this proposal is welcomed and endorsed in this report.<sup>4</sup>

The annual work programmes prepared under the service contracts specify actions and outputs in detail. Large amounts of data are collected and processed by the FSAI and the agencies. The annual reports on Ireland's national control plan lays out inputs, activity and outputs in great detail. Yet, despite the multiplicity of numbers, it is difficult for those within the official control system, for food business operators and the public, to determine whether the system is, in aggregate, effective and performance is improving over time.

A lack of consistent and standardised data across agencies creates significant challenges for the FSAI in assessing control activity outputs and whether the system is operating as it should be. Summary data and audits suggest that control targets are not being met by every agency or local area in every reporting period. Decision-makers would benefit from having prompt access to data on an agreed robust set of performance measures covering the specific objectives of the official controls system. These could be used to: measure the performance of agencies and the system as a whole, assist in the allocation of resources and encourage the uptake of practice and procedures that deliver progress towards the chosen objectives. Measuring performance in a transparent manner should make the system of official controls more effective over time which will ultimately improve compliance in food businesses and better protect public health. Having performance measures in place would strengthen the FSAI's ability to deliver on its strategic priorities as set down in the FSAI Statement of Strategy (FSAI, 2012, p.17) which are:

1. Ensure the effective and consistent enforcement of food legislation
2. Provide the best independent scientific advice to underpin food safety policy and risk management decision
3. Work in partnership with all stakeholders in the food chain to facilitate compliance with food law
4. Ensure that the FSAI is responsive, efficient, effective and delivers value for money

Robust performance measures will provide benefits for managers of the official agencies allowing them to have improved oversight of the system and to better align resources with risk. Moore (1996) states that '*Public Managers can also create value by establishing and operating an institution that meets citizens' (and their representatives') desires for properly ordered and productive institutions. They satisfy these desires when they represent the past and the future performance of their organisations to citizens and representatives for continued authorisation through established mechanisms of accountability. We might think of this activity as helping to define rather than create public value. But this activity also creates value since it satisfies the desires of citizens for a well-ordered society in which fair, efficient and accountable public enterprises exist.*' (see Recommendation 6.1 and 6.2).

### 4.1 Performance Measures

A review of performance measures in other Member States including the Netherlands, Denmark and the UK were considered. In addition, the official agencies were surveyed for their views on appropriate measures<sup>5</sup>. The main measures proposed are summarised in the table below. These are relevant to all agencies reviewed in the scope of this report. Some agencies cannot currently report on all the measures and transitional arrangements would be needed (see Appendix II for the data needed to measure the performance measures).

<sup>4</sup> See [www.fsai.ie](http://www.fsai.ie) Chapter 6 of *Evaluation of the Official Control Inspection System in Ireland* for more detailed information on the selection of performance measures.

<sup>5</sup> See [www.fsai.ie](http://www.fsai.ie) Annex 8 of *Evaluation of the Official Control Inspection System in Ireland*.

**Table 1. Primary Performance Measures**

Objective	Indicator	Definition
Achieve compliance with food legislation and standards	Inspection plan delivery	% food business operators inspected at the frequency required by the agency's risk-based inspection plan agreed with the FSAI
	Compliance programme delivery	% specific agency compliance-related actions detailed in the work programme that have been completed
	Documented procedures	% inspections covered by documented procedures
	Food business operator compliance	% food business operators inspected that are free of non-compliances <sup>6</sup>
Ensure the co-ordinated and consistent enforcement of food legislation	Consistency of controls	% food business operators rating consistency as 'good' or better on a Likert scale (targeted at food business operators with multiple operations or representative bodies)
	Consistency programme delivery	Composite indicator built up from the list of specific coordination actions agreed in the annual work programme of the service contract, with the % of measures that have been completed being measured
Ensure delivery of an effective and efficient food safety control system	Share of high-risk food business operators	% registered food business operators that fall into the 'high-risk' category (based on use of risk categorisation that takes account of food business operator product, process and practice)
	Confidence in the system	Confidence in controls as measured in annual consumer, food business operator and inspection staff surveys
	Capacity deployed	Percentage of the inspection effort (on full-time equivalent basis) that was specified in the service contract that was actually deployed on official control activities
	Data delivery	Proportion of requested inspection data made available to the FSAI
	Effectiveness programme delivery	Composite indicator built up from the list of specific effectiveness-related actions agreed in the annual work programme of the service contract, with the % of measures that have been completed being measured

<sup>6</sup> The risk that this indicator could create incentives not to record non-compliances can be controlled by definition and application of procedures, and by audit. It could be developed further to focus on material non-compliances defined under the various agencies' control schemes, or track major and minor non-compliances.

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Appendix III outlines in more detail, the data behind the measures proposed in this table. Data regarding these measures would need to be provided by the agencies at a sufficient level of detail to ensure its utility in both evaluating performance against a plan but also reviewing and developing future plans, e.g. knowing that an official agency inspected 99% of food business operators at the frequency required by the plan and that 60% of those food business operators were free of non-compliances in the year, does not help to target those non-compliances in the following year's plan. Data from the measures defined need to be available to the FSAI at appropriate levels of business type, geographical region and time frequency. The FSAI also needs to be able to quantify food establishments that might be outside the regulatory system and consider the reduction in this number. This needs to be built into one of the composite indicators listed in Table 1.

## 4.2 From Performance Measures to Performance Management System

A list of measures will not effect change; the data collected need to be monitored, analysed and used to inform decisions to impact the effectiveness of the system and to better protect consumers. A performance management system would typically:

- Have a distinct objective of its own, for example, to facilitate continuous improvement towards the programme objectives
- Include targets for some or all measures
- Incorporate procedures for scrutiny and publication of measures; and
- Involve procedures for implementation of corrective actions and/or sanctions

Key steps to be taken in building the system include:

- Establishing a common understanding amongst the stakeholders of the objectives, the process, how data will be used and issues such as disclosure
- Agreeing a plan for delivery of the data required, including the plan for changing the indicator set over time in a context where further development of information systems and procedures is needed before some of the preferred measures can be tracked; and
- Determining what is achievable on the priority measures and setting targets

The introduction of the performance measures will require a level of commitment from the official agencies and the FSAI to ensure their introduction is productive and that they can be used by all for the purposes for which they are intended. The first suite of performance measures agreed by the FSAI and the official agencies will no doubt evolve and develop with a continued focus on consumer health and with experience of their use over time. Sparrow, (2000a, p.123) does not underestimate the difficulty in achieving accurate and appropriate performance measure for regulators: *'If true value in regulatory performance involves problems solved, compliance rates improved, risks mitigated, then regulators must persevere in the search for performance measurement and reporting techniques to match that kind of performance. They cannot give up on the obligation to develop a clearly articulated and broadly shared understanding of what that account should look like.'*

## CHAPTER 5. GENERAL CONCLUSIONS

The FSAI's mission is **'To protect consumers' health and consumers' interests by ensuring that food consumed, produced, distributed or marketed in the State meets the highest standards of food safety reasonably attainable and that people have accurate and worthwhile information about the nature of the food they eat.'** A study by the Conference Board of Canada (2014) compared food safety performance indicators for 17 Organisation for Economic Cooperation and Development (OECD) countries. It found that Ireland has one of the highest performing food safety systems amongst this group – it tied first in the scoring system with Canada (Canada's Centre for Food, 2014)

The FSAI and its official agencies have worked towards building a more integrated food safety control system in Ireland. To continue to fully protect consumer's health and interests, the FSAI and the official agencies need to be in a position to accurately identify risks in the system and determine appropriate risk-management strategies.

Forfás (2004) has previously argued that *'bad regulation can lead to a misallocation of resources, higher costs and prices and reduced innovation and regulatory reform can lead to productivity improvements that substantially exceed the normal productivity increases in the business sector.'*

This report recommends reforms to the official food control system to make the system more effective in the longer term and to deliver more value for consumers of Irish food, both in Ireland and abroad. It is not enough for the FSAI and the official agencies to continue with the current system of official controls or even that the systems become more efficient in its current tasks. It is also important that the system is future-proofed to be adaptable to new and emerging issues and that it is effective at measuring the changes that occur. Although various attempts to measure the agencies' performance have been made since the FSAI was established, it is time now to formalise the process and track progress so that the FSAI and the official agencies can reassure the consumer, the taxpayer and Government of the public good it is delivering.

Large amounts of aggregated data are collected and processed by the FSAI and agencies. The annual summary report provided to the European Commission on Ireland's national control plan outlines inputs, activity and outputs in great detail. Yet, despite the volume of data, it is difficult for those within the official control system, food business operators and the public to determine whether the system is effective and performance is improving over time. The need to be able to measure the effectiveness of the official controls programmes by using performance measures has been considered in this report and is of significant strategic importance to the FSAI and its official agencies, as well as being a regulatory requirement.

At present, the FSAI is being asked to be more than an auditor and although it does have the mandate, it does not have consistent official agency cooperation, or the capacity or systems to be fully effective as an information integrator. With better access to information held within the system, use of data from beyond the controls system, appropriate technologies and analytical capacity, the FSAI would be well placed to be an 'intelligence hub' for the system as a whole.

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## CHAPTER 6. RECOMMENDATIONS AND SPECIFIC CONCLUSIONS FOR THE OFFICIAL CONTROL INSPECTIONS SYSTEM

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### 6.1 Recommendation 1

**A cross-agency performance management system to measure the effectiveness of the official control system should be established.**

A new performance management system in which a set of key indicators are monitored at an agency level would increase the transparency of how the system is performing and enhance accountability. Some agencies cannot currently report on all the performance measures proposed and transitional arrangements would be needed. A cross-agency plan is needed to deliver infrastructure support and other resources to implement a performance management system. Based around the service contract and regular reporting of the selected measures, this would create greater transparency with regard to the effectiveness of the arrangements for the delivery of official controls.

**Action:** A time-bound plan should be drawn up in consultation with all official agencies for the implementation of a performance management system

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM

### 6.2 Recommendation 2

**A suite of performance measures should be put in place across all official agencies to ensure the effectiveness of the system by allowing it to be properly monitored and reported.**

The official control inspection system would be strengthened by introducing a suite of performance measures. Comprehensive assessment of performance will enable the official agencies to better allocate resources and review the effectiveness of controls in their areas of responsibility. They would also facilitate improved standards in food businesses and better protect consumer health. The data used to generate the measures need to be reportable at diverse levels including sectoral, business type and regional data. These levels of data will require changes to data collection and reporting systems both at the FSAI and within the official agencies and this will need to be considered in the roll out of the measures with the agencies.

**Action:** A suite of performance measures should be drawn up in consultation with the official agencies

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM

### 6.3 Recommendation 3

**Realistic targets should be established for each of the key performance measures.**

The current service contract model has evolved over the last 16 years and despite a move towards harmonisation, variations in reporting arrangements remain in place with official agencies. In light of the introduction of performance measures, targets for key performance measures will need to be agreed and reported.

**Action:** Each official agency to establish targets in consultation with the FSAI including the definitions, mechanism for collection and reporting. Consideration will also need to be given to the level of detail to be provided at national, regional, and local level.

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM

### 6.4 Recommendation 4

**Data and information at a sufficiently detailed level should be collected by official agencies and provided to the FSAI to allow official agencies to manage and report on official controls and the FSAI to carry out and report on its oversight function.**

At present, the official food control agencies working on behalf of the FSAI provide different levels of data to the FSAI but mostly in summarised report format and these reports do not provide sufficient information to establish the effectiveness of the system. The FSAI is able to publish core system indicators but more sophisticated analysis of activities and effectiveness is hindered by challenges of access to and comparability of data from different official agencies.

The FSAI has been successful to a certain degree in achieving many of its data strategy targets but has nevertheless struggled with collecting consistent and sufficiently detailed data sets and accurate reliable summary data. Three key areas for improvement are:

- (a) Availability of consistent and standard data sets at an appropriate level of detail from all contracted agencies
- (b) Consistent and timely reporting of complete and quality assured data and information (particularly around non-compliances)
- (c) Availability of regularly updated data for the national list of registered and approved food establishments

**Action:** The FSAI to review its data strategy in light of the data requirements for performance measures and targets. The FSAI to establish with each official agency, a data plan with time-bound targets for incrementally improving the details of data to be reported.

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM



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## 6.5 Recommendation 5

**The current funding arrangements for food safety controls should be reviewed along with the measures available to the FSAI in the case of non-performance of the official agencies, with a view to strengthening the current organisation model for official controls and maintaining the independence of the FSAI.**

The current model whereby the FSAI acts as 'auditor complemented by the information integrator' (see Section 2.1), should be retained and enhanced. Implementation of this recommendation should deliver the necessary functional benefits of a primary agency model without the need for institutional change. The latter approach is favoured as a means of affirming the independence of the FSAI.

However, further scrutiny is required of how official controls are funded and controlled and the accountabilities that are built into the system. Aligning control of funding for food safety activities to the FSAI could be effective in addressing some of the issues identified in this review, although it cannot resolve the larger issue of funding constraints across the system.

The sanctions available to the FSAI in the event of a material breach or non-performance with service contract requirements need to be considered further.

**Action:** The FSAI to review and report on the implications of changes to (a) arrangements for funding and (b) sanctions available to the FSAI in the event of non-performing service contract.

**Responsibility:** FSAI

## 6.6 Recommendation 6

**Measures to further improve the consistency of official controls need to be strengthened to ensure all businesses are inspected fairly.**

Consistent application of official controls within agencies, across agencies and geographical boundaries is an ongoing challenge for all control systems, in particular where multiple groups are enforcing the same rules. Given the diverse nature of the Irish food industry, the Irish food control system and the complex varied food law, it is particularly demanding in the context of food law enforcement in Ireland.

**Action:** In conjunction with the agencies and industry groups, the FSAI to identify the critical areas where consistency is problematic. A prioritised list of guidance documents and measures to be taken, including a timeframe for completion, should be agreed.

**Responsibility:** FSAI, industry, local authorities, HSE environmental health service, SFPA and DAFM

### 6.7 Recommendation 7

**All official agencies need to develop and implement effective internal audit systems and ensure timely close-out of findings in line with legislative requirements.**

Agencies have a legal obligation to audit their own activities. DAFM has a well-developed and well-functioning internal audit system. The local authorities have a national internal audit system in place but it requires further development. The HSE and the SFPA have yet to complete the establishment of an internal audit system although work is well underway towards this goal

**Action:** Official agencies to implement and/or improve internal audit systems in collaboration with the FSAI.

**Responsibility:** HSE environmental health service, SFPA, DAFM and local authorities

### 6.8 Recommendation 8

**The FSAI, in collaboration with the agencies, should establish a procedure to estimate and monitor the stock of risk in the system.**

All official agencies have risk-based systems of official controls in place. However, the tools used to determine the risk category of a food business are different depending on the agency.

The differences in approaches to risk ranking of food businesses by agencies makes it difficult to track changes in the stock of risk in the system and to assess the overall effectiveness of control activities. A consistent approach would benefit the system as a whole and there are international models e.g. Denmark, Netherlands that may serve as a template.

**Action:** The HSE environmental health service, SFPA, DAFM and local authorities in collaboration with the FSAI to review current systems so that the stock of risk can be assessed and monitored over time.

**Responsibility:** FSAI, DAFM, SFPA, HSE environmental health service and local authorities

### 6.9 Recommendation 9

**A consistent and transparent approach to use of the enforcement powers available needs to be established across all official agencies.**

Agencies generally have sufficient powers to take enforcement actions in cases of food business operator non-compliance and the sanctions available are effective, proportionate and dissuasive. The transparency and consistency of use of these powers (publication, use of powers, consistency and escalation procedures) could be improved in some areas. Where an official agency relies on legislation for enforcement actions that are not publicly reported, there is a need to consider how to align this use with the objectives of the Irish food inspection system.

**Action:** All agencies to review current systems of enforcement to ensure that consistency is improved and enforcement actions are published to improve transparency for all stakeholders.

**Responsibility:** FSAI, local authorities, SFPA, HSE and DAFM

## 6.10 Recommendation 10

**The FSAI should coordinate a review of the flexibility arrangements provided in the EU Hygiene Package whilst ensuring the continued protection of public health.**

Flexibility provisions available in the EU Hygiene Package are available to assist small businesses and those working in traditional food production areas to meet their food safety obligations. These have not been formally availed of by Ireland. For inspectors undertaking controls in smaller establishments, the documented procedures used by the inspectors are considered by staff in some agencies to be too complex and control activities to be too onerous and disproportionate with the scale of some businesses.

**Action:** (i) The FSAI should work with official agencies and relevant Government departments to review Ireland's use of the 'flexibility' clause in the EU Hygiene Package (2004) and EU derogations on traditional food production with a view to ensuring that official controls are commensurate with the nature and size of the food business.

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM

## 6.11 Recommendation 11

**The system of oversight and control for potential institutional conflicts of interest needs to be strengthened.**

Generally, conflicts of interest for individual inspectors appear to be well-managed where the potential for conflict arises. However, potential institutional conflicts of interest create greater challenges for the effective functioning of the official controls system. Robust systems are needed to ensure that the wider public interest is safeguarded.

**Action:** The FSAI to work with official agencies to design a cross-agency protocol on how to manage potential institutional conflicts of interest.

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM

## 6.12 Recommendation 12

**The FSAI should monitor how resources are aligned to risk across the food chain with a view to strengthening the effectiveness of official controls.**

An effective official controls system must have appropriate alignment of staff resources and expertise with the activities required. Variations from the commitments made in the service contract should be explained and actions should be agreed and taken to address these issues.

Under current arrangements, workforce planning and human resource issues are a matter for individual agencies. Data on resources actually deployed each year on controls should be tracked by the agencies and reported more frequently to the FSAI and with more focus on the skills and competencies available within the pool of staffing resources.

**Action:** The official agencies should report to the FSAI on how they are aligning resources to the greatest areas of risk across the food chain. This should also supplement the knowledge and competency framework (see Recommendation 13).

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA, and DAFM

### 6.13 Recommendation 13

**Expertise in specialist food safety control areas needs to be enhanced and maintained commensurate with the requirements of effective official controls.**

The breadth of legislation deemed food legislation is extensive. Agency staff have expressed concerns regarding their knowledge and competencies to carry out official controls in the non-core areas of food legislation, e.g. food additives, food contaminants, food contact materials, etc. This issue was also raised by industry representatives in terms of consistency of official controls. Given resource constraints and the relatively small number of businesses requiring specialist oversight, inspectors could be designated to focus on specialist functions and bear primary responsibility for conducting inspections of these establishments.

**Action:** The FSAI to lead on the development of a knowledge and competency framework for official agency staff in consultation with official agencies. The framework should set down the knowledge and competencies required to carry out official food controls. Due consideration would also need to be given for the development of specialist roles within agencies for these non-core areas and the training required for such roles. This should include a mechanism for regular monitoring by agency management of the levels of knowledge and competency within the inspectorate system.

**Responsibility:** FSAI, local authorities, HSE environmental health service, SFPA and DAFM

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## APPENDIX I. TERMS OF REFERENCE

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### A Review of the Delivery of Official Food Controls in Ireland

#### Background

The FSAI is the competent authority with overall responsibility for the enforcement of food legislation in Ireland. The responsibility for enforcement of food legislation is managed through contractual arrangements (service contracts) between the FSAI and the competent authorities (official agencies) involved in the enforcement of food legislation (Official Agencies are listed in the Second Schedule of the FSAI Act 1998). The FSAI has service contracts with the following official agencies:

- Department of Agriculture and Food and Marine
- Health Service Executive
- Local authorities (27 County Councils and a City Council)
- Sea-Fisheries Protection Authority
- Marine Institute
- National Standards Authority of Ireland

In this regard, it is the responsibility of the FSAI to:

- Achieve compliance with food legislation and standards
- Ensure the coordinated and consistent enforcement of food legislation
- Ensure delivery of an effective and efficient food safety control system

#### Mandate for the Steering Group

The Official Food Control Review Steering Group is an *ad-hoc* working group under the Scientific Committee and chaired by a member of the Scientific Committee. It is tasked with drafting a report within the terms of reference and scope outlined below. The draft report will be submitted to the Scientific Committee within the timescale for consideration and possible amendment before adoption by the Scientific Committee. The final adopted report will be published by the FSAI.

## Terms of Reference

To carry out a detailed review of the efficacy of official food controls, in particular, how resources are aligned to risks in the food chain. The report will:

1. Review the organisation, quality and operation of the official control system in Ireland as detailed in the scope (below), advise the FSAI on the strengths and weaknesses of the current inspection system and identify any potential changes to improve its control of risks. There should be a particular focus on the allocation of staff and other resources and, having regard for the requirements of applicable official control legislation and to the relative risks throughout the food chain
2. In the context of the official controls as detailed in the scope, examine the oversight and accountability arrangements within and between the FSAI and the official agencies and identify opportunities for improvement where necessary
3. Review how best regulatory practice and regulatory assessment might be applied in the FSAI and the official agencies
4. Consider the data on official controls activities collected by the FSAI, advise on whether they are suitable for monitoring the efficacy of the official control system and make recommendations for improvements where necessary

## Scope

The work should focus on official controls activities covered by service contract agreements between official agencies and the FSAI as outlined below:

1. Environmental health service, Health Service Executive
2. Veterinary Inspection Service, local authorities
3. Sea-Fisheries Inspection Service, Sea-Fisheries Protection Authority
4. Department of Agriculture, Food and Marine  
Veterinary Inspection Service, meat and milk  
Dairy Inspection Service, dairy products  
Poultry and Eggs Inspection Service  
Border Inspection Service  
Horticulture Inspection Service  
Bee and Honey Inspection Service  
Food Division Inspection service  
Organic Unit Inspection service
5. National Standards Authority of Ireland – natural mineral water, food contact materials

The scope of the project should consider the implementation and management of the inspection services, human resources, and current organisation structures. It should consider the implementation of all legislation listed in Schedule 1 of the FSAI Act, 1998 as amended, see [www.fsai.ie](http://www.fsai.ie).

The scope does not include official controls as they relate to:

- Food surveillance and monitoring programmes (these are being considered by other sub-groups of the Scientific Committee)
- Feed or on farm official control activities

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## Possible Data Sources

- Multi-Annual National Control Plan and reports produced by the FSAI and official agencies
- Service contract system
- Quality management system documentation or equivalent written procedures for official controls within official agencies
- Annual reports by the FSAI and official agencies where applicable
- The audit reports carried out by the FSAI, the EU Food and Veterinary Office and the internal audit reports of the official agencies
- Data collection, reporting and management systems in the FSAI and official agencies
- Other regulatory bodies and international organisations
- Invited submissions from stakeholders including the official agencies, the food industry and sponsoring departments
- Requests to official agencies for data on resources used for official controls

## Membership

The Scientific Committee considered that the Official Food Control Review Steering Group should be chaired by a member of the Scientific Committee. To maintain independence, the Scientific Committee decided that there should not be representatives from the food industry on the group. However, the Steering Group should consider setting up appropriate sub-groups to examine particular aspects of the food inspection system.

Sub-groups will be chaired by a member of the Steering Group and will include representatives of official agencies and may include food industry representatives as appropriate. The FSAI will provide a technical and administrative secretariat.

Staff from official agencies should be provided with the opportunity to inform the process regarding their service at each relevant stage of the project.

## Timescale

The Steering Group should present a draft report to the Scientific Committee within 18 months of its establishment.

## Phases of the Project

The project shall be delivered in three phases (see following):

### ***Phase 1: Preparatory Steps***

The literature review should include:

- How the current official control system works and provides background information as to how it is structured, the roles and responsibilities, the extent of the official control deliveries etc. A relatively short document should be completed for each inspection service using a defined template (template to be devised by the Steering Group). A short document regarding the FSAI's role managing and auditing official controls shall also be compiled. This information should be available within existing documents such as the Multi-Annual National Control Plan, Food and Veterinary Office reports, FSAI and official agency audit reports, annual reports etc.
- A self-assessment by the official agencies regarding how they measure/assess the efficacy of the official controls they operate. This should also consider the strengths and weakness they perceive in their service and the FSAI
- A comparison of official controls system in selected Member States. This should include a comparison in terms of resources, outputs and organisation of controls. It should consider the overall efficacy of control in Ireland *vis a vis* other Member States
- The FSAI's strategic priorities and the challenges facing the food industry over the next five to ten years
- The current and emerging food safety risks in the food chain

**Delivery Mechanism for Phase 1** - Steering Group, the FSAI in conjunction with stakeholders, in particular, official agency staff. The Steering Group may meet with food business operators or food business operator representatives to consider representations regarding their views of official controls at this stage.

### ***Phase 2: Measuring Efficacy***

Using the information garnered in Phase 1 of the project, the Steering Group will need to identify appropriate measures of efficacy on which to evaluate the official control inspection system in Ireland. To this end, the Steering Group will need to consider what the FSAI and its official agencies, Government departments and stakeholders want from an official controls system, taking account of legal requirements and best practice. The Steering Group will need to agree a model of performance measurement that will allow the food control system's inputs, outputs and outcomes to be measured and evaluated.

**Delivery Mechanism for Phase 2** - The majority of this phase will be contracted out and overseen by the Steering Group.

### ***Phase 3: Reporting on the Efficacy of the Food Inspection Service***

Using the measures agreed in Phase 2, each official agency and the FSAI will be reviewed to evaluate if, individually and collectively, the official control system is fit for purpose. This will allow the Steering Group to establish how well the current system is working and identify features that are working well and areas for improvement. In addition, the review should consider what can be learned from other Member States enforcing the same regulations.

The draft report should be provided to official agencies for observations and comments before it is sent to the Scientific Committee.

**Delivery Mechanism for Phase 3** - The majority of this phase will be contracted out overseen by the Steering Group.



## APPENDIX II: DATA NEEDED TO MEASURE PERFORMANCE INDICATORS\*

Objective	Indicator	Measure	Source and data required by the FSAI	Data/Reporting capability required by the FSAI and agency
Achieve compliance with food legislation & standards	Food business operator compliance	% food business operators that are free of non-compliances	Agency inspection records	(i) Count of the number of food business operators inspected in the reporting period (ii) Count of the number of food business operators against which non-compliances were recorded in the reporting period
	Inspection plan delivery	% food business operators inspected at the frequency required by the agency's inspection plan	Agency inspection records	(i) Count of the number of inspections for each food business operator within the reporting period (ii) Record of the planned number of inspections for each food business operator within the reporting period
	Compliance programme delivery	Details of the completion status of each of the agreed actions codified in the agency annual work programme agreed under the service contract	Agency management information	(i) Records of the specific actions agreed with the FSAI in the annual work programme for the reporting period and (ii) Information on whether they have been completed, with a short commentary on each item
	Documented procedures	% inspections covered by documented procedures	Agency inspection records & management information	i) Number of inspections of each type completed in the reporting period (ii) Availability of documented procedures for each category of inspection as of the mid-point of the reporting period
	Inspection reports	% inspections in which the food business operator was issued with an inspection report	Agency inspection records	(i) Number of inspections completed in the reporting period (ii) Number of inspection reports issued to food business operators in the reporting period
	Audit results	Average number of corrective actions per FSAI audit	FSAI records	i) Number of FSAI audits of specific agency within the reporting period (ii) Number of corrective actions identified for each audit within the reporting period

Objective	Indicator	Measure	Source and data required by the FSAI	Data/Reporting capability required by the FSAI and agency
<b>Coordinated and consistent enforcement of food legislation</b>	Consistency of controls	% respondents rating consistency of controls as 'poor', 'satisfactory' or 'good'	Representative survey of food business operators registered by each agency starting with multi-site food business operators	If question is to be directed at multi-site food business operators, there is a need for each register to enable identification of multi-site food business operators and a lead contact for each food business operator
	Consistency programme delivery	Details of the completion status of each of the agreed actions in the consistency programme codified in the agency annual work programme agreed under the service contract	Agency management information	(i) Records of the specific actions agreed with the FSAI in the annual work programme for the reporting period and (ii) Information on whether they have been completed, with a short commentary on each item

\*Data used to generate indicators need to be reportable at diverse levels including sectoral, business type and regional data.

Objective	Indicator	Measure	Source and data required by the FSAI	Data/Reporting capability required by the FSAI and agency
<b>Ensure delivery of an effective and efficient food safety control system</b>	Share of high-risk food business operators	% approved/registered food business operators that fall into the 'high risk' category, based on use of risk categorisation that takes account of food business operator product, process and practice	Agency inspection records/ food business operator register	(i) Food business operators that are classified as 'high' risk (ii) Total number of food business operators on the register.  NB: Ideally, the official agencies should be able to record the classification of food business operator risk management practice, e.g. high/medium/low. The indicator could focus on this aspect only, i.e. the controllable aspect of risk, for any given product/process
	Confidence in the system	Responses to survey question about stakeholder confidence in the arrangements in place in Ireland that ensure food is safe, e.g. % answering 'high' or better on Likert scale	Consumer/ food business operator/Staff surveys	Analysis of survey results
	Capacity deployed	% planned inspection assigned (staff resources) deployed	Agency management information	(i) Number of full-time equivalent of inspection staff assigned specified for the reporting period in the agency annual work programme as agreed under the service contract (ii) Number of staff (on full-time equivalent basis) deployed on activities in scope within the reporting period
	Data delivery	% required inspection data available to the FSAI	FSAI records	(i) Schedule of data requirements agreed by FSAI with agencies (ii) records of data submissions to the FSAI

Objective	Indicator	Measure	Source and data required by the FSAI	Data/Reporting capability required by the FSAI and agency
	Effectiveness programme delivery	Details of the completion status of each of the agreed actions in the consistency programme codified in the agency annual work programme agreed under the service contract	Agency management information	(i) Records of the specific actions agreed with the FSAI in the annual work programme for the reporting period and (ii) Information on whether they have been completed, with a short commentary on each item

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