

AUDIT  
REPORT

Audit of Official Controls in  
Horticultural Produce Sector  
– Department of Agriculture,  
Food and the Marine

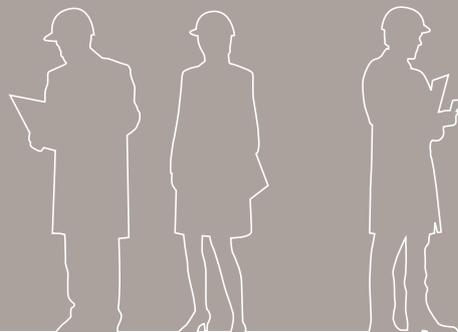
JULY 2014



# AUDIT REPORT

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## **1. GLOSSARY**

CCP	Critical Control Point
DAFM	Department of Agriculture, Food and the Marine
FSAI	Food Safety Authority of Ireland
HACCP	Hazard Analysis Critical Control Point
VTEC	Verocytotoxigenic <i>E. coli</i>

## **2. EXECUTIVE SUMMARY**

The Food Safety Authority of Ireland (FSAI) conducted an audit of the inspection services in the horticulture inspectorate and Crop Policy, Production and Safety Division of the Department of Agriculture, Food and the Marine (DAFM) this year. Internationally horticultural produce has recently been associated with a number of food poisoning outbreaks, e.g. sprouted seeds and ready-to-eat salads. It is now recognised such products are potentially high-risk which must be farmed and produced under the appropriate hygienic conditions. The number of establishments supervised by the horticultural inspectorate is estimated to be 400 (excluding potato growers and beekeepers). The horticultural inspectorate operates nationally reporting to a Senior Inspector. One Agriculture Inspector (0.6 whole time equivalent) manages the activities of six Assistant Agriculture Inspectors (2.2 whole time equivalent), who are responsible for the day-to-day implementation of official controls in horticulture establishments and other functions such as nursery controls, plant health and grant aid. The horticultural inspectorate commenced hygiene inspections in 2008 and since then, the number of inspections has increased annually. Detailed and thorough inspections, particularly when carried out by the Agriculture Inspector, were evident from the files reviewed. Nevertheless, very significant findings have been identified during the audit in relation to the organisation and implementation of food safety controls.

The findings included:

1. The whole time equivalent number of staff tasked with the organisation, management and delivery of official controls in this area is 3.4. The number was 2.4 in 2013. Other functions such as nursery controls, plant health and grant aid etc. are carried out by the same group of inspectors. These tasks are time specific (grant aid inspections have to occur before year-end) and often take priority over food control
2. Two establishment registers are maintained by the DAFM with significant differences. Both registers are incomplete and have inaccuracies
3. A high proportion of premises are not risk-categorised
4. Some high-risk establishments have not been inspected since 2010 and 2011
5. Access to laboratory facilities is very limited with regard to capacity for sample numbers and the time period for submitting samples
6. The suite of tests available for sample testing is limited, e.g. only sprouts are tested for Verocytotoxigenic *E. coli* (VTEC)
7. The four EU Commission Regulations introduced to strengthen controls in sprouts and seeds used for sprouting following the large German outbreak in 2011 have not been transposed
8. Establishments producing sprouts are not approved in accordance with Commission Regulation (EU) No 210/2013
9. Seven onsite audits of horticultural establishments were conducted resulting in two establishments being closed for public health reasons and one establishment received a compliance notice for breaches of food safety regulations.
10. Significant non-compliances, not previously identified by DAFM inspections, were found in the establishments audited
11. The audit identified training needs for inspectors and a need for more detailed documented procedures
12. Where non-compliances were identified and enforcement notices issued previously, re-inspections frequently did not occur until one year later and in a number of cases the close-out was either by phone or by email correspondence
13. Non-compliances were identified in 19 of the 24 labels examined

The audit team considered that the current organisation of controls and shortfall in resources result in a system that is not identifying hazards that could potentially put consumers' health at risk. A structured and organised approach for the prioritisation, planning, co-ordination and delivery of official controls is not in place.

## **3. INTRODUCTION**

### **3.1. Audit Objective**

The FSAI is responsible for the enforcement of food legislation in Ireland. The FSAI carries out this enforcement function 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. DAFM has entered into a service contract with the FSAI and is responsible for the enforcement of food legislation as it applies to horticultural establishments. It is a requirement of the service contract and food legislation that DAFM ensures official controls are carried out regularly, on a risk basis and with the appropriate 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 effectiveness and appropriateness of the delivery of official controls by DAFM in horticultural establishments. Compliance by the DAFM agricultural inspectorate (horticulture) with relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, were assessed.

This audit was undertaken as part of the FSAI's audit programme for 2014. This report describes the audit objective, scope, methodology and the findings of the audit.

### **3.2. Audit Scope**

The audit covered the organisation, planning, implementation and review of official controls within the agricultural inspectorate<sup>1</sup> and Crop Policy, Production and Safety Division at national and local levels in order to confirm compliance with the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004 and the Multi-annual National Control Plan.

### **3.3. Audit Criteria and Reference Documents**

The audit criteria referred to during the audit included the following:

- 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
- FSAI Service Contract (including FSAI Act)
- Regulation (EC) No 853/2004 on the hygiene of foodstuffs, as amended
- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs
- European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009) as amended

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<sup>1</sup> DAFM's agricultural inspectorate is made up of different inspectorates supervising different parts of the food and farming industry in Ireland. This audit report only examines the official controls carried out by the horticulture and plant health division inspectorate of the overall Department's Agricultural Inspectorate. The inspectorate is referenced as the Horticultural Inspectorate throughout the document. The Crop Policy, Production and Safety Division provides administrative support to the Horticultural Inspectorate by maintaining the register of producers of the different horticulture production categories.

- Commission Implementing Regulation (EU) No 208/2013 on **traceability** requirements for sprouts and seeds intended for the production of sprouts
- Commission Regulation (EU) No 209/2013 amending Commission Regulation (EC) No 2073/2005 of 15 November 2005 as regards **microbiological criteria** for sprouts and the sampling rules for poultry carcasses and fresh poultry meat
- Commission Regulation (EU) No 210/2013 on the **approval** of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
- Commission Regulation (EU) No 211/2013 on **certification** requirements for imports into the Union of sprouts and seeds intended for the production of sprouts
- Commission Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
- Commission Regulation (EC) No 1882/2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs
- Commission Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
- 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
- Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended
- Regulation (EC) No 1924/2006 on nutrition and health claims made on foods
- The National Control Plan for Ireland 2012 - 2016
- Horticultural Inspectorate Hygiene Plans and data supplied to the FSAI
- Horticultural Inspectorate Documented Procedures

### **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. These procedures implement the FSAI audit obligations, defined in Schedule 5 of the service contract between the FSAI and DAFM, and in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 2006/677/EC) and also the FSAI Act.

An evaluation plan describing the audit process and approach (including the scope, objectives, criteria and the audit team) was sent to the horticultural inspectorate ahead of the onsite activities. As part of the desktop element of this audit, a review of relevant information held within FSAI was also carried out ahead of on-site activities.

The audit included a review of the performance and delivery of official controls by DAFM Horticultural Inspectorate at central and local levels. The audit team evaluated whether the official controls were being carried out in accordance with DAFM's own documented procedures which are used to implement the service contract requirements with the FSAI and related legislation.

As part of the audit of the food business operators, the audit team assessed the adequacy and performance of the controls put in place at establishment level in relation to the implementation of good hygiene practices and principles of HACCP (Hazard Analysis Critical Control Point) as part of the food business operator's food safety management system and sampling programmes, and assessed whether these were effective, adequately maintained and in compliance with food law.

On completion of the onsite visits to establishments the audit findings relevant to each food business operator were outlined by the FSAI audit team. The food business operator was informed that follow-up in relation to these would be carried out by the horticultural inspectorate and that the FSAI would communicate the audit findings to DAFM following completion of the audit. Following completion of all establishment audits, a final closing meeting was also held with DAFM staff at central level where findings were discussed.

## **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.**

**Article 4(2)c states that competent authorities shall ensure: that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.**

#### **Findings**

The horticultural inspectorate operates nationally reporting to a Senior Inspector. At the time of the audit, one Agriculture Inspector manages the activities of six Assistant Agriculture Inspectors who are responsible for the day-to-day implementation of food safety controls and other functions such as nursery controls, plant health and grant-aid in horticultural establishments. In 2012 and 2013, there were six Assistant Agriculture Inspectors which translated into 1.2 whole time equivalent inspectors available to implement food safety controls. The whole time equivalent numbers of staff have not changed substantially since 2012 (Table 1); although one extra Assistant Agricultural Inspector has been recruited to work full-time on food control in 2014 bringing the total number of staff to 3.2 whole time equivalent at the time of the audit.

**Table 1: Horticultural Inspectorate Numbers for 2014, 2013 and 2012**

Whole Time Equivalent	2014	2013	2012
Senior Inspector	0.2	0.2	0.2
Agriculture Inspector	0.6	0.6	0.6
Assistant Agriculture Inspector	2.2	1.2	1.2
Senior Agriculture Officer	<u>0.2</u>	<u>0.2</u>	<u>0.2</u>
Total	3.2	2.2	2.2

\*Source: Horticultural inspectorate whole time equivalent food control

Access to laboratory facilities is agreed with the laboratories at the beginning of each year and is limited in terms of capacity, e.g. the plan for 2014 is 30 water samples and 63 food samples for *Salmonella*, *Listeria monocytogenes* and *E coli* and 36 spouted seed samples for VTEC. Sampling has to be coordinated around available laboratory times which do not always correspond with scheduled inspections, often leading to separate sampling and hygiene inspections.

#### **4.1.2 Coordination and Planning of Official Controls<sup>2</sup>**

**Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.**

**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.**

#### **Findings**

Official control activities are planned annually by the Agricultural Inspector in conjunction with the Senior Inspector. Inspection and sampling targets are agreed nationally and forwarded to central management and to local inspectors. Sampling numbers are agreed with the laboratories depending on available resources. It was noted that there is an organised structure of official controls in place and in general the number of planned inspections

<sup>2</sup>**Recital 15** The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.

**Recital 16** The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

are increasing although inspections listed in the hygiene plan are not always carried out. In 2013, 81 premises were listed in the hygiene plan and 66 inspections took place. In 2012, 44 of the 49 inspections were completed. In addition, follow-up inspections to close-out non-compliances identified are frequently not carried out by the year end or within six months as targeted. The numbers of inspections per Assistant Agricultural Inspector whole time equivalent was 37 in 2012 (44/1.2) and 55 in 2013 (66/1.2).

**Table 2: Numbers of Inspections by Year**

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<b>Year</b>	<b>No. of Hygiene Inspections</b>
2009	14
2010	13
2011	20
2012	44
2013	66
2014 Planned	100

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### **Sampling**

The 2014 microbiological sampling plan is outlined in Table 3. The horticultural inspectorate samples a wide range of products and water for different microbiological parameters. However, given the large number of food businesses under the inspectorate's supervision, the numbers of samples are low. The chemical sampling programme covers parameters such as nitrates, heavy metals and patulin. Sampling targets were generally met in 2012 and 2013 except for patulin samples in apple juice in 2013 which was due to a poor harvest.

**Table 3: Planned Number of Samples for Microbiological Contaminants in 2014**

Sample Type	Parameter	Food Business Operator	Proposed Target No. Samples
Water	Enterococci, coliforms, <i>E. coli</i>	At least all food business operators producing high risk product scheduled for inspection in 2014 and others based on risk	Minimum 30
Food	<i>Salmonella</i> spp., <i>Listeria monocytogenes</i> , <i>E. coli</i>	Food business operators of ready-to-eat (RTE) food (particularly sprouted seeds and sliced mushrooms as a RTE pre-cut vegetable) scheduled for inspection in 2014 and others based on risk	Minimum 77
Spouted Seeds	VTEC	Sprouted seed producer	36

### 4.1.3 Registration/Approval of Establishments

Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments in accordance with Regulation (EC) No 852/2004. In addition, it requires competent authorities to draw up and keep up to date a list of food business operators which have been registered.

Article 2 of Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts states food business operators shall ensure that establishments producing sprouts are approved by the competent authority in accordance with Article 6 of Regulation (EC) No 852/2004. The competent authority shall approve those establishments only provided that they comply with the requirements set out in Annex I to Regulation (EC) No 852/2004 and in the Annex to this Regulation.

#### Findings

The audit team was provided with two registers with very significant differences and hence, was unclear as to the number of establishments that need to be considered for the hygiene inspection plan. Differences in the total numbers of establishments, differences in risk categories, in numbers of establishments by commodities and number of establishments by county were identified. The audit team noted that DAFM currently has a project underway to amalgamate, sort and verify the content of the registers of horticulture establishments. To manage and implement official controls effectively and in line with Regulation (EC) No 882/2004 competent authorities need to be able to break down the number and type of establishments and align the resources appropriately.

Commission regulation (EU) No 210/2013 has not been transposed by DAFM. Establishments producing sprouts are not approved in accordance with this regulation (see Section 4.2 Sprouts Legislation).

#### **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 operators, the reliability of own checks and any additional information on non-compliance.**

##### **Findings**

The audit team was provided with a document which outlines how the division should risk categorise all establishments under their supervision and determine inspection frequencies. This document has not been fully implemented. Establishments are allocated a risk category following an inspection. However, some establishments do not have a risk category allocated as they have not been inspected to-date.

Records of the risk categorisations carried out following inspections were available on the establishment file. Of the 19 inspection files reviewed by the audit team, 13 were categorised as high-risk, one medium, two low, and two had no allocated risk categorisation. One premises had not yet commenced production. It was noted by the audit team that the frequency of inspection for high-risk establishments was inconsistent and sometimes gaps of up to four years were seen between inspections, e.g. a large fruit and vegetable packer's last inspection was in May 2012, a large apple juice producer's last inspection was in July 2010 and a large mushroom packer's last inspection was in July 2011. All of these premises had been allocated a high risk status.

Checks by the horticultural inspectorate for non-hygiene areas of the service contract, e.g. additives, labelling are not routinely carried out.

#### **4.1.5 Documented Procedures**

**Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff and must keep these procedures up-to-date.**

##### **Findings**

The horticultural inspectorate has developed a series of documented procedures which describe how official controls are carried out. These procedures are attached to the annual hygiene inspection plan which sets down how the horticultural inspectorate implements food safety controls. Also included in the plan are:

- List of premises to be inspected
- Procedure for general hygiene inspections
- Sampling procedures – water, food, heavy metals, patulin (apple juice)
- Hygiene forms
- Sampling forms

Instructions are included for dealing with microbiological criteria and patulin levels non-compliances, but there are no procedures provided for heavy metal non-compliances.

A risk-based system is referred to in the inspection plan and a document was circulated to the audit team regarding the risk categorisation of food business operators for horticulture and plant health. However, this document is not fully implemented, e.g. the document states that no high-risk business should have greater than

12 months between inspections. The audit team noted that this is not currently achieved by the horticultural inspectorate (see Section 4.1.4). Additionally, the procedure does not detail how risk categorisations are assigned to individual establishments, i.e. there is no scoring system by establishment, instead there is a general guidance for the risk categorisation of groups of establishments.

Inspections were generally documented in line with procedures. Following an inspection, an inspection outcome was allocated and the premises were risk categorised. During the file review, the audit team noted some exceptions to this and in addition, on a number of occasions, there was a delay in issuing letters to food business operators.

During the on-site audits non-compliances were identified in horticulture premises that were not identified by the Assistant Agricultural Inspector during previous official controls. This identifies a need for further instructions regarding the application of Annex I and Annex II of Regulation (EC) No 852/2004 in horticulture establishments, e.g. what should an inspector be looking for in terms of pest control.

The audit team noted that no standard operating procedures were in place for the following:

- Registration – maintenance of register of food business operators
- Enforcement – issuing and lifting of legal notices
- Non-hygiene areas of the service contract, e.g. additives, labelling

#### **4.1.6 Identification, Follow-up and Close-out of Non-compliances**

**Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies 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 with regard to non-compliance.**

**Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.**

#### **Findings**

Official controls did not identify a significant number of the non-compliances identified by the audit team during onsite activities, including deficiencies in:

- HACCP
- Pest control
- Structure and maintenance
- Sampling and testing in relation to Regulation (EC) No 2073/2005
- Controls/Testing of Water

The audit team noted that where non-compliances were identified and Enforcement Notices were issued by DAFM, the close-out of these non-compliances did not always result in a follow-up inspection, e.g. two premises that were issued with Compliance Notices in 2012 and 2013 respectively had not received follow-up inspections at the time of the audit. The horticultural inspectorate informed the audit team that this was due to a shortage of resources.

In addition, the action taken by DAFM was not in all cases, effective at remedying certain deficiencies and non-compliances identified, e.g. one establishment that was inspected in Oct 2012 was issued with a legal notice and a follow-up inspection was carried out in June 2013. The follow-up inspection identified that some findings were still not closed out and these findings remained open in April 2014.

#### **4.1.7 Reports to Food Business Operators and Announcing Inspections**

**Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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 3 (2) of Regulation (EC) No 882/2004 requires official controls to be carried out without prior warning, except in cases such as audits where prior notification of the food business operator is necessary. Official controls may also be carried out on an ad hoc basis.**

##### **Findings**

Reports were forwarded to food business operators after official control audits. In general, the reports issued were detailed and well documented although evidence of reports being issued a significant time after inspections were taking place was seen on a number of files. There is no system in place for tracking unannounced inspections when they do occur.

#### **4.1.8 Verification and Review of Official Controls and Procedures**

**Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities 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 the 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**

Inspection and sampling targets are monitored nationally and in general, the target numbers are met for planned controls. Onsite supervisory inspections are comprehensively conducted by the Agricultural Inspector including sign off procedures. Internal audits are carried out by DAFM's Internal Audit Unit. The audit team noted that staff are carrying out extensive duties in other activities such as grant aid and plant health. The audit team was informed that this work can impact on the delivery of the hygiene plan particularly at certain times of the year. In addition, due to restricted access to laboratory resources, sampling activities do not always compliment inspection duties which results in an inefficient use of inspectors' time.

Significant issues in terms of inspection frequency were identified during the course of the audit, e.g. some establishments had not received a hygiene inspection since July 2010. Weaknesses in how inspectors close out non-compliances and follow-up on legal notices were identified. Three of the seven premises audited required legal action to be taken. There are two registers currently in operation in DAFM with significant differences identified. Establishments not inspected do not have a risk rating.

The audit team does not consider the official controls to be effective and appropriate.

#### **4.1.9 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**

Legal authorisations for horticultural inspectors as required by food legislation were in place for inspectors. The Agricultural Inspector has a coordinating role in relation to oversight of Assistant Agricultural Inspector and technical staff work, which is usually organised at central level. Training is carried out based on Assistant Agricultural Inspectors' training plan, e.g. HACCP training was done in 2013 and microbiological training was completed in 2011. Assistant Agricultural Inspectors meet the Agricultural Inspector regularly to discuss inspections and related work. Given the numbers of non-compliances identified by the audit team, more training is required to ensure staff are kept up-to-date in their areas of competence, e.g. in particular in relation to the requirements of Annex I and Annex II of Regulation (EC) No 852/2004, HACCP training, microbiological criteria and non-hygiene areas of the service contract.

## **4.2 Official Controls Performed in Food Establishments**

An overview of the onsite verification work in each of the seven establishments audited is provided in Annex I of the report. An assessment was made under (a) Structure, Maintenance & Operational Hygiene (b) Food Safety Management System (c) Sampling and Testing (d) Water Testing and (e) and Labelling. During the audit, two establishments were issued with Compliances Notices requiring them to cease trading and production. One premises was issued with a Compliance Notice requiring improved compliance with food legislation.

#### **Findings**

##### **Structure, Maintenance & Operational Hygiene**

**Article 4(2) of Regulation (EC) No 852/2004 establishes 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, sitting and size of food premises.**

The general hygiene requirements relating to the design/layout, structure, equipment and facilities were not met in the three establishments issued with legal notices and one other food business operator requires some structural modifications to improve operational hygiene.

There were serious deficiencies in cleaning and hygiene identified in five of the seven establishments audited.

### **Food Safety Management System**

**On the basis of Article 5 of Regulation (EC) No 852/2004 ,the food business operator shall 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.**

A documented food safety management system based on the principles of HACCP (including procedures and records) was not in place in two food business operators processing fruit. In the five other establishments, non-compliances with their own procedures or inadequacies with the HACCP plans presented were identified, although very minor in the two large fruit and vegetable packers audited.

The audit team noted serious deficiencies in relation to pest control and/or associated procedures in five of the seven food business operators inspected.

### **Sampling and Testing**

The audit noted that in five of the seven establishments inspected, some microbiological sampling and testing was carried out by the food business operator, but not necessarily in compliance with the requirements of Regulation (EC) No 2073/2005. Regulation (EC) No 2073/2005 requires food business operators to self-assess the hazards in their premises and the need to sample is based on the requirement to ensure hazards are appropriately controlled. This assessment should be documented. The audit team noted that the self-assessment was not carried out in five of the seven establishments audited. In general, the audit noted a poor awareness and understanding by food business operators of their legal obligations in relation to sampling and testing.

### **Water testing**

Five of the seven food business operators inspected by the audit team were on public water supply systems. However, evidence to support the potability of these supplies at points-of-use within these food business operators was not always available to the audit team. One of the food business operators inspected chlorinated the public water supply prior to use.

Two other food business operators inspected by the audit team abstracted their water supplies from private wells. In one of these food business operators the water was treated by ultra violet light prior to use. However, the audit team noted that a storage tank used to store treated water was not fully covered and the presence of agricultural animals onsite presented a hazard to the potability of the water supply. The audit team noted that there was no evidence, e.g. analysis for microbiological parameters listed under Schedule 1 of European Union (Drinking Water) Regulations, 2014, S.I. No. 122 of 2014, to verify that water used by this food business operator met potability requirements.

In another food business operator, there was also no evidence to support the adequate supply of potable water. The audit team noted that this food business operator abstracted untreated water from a shallow, unprotected, private well for direct use in food processing and cleaning operations.

## **Labelling**

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

### **Regulation (EC) No 1924/2006 on nutrition and health claims made on foods**

During the audit, 24 labels were provided to the audit team. The labels which would be attached to the final product were reviewed for compliance with general labelling rules and nutrition/health claims. Non-compliances were identified in 19 of the 24 labels. The non-compliances identified were generally technical in nature, e.g. presentation of information or omission of information. One label had misleading information in relation to nutrition and health claims, i.e. using an unauthorised health claim. As part of the close-out to this audit detailed information has been provided to DAFM identifying the non-compliances by food business for follow up as appropriate (see Annex II for more information).

## **Sprouts Legislation**

Following the *E. coli* O104 outbreak identified in Germany in May 2011 which resulted in 54 deaths, the European Food Safety Authority (EFSA) adopted a Scientific Opinion on the risk posed by Shiga toxin-producing *E. coli* and other pathogenic bacteria in seeds used for sprouting and sprouts. It concluded that the contamination of dry seeds with bacterial pathogens was the most likely initial source of the sprout-associated outbreaks and that due to the high humidity and the favourable temperature during sprouting, bacterial pathogens present on dry seeds can multiply during sprouting and result in a public health risk. In order to mitigate the identified risks, it was considered necessary to introduce additional requirements for sprouts. This has resulted in four new Commission Regulations to cover the import, traceability, microbiological criteria and approval of establishments producing sprouts. These Regulations have not been transposed by DAFM into Irish laws which will set down penalties and sanctions for non-compliance.

### **Commission Implementing Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts.**

Traceability records for sprouts and seeds were available in the two establishments producing sprouts audited.

### **Commission Regulation (EU) No 209/2013 amending Commission Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcasses and fresh poultry meat.**

The audit team noted that those food business operators inspected, producing sprouted seed products, were not in compliance with the requirements of Regulation (EC) No 2073/2005. A prescribed derogation in relation to testing of seeds outlined under Annex I; Chapter 3.3: Part B of Regulation (EC) No 2073/2005 has not been implemented by DAFM.

### **Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 on the hygiene of foodstuffs.**

Commission regulation (EU) No 210/2013 has not been transposed by DAFM. Sprouted seeds establishments are not approved in accordance with the Regulation.

**Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts.**

Import certification was not reviewed during this audit.

## **5 REVIEW OF PREVIOUS FVO MISSIONS TO IRELAND**

A review of an EU Commission Food and Veterinary (FVO) office mission (audit) carried out from 14 to 24 June 2011 in order to evaluate the official controls on food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005), was incorporated into this audit. The audit team noted that the FVO has determined from documentation submitted by the Irish authorities that six of the seven findings have been satisfactorily closed out since the mission. The main finding of the FVO report relevant to the horticultural inspectorate was a gap in the delivery of official controls in the production of sprouted seeds. DAFM, the FSAI and the Health Service Executive (HSE) have agreed the supervisory criteria for the supervision of these establishments.

The final finding **‘To ensure that sprouted seeds and sliced mushrooms as a RTE pre-cut vegetable are controlled by the food business operator and competent authorities in line with Articles 1 and 4 of Regulation (EC) No 2073/2005 as a matter of urgency.’** was deemed by the FVO as not satisfactorily closed out by the competent authorities in January 2012. Since then, DAFM has provided a more detailed response on the action being taken to address the finding and is awaiting confirmation that the finding is now closed.

## **6 CONCLUSIONS**

A structured and organised approach for the prioritisation, planning, coordination and delivery of official controls is not in place. The audit team considered that the current organisation of controls and shortfall in resources results in a system that is not identifying hazards that could potentially put consumers’ health at risk. Although much progress has been made since the unit became part of the DAFM service contract and commenced hygiene inspections in 2008, serious findings have been identified during the audit in relation to the organisation and implementation of food safety controls. Implementation to correct these findings needs to be implemented as a matter of urgency.

Following onsite establishment audits, two establishments were closed for public health reasons and one establishment was issued with a compliance notice.

## **7 AUDIT FINDINGS REQUIRING CORRECTIVE ACTION**

The findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented.

Audit findings requiring corrective action are listed in the corrective action plan.

## Annex I: Summary of Onsite Findings

Food Business Operator 1 is an apple grower and juicer, supplying the Irish market with fresh apple juice and other fruit juices.

Findings	
1	<p><b>HACCP</b></p> <p><b>Regulation (EC) No 852/2004, Article 5(1)</b> <i>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</i></p> <p><b>Regulation (EC) No 852/2004, Article 5(2)</b></p> <ul style="list-style-type: none"> <li>(a) <i>Food business operators shall identify any hazards that must be prevented, eliminated or reduced to acceptable levels;</i></li> <li>(b) <i>identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</i></li> <li>(c) <i>establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</i></li> <li>(d) <i>establishing and implementing effective monitoring procedures at critical control points;</i></li> <li>(e) <i>establishing corrective actions when monitoring indicates that a critical control point is not under control;</i></li> <li>(f) <i>establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</i></li> <li>(g) <i>establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</i></li> </ul> <p>The food business operator's food safety management system was not up-to-date and reflective of its current operation.</p> <p>There was no validation of critical control points (CCPs) to ensure the system of control is effective and there was limited evidence to support the time/temperature combination used for pasteurisation.</p> <p>Limited description and evidence available of monitoring and verification procedures for each CCP, e.g. There was no evidence of calibration of plate heat pasteuriser available. No verification of bottle pasteurisation process except the temperature checks on the water in the water bath.</p> <p>The hazard analysis was incomplete, e.g.</p> <ul style="list-style-type: none"> <li>• Identification and control of Patulin in apple juice was not documented</li> <li>• Sulphur dioxide was not identified as an allergen in the hazard analysis for cider</li> <li>• Imported soft fruit from South America/Uruguay – not included in the hazard analysis</li> </ul> <p>The supplier list was incomplete.</p> <p>Records were not fully completed:</p> <ul style="list-style-type: none"> <li>• The food safety management system identified a hygiene checklist as a monitoring point and this was not in place</li> <li>• Incomplete production checklist, e.g. temperature checks not completed, enzyme batch code not completed on production sheet for traceability</li> </ul>

	<ul style="list-style-type: none"> <li>As part of the food business operator's own food safety management system, traceability records were not reflective of the food safety management system (and consequently, the food business operator was not in conformance with their own procedural requirements), e.g. old batch codes</li> </ul>
2	<p><b>Pest Control</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX</b>  <b>4. Adequate procedures are to be in place to control pests.</b></p> <p>Inadequate procedure for pest control, i.e. baits points were present however, a bait map and schedule for checking points was not in place. Doors were opening directly onto the yard in the goods intake area of the processing hall which was a potential pest entry point.</p> <p>No fly screens in processing area and there were flies present in the processing area during the audit.</p>
3	<p><b>Heat Treatment</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter XI</b>  <b>The following requirements apply only to food placed on the market in hermetically sealed containers:</b></p> <ol style="list-style-type: none"> <li><b>any heat treatment process used to process an unprocessed product or to process further a processed product is:</b> <ol style="list-style-type: none"> <li><b>to raise every party of the product treated to a given temperature for a given period of time; and</b></li> <li><b>to prevent the product from becoming contaminated during the process;</b></li> </ol> </li> <li><b>to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;</b></li> </ol> <p>There was no evidence of validation of the pasteurisation process. The temperature of the product was not monitored to ensure the correct temperature is achieved.</p>
4	<p><b>Cleaning and Maintenance</b></p> <p><b>Regulation (EC) No 852/2004: Annex II, Chapter I (1)</b>  <b>Food premises are to be kept clean and maintained in good repair and condition.</b></p> <p><b>Regulation (EC) No 852/2004: Annex II, Chapter I (2)</b></p> <ol style="list-style-type: none"> <li><b>The layout, design, construction, siting and size of food premises are to:</b> <ol style="list-style-type: none"> <li><b>permit good food hygiene practices, including protection against contamination and, in particular, pest control</b></li> <li><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;</b></li> <li><b>permit good food hygiene practices, including protection against contamination and, in particular, pest control;</b></li> </ol> </li> </ol> <p>Dirt was observed on the floor in the main processing hall and on floors of the chills and freezer.</p> <p>Cleaning was inadequate in some parts of the processing area, e.g. floors/walls around packaging areas</p>

	<p>and the pasteuriser.</p> <p>A spillage with broken glass was observed on the floor of processing area.</p>
5	<p><b>Staff Training</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter XII (2)</b> <b><i>Food business operators are to ensure that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles</i></b></p> <p>The audit team was informed that food safety training is about to commence for the production manager and an operative. Gaps in HACCP and sampling indicate a requirement for further training.</p>
6	<p><b>Labelling</b></p> <p><b>Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs_ As updated by Directive 2006/142/EC and Directive 2007/68/EC.</b></p> <p>Spring water was stated as an ingredient on the labels but the water used in manufacture was taken from a well (spring water has a specific definition in food legislation, see <a href="http://www.fsai.ie/uploadedFiles/Legislation/Food_Legislation_Links/Water/S.I_No_225_of_2007.pdf">http://www.fsai.ie/uploadedFiles/Legislation/Food_Legislation_Links/Water/S.I_No_225_of_2007.pdf</a>) See Annex II for label review.</p>
7	<p><b>Storage</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX (2)</b> <b>Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</b></p> <p>Food products and berries in the freezer were stored on the floor and were not labelled.</p>
8	<p><b>Contamination</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX (3)</b> <b><i>At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</i></b></p> <p>Food products, e.g. blueberries in the processing hall, were stored uncovered close to broken glass.</p>
9	<p><b>Thawing of Foodstuffs</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX (7)</b> <b><i>The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.</i></b></p>

	<p>Frozen berries in plastic lined cardboard boxes from Uruguay were thawing at room temperature in the production area with no facilities for run off liquid or other controls in place. The thawing process was not recorded.</p>
10	<p><b>Wrapping and Packaging Material</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter X (2)</b> <i>Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</i></p> <p>Wrapping and packaging material were stored on the floor of the processing area.</p>
11	<p><b>Traceability</b></p> <p><b>Regulation (EC) No 178/2002, Article 18</b></p> <ol style="list-style-type: none"> <li>1. <i>The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be incorporated into a food or feed shall be established at all stages of production, processing and distribution.</i></li> <li>2. <i>Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.</i></li> <li>3. <i>Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.</i></li> <li>4. <i>Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions. No traceability system in place to identify where food is purchased.</i></li> </ol> <p>It was not clear to the audit team that the traceability of ingredients could be maintained throughout the process:</p> <ul style="list-style-type: none"> <li>• Boxes of bruised apples and pulp were being collected unlabelled and used for other products</li> <li>• Unlabelled bags of juice were seen in the processing hall</li> </ul>
12	<p><b>Microbiological Criteria</b></p> <p><b>Regulation (EC) No 2073/2005</b> <b>Article 2 - Definitions</b></p> <p>The food business operator defined a batch as a day's production but this is not documented in the food safety management system.</p> <p><b>Article 3(1) - General Requirements</b></p> <p>The food business operator has not considered its full range of products against process and food safety criteria when designing their food safety management system for all products.</p>

**Article 3(2) - General Requirements**

The food business operator has provided a shelf life of 12 months but has not conducted studies in accordance with Annex II of the Regulation to investigate compliance with the criteria throughout product shelf-life for all products or documented the reasons for not conducting these studies.

**Article 4(1) - Testing Against Criteria**

The food business operator does not test end product against micro criteria set out in Annex I of the Regulation when validating/verifying the correct functioning of their procedures based on HACCP principles and Good Hygiene Practice.

End product has tested positive for *L. monocytogenes* in the past by a research study that the food business operator was involved in.

**Food Business Operator 2 is a fresh fruit and vegetable producer and packer.**

<b>Findings</b>	
<b>1</b>	<p><b>HACCP</b></p> <p><b>Regulation (EC) No 852/2004, Article 5(1)</b> <i>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</i></p> <p><b>Regulation (EC) No 852/2004, Article 5(2)</b></p> <ul style="list-style-type: none"> <li><i>(a) Food business operators shall identify any hazards that must be prevented, eliminated or reduced to acceptable levels;</i></li> <li><i>(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</i></li> <li><i>(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</i></li> <li><i>(d) establishing and implementing effective monitoring procedures at critical control points;</i></li> <li><i>(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;</i></li> <li><i>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</i></li> <li><i>(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</i></li> </ul> <p>A fully documented HACCP system was in place although a number of minor non-compliances were identified on the day of the audit:</p> <ul style="list-style-type: none"> <li>• Scheduled weekly hygiene audit were not always conducted</li> <li>• Verification of cleaning records not always carried out</li> <li>• Although external traceability was in place the food business operator's internal traceability system was not fully compliant (and consequently, the food business operator was not in conformance with their own procedural requirements). Records were checked by the audit team and one record of a batch rejected on the factory floor was not rejected on the automated traceability system</li> </ul>
<b>2</b>	<p><b>Cleaning and Maintenance</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (1)</b> <i>Food premises are to be kept clean and maintained in good repair and condition.</i></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (2)</b></p> <ul style="list-style-type: none"> <li><i>(a) The layout, design, construction, siting and size of food premises are to: permit good food hygiene practices, including protection against contamination and, in particular, pest control</i></li> <li><i>(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;</i></li> <li><i>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;</i></li> </ul>

	The cleaning schedule did not incorporate the 'Controlled Atmosphere Warehouses'.
3	<p><b>Personal Hygiene</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VIII</b></p> <p>The Back to Work policy did not reflect adequately the control for food handlers returning to work post-illness/gastroenteritis.</p>
4	<p><b>Micro Sampling Review Risk Assessment</b></p> <p><b>Article 3(1) - General Requirements</b> The food business operator risk assessed his suppliers and proposes to commence a micro sampling programme of where the perceived risk might be.</p> <p><b>Article 4(1) - Testing Against Criteria</b> The food business operator does not perform testing as appropriate against micro-criteria set out in Annex I of the Regulation when validating/verifying the correct functioning of their procedures based on HACCP principles and Good Hygiene Practice.</p> <p><b>Article 4(2) - Testing Against Criteria</b> The appropriate sampling frequency has not been decided in the context of the food business operator's HACCP and Good Hygiene Practice.</p>

**Food Business Operator 3 is a micro salads producer and packer.**

Findings	
1	<p><b>Hygiene Provisions</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, Part A II</b></p> <p>2. <i>As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.</i></p> <p>3. <i>Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:</i></p> <p>(a) <i>measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;</i></p> <p>(b) <i>measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.</i></p> <p><b>Regulation (EC) No 852/2004, Annex I, Chapter II 5(c)</b> <i>to use potable water or clean water whenever necessary to prevent contamination</i></p> <p>A potential for cross contamination of water post-UV treatment was evident. The food business operator needs to consider the hazards and the distribution of water from the tank via pipes, especially as pigs are kept on the land near the water tank and growing rooms. The audit team was unable to verify that the water tank was sufficiently covered.</p>
2	<p><b>Cleaning and Personnel Hygiene</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, Chapter II 5(a) and (b)</b> <i>Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</i></p> <p>(a) <i>to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;</i></p> <p>(b) <i>to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products</i></p> <p>The storage area and the fridge were not sufficiently clean. There were dirty crates in the store room.</p> <p>No schedule or evidence for knife replacement/cleaning.</p> <p>The yard was untidy with water pooling that could attract pests and cause contamination in the production area, staff walk directly from farmyard into main growing/cutting room without changing shoes or clothes.</p> <p>Hand-washing facilities for staff were across a yard and away from production/harvesting.</p>
3	<p><b>Pest Control</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, Chapter II 5(e)</b></p>

	<p><b>Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</b>  <b>(e) as far as possible to prevent animals and pests from causing contamination;</b></p> <p>Bait points were in place but there was no schedule or evidence of the inspection of bait points.</p>
4	<p><b>Records</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, Chapter III (7)</b>  <b>Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.</b></p> <p>A documented HACCP plan was in place. However, it was not fully reflective of the current operation and not fully adhered to.</p> <p>The food business operator had not identified or controlled the hazards associated with the following, e.g.</p> <ul style="list-style-type: none"> <li>• Private well water supply not identified as a hazard</li> <li>• Pigs close to production area on the same site is a potential hazard</li> <li>• Physical hazard of knives breaking not identified as a hazard</li> <li>• Footwear not identified as a source of micro-contamination</li> <li>• Birds can enter the greenhouse</li> </ul> <p>Process Step 1:  The food business operator stated that the measure in place to control microbiological contamination of seeds was sourcing seeds from accredited suppliers. There was limited information regarding the registration status or approval of seed suppliers.</p> <p>Also there was no evidence of hygiene inspection procedure in place as outlined.</p> <p>Process Step 1:  No evidence of the accreditation of the media for growing plants as identified in HACCP plan.  Limited evidence available for the monitoring of control points.</p> <p>Process Step 2a:  Incorrect water supply referenced in HACCP plan under the heading 'control measure'.</p> <p>Process Step 5:  No certificate of conformance for food grade plastic available.  Insufficient description of monitoring for each control point.  No monitoring of critical limits as described in the validation table.  Review of HACCP not taking place as outlined in the procedures.</p>
5	<p><b>Microbiological Criteria</b></p> <p><b>Regulation (EC) No 2073/2005</b>  <b>Article 2 - Definitions</b></p> <p>The food business operator defined a batch as a day's production but this is not documented in the food safety management system.</p>

**Article 3(1) - General Requirements**

The food business operator has not considered process and food safety criteria when designing their food safety management system for all products.

**Article 3(2) - General Requirements**

The food business operator has no evidence to support the product shelf-life or compliance with the criteria throughout product shelf-life for all products or documented the reasons for not conducting these studies.

**Article 4(1) - Testing Against Criteria**

The food business operator does not test end product against micro-criteria set out in Annex I of the Regulation when validating/verifying the correct functioning of their procedures based on HACCP principles and Good Hygiene Practice.

Food Business Operator 4 is a large mushroom grower and packer.

Findings	
1	<p><b>HACCP</b></p> <p><b>Regulation (EC) No 852/2004, Article 5(1)</b>  <i>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</i></p> <p><b>Regulation (EC) No 852/2004, Article 5(2)</b></p> <ul style="list-style-type: none"> <li>(a) <i>Food business operators shall identify any hazards that must be prevented, eliminated or reduced to acceptable levels;</i></li> <li>(b) <i>identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</i></li> <li>(c) <i>establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</i></li> <li>(d) <i>establishing and implementing effective monitoring procedures at critical control points;</i></li> <li>(e) <i>establishing corrective actions when monitoring indicates that a critical control point is not under control;</i></li> <li>(f) <i>establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</i></li> <li>(g) <i>establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</i></li> </ul> <p>A documented HACCP plan was in place, however:</p> <ul style="list-style-type: none"> <li>• The steam cleaning used in the growing rooms had not been validated in-house</li> <li>• The specification/controls for compost was not documented</li> <li>• Supplier (farm) controls were not fully documented or consistent</li> </ul>
2	<p><b>Microbiological Criteria</b></p> <p><b>Regulation (EC) No 2073/2005</b>  <b>Article 3(2) – General Requirements</b>                      The food business operator has provided a shelf life of 5-7days but has not conducted studies in accordance with Annex II of the Regulation to investigate compliance with the criteria throughout product shelf-life for all products or documented the reasons for not conducting these studies.</p> <p><b>Article 4(1) - Testing Against Criteria</b>                      The food business operator is testing for <i>L. monocytogenes</i> but does not perform testing as appropriate against micro-criteria set out in Annex I of the Regulation when validating/verifying the correct functioning of their procedures based on HACCP principles and Good Hygiene Practice.</p> <p><b>Article 5(1) – Specific Rules for Testing and Sampling</b>                      Sampling plan outlined in Annex I, e.g. n=5 is not followed by the food business operator.</p> <p><b>Annex I – Chapter 2.2</b>                      Some evidence of environmental monitoring of growing areas e.g. one annual swab for <i>Listeria</i> was seen but not in the packing area.</p>

**Food Business Operator 5 is a Producer sprouted seed, wheat grass and shoots grower and packer.**

<b>Significant Preliminary Findings</b>	
1	<p><b>Structure, Design and Layout</b></p> <p><b>Regulation (EU) No 210/2013 Annex (1)</b>  <i>The design and layout of establishments shall permit good food hygiene practices, including protection against contamination between and during operations. In particular, surfaces (including surfaces of equipment) in areas where foods are handled and those in contact with food shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect.</i></p> <p>The design and layout of the establishment does not permit hygienic practise and allows potential contamination of products, particularly by pests, during growing and harvesting. Significant levels of rodent activity were observed regularly by the pest control company. The food business is operating in a field with no hard core surface to minimise risk of contamination and pest entry.</p>
2	<p><b>Pest Control</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, II(2)</b>  <i>As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.</i></p> <p>Food was not protected at all stages of harvesting and growing against contamination. There was significant possibility of food being contaminated when moved from harvesting to packing. The harvesting area was very exposed as the door was not screen protected from a yard where there are significant pest issues.</p> <p>A pest control system was in place however, no preventative action was being taken to reduce the level of rodent activity</p> <p>Significant levels of rodent activity were regularly observed by the food business operator and the pest control company.</p> <p>Doors open directly onto the yard at the entrance to the harvesting area and in the packing area which are significant potential pest and bird entry points.</p> <p>Fly screens were not in place at all windows or doors.</p> <p>Changing facilities for staff were away from processing and packing areas. Staff have to walk across a muddy yard to get to work areas. There was no shoe changing facility on entry to harvesting/packing areas.</p>
3	<p><b>Control of Hazards</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, II(3)</b>  <i>Food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:</i></p> <p>(a) <i>measures to control contamination arising from the air, soil, water, feed, fertilisers,</i></p>

	<p><b><i>veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;</i></b></p> <p>There is no system in place for the adequate disposal of by products, waste materials, e.g. water.</p> <p>There was no evidence of an adequate drainage system on site. One mobile toilet was onsite and it was not connected to a drainage system. A pipe from the harvesting area was leading out onto a bowl in the yard. There was no provision for the storage of waste materials from harvesting. Waste product was stored in the front of the harvesting area in the middle of the yard.</p> <p><b>Regulation (EC) No 852/2004, Annex I, II(5)(e)</b> <b><i>Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</i></b></p> <p><b><i>(e) As far as possible to prevent animals and pests from causing contamination</i></b></p> <p>Food was not protected at all stages of harvesting and growing against contamination.</p> <p>There was a serious and immediate risk of product being contaminated by pests in the harvesting and packing areas in particular. Ongoing pests were being observed in the surrounds of the establishment by the pest control company and there was no preventative action being taken to reduce the risk associated with pest activity.</p> <p><b>Regulation (EC) No 852/2004, Annex I, II(5)(f)</b> <b><i>Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</i></b></p> <p><b><i>(f) to store and handle wastes and hazardous substances so as to prevent contamination</i></b></p> <p>There was no provision for the storage of waste materials from harvesting. Waste product was stored in the front of the harvesting area in the middle of the yard. This was a serious pest control issue.</p>
4	<p><b>Cleaning</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, II(5)(a) and (b)</b> <b><i>Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</i></b></p> <p><b><i>(a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;</i></b></p> <p><b><i>(b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products</i></b></p> <p>In the harvesting areas, the floors, walls and doors were not smooth or sealed and therefore, did not facilitate cleaning and disinfection.</p> <p>In the growing rooms, the walls, floors and ceilings were uneven, damaged, unsealed and dirty with evidence of rust.</p> <p>Unused rusty ventilation units were in place over the shelving in two growing rooms.</p> <p>Large doors constructed of wood and perspex led into the main harvesting area. The surface was very uneven and not clean.</p>

5	<p><b>Records</b></p> <p><b>Regulation (EC) No 852/2004, Annex I, III(7)</b> <i>Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.</i></p> <p>Some procedures outlined in the HACCP plan were not being followed, e.g. the system of traceability and the procedure for controlling knives</p> <p>Procedure for temperature monitoring of vans was falsified.</p> <p>No evidence to support the shelf- life.</p>
6	<p><b>Structure and Equipment</b></p> <p><b>Regulation (EU) No 210/2013, Annex I</b></p> <p><b>4. All equipment with which seeds and sprouts come into contact shall be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination, and to enable it to be kept clean and, where necessary, to be disinfected.</b></p> <p><b>5. Appropriate procedures shall be in place to ensure that:</b></p> <p><b>(a) the establishment producing sprouts is kept clean and, where necessary, disinfected;</b></p> <p><b>(b) all equipment with which seeds and sprouts come into contact is effectively cleaned and, where necessary, disinfected. The cleaning and disinfection of such equipment shall take place at a frequency sufficient to avoid any risk of contamination</b></p> <p>The shelving and piping in the growing room were in a poor and unhygienic condition.</p>

Food Business Operator 6 is an apple grower and juicer.

Findings	
1	<p><b>Traceability</b></p> <p><b>Regulation (EC) No 178/2002, Article 18</b></p> <ol style="list-style-type: none"> <li><b>1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be incorporated into a food or feed shall be established at all stages of production, processing and distribution.</b></li> <li><b>2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.</b></li> <li><b>3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.</b></li> <li><b>4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions. No traceability system in place to identify where food is purchased.</b></li> </ol> <p>Bottles of unlabelled product, including apple juice and fruit juices were evident throughout the establishment. The source/traceability of the apples and fruit used in the food business operator's own products was not adequately documented. The food business operator informed the audit team that apples are supplied by local farmers for pressing but there was no documentation to support this. Reused cardboard packaging incorrectly identifying product was evident.</p> <p>Unlabelled pots of honey were seen in the storage area and bulk containers of honey were in the pasteurising room and there were no traceability records available for any honey.</p>
2	<p><b>HACCP</b></p> <p><b>Regulation (EC) No 852/2004, Article 5(1)</b> <b>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</b></p> <p><b>Regulation (EC) No 852/2004, Article 5(2)</b></p> <ol style="list-style-type: none"> <li><b>(a) Food business operators shall identify any hazards that must be prevented, eliminated or reduced to acceptable levels;</b></li> <li><b>(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</b></li> <li><b>(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</b></li> <li><b>(d) establishing and implementing effective monitoring procedures at critical control</b></li> </ol>

	<p><b>points;</b></p> <ul style="list-style-type: none"> <li><b>(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;</b></li> <li><b>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</b></li> <li><b>(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</b></li> </ul> <p>There was no documented food safety management system based on HACCP principles in place. There was no documented procedure to outline the controls. Two critical control points were identified on notices on the wall of the pasteurising room but there was no evidence of implementation of effective monitoring procedures of these critical control points. There was no validation of critical control points. The food business operator had a record for verifying the pasteurisation temperature for some batches but not all batches. The food business operator was not aware of a batch of juice produced over the previous weekend and there were no records to verify effective pasteurisation had taken place. Batch coding and storage were identified as the other CCP. The system of batch coding did not operate effectively and records to controls batches were seen to be ineffective.</p> <p>The food business operator uses a household bleach for disinfection of equipment, however no cleaning of equipment using detergents is carried out by the food business operator prior to the disinfection.</p> <p>The pasteurisation room and equipment were not cleaned adequately as there was evidence of apple on the cheese cloth used in pressing and the pressing machine had apple debris on it. The wall, floors and ceiling in the pasteurising room were dirty and there was a lot of condensation evident.</p> <p>Water from a private well has not been identified as a risk or controlled in any way. Bleach was used to disinfect the well a number of years ago but this was not documented.</p> <p>Bruised and damaged apples in crates in the storage area were evident. Identification and control of other hazards such as patulin, was not in place.</p>
3	<p><b>Cleaning and Maintenance</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (1)</b> <b><i>Food premises are to be kept clean and maintained in good repair and condition.</i></b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (2)</b></p> <ul style="list-style-type: none"> <li><b>(a) <i>The layout, design, construction, siting and size of food premises are to: permit good food hygiene practices, including protection against contamination and, in particular, pest control</i></b></li> <li><b>(b) <i>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;</i></b></li> <li><b>(c) <i>permit good food hygiene practices, including protection against contamination and, in particular, pest control;</i></b></li> </ul> <p>Serious maintenance issues were observed; the walls, floors and ceilings were rusty in parts and</p>

	<p>not sealed appropriately, causing the accumulation of dirt in the storage areas and pasteurising room. There was evidence of extensive condensation as a result of no ventilation in the pasteurisation room. There was an open drain in the middle of the floor of the pasteurising room.</p> <p>There was no food product in the chill at the time of audit, but the maintenance and hygiene of the chill where apples are stored were poor.</p> <p>There was dirt, dust, faeces and mud observed on the floor in the main storage area for finished product. In addition to product being stored in the shed, the following were in close proximity to the finished products and packaging materials:</p> <ul style="list-style-type: none"> <li>• Live goats</li> <li>• Bedding material – straw</li> <li>• Peat with cat/dog faeces</li> <li>• Bird nests in the shelves over the product</li> <li>• Rotten apples with evidence of rodent activity</li> </ul> <p>Doors opening directly onto the yard were observed at the entrance door in the storage area and in the labelling area which are significant potential pest entry points.</p>
4	<p><b>Hygiene Facilities for staff</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (3) &amp;(4)</b>  <i>An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.</i></p> <p>One toilet was onsite for all staff (including food workers (food business operator and two part-time) and horticultural workers (up to 10)) and no hot water or hand-washing materials were available.</p>
5	<p><b>Ventilation</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (5)</b>  <i>There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.</i></p> <p>There was evidence of extensive condensation as a result of no ventilation in the pasteurisation room. As a result, the food business operator said the door from the lobby area and the pasteurising room opening onto the yard are kept open.</p>
6	<p><b>Lighting</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (7)</b>  <i>Food premises are to have adequate natural and/or artificial lighting.</i></p> <p>The storage/labelling area was dark as the lights were not working and a broken light was</p>

	observed over finished product.
7	<p><b>Drainage Facilities</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (8)</b> <i>Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.</i></p> <p>It was not possible to fully assess the drainage onsite. The pipe from the processing area was leading out into a field.</p>
8	<p><b>Changing Facilities</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (9)</b> <i>Where necessary, adequate changing facilities for personnel are to be provide.</i></p> <p>There were no changing facilities for staff. Staff have to walk across a muddy yard to get to work areas.</p>
9	<p><b>Cleaning Agents and Disinfectants</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (10)</b> <i>Cleaning agents and disinfectants are not to be stored in areas where food is handled</i></p> <p>Vitamin C (Ascorbic Acid) was stored beside the household bleach used for disinfection, in the lobby area of the pasteurisation room.</p> <p>Bleach was also stored in the daffodil storage shed.</p>
10	<p><b>Structure and Maintenance</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter II</b></p> <p><b>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. In particular:</b></p> <p><b>(a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;</b></p> <p>This was not in place. Floors were uneven and unsealed in the pasteurising room. In the storage/labelling area, the floors were damaged and extremely dirty.</p> <p><b>(b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business</b></p>

	<p><b><i>operators can satisfy the competent authority that other materials used are appropriate;</i></b></p> <p>Walls were uneven, damaged, unsealed and dirty with evidence of rust in the pasteurising room. The storage area was unsealed and dirty.</p> <p><b><i>(c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;</i></b></p> <p>Ceilings were uneven, damaged, unsealed and dirty with evidence of rust. In particular, in the storage/labelling area, the ceilings were completely inadequate with birds' nests, spiders webs etc. evident.</p>
11	<p><b>Structure and Maintenance</b></p> <p><b><i>(f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.</i></b></p> <p>Rust was evident on some of the equipment in the pasteurising room, e.g. in the outlet pipe of settling tank and on the side of the pasteurising baths.</p>
12	<p><b>Equipment requirements</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter II</b></p> <p><b><i>(2) Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.</i></b></p> <p>The food business operator informed the audit team that a blue plastic barrel in the pasteurising room was used to drain juice from the settling tank. However, the barrel was being used to soak piping and clean a cheese cloth, i.e. the same barrel was used for, cleaning and for collecting food products.</p>
13	<p><b>Equipment Requirements</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter V</b></p> <p><b><i>1. All articles, fittings and equipment with which food comes into contact are to:</i></b></p> <p><b><i>(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</i></b></p> <p>There was no cleaning of equipment, only disinfection taking place. There were no procedures in</p>

	<p>place to establish the cleaning frequency and the cleaning was not documented.</p> <p><b>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</b></p> <p>Evidence of rust and dirt on some food equipment in the pasteurising room was evident.</p> <p>In the pasteurising room, two large rusty metal barrels on a pallet were storing congealed and unlabelled honey. It was not clear if this honey was intended for human consumption.</p>
14	<p><b>Food Waste</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VI</b></p> <p><b>2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.</b></p> <p><b>3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.</b></p> <p>There was no provision for the storage of waste apples. Waste product was stored in:</p> <ul style="list-style-type: none"> <li>• Front of the storage area in the middle of the yard</li> <li>• Crates in the storage area</li> <li>• An overflowing wheelie bin at the site entrance</li> </ul>
15	<p><b>Water Supply</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VII</b></p> <p><b>1(a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;</b></p> <p>There was no evidence to support the adequate supply of potable water. Water is taken from a shallow, unprotected and untreated private well. Coliforms were identified by DAFM in the water supply previously but no measures are taken to assess the ongoing potability of the water by the food business operator, i.e. no evidence provided to demonstrate that the water is potable.</p>
16	<p><b>Personal Hygiene</b></p> <p><b>Reg. 852/2004 Annex II, Chapter VIII</b></p> <p>There was no procedure or policy for food handlers returning to work post- illness/gastroenteritis.</p>
17	<p><b>Provisions Applicable To Foodstuffs</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX</b></p> <p><b>2. Raw materials and all ingredients stored in a food business are to be kept in</b></p>

	<p><i>appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</i></p> <p><b>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</b></p> <p>Raw materials, packaging and finished products were stored in areas directly opening onto a dirty farm yard accessible to animals and pests. Food was not protected at all stages against contamination;</p> <ul style="list-style-type: none"> <li>• The product packaged was stored in an open shed with direct access to the yards and potential pests/goats</li> <li>• During pasteurising the doors are open to allow some natural ventilation</li> <li>• Product is moved from the pasteurising unit to the storage area via a dirty yard</li> </ul>
18	<p><b>Pest Control</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX</b></p> <p><b>4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</b></p> <p>An in-house pest control system was in place and levels of rodent activity were documented. No preventative action was being taken to reduce the level of rodent activity. The number and position of bait points was inadequate to control pests. In the storage/labelling area, open crates of apples had evidence of rodent infestation and there were faeces in the peat pile in the storage area possibly from domestic animal or goats. The open drain in the middle of the pasteurising room was a significant potential pest entry point.</p>
19	<p><b>Thawing of Foodstuffs</b></p> <p><b>Regulation (EC) No 852/2004, Chapter IX</b></p> <p><b>7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.</b></p> <p>The food business operator informed the audit team that frozen berries are thawed at ambient temperatures overnight in a van or on the production floor in the pasteurisation area. No records of controls for this activity were available.</p>

<p>20</p>	<p><b>Wrapping and Packaging Material</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter X</b> <b>Material used for wrapping and packaging are not to be a source of contamination.</b></p> <ol style="list-style-type: none"> <li><b>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</b></li> <li><b>3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.</b></li> <li><b>4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.</b></li> </ol> <p>There were no controls in place to ensure the safety and integrity of the packaging materials used. Packaging material was stored in the open shed referred to above. There were no specifications or procedure in place to ensuring packaging was not contaminated or of food grade. No evidence was provided to demonstrate that the bottles used for pasteurised juice were sterile.</p>
<p>21</p>	<p><b>Heat Treatment</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter XI</b> <b>The following requirements apply only to food placed on the market in hermetically sealed containers:</b></p> <ol style="list-style-type: none"> <li><b>1. any heat treatment process used to process an unprocessed product or to process further a processed product is:</b> <ol style="list-style-type: none"> <li><b>(a) to raise every party of the product treated to a given temperature for a given period of time; and</b></li> <li><b>(b) to prevent the product from becoming contaminated during the process;</b></li> </ol> </li> <li><b>2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;</b></li> </ol> <p>There was a limited description of how the monitoring procedure for the CCP for pasteurisation was to take place. There were no pasteurisation records available for some batches of product.</p> <p>No evidence of validation of the pasteurisation process.</p>
<p>22</p>	<p><b>Training</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter XII</b> <b>Food business operators are to ensure:</b></p> <ol style="list-style-type: none"> <li><b>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;</b></li> <li><b>2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles;</b></li> </ol> <p>The audit team was informed that food safety HACCP training took place approximately five years ago. There was no evidence of any training available for food workers or the food business operator.</p>

Food Business Operator 7 is a wheat grass juice and broccoli juice producer and packer.

Findings	
1	<p><b>HACCP</b></p> <p><b>Regulation (EC) No 852/2004, Article 5(1)</b> <i>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</i></p> <p><b>Regulation (EC) No 852/2004, Article 5(2)</b></p> <ul style="list-style-type: none"> <li>(a) <i>Food business operators shall identify any hazards that must be prevented, eliminated or reduced to acceptable levels;</i></li> <li>(b) <i>identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</i></li> <li>(c) <i>establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</i></li> <li>(d) <i>establishing and implementing effective monitoring procedures at critical control points;</i></li> <li>(e) <i>establishing corrective actions when monitoring indicates that a critical control point is not under control;</i></li> <li>(f) <i>establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</i></li> <li>(g) <i>establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</i></li> </ul> <p>There was no documented food safety management system based on HACCP principles available onsite. There were no documented procedures outlining how the controls seen at the establishment are to be implemented. Two Critical Control Points were identified by the food business operator; control of the pH and a high pressure process (540 MP for 90 seconds) but there was no documentation available onsite for the validation of either critical control points.</p> <p>There were no procedures in place to check incoming ingredients and ensure the safety of supply of raw materials. No raw material specifications.</p> <p>A record of pH readings and the high pressure treatment was available for each batch however, there was limited evidence available for the calibration of the pH meter and no evidence of validation of the high pressure process.</p>
2	<p><b>Cleaning and Maintenance</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (1)</b> <i>Food premises are to be kept clean and maintained in good repair and condition.</i></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (2)</b></p> <ul style="list-style-type: none"> <li>(a) <i>The layout, design, construction, siting and size of food premises are to: permit good food hygiene practices, including protection against contamination and, in particular, pest control</i></li> </ul>

	<p><b>(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;</b></p> <p><b>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;</b></p> <p>A weekly inspection checklist was provided which the food business operator completes every Sunday.</p> <p>Containers in the growing room were not cleaned adequately. There was evidence of rust and mould on the floors, walls, ceiling and equipment. Serious maintenance issues were observed; the walls, floors and ceilings were rusty in parts and not sealed appropriately causing the accumulation of dirt in the two growing rooms.</p> <p>A third growing room was seen but was not yet operational.</p> <p>Doors opening directly onto the yard were observed in both growing rooms which are significant potential pest entry points.</p>
3	<p><b>Hygiene Facilities for Staff</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (3) &amp;(4)</b>  <b><i>An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.</i></b></p> <p><b><i>An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.</i></b></p> <p>One toilet was onsite for staff and no hot water or hand-washing materials were available.</p>
4	<p><b>Drainage Facilities</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (8)</b>  <b><i>Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.</i></b></p> <p>It was not possible to fully assess the drainage onsite. The pipe from the growing rooms was leading out onto a neighbouring field.</p> <p>Drainage in the yard was poor with waste and dirt evident around the containers.</p>
5	<p><b>Changing Facilities</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I (9)</b>  <b><i>Where necessary, adequate changing facilities for personnel are to be provided</i></b></p> <p>There were no changing facilities for staff. A toilet area was provided in an old school house across a muddy yard. There was no hot water or hand-washing available beside the toilet.</p>

<p>6</p>	<p><b>Structure</b></p> <p>Regulation (EC) No 852/2004, Annex II, Chapter II</p> <p>1. <i>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. In particular:</i></p> <p>(a) <i>floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;</i></p> <p>(a) <i>wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;</i></p> <p>(b) <i>ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;</i></p> <p>(c) <i>surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.</i></p> <p>Rust was evident on some of the equipment in the growing room, e.g. in particular on the pipes, fans and on the unused ventilation units.</p> <p>Walls, floors and ceilings were uneven and dirty with evidence of rust in both growing rooms.</p> <p>Rusty pipes over the germinating tank in one of the growing rooms</p> <p>Mould on water pipes in both growing rooms.</p>
<p>7</p>	<p><b>Equipment Requirements</b></p> <p>Regulation (EC) No 852/2004, Annex II, Chapter V</p> <p>1. <i>All articles, fittings and equipment with which food comes into contact are to:</i></p> <p>(a) <i>be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</i></p> <p>Cleaning procedure and frequency were inadequate as the containers were dirty and the yard and surrounds were dirty with waste material.</p> <p>(b) <i>be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</i></p>

	<p>Fluorescent lights were in both growing rooms with no covers to allow cleaning and to prevent possible glass contamination. Open electrical sockets on the walls of the growing rooms would not facilitate cleaning.</p>
8	<p><b>Food Waste</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VI</b></p> <p><b>2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.</b></p> <p><b>3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.</b></p> <p>Three green bins and one blue bin were in the yard in front of a new container which has yet to be commissioned. Waste material from the growing rooms was stored in the middle of the yard beside the growing containers. There was a strong smell from this waste and it is a significant pest attraction. Other packaging waste and materials were around the back of containers and the yard was dirty and untidy with poor drainage.</p>
9	<p><b>Water Supply</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VII</b></p> <p><b>1(a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;</b></p> <p>The food business operator informed the audit team that the water supply was from the mains but there was no evidence to support the potability of the water, either from local authority tests or the food business operator own testing.</p>
10	<p><b>Pest Control</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX Pest Control</b></p> <p><b>3. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</b></p> <p>The audit team was informed that there was an in-house pest control system in place, whereby the food business operator puts down bait monthly. According to the food business operator, when bait is put down it is gone within 24 hours indicating a high level of rodent activity. There was no documentation of any pest control and no bait points were in place on the day of the audit. No preventative action was being taken to reduce the level of rodent activity. Waste material in the yard and surrounds as well as poor drainage would facilitate increased activity. There was an open ventilation hole in the wall of one of the growing rooms which would allow easy access to growing rooms for birds, pest etc.</p>

<p>11</p>	<p><b>Wrapping and Packaging Material</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter X</b> <b>Material used for wrapping and packaging are not to be a source of contamination.</b></p> <ol style="list-style-type: none"> <li>2. <b>Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</b></li> <li>3. <b>Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.</b></li> <li>4. <b>Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.</b></li> </ol> <p>There were no controls in place to ensure the safety and integrity of the packaging materials used. Packaging material was stored in a container. There were no specifications or procedures in place to ensure packaging was food grade.</p>
<p>12</p>	<p><b>Training</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter XII</b> <b>Food business operators are to ensure:</b></p> <ol style="list-style-type: none"> <li>1. <b>that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;</b></li> <li>2. <b>that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles;</b></li> </ol> <p>The audit team was informed that a new food worker would receive food safety and HACCP training soon. There was no evidence of any training available for food workers or the food business operator.</p>
<p>13</p>	<p><b>Personal Hygiene</b></p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VIII Personal Hygiene</b> There was no procedure or policy for food handlers returning to work post- illness/gastroenteritis.</p>
<p>14</p>	<p><b>Microbiological Criteria</b></p> <p><b>Regulation (EC) No 2073/2005</b> <b>Article 3(2)</b> The food business operator has not conducted studies in accordance with Annex II of the Regulation to investigate compliance with the criteria throughout product shelf-life for all products or documented the reasons for not conducting these studies.</p> <p><b>Article 4(1) - Testing Against Criteria</b> The food business operator performs testing as appropriate against micro-criteria set out in Annex I of the Regulation when validating/verifying the correct functioning of their procedures based on HACCP principles and Good Hygiene Practice. No testing for <i>L. monocytogenes</i> had taken place.</p> <p><b>Article 4(2) - Testing Against Criteria</b> The food business operator has not decided on an appropriate sampling frequency in relation to</p>

	<p>Annex I</p> <p>The food business operator has not decided on an appropriate sampling frequency in the context of the HACCP and Good Hygiene Practice.</p> <p><b>Article 5(1) – Specific Rules for Testing and Sampling</b> Sampling plan outlined in Annex I, e.g. n=5 is not followed by the food business operator.</p>
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## Annex II: Summary of Labelling Findings

<u>Name</u>	<u>General Labelling</u> <i>Directive 2000/13/EC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs</i>	<u>Nutrition/Health Claims</u> <i>Regulation (EC) No 1924/2006 on nutrition and health claims made on foods</i>
Wheat Grass Juice	<ol style="list-style-type: none"> <li>Lactic acid as a food additive needs to be listed accordingly, i.e. food additives need to be listed in the list of ingredients by the: <ul style="list-style-type: none"> <li>Functional class of the additive and</li> <li>Specific name or designated E number</li> </ul> </li> <li>Net quantity on the box containing the sachets need to include the total net quantity as where a pre-packaged item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.</li> </ol>	No issues identified
Broccoli sprout juice	<ol style="list-style-type: none"> <li>Lactic acid as a food additive needs to be listed accordingly, i.e. food additives need to be listed in the list of ingredients by the: <ul style="list-style-type: none"> <li>Functional class of the additive and</li> <li>Specific name or designated E number</li> </ul> </li> <li>Net quantity on the box containing the sachets currently only indicates 1x33ml - this should be 7x33ml and the net quantity needs to include the total net quantity as where a pre-packaged item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.</li> </ol>	No issues identified
Vegetable Juice drink	<ol style="list-style-type: none"> <li>Citric acid needs to be listed in the ingredients list accordingly, i.e. food additives need to be listed in the list of ingredients by the: <ul style="list-style-type: none"> <li>Functional class of the additive and</li> <li>Specific name or designated E number</li> </ul> </li> <li>Net quantity needs to be in metric and therefore '1US Fl oz' needs to be removed. The metric quantity of 30ml is correct.</li> <li>The name or business name and address of the manufacturer or packager, or of a seller in the EU is not indicated on the label.</li> </ol>	<ol style="list-style-type: none"> <li>The name of the product seems to be a trade mark, which could be construed as a claim. As there is no approved claim on the label, the use of this product name without the accompaniment of an approved claim is not permitted.</li> <li>The label is also is non-compliant with Article 2 (1) b of Directive 2000/13 as it suggests a food can prevent disease.</li> <li>No added sugar - should have nutrition labelling to accompany this nutrition claim.</li> </ol>

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<u>Name</u>	<u>General Labelling</u> <a href="#"><i>Directive 2000/13/EC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs</i></a>	<u>Nutrition/Health Claims</u> <a href="#"><i>Regulation (EC) No 1924/2006 on nutrition and health claims made on foods</i></a>
Apple Juice (250ml)	<p>Vitamin C (ascorbic acid) - this is listed as an ingredient in the juice. Depending on the purpose of its addition the following would apply:</p> <ol style="list-style-type: none"> <li>1. If the Vitamin C is in the product for fortification purposes, Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods states that nutrition labelling of products to which vitamins and minerals have been added shall be compulsory. The information to be provided shall consist of that specified in Article 4(1), Group 2 of Directive 90/496/EEC and of the total amounts present of the vitamins and minerals when added to the food.</li> <li>2. If the ascorbic acid is in the product for its additive function then it needs to be labelled accordingly, i.e. by the: <ul style="list-style-type: none"> <li>• Functional class of the additive and</li> <li>• Specific name or designated E number</li> </ul> </li> </ol>	No issues identified
Apple & Blackcurrant Juice	<ol style="list-style-type: none"> <li>1. Where two or more fruits are used in production of a fruit juice, the quantity of each fruit used must be expressed as a percentage of the product and must be indicated on the label (QUID)</li> <li>2. Nutrition labelling is incorrect – currently, protein should be listed before carbohydrate - otherwise to future proof the labels, consider nutrition declaration as per <a href="#"><i>Regulation (EU) 1169/2011</i></a> on the provision of food information to consumers</li> <li>3. RDA % is incorrect - it refers to the older RDAs that were only valid until the 31/10/2012 – <a href="#"><i>Directive 90/496/EEC</i></a> on nutrition labelling for foodstuffs.</li> </ol>	No issues identified
Pure Apple Juice (750ml)	<ol style="list-style-type: none"> <li>1. Nutrition labelling is incorrect – currently, protein should be listed before carbohydrate - otherwise to future proof the labels, consider nutrition declaration as per <a href="#"><i>Regulation (EU) 1169/2011</i></a> on the provision of food information to consumers</li> <li>2. RDA % is incorrect - it refers to the older RDAs that were only valid until the 31/10/2012 – <a href="#"><i>Directive 90/496/EEC</i></a> on nutrition labelling for foodstuffs.</li> </ol>	No issues identified

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Pure Apple & Strawberry Juice (750ml)	<ol style="list-style-type: none"> <li>1. Where two or more fruits are used in production, the quantity of each fruit used must be expressed as a percentage of the product and must be indicated on the label (QUID).</li> <li>2. Nutrition labelling is incorrect – currently, protein should be listed before carbohydrate - otherwise to future proof the labels, consider nutrition declaration as per <a href="#">Regulation (EU) 1169/2011</a> on the provision of food information to consumers.</li> <li>3. RDA % is incorrect - it refers to the older RDAs that were only valid until the 31/10/2012 – <a href="#">Directive 90/496/EEC</a> on nutrition labelling for foodstuffs.</li> </ol>	No issues identified
Apple juice with calcium	<ol style="list-style-type: none"> <li>1. Nutrition labelling is incorrect – currently, protein should be listed before carbohydrate - otherwise to future proof the labels consider nutrition declaration as per <a href="#">Regulation (EU) 1169/2011</a> on the provision of food information to consumers</li> <li>2. RDA % for Vitamin C is incorrect - it refers to the older RDAs that were only valid until the 31/10/2012 – <a href="#">Directive 90/496/EEC</a> on nutrition labelling for foodstuffs.</li> </ol>	No issues identified
Irish Cider	No issues identified.	No issues identified

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Apple Juice	<ol style="list-style-type: none"> <li>1. The name or business name and address of the manufacturer or packager, or of a seller in the EU is not indicated on the label.</li> <li>2. RDA % is incorrect - it refers to the older RDAs that were only valid until the 31/10/2012 – <a href="#">Directive 90/496/EEC</a> on nutrition labelling for foodstuffs</li> <li>3. Declaration that the product is free from artificial colours, preservatives &amp; sweeteners needs to be removed from the label as apple juice is not permitted to contain colours, preservative (for normal retail sale, although it would be permitted to contain sulphite as a preservative if it was intended for bulk dispensing in catering establishments) &amp; sweeteners and labelling legislation (<a href="#">Directive 2000/13/EC</a>) requires that the label must not:               <ol style="list-style-type: none"> <li>1. be such as could mislead the purchaser to a material degree, particularly:                   <ol style="list-style-type: none"> <li>(iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;</li> </ol> </li> </ol> <p>Certain additives are permitted in apple juice so the declaration that the product is free from additives would be permitted.</p> </li> </ol>	No issues identified
Sparkling Natural Lemonade	<ol style="list-style-type: none"> <li>1. No name or business name and address of the manufacturer or packager, or of a seller in the EU</li> <li>2. Nutrition labelling incorrect - KJ should be before Kcal; carbohydrates should be before fat and salt removed - otherwise to future proof the labels, consider nutrition declaration as per <a href="#">Regulation (EU) 1169/2011</a> on the provision of food information to consumers.</li> </ol>	No issues identified

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<p><u>Name</u></p>	<p><u>General Labelling</u> <i><a href="#">Directive 2000/13/EC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs</a></i></p>	<p><u>Nutrition/Health Claims</u> <i><a href="#">Regulation (EC) No 1924/2006 on nutrition and health claims made on foods</a></i></p>
<p>Pure Irish apple juice with strawberry</p>	<ol style="list-style-type: none"> <li>1. 'No added sugar' is no longer permitted on fruit juice labels - foods placed on the market or labelled before 28th October 2013 will be permitted on the market until 28th April 2015. From 28th October 2013 until 28th October 2016, the statement 'From 28 April 2015, no fruit juices contain added sugars' may appear on the label of fruit juice, fruit juice from concentrate, concentrated fruit juice, water extracted fruit juice, and dehydrated/powdered fruit juice. This statement must appear in the same field of vision as the product name – see <a href="#">Directive 2001/112/EEC</a> relating to fruit juices and certain similar products intended for human consumption</li> <li>2. Where two or more fruits are used in production of a fruit juice, the quantity of each fruit used must be expressed as a percentage of the product and must be indicated on the label (QUID)</li> <li>3. Vitamin C - this is listed as an ingredient in the juice - Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods states that nutrition labelling of products to which vitamins and minerals have been added shall be compulsory. The information to be provided shall consist of that specified in Article 4(1), Group 2 of Directive 90/496/EEC and of the total amounts present of the vitamins and minerals when added to the food.</li> </ol> <p><b>Note:</b> It is not obvious whether the name and address that are included in the paragraph about the food business operator is fulfilling the requirement to have the name or business name and address of the manufacturer or packager, or of a seller in the EU on the label.</p>	<p>No issues identified</p>

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Alfalfa & Fennel	<p>1. Ingredients list and QUID required</p> <p>2. Min 100g - the product needs to list the net quantity of the product - 'Min' should be removed. If the food business operator wants to use average amounts then would need to use e mark - contact <a href="http://www.nsai.ie">www.nsai.ie</a> under Legal Metrology Service. The e-mark, which often follows the quantity declaration, is placed on pre-packaged goods to indicate conformance to the EU Directives regulating the average system, i.e. the contents of each pre-package in a batch must on average be equal to the indication on the package</p> <p><b>Note:</b> Date of minimum durability - an indication of the durability date shall not be required for: — Fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts</p>	No issues identified
Pea Shoots	<p>1. Min 100g - the product needs to list the net quantity of the product - 'Min' should be removed. If the food business operator wants to use average amounts then would need to use e mark - contact <a href="http://www.nsai.ie">www.nsai.ie</a> under Legal Metrology Service. The e-mark, which often follows the quantity declaration, is placed on pre-packaged goods to indicate conformance to the EU Directives regulating the average system, i.e. the contents of each pre-package in a batch must on average be equal to the indication on the package</p> <p><b>Note:</b> Date of minimum durability - an indication of the durability date shall not be required for: — Fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts</p>	No issues identified

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Wheatgrass	<ol style="list-style-type: none"> <li>1. Min 100g - the product needs to list the net quantity of the product - 'Min' should be removed. If the food business operator wants to use average amounts then would need to use e mark - contact <a href="http://www.nsai.ie">www.nsai.ie</a> under Legal Metrology Service. The e-mark, which often follows the quantity declaration, is placed on pre-packaged goods to indicate conformance to the EU Directives regulating the average system, i.e. the contents of each pre-package in a batch must on average be equal to the indication on the package</li> <li>2. Date of minimum durability required</li> </ol>	No issues identified
Broccoli Shoots	<ol style="list-style-type: none"> <li>1. Min 100g - the product needs to list the net quantity of the product - 'Min' should be removed. If the food business operator wants to use average amounts then would need to use e mark - contact <a href="http://www.nsai.ie">www.nsai.ie</a> under Legal Metrology Service. The e-mark, which often follows the quantity declaration, is placed on pre-packaged goods to indicate conformance to the EU Directives regulating the average system, i.e. the contents of each pre-package in a batch must on average be equal to the indication on the package</li> </ol> <p><b>Note:</b> Date of minimum durability is needed - an indication of the durability date shall not be required for: — Fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts</p>	No issues identified
Seed Mix	<ol style="list-style-type: none"> <li>1. QUID (quantity ingredient declaration) is required</li> <li>2. Min 100g - the product needs to list the net quantity of the product - 'Min' should be removed. If the food business operator wants to use average amounts then would need to use e mark - contact <a href="http://www.nsai.ie">www.nsai.ie</a> under Legal Metrology Service. The e-mark, which often follows the quantity declaration, is placed on pre-packaged goods to indicate conformance to the EU Directives regulating the average system, i.e. the contents of each pre-package in a batch must on average be equal to the indication on the package</li> <li>3. Date of minimum durability is required</li> </ol>	No issues identified

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<u>Name</u>	<u>General Labelling</u> <i>Directive 2000/13/EC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs</i>	<u>Nutrition/Health Claims</u> <i>Regulation (EC) No 1924/2006 on nutrition and health claims made on foods</i>
Alfalfa & Carrot	<ol style="list-style-type: none"> <li>1. QUID (quantity ingredient declaration) is required</li> <li>2. Min 100g - the product needs to list the net quantity of the product - 'Min' should be removed. If the food business operator wants to use average amounts then would need to use e mark - contact <a href="http://www.nsai.ie">www.nsai.ie</a> under Legal Metrology Service. The e-mark, which often follows the quantity declaration, is placed on pre-packaged goods to indicate conformance to the EU Directives regulating the average system, i.e. the contents of each pre-package in a batch must on average be equal to the indication on the package</li> <li>3. Date of minimum durability is required</li> </ol>	No issues identified
Baby Button Mushrooms	<b>Note:</b> 'See reverse for nutrition' - Nutrition labelling legislation states that nutrition labelling shall be printed in legible and indelible characters in a conspicuous place.	No issues identified
Family Pack Mushrooms	<b>Note:</b> 'See reverse for nutrition' - Nutrition labelling legislation states that nutrition labelling shall be printed in legible and indelible characters in a conspicuous place.	No issues identified
Mushrooms	<b>Note:</b> 'See reverse for storage and cooking instruction' - The particulars mentioned in Article 3 and Article 4(2) shall be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.  They shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.	No issues identified
Freshly Grown Products	Labels sampled were not yet completed. Following information should be included:  * Name * List of ingredients - if it is necessary * Date of minimum durability - if it is necessary * Origin - if needed under marketing standards	No issues identified

**Audit of Official Controls in Horticultural Produce Sector  
– Department of Agriculture, Food and the Marine**

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Sweetcorn	<ol style="list-style-type: none"> <li>1. Net quantity required</li> <li>2. Date of minimum durability is required</li> </ol>	No issues identified
Raspberries	No issues identified	No issues identified





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