Food Safety
AUTHORITY OF IRELAND

AUDIT REPORT

Audit of Official Controls in Food Supplement Establishments supervised by Environmental Health Officers in the Health Service Executive

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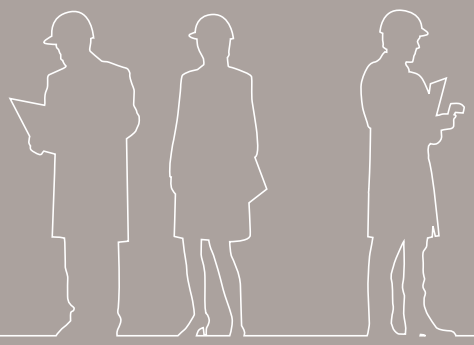

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1. GLOSSARY

EHO	Environmental Health Officer
FSAI	Food Safety Authority of Ireland
HACCP	Hazard Analysis Critical Control Point
HSE	Health Service Executive
PEHO	Principal Environmental Health Officer
SEHO	Senior Environmental Health Officer

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI[1]) completed an audit of the food safety controls performed by the Environmental Health Service of the Health Service Executive (HSE) in food supplement establishments. The audit was undertaken as part of the planned programme of audits carried out by the FSAI in 2013 to determine the level of compliance with European legislation and conformance with the service contract in place between the HSE and the FSAI.

The audit was carried out in seven HSE local areas and included all four HSE regions. The first part of the audit involved an examination of paperwork associated with official controls, including the establishments' files and inspection reports. The second part involved an audit of seven food supplement establishments.

In 2012, the FSAI and the HSE put in place, an *aide-memoire* and checklist to provide environmental health officers (EHOs) with some of the necessary tools to carry out official controls in a consistent and uniform manner in food supplement establishments such as manufacturers and distributors. This audit enabled the FSAI to assess the effectiveness of the official controls now in place.

All food supplements that are placed on the market in Ireland for the first time are required by law to be notified to the FSAI, together with a sample or artwork of their label. The administration of these notifications and specific labelling controls associated with them, are carried out directly by the FSAI. The FSAI keeps a database of all notifications and provides a list of these to the HSE approximately three times annually. The purpose of informing the HSE of notifications is to allow EHOs to check during their inspections whether food supplements have been notified to the FSAI and also to identify establishments that have not been registered as food business operators. The numbers of food supplement manufacturers and distributors was not known to the Environmental Health Service and the FSAI at the time of the audit. Several inaccuracies with the FSAI lists sent to the HSE were identified during the preparatory phase of the audit. These will need to be corrected. In addition, some Principal Environmental Health Officer (PEHO) areas were not using the lists to identify food supplement establishments for supervision. The lists of food supplement manufacturers, packers and distributors provided by the Environmental Health Service to the FSAI prior to the audit were not complete and changed a number of times during the audit.

When food supplements are notified to the FSAI checks on specific ingredients to identify if they are medicinal, novel etc., as well as nutrition and health claim checks, are carried out by the FSAI and non-compliances are notified to the food businesses. At the time of the audit, the FSAI was not copying the EHOs supervising the food business of non-compliant labels and thereby, not facilitating follow-up action with the food business operator.

Thirteen of the 14 food supplement labels selected at random at the food business operators and reviewed as part of the audit, were deemed non-compliant with some aspect of labelling requirements. Some of these products and model labels had not been notified to the FSAI. The system of official controls on food supplement labels as it is currently organised is not fully effective and needs to be reviewed.

All environmental health local areas visited were operating risk-based systems of official controls. Much work has been done to use the *aide-memoire* and checklist. However, the audit identified a number of non-compliances unique to these types of businesses that had not being identified during official control inspections.

The audit team found that the food business operators in most of the food supplement businesses audited and some EHOs were not sufficiently considering, as part of own checks or official controls:

[1] The FSAI recruited an external consultant to the audit team in order to facilitate this audit.

- The hazards associated with potential cross-contamination of food supplements in multi-product facilities by:
  - Non-food products and ingredients such as medicines, cosmetics and medical devices
  - Ingredients used in other food supplement and food products
- The level of evidence required to support label claims for quantity of ingredients and stability of the product
- The hazards associated with the use of ingredients if insufficient supplier approval and/or testing had been carried out

A procedure or procedures based on the principles of HACCP (Hazard Analysis Critical Control Point), which is a legal requirement for all food businesses, was not in place in four of the seven businesses, although some other documented procedures were available. In line with the agreed guidance notes in place between the FSAI and the HSE, at the end of every inspection, the EHO grades the outcome of the inspection on a scale from grade 1 satisfactory to grade 5 unsatisfactory serious. This grading determines the follow-up action to be taken by the inspector. During the course of the audit, 27 inspection reports were reviewed; 12 of which were satisfactory (grade 1), 14 of which were minor (grade 2) and one was unsatisfactory (grade 3). No establishments were allocated a grade 4 (unsatisfactory significant) or grade 5 (unsatisfactory serious) inspection outcome. The audit team considered that given the nature of non-compliances identified, some of the inspection outcomes allocated by EHOs in three of the seven areas were not aligned with the guidance.

The Environmental Health Service has put in place, national and local training to ensure officers are competent and kept up-to-date with food legislation. In some regions, specialist EHOs are trained to supervise food supplement establishments, whereas in other areas, the supervision is allocated to the EHOs in whose district the establishment is located. Although officers have started to use the guidance provided for implementation of official controls in food supplement establishments, more training and further guidance is required in this area. EHOs need enhanced guidance on what official controls should be carried out at different types of food supplement establishments, e.g. contract manufacturers, brand owners, packers, distributors etc.

In addition to assessing the controls in place regarding food supplement establishments, the audit team examined how official controls are organised in the seven areas to meet the targets set down in the Environmental Health Service Business Plan. It is the responsibility of each PEHO to ensure national inspection targets are met for their area. Although the Environmental Health Service is a national service, there is no reallocation of staff across PEHO areas if targets are not achieved due to staff shortages, public recruitment embargoes, maternity leave etc. This has a negative implication for some areas which fail to meet inspection targets and other performance indicators. In 2012, one of the areas audited could not meet inspection targets in Category 3 establishments (medium-risk), whereas six of the seven areas met targets even in the majority of their low-risk establishments. PEHOs assess the effectiveness of official controls at local level but this process is not part of the Environmental Health Service documented procedures and as such, was found to be more rigorous in some areas than in others.

The official control system performed by the Environmental Health Service and the FSAI at the time of the audit was not fully effective. This report makes a number of findings requiring corrective action which, if implemented nationally, will enhance inspections and official controls in food supplement establishments in Ireland.

3. INTRODUCTION

The FSAI is responsible for the enforcement of all food legislation in Ireland. The FSAI carries out this enforcement function mainly through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI. The HSE has entered into a service contract with the FSAI and is responsible for the implementation and enforcement of national and EU legislation as it applies to food businesses under its supervision. It is a requirement of the service contract and food legislation that the HSE ensures that official controls are carried out regularly, on a risk basis, effectively and at an agreed frequency.

As part of its legal mandate, and in accordance with Schedule 5 of the service contract, the FSAI is required to verify that the system of official controls is working effectively. This audit was carried out for the purposes of assessing the official controls carried out by HSE in food supplements establishments. Compliance by the HSE with relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, was assessed.

3.1 Audit Objective

The primary objective of this audit was to assess the delivery and effectiveness of official controls carried out by the Environmental Health Service in food supplement establishments. The audit focused in particular, on how inspections are scheduled, carried out and followed up in selected establishments against the specific requirements of Regulation (EC) No 882/2004.

3.2 Audit Scope

The scope of the audit was the implementation of official controls by the Environmental Health Service in food supplement establishments including establishments manufacturing, packing, wholesaling and/or distributing food supplements. The audit excluded premises involved in retail sales only. Compliance by the Environmental Health Service with food legislation including Regulation (EC) No 882/2004 (Official Controls) and adherence to the FSAI service contract requirements, as well as relevant documented procedures but in particular, the *aide-memoire* and checklist agreed by the Environmental Health Service and the FSAI for the supervision of food supplement establishments, was reviewed.

Seven local PEHO areas in the four Environmental Health Service regions were audited. The audit also included an inspection in seven food supplement establishments (five manufacturers, one packer and one distributor) to check compliance by food businesses with food law and to verify official controls.

3.3 Audit Criteria and Reference Documents

During the audit, compliance with the audit criteria was assessed, which included:

Principal audit criteria

- Food Safety Authority of Ireland Act, 1998 (S.I. No. 29 of 1998), as amended
- Regulation (EC) No 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- The FSAI/HSE Service Contract (including FSAI Act) and work programme for 2013
- Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements
- Directive 2006/37/EC of the 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the council as regards the inclusion of certain substances
- Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements
- European Communities (Food Supplements) Regulations, 2007 (S.I. No. 506 of 2007)
- European Communities (Food Supplements) Regulations, 2010 (S.I. No. 355 of 2010)
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, as amended
- FSAI Guidance Note 1, Revision 2
- FSAI/HSE Food Supplement *Aide-memoire* and Checklist, 2012
- FSAI Guidance Note No. 21 (Revision 1) Food Supplements Notifications
- 2013 Protocol for HSE national chemical sampling and analysis programme for food supplements manufactured in Ireland
- 2013 HSE chemical sampling plan
- Labelling legislation, including nutrition and health claims legislation listed in the service contract

Secondary criteria

- Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs
- The National Control Plan for Ireland, 2007-2011 & 2012 - 2016
- Health Service Executive Business/Service Plans and data supplied to the FSAI
- Business Protocols for the HSE Environmental Health Service
- Guidance Notes/Codes of Practice and other relevant legislation detailed in the FSAI Service Contract

3.4 Audit Methodology

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations defined in Schedule 5 of the service contract between the FSAI and the HSE and are in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6(1) of Commission Decision 2006/677/EC) and the FSAI Act.

A pre-audit questionnaire was forwarded to the seven PEHO areas audited. The purpose of the pre-audit questionnaire was to collate and confirm information regarding official controls and the food supplement establishments under the supervision of these areas.

An evaluation plan was then developed, which provided an overview of the audit including audit scope, objectives, criteria and team. The evaluation plan also included a proposed itinerary for on-site activity. The onsite activity took place in October–November 2013.

The first part of each of the audits took place in the PEHO's area and involved a review of the information provided as part of the pre-audit questionnaire, as well as an audit of paperwork associated with official controls. The evidence examined as part of the desktop audit included:

- Inspection reports for official control inspections
- Communications, reports and letters to food business operators
- Records of supervisory activities and training carried out by the PEHO and the Senior Environmental Health Officer (SEHO)

The second part involved onsite verification of official controls in a food supplement establishment(s) under the supervision of the areas audited. This verified the delivery and effectiveness of official control activities being carried out, as well as an audit of the establishments to determine compliance with food legislation at the time of the visit and to verify official controls.

Preliminary findings for both the official controls and the establishments audited were issued to the seven areas after each audit for follow-up by the PEHO locally.

4. AUDIT FINDINGS

4.1 Official Controls performed in accordance with Regulation (EC) No 882/2004

4.1.1 Organisation and Structure of Official Controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

Findings

The Environmental Health Service provides a range of food safety/food control services in accordance with the service contract between the FSAI and the HSE. These services include inspection of food businesses and food sampling to ensure compliance with food legislation, the management of food incidents and a range of compliance building/ education measures. The Environmental Health Service operates locally under the supervision of a PEHO. The PEHO organises the inspection of food establishments in their functional area. If targets are not likely to be achieved, the PEHO reorganises the workload within their area to ensure the highest risk establishments are inspected first. The Environmental Health Service National Management Team indicated that there is a plan to reorganise resources nationally to address shortfalls in the number of EHOs in some regions. At the time of the audit, the movement of staff across local areas had not commenced.

The organisation of official controls in food supplement manufacturing establishments varies by area. In some areas, SEHOs or specific EHOs are allocated responsibility for supervision while in other areas supervision is by the local EHO if a supplement manufacturer is located in his or her district. Food supplement distributors are generally supervised by the EHOs in the district they are located.

4.1.2 Coordination and Planning of Official Controls

Article 4(2) of Regulation (EC) No 882/2004 requires competent authorities to carry out effective and appropriate official controls. Article 4(5) of the Regulation requires that, when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

S.I. No. 506 of 2007 requires any person placing a food supplement product on the market in the State, to notify the FSAI of that placing on the market by forwarding the FSAI a model of the label used for the product.

Findings

Official controls are planned in order to meet the requirements of FSAI Guidance Note No.1 (Revision 2) which is a risk-based approach to the coordination and planning of official controls: establishments are risk profiled and are then allocated an inspection frequency based on whether they are high or low-risk. In 2012 and 2013, there were significant efforts made by the Environmental Health Service to ensure that available resources were used in the first instance to inspect higher risk establishments. In the Wexford area in 2012, a shortfall in targets was identified following a review by SEHOs. On one SEHO team, 73 Category 3 establishments had not been inspected since 2010 or before. Evidence of 14 premises not inspected since 2008 were identified in that review. The main reason provided for the failure to achieve targets was due to significant staff shortages (loss of 2.2 whole time equivalents) in the area from illness and maternity leave. As a result of this review, teams were reallocated to address shortfalls in inspection numbers, all Category 1 (highest risk) and Category 2 establishments were inspected but only 48% of Category 3 establishments were inspected by the end of 2012. Nevertheless, this was in contrast to other areas which had achieved all inspection targets including risk Category 5, i.e. low-risk. A review of inspection targets for 2013 had not taken place in the Wexford area at the time of the audit.

In addition to the controls in place by the Environmental Health Service, some official controls for food supplements are carried out directly by the FSAI. The FSAI is responsible for the development and management of the notification system by food business operators of products placed on the market for the first time. On notification of a food supplement to the FSAI, the label is checked for:

- Prohibited products containing medicinal herbal and botanical ingredients
- Nutrition information and nutrition and health claims
- Nutrients at medicinal level
- Unauthorised novel food ingredients
- Non-permitted types and forms of vitamins and minerals and
- Medicinal claims

Following the labelling review, the FSAI informs the food business of any non-compliance identified. It was agreed by the FSAI and the Environmental Health Service in 2012 that letters to food business operators regarding non-compliant labels would be copied to the relevant PEHO areas for follow-up with the food business operator to ensure compliance. At the time of the audit however, the HSE was not being informed of the non-compliant labels and as a result, there was limited follow-up action taken with the food business operators.

The FSAI provides updates on the list of food supplement notifications to the Environmental Health Service by email three/four times annually. During the audit, inaccuracies were noted with the list of notifications sent to the HSE, e.g. a number of establishments that had been notified to the FSAI were not included on the lists, some food business operators were included in duplicate and some food business operators had ceased trading. The list included all notifications since 2000.

Some PEHO areas were using the notifications list to identify establishments for supervision and also to facilitate checks in food supplements establishments regarding label notifications. However, in three PEHO areas (Tallaght, Wexford and Louth), the lists were not being reviewed and as a result, some establishments were not being supervised or registered by the Environmental Health Service. During the audit, the Environmental Health Service provided three revisions of lists of food supplement establishments under their supervision. The number of distributors was 24 in the initial list provided by the Environmental Health Service and at the end of the audit, two lists with up to 54 distributors/packers were circulated. The audit team estimates the numbers of establishments is significantly higher than that identified by the Environmental Health Service.

4.1.3 Registration of Food Businesses

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration of food and feed business establishments. Article 6 (2) of Regulation (EC) No 852/2004 requires every food business operator to notify the appropriate competent authority with a view to the registration of each establishment.

Findings

Food businesses should be inspected by the Environmental Health Service whether they are registered or not. However, if food business operators do not register, then it may be difficult for the Environmental Health Service to identify them for official controls. The majority of food supplement establishments known to the HSE are registered and risk profiled in accordance with FSAI Guidance Note No.1. At the time of the audit in the Tallaght area, there were a number of food supplement distributors not registered as the Environmental Health Service had only recently identified these establishments from the notification list and supervision had commenced prior to the audit.

4.1.4 Prioritisation of Official Controls and Risk Categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of food business operator compliance, the reliability of own checks and any additional information on non-compliance. Controls shall in general be carried out without prior warning.

Findings

FSAI Guidance Note No. 1 sets down the process for risk categorisation of food businesses to determine the frequency of planned inspections. The guidance document also determines the way the EHO shall carry out the inspection and the action in the case of non-compliance. The document aims to facilitate a consistent approach within the Environmental Health Service in prioritising and conducting inspections of food businesses in order to verify and/or secure compliance by food business operators with relevant food legislation. Implementation of FSAI Guidance Note No.1 commenced during 2011 and in some areas, at the beginning of 2012.

Food business operators supervised by the Environmental Health Service are profiled using a risk rating which sets down criteria for a risk to be applied to an establishment, this is called a risk profile. The risk profile

determines the nature and frequency of official controls to be performed. Risk profiles were available for establishments, although a review of the profiles provided during the audit identified some inconsistencies in how the risk scores were achieved, see Appendix I. The method of handling/processing/manufacturing defined in the risk profile was in some instances found to be incorrect.

In five areas audited, food supplement manufacturers are receiving unannounced audits in line with the inspection frequency laid down in FSAI Guidance Note No. 1. However in the Tallaght area at the time of the audit, targets were not achieved for some food supplement distributors and, in the Wexford area, inspection targets were not being achieved for a significant number of Category 3 establishments (see Section 4.2).

4.1.5 Documented Procedures

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Documented Procedures

FSAI Guidance Note No.1 – Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 2)

The FSAI, in consultation with the Environmental Health Service, developed inspection guidance and provided training in the application of food law and food supplement legislation to the specific risks posed by food supplements, due to their micronutrient composition and methods of manufacture. This documentation became effective in October 2012.

Findings

The FSAI/HSE Food Supplements *Aide-memoire* and Checklist had been used in all manufacturers in the areas audited, except Louth. In the Tallaght area, there was one food supplement manufacturer and 23 distributors that had notified the FSAI of food supplements they had placed on the market. Following the introduction of the *aide-memoire* in October 2012, it had been used during subsequent inspections in the manufacturer but not in any of the distributors that had been inspected from that time. This was inconsistent with the inspections of food supplement distributors in other areas audited.

4.1.6 Reports to Food Business Operators and Follow-up and Close-out of Non-compliances

Article 9 of Regulation (EC) No 882/2004 requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies a non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record of non-compliance.

Findings

Copies of inspection reports were available for all establishments audited. The essential official control information is recorded in the local Environmental Health Service database and in the letters to food business operators. Official control legislation requires inspection reports to be issued to the food business operator when non-compliances are found. In the files audited, the food business operators receive a report after all inspections and generally, in a timely manner.

Template letters

Protocol 3 of the Environmental Health Service documented procedures states that correspondence shall be sent to the food business operator following the inspection where non-compliances are identified in the form of a template letter. The template letter for both a minor and unsatisfactory outcome requires the EHO to identify the non-compliances, i.e. 'The following non-compliances were identified'. This statement was not included in some inspection letters in Limerick and Tallaght. In addition, the wording 'You must take appropriate action to address the issues identified' is required when the outcome is minor and this was not included on some letters in Tallaght, Limerick and Louth.

Identification of Non-compliances

Although the *aide-memoire* and checklist have been used for most of the recent inspections of food supplement manufacturers, EHOs had not identified some non-compliances unique to these types of businesses (see Section 4.2 Official Controls performed in Food Establishments). Overall, the audit team considered that non-compliances were not appropriately identified in four of the seven establishments audited. In one establishment, the last inspection had taken place in September 2011, which was prior to the introduction of the *aide-memoire*/checklist and the training for food supplements. Nevertheless, the outcome of the inspection was recorded as satisfactory and the food business operator was informed that the HACCP records were 'well maintained', even though there was no food safety management system based on HACCP principles in place (see Appendix II).

Inspection Outcomes

FSAI Guidance Note No.1 provides for five inspection outcomes varying from satisfactory (grade 1) to unsatisfactory serious (grade 5). During the course of the audit, 27 letters were reviewed and it was noted that the inspection outcomes assigned during the 27 inspections were 12 satisfactory (grade 1), 14 minor (grade 2) and one unsatisfactory (grade 3).

The audit team considered that, based on the nature of non-compliances identified during the audits and the fact that many of these non-compliances would have been evident at the last inspection, the inspection outcomes allocated in three areas were not an accurate reflection of the level of compliance in these establishments. For example, in one establishment inspected in September 2013, eight non-compliances were identified in a letter to the food business operator but the inspection outcome was graded as satisfactory (see Appendix III for further information).

4.1.7 Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced staff, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Findings

Training is structured in accordance with the Environmental Health Service Protocol 52 in relation to professional development. This includes national, regional and local training as necessary depending on the training needs assessment. Local staff meetings in PEHO areas, as well as cascade training, are taking place at the instruction of the PEHO and/or SEHOs. In addition, a 2013 national training plan was put in place by the Environmental Health Service in conjunction with the FSAI. All local areas which had food business operators with food supplement activities notified to the HSE, had a representative at the training on food supplements, yet non-compliances were not identified in four of the seven areas audited.

4.1.8 Verification and review of official controls and procedures

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authority to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 4(6) of the Regulation requires competent authorities to carry out internal audits or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner. Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

Findings

Verification and review of official controls is organised locally by the PEHO and/or SEHOs. Different arrangements were in place in the PEHO areas audited including:

- File reviews, conducted periodically by PEHOs or SEHOs to ensure that consistency and quality of inspections in the local area were in place
- Regular staff meetings and management meetings held to discuss enforcement issues and inspection activities
- Data reviews of inspection activities carried out are summarised periodically
- EHOs provide monthly returns to present an overview of inspections carried out
- In some areas, the SEHOs carry out onsite visits with EHOs on a regular basis and in other areas, a SEHO accompanies an EHO in the event of a serious problem in a food establishment
- Joint inspections in higher risk establishments for planned inspections, and in some areas, the management reviews the teams every six months to allow different EHOs to work together
- In one area, as part of staff training and to facilitate consistency, peer review of files takes place

Internal audits were in place in the Mayo area but not in the other areas audited. The Environmental Health Service National Management Team has not developed and implemented an internal audit system as required by Article 4(6) of Regulation (EC) No 882/2004.

The audit team found evidence that review procedures were in place in all areas audited however, systems were more rigorous in some areas. This demonstrates a variation in consistency and effectiveness of official controls between the regions, e.g. Wexford had not reviewed 2013 inspection targets at the time of the audit.

4.2 Official Controls performed in Food Establishments

Seven food business operators - five manufacturers, one packer and one importer/distributer - were audited to verify the official controls taking place and to assess compliance with food legislation. This section highlights findings in the food supplements establishments audited. Some of these findings were previously identified by the local EHO during routine official control inspections and Appendix IV summarises the non-compliances found at food business operators by the audit team and indicates whether or not these had been identified by the EHO on previous inspections.

4.2.1 Manufacturers Food Safety Management System Procedures based on HACCP Principles

Article 5 of Regulation (EC) No 852/2004 requires the food business operator to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Regulation (EC) No 852/2004 allows the HACCP based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations.

Findings

Food Safety Management System Procedures based on HACCP

In four food business operators audited, there were no procedures based on the HACCP principles in place for food supplements. Documented procedures were in place in six of seven food business operators to control activities. Environmental Health Service inspection records for a manufacturer/retailer in one area revealed that the food business operator had no documented procedures in place to control the manufacture and sale of food supplements. At the time of the audit, the manufacturer had recently moved premises and was not making food supplements. Nevertheless, the food business operator was selling the food supplements made in the original uncontrolled establishment. The supporting documentation and procedures to validate the quality and consistency of the food product for sale was not available. This non-compliance was highlighted to the food business operator in a recent Environmental Health Service inspection.

Adequacy of Hazard Identification and Control Procedures

In the three establishments that had a food safety management system, two of the plants had significant deficiencies and one had minor deficiencies. Overall, it was found that the identification and control of the following hazards, either through a food safety management system or other risk management systems (in place for medicinal products/devices), was inadequate.

- *Cross-contamination*
  The hazard identification and control procedures associated with minimising the potential for cross-contamination of food supplements in multiproduct facilities, were inadequate. Three manufacturers were involved in the manufacture of non-food products such as medicines, cosmetics and medical devices. Cross-contamination as a hazard had been identified in quality risk management systems at only two of these establishments and limited cleaning verification studies were conducted but these did not identify the risk to food products. Three manufacturers were involved in the manufacture of food supplements only. The risk of cross-contamination by other novel or allergenic food supplement ingredients had not been identified in two of these establishments and a third had conducted a preliminary study.

- *Ingredient Identity and Quality*
  The hazard identification and control procedures associated with preventing use of counterfeit, contaminated, or poor quality ingredients, were inadequate. Supplier controls and checks on incoming ingredients were reviewed in five of the seven food business operators and found to be inadequate in all five establishments audited. In the majority of manufacturers, incoming ingredients are accepted based on certificates of analysis without confirmatory tests (verification) for identity or content. Other assurances of quality by way of rigorous supplier approval were also deficient in the majority of establishments audited.

- *Label Claim for Ingredient Content in Dosage Form*
  The hazard identification and control procedures associated with ensuring accurate ingredient content were inadequate. The food business operator controls in place to ensure the ingredient content was consistent with label claims in the final dosage form (tablets, capsules, liquids etc.) were inadequate in four of the six establishments audited (not audited at the distributor).

  Only two of six establishments, through an alternative risk management system in place for medicinal products, routinely test the finished product for the content of all ingredients stated on the label.

  Adequate verification of the bulk mixing/blending process to ensure homogeneity of content had been identified through an alternative risk management system and conducted at only one of six establishments.

- *Label Claim for Shelf Life*
  The hazard identification and control procedures associated with ensuring that product is stable to the end of the stated shelf life in establishments audited were inadequate. Stability testing was being conducted in only two of the six establishments. In one of the establishments, preliminary data suggested that one ingredient would not meet the label claim at the end of the shelf-life and this was under investigation by the food business operator. In the importers/distributors, there was no evidence available for the shelf-life of the products being placed on the market as the food business operator considered that it was the responsibility of the manufacturer.

4.2.2 Manufacturers Cleaning Systems and the Controls to reduce the Risk of Cross-contamination

Regulation (EC) No 852/2004, Annex II Chapter I:

1. **Food premises are to be kept clean and maintained in good repair and condition.**
2. **The layout, design, construction, siting and size of food premises are to:**
   - **(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;**
   - **(b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;**
   - **(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;**

Findings

While most premises were visually clean, the cleaning methods to minimise cross-contamination on product contact equipment were considered to be deficient. In three of the six manufacturers/packers, no cleaning validation studies were available to prove the effectiveness of the cleaning methods for removal of chemical residues. One of these establishments was also packing medicines. One manufacturer had no evidence to support the effectiveness of a dry cleaning method, employing compressed air/vacuum treatments to remove powder between food supplement products and no wet cleaning was employed.

At two manufacturers making non-food products such as a high potency medicine, cosmetics and medical devices on the same equipment as food supplements, limited cleaning validation studies had been conducted and were considered to be inadequate as the requirements of food law were not incorporated. In one of these manufacturers, the cleaning validation study viewed was based on a batch of product no longer manufactured and which requires only the two-step cleaning process. Currently, a skin barrier film is filled on the same line as the food product and requires a three-step cleaning process. This had not been validated. In the other manufacturer, the cleaning procedure did not reference the food supplement product. In addition, the audit team identified that a second check for room and equipment cleanliness had not been conducted prior to proceeding with food supplement manufacturing,g even though this is required by the manufacturer's own documented procedure.

The third manufacturer was producing only food supplements but had conducted only one preliminary cleaning validation study employing one indicator allergenic ingredient.

Failure to identify cross-contamination risks described in Section 4.2.1 has led to inadequate cleaning systems and a lack of controls in place for reducing the risk of cross-contamination.

Pest control issues were identified in one establishment.

4.2.3 General and Specific Hygiene Requirements

Article 4(2) of Regulation (EC) No 852/2004 requires that the food business operator carrying out any stage of production, processing and distribution of food after the stage of primary production/ associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

Findings

In general, the visual standard of operational hygiene was found to be adequate in six of the seven food business operators inspected however, hygiene non-compliances were found in one premises.

4.2.4 Traceability

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The food business operator shall have in place systems and procedures to identify from whom they have been supplied.

Findings

Traceability was in place in all establishments audited as required by Article 18 of Regulation (EC) No 178/2002 and with a few minor exceptions, the systems in place were satisfactory.

4.2.5 Structural Requirements

Regulation (EC) No 852/2004 Annex II Chapter II Point 1:

In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations.

Findings

In one establishment, major structural issues were evident however, the food business operator has commenced building works to resolve this.

4.2.6 Labels

Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

Council Directive 2000/13/EC of 20 March on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

Findings

During the audit, 21 labels were provided to the audit team: 14 food supplements labels, 4 PARNUTS (foods for particular nutritional uses), one medicine, one energy drink and one olive oil for skin application (the food business operator intends to market this as a food supplement). Excluding the two non-food items (the medicine and the olive oil), there were non-compliances with 18 of the 19 food labels.

Non-compliances were identified with 13 of the 14 food supplement labels. Three food supplement labels had misleading information in relation to nutrition and health claims, e.g. using an unauthorised health claim. The other types of non-compliances identified during the label review included the omission of mandatory statements as required by the Food Supplements Directive, incorrect additive labelling, reference to incorrect Recommended Daily Amounts, issues with date of minimum durability etc. Of the 14 food supplement labels, 11 were notified to the FSAI and three of the labels were not notified.

As part of the close-out to this audit, the FSAI is following up with the relevant food business operators identifying the non-compliances and copying the local PEHO.

5. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings requiring corrective action are listed in the corrective action plan. The findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across regions if relevant.

Corrective Action Plan

6. CONCLUSIONS

The food supplements sector is a competitive and growing industry with many complexities in production. It is incumbent on the industry to ensure the foods it produces and markets are safe and do not mislead consumers. It is the role of regulators to enhance consumer protection by carrying out effective risk-based controls of the industry. This report identifies issues for the HSE and the FSAI that need to be corrected and improved to ensure controls are more effective nationally. In the EU, legislation focuses on the content and labelling of food supplements and there is limited reference made to the specific risks associated with the manufacturing and control of these types of products. In 2012, the FSAI and the HSE put in place an *aide-memoire* and checklist to assist EHOs carry out official controls in a consistent and uniform manner in food supplement establishments. The FSAI is working with the Environmental Health Service to improve the application of this guidance in the food supplements industry, where the number and variety of ingredients and low level dosages present particular challenges to both industry and regulators. The industry needs to understand it has a responsibility to comply with food legislation and to carry out checks that ensure the authenticity and safety of the food products they are selling.

Appendix I Risk Profiles

The FSAI's Guidance Note No. 1 requires EHOs to complete a risk profile for all food businesses they supervise to help determine the inspection frequency. The risk profile is based on the nature and extent of the food businesses. This appendix highlights some of the inconsistencies found in the risk profiles reviewed during the audit.

Examples of inconsistencies in how establishments are profiled:

- Types of Food Handled/Processed/Manufactured: Food Business Operator 2 is a distributor, no handling of product and Food Business Operator 3 is handling exposed/unpackaged product – same score
- Types of Food Handled/Processed/Manufactured: Food Business Operator 6 and Food Business Operator 10 both distributing similar products – different score
- Method of Handling/Processing/Manufacturing: Food Business Operator 3 (packing exposed product) and Food Business Operator 6 (distributor) – same score
- Food Business Operator 14 – error in calculation
- Food Business Operator 8, 9 and 15 – risk category incorrectly assigned.

Premises	Types of Food Handled/ Processed/ Manufactured	Method of Handling/ Processing/ Manufacturing	Scale of Operation - Consumer profile	Scale of Operation - Distribution	Scale of Operation - Stage in Supply Chain	At Risk Consumers	Total Risk	Risk Category
1	10	10	0	0	0	0	20	4
2	10	0	0	5	10	0	25	4
3	10	0	10	5	10	0	35	3
4	10	0	0	0	10	0	20	4
5	10	0	10	5	10	0	35	3
6	10	5	10	5	10	0	40	3
7	10	0	10	5	10	0	35	3
8	100	100	100	100	100	100	600	6
9	100	100	100	100	100	100	600	6
10	0	0	10	5	10	0	25	4
11	10	25	10	5	10	0	60	2
12	5	20	5	5	10	0	45	2
13	10	20	10	5	10	0	55	2
14	15	105	15	5	20	20	15	5

Premises	Types of Food Handled/ Processed/ Manufactured	Method of Handling/ Processing/ Manufacturing	Scale of Operation - Consumer profile	Scale of Operation - Distribution	Scale of Operation - Stage in Supply Chain	At Risk Consumers	Total Risk	Risk Category
15	10	100	100	100	100	100	**510**	6
16	10	0	10	5	0	0	25	4
17	0	15	10	5	0	0	30	4
18	0	0	10	0	0	0	10	5
19	0	0	10	5	10	0	25	4

Appendix II Non-compliances not identified to the Food Business Operator at Last Inspection

This appendix lists examples of non-compliances identified by the audit team that were not identified by the EHO at previous inspections (it should be noted that in some cases, the EHO inspection took place after the national training on food supplements and after the introduction of the *aide-memoir* and Food Supplement Checklist.

Manufacturer
Date of last EHO inspection: 28 June 2013. The Food Supplement Checklist was available but was not used.

Examples of non-compliances identified by the FSAI audit:

- There was no food safety management system based on the principles of HACCP in place at the time of the FSAI audit. *Note: HACCP had been reviewed and deemed compliant at a previous EHO inspection in 2012*
- Risk of cross-contamination of medicinal products into food is not adequately controlled in the establishment. *Note: General hygiene was inspected by the EHO in a 2013 inspection, risk assessment and HACCP was checked at previous inspection in 2012 – neither inspection raised this as a non-compliance to the food business operator*

Manufacturer
Date of last EHO inspection: 8 Oct 2013. The Food Supplement Checklist was completed and there was a note that HACCP was reviewed as part of that inspection.

Examples of non-compliances identified by the FSAI audit:

- The food safety management system did not consider all of the cross-contamination risks and did not provide sufficient evidence to demonstrate the effectiveness of the cleaning system to remove other identified high risk ingredients
- The food safety management system did not identify the need to provide evidence to prove that processing parameters can consistently produce finished product meeting the label claims for ingredient content. Controls are based solely on accurate addition of ingredients, although neither ingredients nor finished product are tested for content. The flow properties of the ingredients and blends are not assessed for suitability for manufacturing equipment prior to routine manufacture

Note: Neither of these non-compliances was identified by the EHO to the food business operator at previous inspections.

Manufacturer
Date of last inspection: 30 Sept 2013. The Food Supplement Checklist was completed and there was a note that HACCP and SOPs were reviewed as part of that inspection. However, the last inspection was prior to training on the use of the *aide-memoir* or checklist.

Examples of non-compliances identified by the FSAI audit:

- The food safety management system did not identify the need to provide evidence to prove that processing parameters can consistently produce finished product meeting the label claims for ingredient content. Controls are based solely on accurate addition of ingredients, although neither ingredients nor finished product are tested for content

- Managing the selection of ingredients and suppliers is inadequate and is based solely on questionnaire and checks of certificates of analysis. No supplier auditing or testing of incoming ingredients is conducted. An approved suppliers list was checked. A risk rating system is applied to all suppliers. However, all suppliers were rated low to medium-risk and the requirements for both are the same. Supplier audits are required only if a supplier is rated high-risk.

Note: Neither of these non-compliances was identified by the EHO to the food business operator at previous inspections.

Packer

Date of last inspection: 20 Sept 2011. The Food Supplement Checklist was not published. Cleaning, management interviews, records and critical control points were listed on the files as inspected by the EHO.

Examples of non-compliances identified by FSAI audit:

- No food safety management system in place
- The only checks performed to control the risk of cross-contamination are visual examinations of the equipment for cleanliness and these were documented. No risk assessment or verification data were available to prove the effectiveness of this method in terms of removal of residues of medicinal products from the product contact parts of the equipment prior to filling food supplements nor of effectiveness of microbiological sanitation
- Stability reports requested for a number of products were not available
- On receipt of bulk product from contract manufacturers in the warehouse, samples are removed for a visual check to confirm identity. These visual checks are not performed against a reference sample although the retained samples are sometimes checked. No samples are sent for identity tests to confirm that the product is correctly labelled

Note: These non-compliances were not identified by the EHO to the food business operator at previous inspections.

Appendix III Inspection Outcomes

This appendix identifies examples of when inspection outcomes allocated by EHOs were not an accurate reflection of the level of compliance in establishments.

Packer: Date of inspection 20.09.11. Inspection outcome: satisfactory. This food business operator did not have a food safety management system in place.

Manufacturer: Date of inspection 23.09.11. The report indicated 'A food safety management system shall be put in place' – minor unsatisfactory inspection outcome. Two years later, the inspection identified no critical control points were identified by the food business operator and the inspection outcome remains minor unsatisfactory.

Distributor: Date of inspection 30.09.13. Eight non-compliances were identified in the letter to the food business operator but the inspection outcome was graded as satisfactory. The letter stated the areas needed to be addressed to ensure compliance.

Manufacturer: Date of inspection 30 June 2013. Letter stated no contraventions but included observations which included a recommendation to have a supplier list. This premises did not have a food safety management system. The inspection outcome was satisfactory.

Manufacturer: Date of last inspection 30 Sept 2013. Inspection outcome: minor non-compliance. On the day of the FSAI audit, a significant number of issues were identified regarding the controls in the establishment, e.g. the food safety management system did not identify risks or propose controls for establishing quantitative levels of ingredients to support the label ingredient list, stability and claims, either by testing and/or process verification.

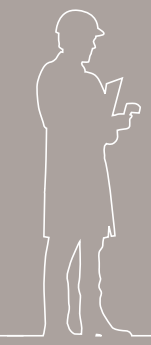
Appendix IV Food Business Operator Findings

This appendix is a summary of the findings in the seven establishments audited. The table lists:

(a) The number of establishment where a requirement was reviewed
(b) The number of compliant establishments and the areas
(c) The number of non-compliant establishments and the areas
(d) If the non-compliance had been previously identified by the local EHO during a previous inspection

	Number of Establishments	Compliant Establishments	Non-compliant Establishments	Identified by EHO in Previous Inspections
General Hygiene	7	6/7	1/7	No, but may not have been non-compliant
Documented Procedures	7	6/7	1/7	Yes
HACCP/Food safety management system in place	7	3/7 had a food safety management system 1/3 had minor deficiencies in the food safety management system 2/3 had significant deficiencies in the food safety management system	4/7	2/4
Controls on ingredients and supplier approval	5	0	5/5	1 /5
Controls to ensure label claims are met– (ingredients checked, process checked or end product checked)	6 (1 est. not manufacturing)	2/6	4/6	2 /4
Stability testing or evidence of shelf-life	7	2 /7 establishments checking	5/7	No
Manufacturers cleaning systems	6	2 /6 establishments	4/6	No

	Number of Establishments	Compliant Establishments	Non-compliant Establishments	Identified by EHO in Previous Inspections
and the controls to reduce the risk of cross-contamination with other substances				
Traceability	7	7/7		n/a
Structural requirements	7	6/7	1/7	Yes



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