



## **AUDIT CHARTER OF THE FSAI**

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**Audits performed by the Food Safety Authority of Ireland in accordance with requirements of the Food Safety Authority of Ireland Act 1998 and Regulation (EC) No 2017/625**

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<sup>1</sup> Health and Food Safety (SANTE) F – Health and Food Audits and Analysis

## 1. Background

The Food Safety Authority of Ireland (FSAI) is the competent authority with overall responsibility for the enforcement of food legislation in Ireland. Enforcement of this food legislation is managed through contractual arrangements (Service Contracts) between the FSAI and the relevant competent authorities (official agencies) responsible for specific sectors or activities, e.g. Department of Agriculture Food and the Marine, Health Service Executive, Sea Fisheries Protection Authority, National Standards Authority of Ireland and the Local Authorities.

Schedule 5 of these Service Contracts details the means by which the Authority proposes to audit official agencies as required by Section 48(9) of the FSAI Act 1998. FSAI audits determine compliance by official agencies with the terms and requirements of their contract. They also determine how official control legislation is implemented and how such controls determine compliance by food business operators with food law.

## 2. Legal Basis

The statutory basis in Irish legislation for audit is contained in Section 48(9) of the Food Safety Authority of Ireland Act 1998 as amended by the British Irish Agreement Act 1999 which states that:

*“The Authority shall take such measures as it considers appropriate to determine whether an official agency is adequately carrying out its functions under a service contract.”*

These requirements are further enforced by the provisions of Section 17 of the Food Safety Authority of Ireland Act 1998 which require the Authority to:

*“keep under review the efficacy of food inspection services”*

Under Section 47 of the FSAI Act:

*“the Authority may carry out or arrange to have carried out such additional inspections as it considers necessary for the discharge of its functions under this Act”*

Regulation (EC) No 2017/625 lays down requirements on the performance of official controls by competent authorities. Article 6(1) of this Regulation specifies that:

*“The Competent Authorities shall carry out internal audits or have audits carried out on themselves and shall take appropriate measures in the light of the results of those audits”.*

### **3. Mission, Objectives & Role of the FSAI Audit Function**

#### **3.1. Mission**

*“To effectively evaluate the performance of official controls and to confirm that the food safety control network and planned arrangements adequately safeguard & protect consumers’ health & interests, and comply with food law”*

#### **3.2. Objectives**

The objectives of the FSAI audit function are:

1. To verify compliance with food legislation, service contracts and relevant sections of the Multi Annual Control Plan (MANCP)
2. To assess the coordination, effectiveness and consistency of the enforcement of food legislation and to comment on its appropriateness and suitability.

These objectives compliment the goals, mission and the statement of strategy of the Authority which are implemented through the Service Level Agreements with the Department of Health and Service Contracts with the relevant official agencies.

#### **3.3. Role**

FSAI audits of official controls verify compliance by official agencies with relevant legislation, implementation of MANCP and adherence to Service Contract requirements. Where relevant they will also verify at food business operators that the necessary supervisory arrangements are being implemented by official agencies.

FSAI audits also verify the effectiveness and appropriateness of official controls by testing agencies against their own systems. They also evaluate whether the documented procedures and planned arrangements put in place by official agencies are being followed, whether they are effective and are suitable to achieve the objectives of Regulation (EC) No 2017/625.

Evaluation of effectiveness of official controls by means of audit adopts the current best practice approach as required by Article 6(1) of Regulation (EC) No 2017/625.

FSAI audits conducted under the requirements of Schedule 5 of the Service Contract are external audits of its official agencies as required by Section 48(9) of the FSAI Act; as described in Appendix I. These audits also assess whether agencies are achieving the objective of Regulation (EC) No 2017/625 regarding official controls carried out by them to verify compliance with food law.

Through an ongoing programme of internal audits FSAI evaluates conformance with its

Business Management System (BMS), which is based on the requirements ISO 9001:2015. External assessment of the BMS is carried out by the FSAI's registrar, the National Standards Authority of Ireland.

### **3.4. Internal Audits Conducted By Official Agencies**

Official agencies in their role as competent authorities must independently assess through internal audit whether their official control activities are meeting the objectives of Regulation (EC) No 2017/625 as specified in Article 6(1).

FSAI audits do not replace the requirement for official agencies to implement their own internal audit programme, as required by official control legislation. The Authority will take into consideration the results of official agency internal audits when planning FSAI audits.

## **4. Implementation of the Audit Function**

Implementation of the audit function is carried out using the guidance provided by the European Commission, the principles of ISO 9001:2015, ISO 19011:2018 and the mandatory requirements from Regulation (EC) No 2017/625. The implementation of the audit function will also utilise additional guidance developed by national experts coordinated by SANTE F.

- Risk-based audit programmes
- Auditing the effectiveness of official controls
- Independence and Independent scrutiny.

## **5. The Audit Process**

### **5.1 Audit Planning**

The FSAI applies a risk approach to audit planning and defining the audit priorities for the Authority in line with its primary responsibilities. The approach applied is illustrated in Appendix II.

The FSAI applies a systematic approach in relation to the planning, conduct, follow-up and management of audits, which are supported by documented procedures incorporated into the Authority's BMS.

The FSAI audit programme takes into account all areas of the MANCP within its remit. It also covers the performance of official controls as defined in Regulation (EC) No.2017/625 and also those requirements specified in the Service Contracts with official agencies. The programme also includes audits which assess compliance of food business operators with statutory requirements and responsibilities, as set out in food law. These audits also take into account whether the necessary supervisory arrangements are present, appropriate and are effective.

In accordance with the guidance provided by the European Commission the FSAI audit programme is monitored and reviewed and any opportunities for improvement highlighted are incorporated into future planning.

### **5.2 Audit Activities**

The FSAI Audit and Investigations Division is responsible for carrying out the audits detailed in the programmes circulated to official agencies. These audits are performed against the FSAI documented protocols and procedures.

### **5.3 Monitoring, Corrective Action and Follow-Up Activities**

The FSAI Enforcement Policy Division is responsible for the day-to-day monitoring of the performance of official controls carried out by official agencies, in accordance with the planned arrangements as set out in the service contracts with the official agencies.

Follow-up to corrective actions on audit findings is the responsibility of the Enforcement Policy Division of FSAI. The Enforcement Policy Division monitors progress on corrective action with the official agencies.

## **6. Types of Audits**

### **6.1 Audit of Official Controls**

These audits examine the effectiveness and appropriateness of all aspects of official controls as implemented by official agencies in relation to food law, service contracts and MANCP requirements.

### **6.2 Targeted or Focused Audits**

These audits examine the effectiveness and appropriateness of official controls and/or food business operators' compliance with respect to a specific aspect of food law.

### **6.3 Health and Food Safety – Health and Food Audits and Analysis Close-out Audits (SANTE F)**

These audits examine and update the corrective actions taken to address findings from SANTE F missions. They also verify their closure and their current state of compliance.

### **6.4 Other Audits**

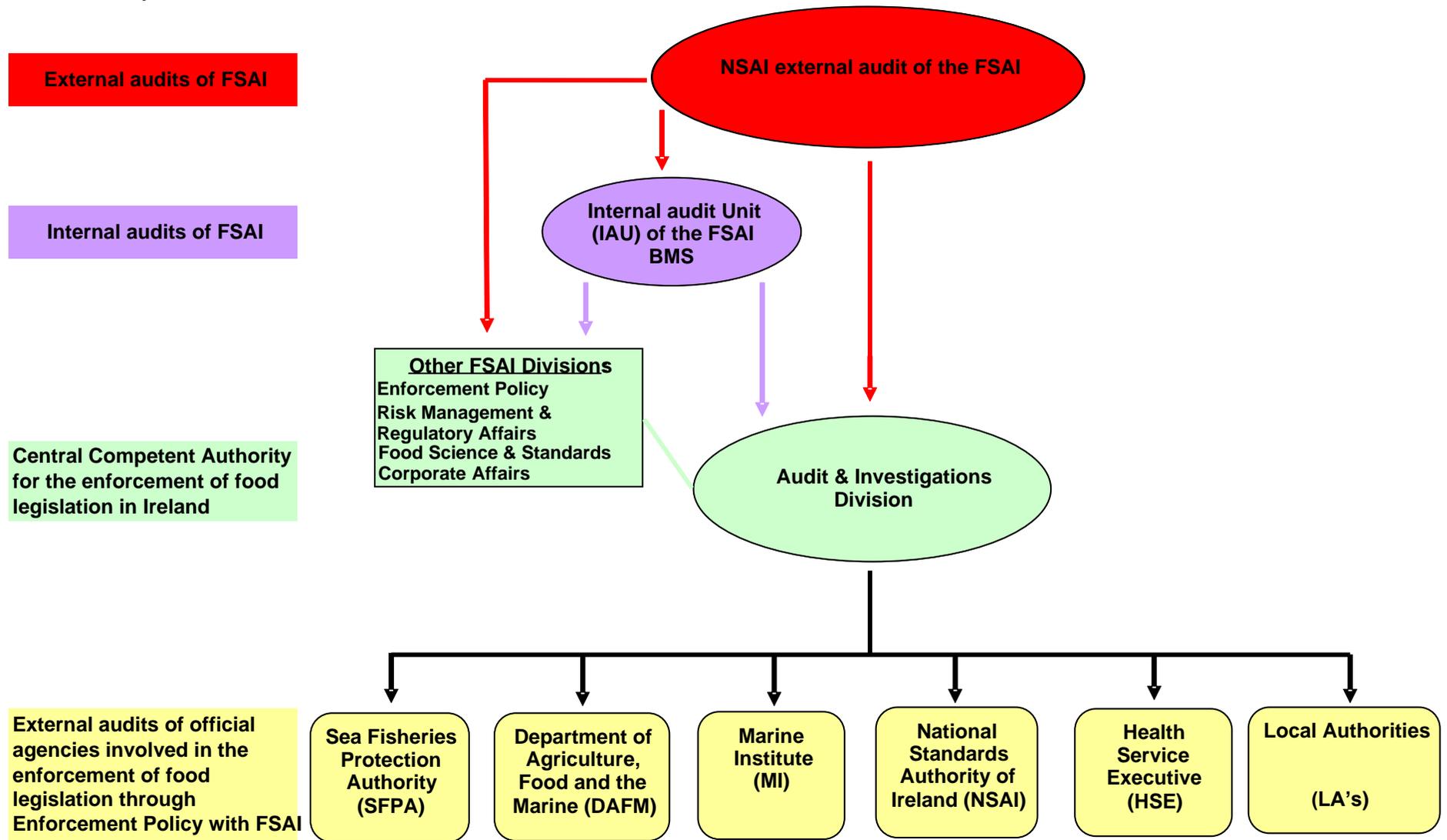
FSAI may carry out from time to time any other audit it considers appropriate to verify that all components of the food safety control network, planned arrangements and/or official controls are adequately safeguarding and protecting consumers' health & interests.

## **7. Business Management System**

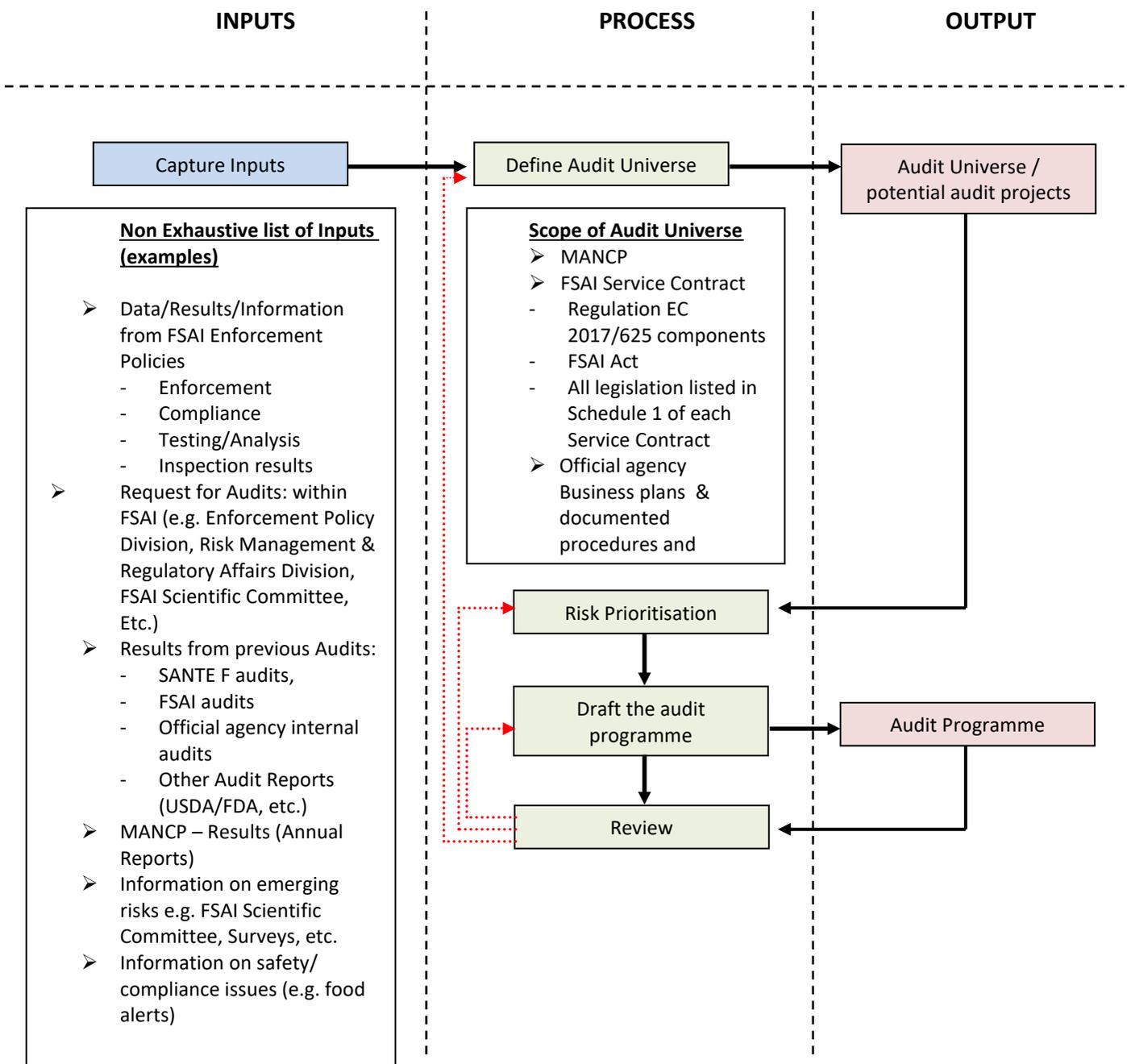
The FSAI has a BMS registered to ISO 9001 since 2001. The Authority views the BMS as the tool which builds and integrates the requirements of the FSAI Act, Regulation (EC) No. 2017/625 and other official control legislation into its management systems.

The FSAI applies the continuous improvement approach defined in ISO 9000 series of standards in the conduct and fulfilment of its audit requirements and as described in Appendix III.

# Appendix I - Internal/External audits of Competent Authorities conducted in accordance with Regulation 2017/625



## Appendix II - Audit Planning Process



Appendix III - Application of the Continuous Improvement Cycle to FSAI Audits

### FSAI Audit Process

